Linx

Continuous Glucose Monitoring System

Instructions for Use

CE 0197

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System Description

Thank you for choosing the LinX Continuous Glucose Monitoring System (hereafter referred to as CGMS). The CGMS consists of the LinX Sensor and the LinX CGM App (hereafter referred to as the App) that is downloadable on a compatible mobile device (available on iOS and Android).

The LinX Sensor records and transmits real-time sensor glucose readings to the App. The sensor is inserted subcutaneously and measures the glucose values every minute in the interstitial fluid (fluid between the cells).

The CGMS detects trends, tracks patterns and provides custom alerts that aid in the detection

of hyperglycaemic and hypoglycaemic episodes, 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 Instructions 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 fingerstick 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 hyperglycaemia and hypoglycaemia, 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 glycaemic control
5) People requiring frequent or continuous monitoring of blood glucose

1.2 Patients

Patients with diabetes (≥2 years old).

1.3 Intended User

The primary users of this medical device are individuals aged 18 years and older, 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. For paediatric patients aged 2–17 years, the LinX App

and Sensor must be overseen by a responsible adult caregiver (such as a parent or guardian). The caregiver is responsible for the correct setup, daily management, and interpretation of glucose data on behalf of the child, including responding to alerts and ensuring the sensor is securely applied.

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:

- Pregnant women
- 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 using electrocautery, electrosurgical units and diathermy 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 LinX System, review all the product instructions.

- The CGMS should not be used by Patients who have diffuse subcutaneous nodules.
- Before you use the LinX 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 not be used closer than 30 cm to any part of the GX-01S, including cables specified by the manufacturer. Otherwise, the performance of this equipment may be compromised.
- After restarting your mobile device, always check that Bluetooth is switched on. If Bluetooth is off, please enable Bluetooth again to ensure real-time data transmission and notifications.

- Avoid sensor insertion sites:

  1. With loose skin or without enough fat to avoid muscles and bones.
  2. That get bumped, pushed, or you lie on while sleeping.
  3. Within 5-7.5cm 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. Unauthorised

modification of the CGMS may cause the product to malfunction and become unusable.

- Before using this product, you need to read the Instruction 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. Please confirm the sensor's reading by performing a fingerstick blood glucose test using a blood glucose meter.
- Severe dehydration or excessive loss of water may result in inaccurate results. When you suspect you are dehydrated, consult a healthcare professional immediately.

- If you suspect the CGMS sensor reading is inaccurate or inconsistent with your 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.
- Refer to “Potential Interference Information” for details of interferences that may affect the accuracy of the CGMS.
- If the sensor loosens or is bumped off, it may result in zero readings on the App.
- If the sensor filament tip breaks underneath the skin, do not try and remove it yourself. Please seek professional medical assistance.
- The sensor is water resistant and may be worn during showering, bathing, and swimming at depths of up to 2 metres for a maximum of 1 hour.
- While extensive user testing was performed using the LinX CGMS in persons with Type 1 and Type 2

diabetes, the study groups did not include women with gestational diabetes.

- If the product is not working properly or has been damaged, stop using the product and contact your local distributor.

1.7 Potential Clinical Side-Effects

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

1.8 Additional Safety Information

- Physiological difference between interstitial fluid and capillary whole blood may result in variances in 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 medical procedure that includes strong magnetic or electromagnetic radiation (for example, MRI or CT), remove your sensor, and install a new sensor after the procedure. The impact of these procedures on sensor performance has not been evaluated.
- The sensor applicator is sterile in an unopened and undamaged package. Please ensure that you open it only when you are ready to insert a new sensor.
- Do not freeze the sensor.
- Do not use the sensor after the expiration date.
- If you suspect an adverse cyber security event related to the LinX App, contact your local distributor.
- Ensure you keep your mobile device and sensor kit safe to prevent anyone from accessing or tampering with the system.
- The LinX App is not intended for use on a mobile device 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.

1.9 Use by Caregivers for Paediatric Patients (Ages 2-17)

This section contains critical information for caregivers, such as parents and guardians using the LinX CGM System to monitor a child.

A. Your Role as a Caregiver:

You are responsible for the setup, daily management, and data interpretation of the LinX CGM System on behalf of the child.

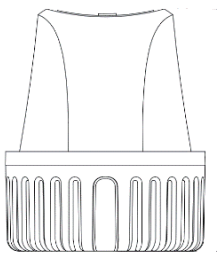
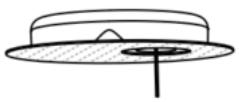
- You must ensure the sensor is applied and functioning correctly.
- You are responsible for setting and responding to alerts.

B. Key Differences in Paediatric Diabetes Management:

- Hypoglycaemia Awareness: Young children may not be able to recognise or communicate the symptoms of low blood sugar. You cannot rely on the child to tell you how they feel. It is critical to pay close attention to CGM trends and alerts, through sharing function.
- Rapid Glucose Changes: Children's glucose levels can change more rapidly than adults due to activity, growth hormones, and varying food intake.
- Sensor Site Management: Children may be more active and prone to catching the sensor on clothing or furniture. Ensure the sensor is securely attached and consider using an additional adhesive overlay if recommended by your healthcare professional.
- Data Sharing: The Share/Follow feature (Section 6.2) is a critical tool for caregivers. It allows multiple caregivers (e.g., both parents, a school nurse) to monitor the child's glucose levels remotely.

2. Product Components

The LinX CGMS consists of the 15-day sensor and the App, downloadable on a compatible mobile device (available for iOS and Android).

Product Components	Product Name	Model Number	Function
 Glucose Sensor before insertion (Sensor applicator)	Continuous Glucose Monitoring System sensor	GX-01S (15-day sensor))	The sensor applicator helps you insert the sensor underneath your skin. It contains a needle which is used to puncture the skin to introduce the flexible sensor filament underneath the skin and then retracts into the applicator once the sensor is inserted. The sensor measures and stores glucose readings every minute.
 Glucose Sensor after insertion			

Product Components	Product Name	Model Number	Function
	Continuous Glucose Monitoring App	RC2107 (For iOS)	It is an application available on your phone used 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 system Settings and other functions to help users analyse and evaluate the glucose reading of the continuous glucose monitoring system and form a report.
		RC2109 (For Android)	

3. System App and Software

3.1 Software Download

The LinX App can be downloaded from the Apple App Store (iOS) or Google Play Store (Android). Please check the Operating System (OS) on your mobile device to ensure you download the correct App version.

3.2 Minimum Requirements for Software Installation

iOS

Model No.: RC2107

Operating System (OS): iOS 14 and above

Memory: 2GB RAM

Storage: Minimum 200 MB

Network: WLAN (Wireless Local Area Network) or cellular network and Bluetooth functionality

Screen Resolution: 1334 x 750 pixels

Android

Model No.: RC2109

Operating System (OS): Android 10.0 and above.

Memory: 8GB RAM

Storage: Minimum 200 MB

Network: WLAN (Wireless Local Area Network) or cellular network and Bluetooth functionality

Screen Resolution: 1080 x 2400 pixels and above

Note

- To receive alerts, make sure:

  - The alert function is switched on.

  - Keeping your mobile phone and CGMs equipment within 6 meters (19.69 ft) maximum. If you want to receive alerts from the app, make sure your device is connected.

  - The sensor is connected to the App.

  - Do not force-quit LinX, it must be running in the background to receive alerts. Otherwise, alerts cannot be received. If alerts are unavailable, restarting the application may help you.

  - Confirm the correct mobile device settings and permissions are enabled. If your mobile device is not configured properly, you will not receive alerts.

- When you are not using headphones or speakers, disconnect them from your mobile device, otherwise you may not hear the alert.
- If you have peripherals such as a wireless headset or smart watch connected to your mobile device, you may receive alerts on one device or peripheral only, rather than all devices.
- Your mobile device is always charged and switched on.
- Open the App after the operating system has updated.

3.3 IT Environment

Do not use the App when the Bluetooth function is switched off, in an environment with poor Bluetooth connectivity or a high electrostatic discharge, as this may result in failure of the glucose data being transferred to the App.

Avoid such environments and ensure that the Bluetooth function is switched on.

No other external software or applications have been found to cause critical defects. CGMS use in an environment with poor communication may cause signal loss, connection interruption or incomplete data.

4. LinX 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

Once you have downloaded the App on your mobile device, you will need to register an account first.

1. Click the “Register” button to enter the registration screen.
2. Enter your email address and a password.
3. 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.
4. Click “Send verification code to my email” to receive a six-digit code. Enter the verification code on the App, click “Continue” to complete your registration.

Note the following when Registering an Account:

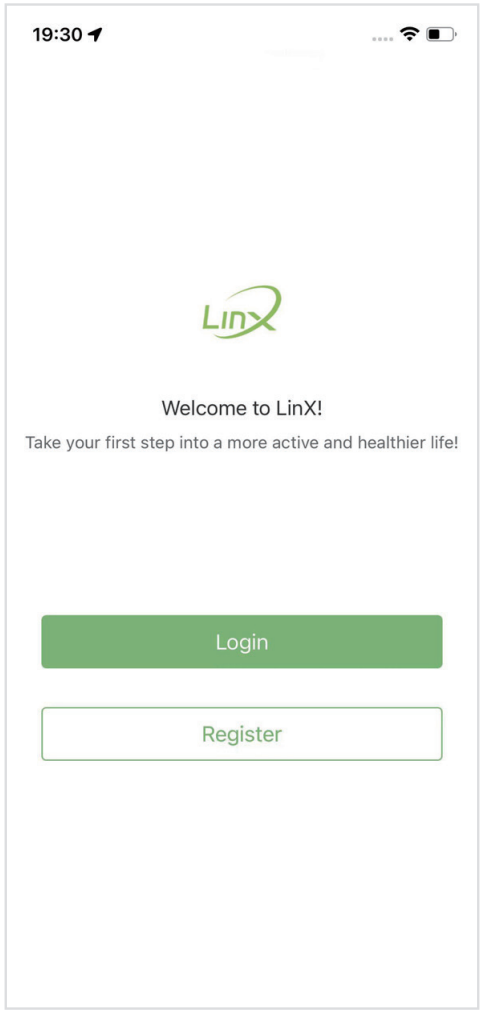
Username:

✓ 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.

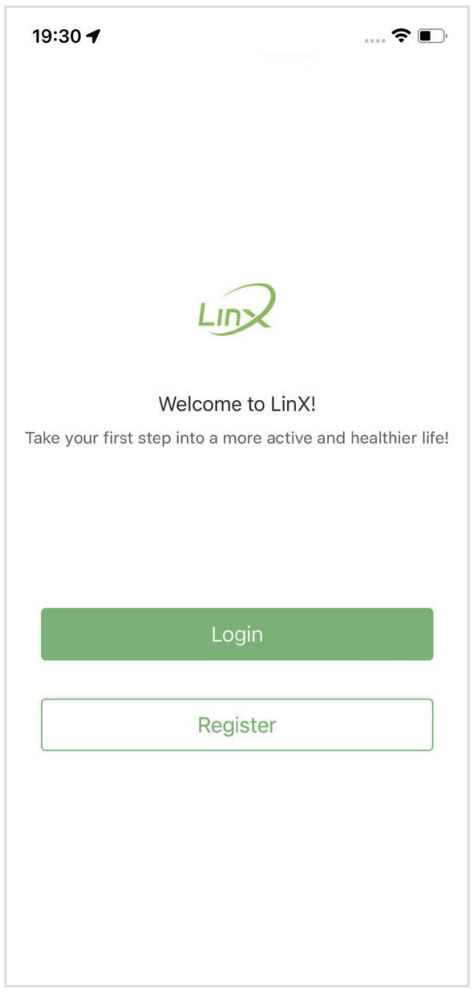


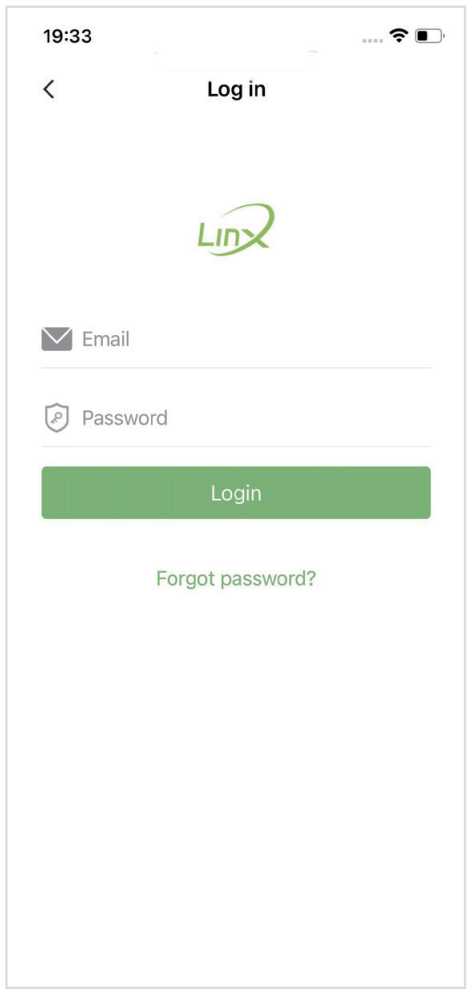
4.2.2 Software Login

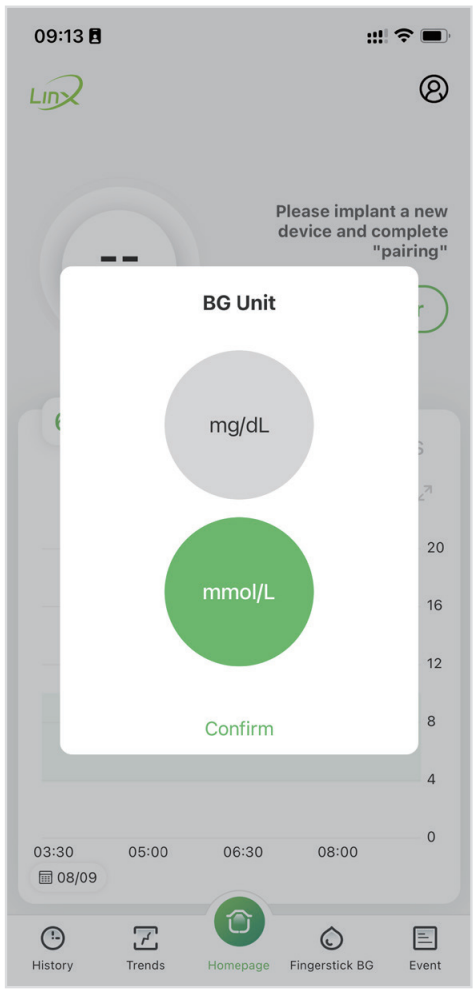
Use your registered account email address and password to log in to the App.

Note

- You may only log in your account on one mobile device at a time.
- If you suspect an adverse cybersecurity event related to the LinX App, contact your local distributor. Make sure that your phone is kept in a safe place. 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 device, such as lock screen password, biometrics, to strengthen the data protection of the App.





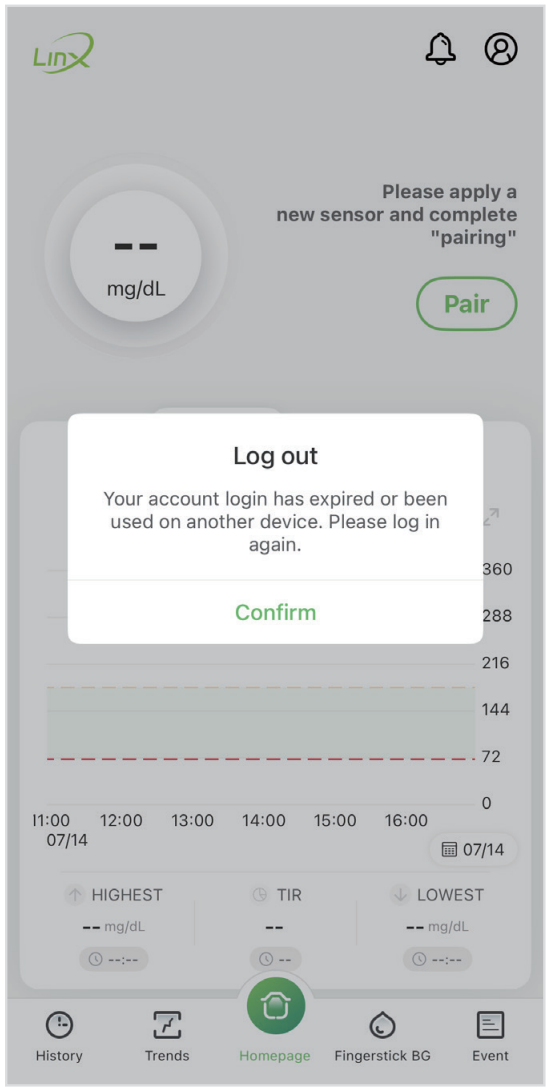


Note

Ensure you select the correct measurement unit (mmol/L or mg/dL). In South Africa, mmol/L is used.

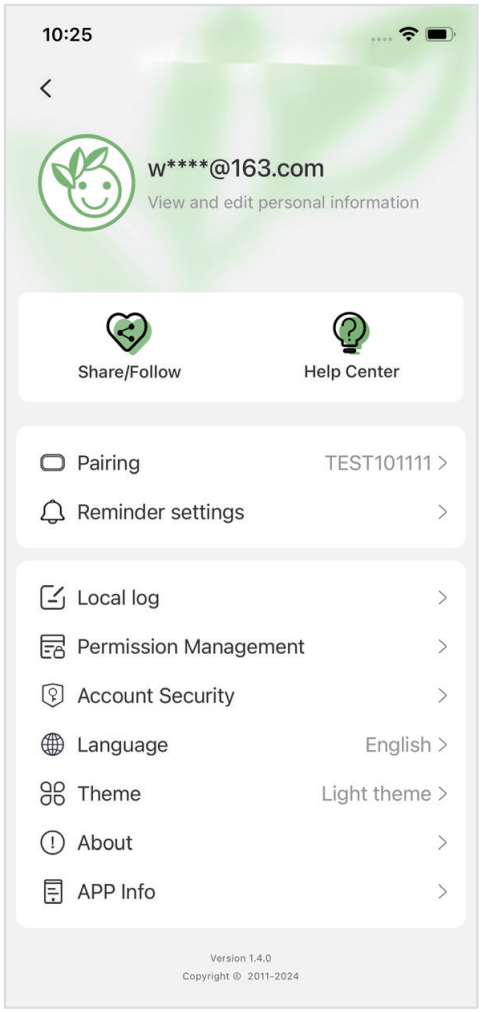
Note

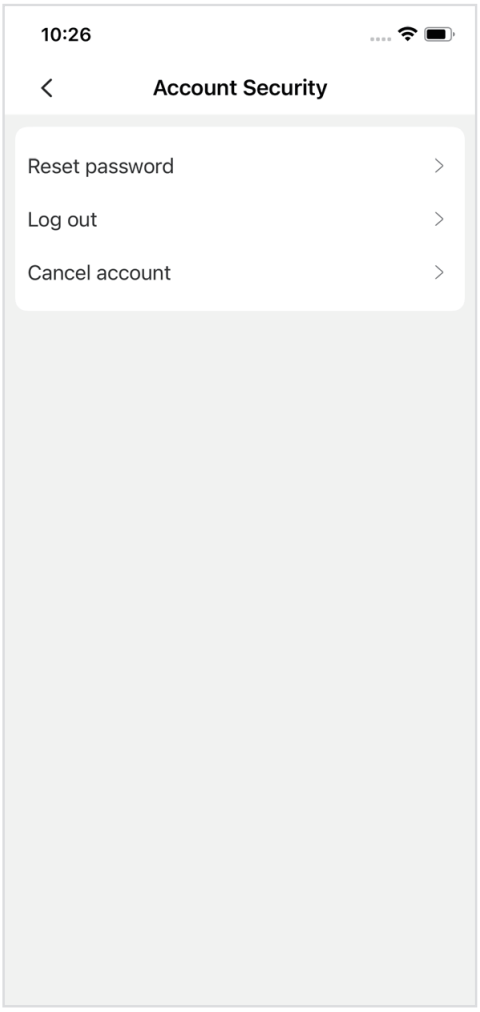
If login fails, another mobile device can be used to try log in to the account, using the same email and password for registration of the account.



4.2.3 Software Logout

To log out of the current account, click “Log out” under “Account Security” on the “Personal Settings” screen.





4.2.4 Software Update

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

4.3 Dashboard Functions

4.3.1 Home

The 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, the blood glucose against time graph is displayed.

You can select the time interval to see the glucose level history and trend over the past 6, 12 or 24 hours.

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

When your sensor expires, the sensor status on the LinX 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.

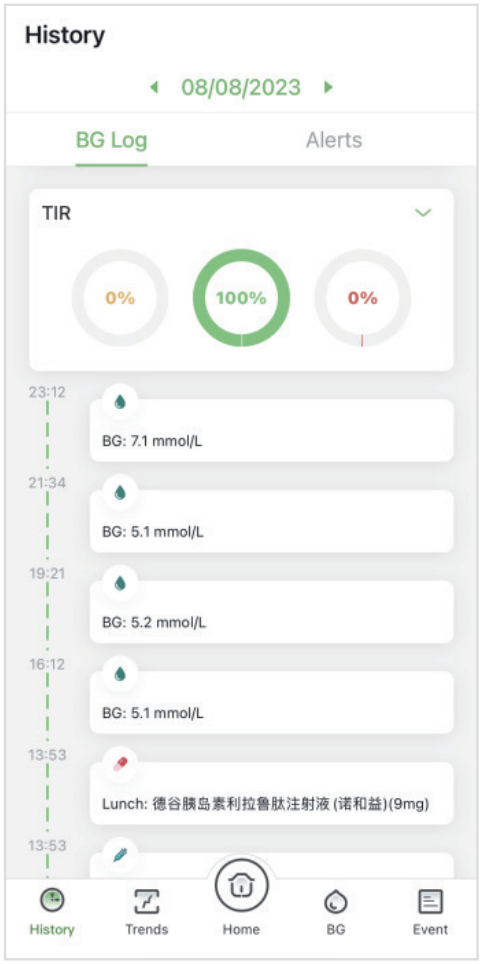
There is no need to unpair the sensor when replacing the sensor.

4.3.2 History

The History dashboard displays glucose alert records, events, and daily glucose data.

1. When the sensor blood glucose level is lower/ higher than the pre-set alert value, the App will alert you according to the custom alert time selected, displaying your glucose levels. The alert value (mmol/L) and time are displayed in the History dashboard.
2. Any events added (i.e carbs, exercise, insulin, medication) will be displayed on the History dashboard.
3. The glucose levels recorded on the “Home” screen will be displayed on the History dashboard.

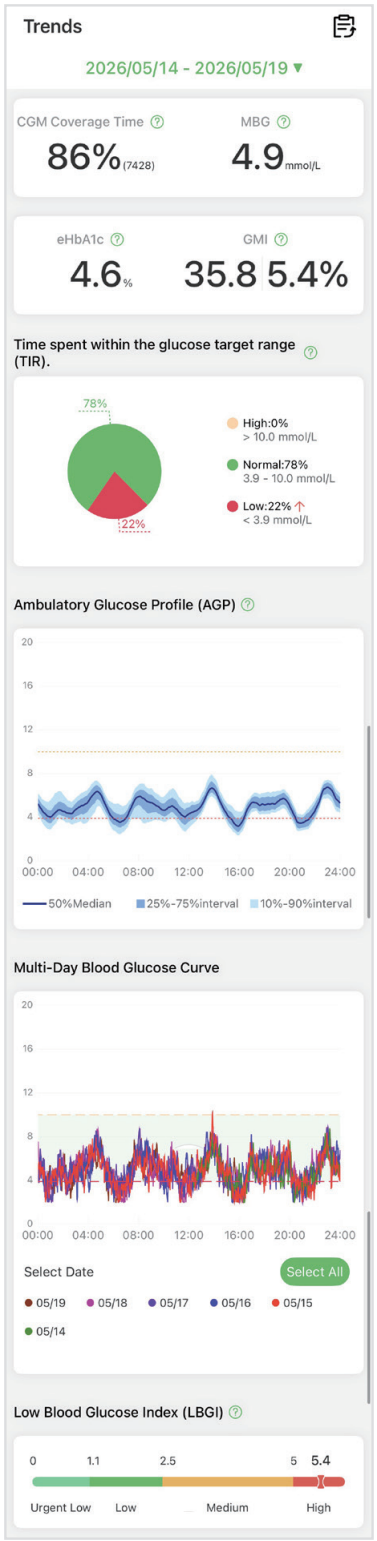

History
08/08/2023
BG Log
Alerts
Carb
65.6g
Protein
18.6g
Fat
1.1g
Exercise time
9.85min
Medication times
1Times
Total Insulin
6.987U
mmol/L
20
16
12
8
4
0
00:00
04:00
08:00
12:00
16:00
20:00
24:00
Maximum fluctuation
4.7
Highest(10:07)
Lowest(02:07)
2.8
History
Trends
Home
BG
Event


History
08/08/2023
BG Log
Alerts
TIR
0%
100%
0%
23:12
BG: 7.1 mmol/L
21:34
BG: 5.1 mmol/L
19:21
BG: 5.2 mmol/L
16:12
BG: 5.1 mmol/L
13:53
Lunch: 德谷胰岛素利拉鲁肽注射液 (诺和益)(9mg)
13:53
History
Trends
Home
BG
Event

4.3.3 Trends

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

1. The display includes an estimated HbA1c, Average Glucose Value, Time-in-Range, AGP profile, Multi-day BG curves and Low BG Index over a period.
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 Blood Glucose (BG) - Calibration

In the Blood Glucose (BG) 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.

It is recommended to take a fingerstick blood glucose test to confirm your BG level in the following situations:

1. When you perceive symptoms of hypoglycaemia such as palpitations, hand tremors or sweating, but the sensor glucose reading is within normal range.
2. When the sensor reading indicates hypoglycaemia (low blood glucose) or close to hyperglycaemia (high blood glucose).

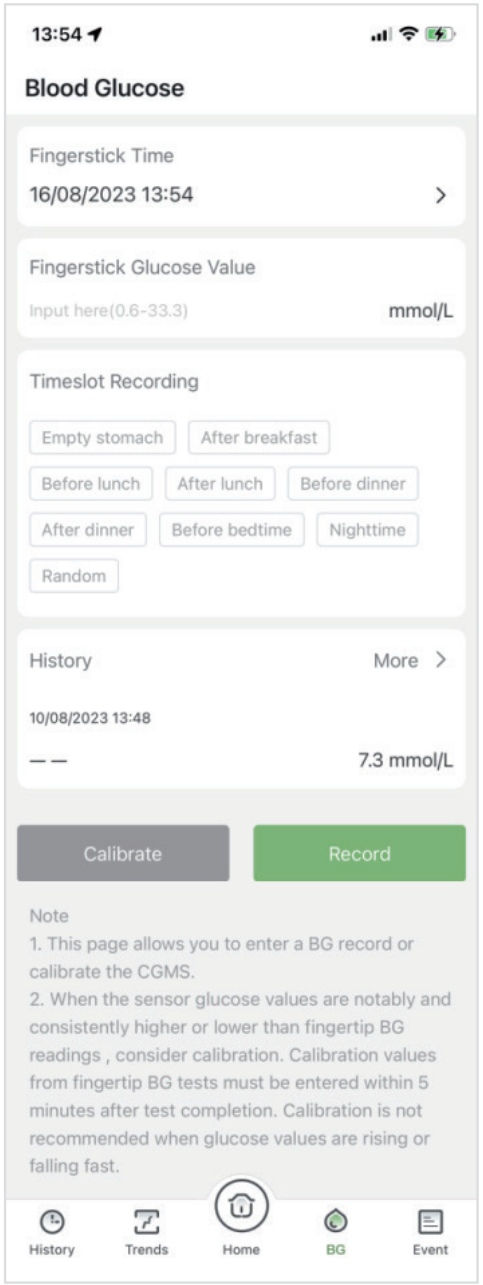
3. If the current sensor reading is 20% higher or lower than the fingerstick blood glucose value, please perform a fingerstick blood glucose test again after 2 hours. If the second reading is still more than 20% higher or lower, you can calibrate the current sensor.

If you choose to calibrate, please ensure 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 confirm the current blood glucose trend by looking at the trend arrow shown on the Home screen of LinX App). The blood glucose value entered for calibration should be the finger blood glucose value measured within 5 minutes. If your current blood glucose trend is rising or falling rapidly, please wait for the blood glucose change to stabilize before taking a fingerstick blood glucose test and calibrating the product.

On the Blood Glucose (BG) dashboard, there are two

functions “Calibration” and “Recording”.

1. Click “Record” to enter the blood glucose value measured using a blood glucose meter. The values will be displayed on the Home and History dashboard.
2. When the glucose value from a fingerstick blood glucose test is different from the sensor glucose value displayed on the Home dashboard, the user can manually input the calibration glucose level to calibrate the sensor.



Note

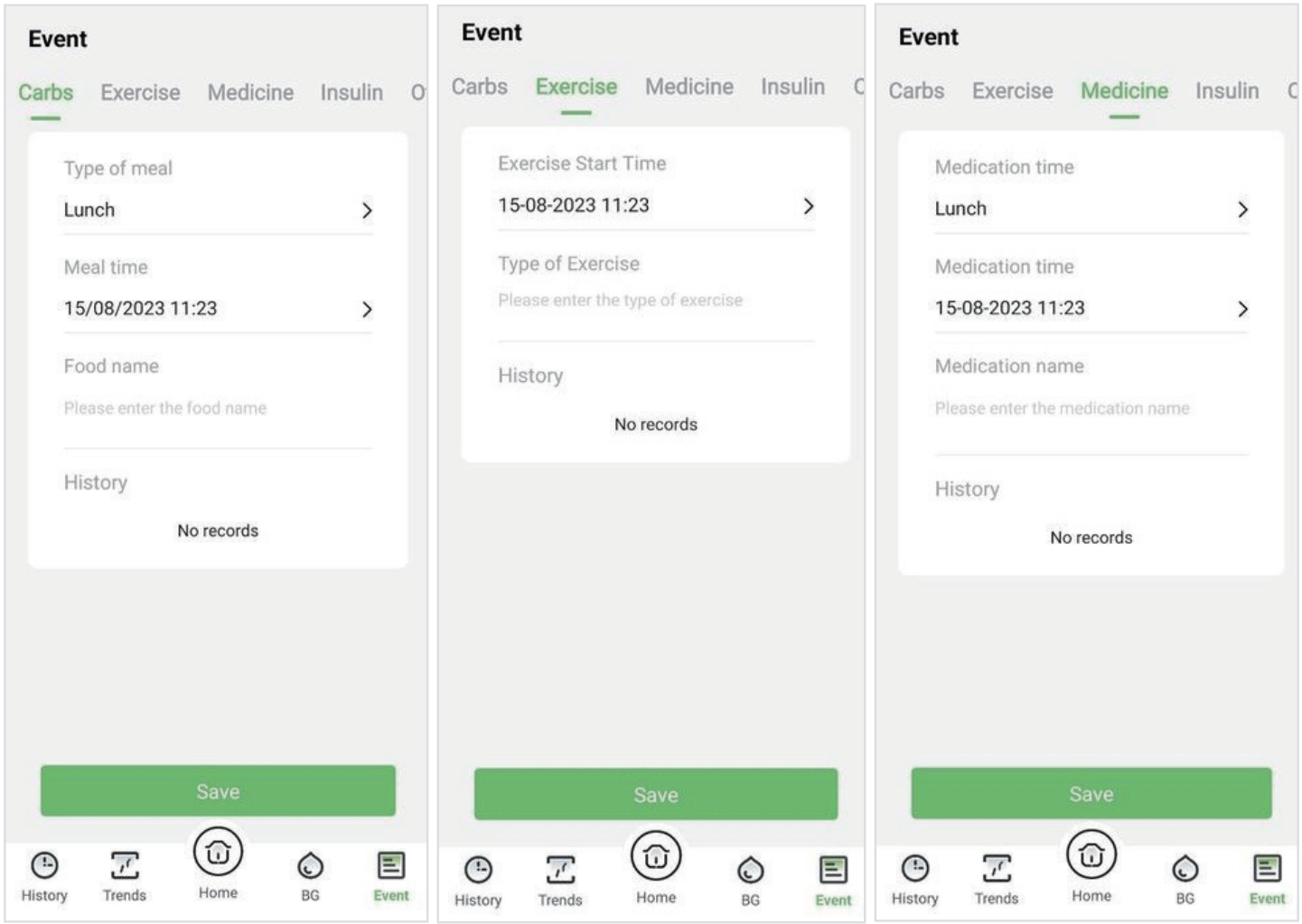
Do not calibrate the system frequently afterward. Do not calibrate while your blood glucose is rising or falling rapidly. The glucose value used for calibration should be the value measured within 5 minutes before the blood glucose test.

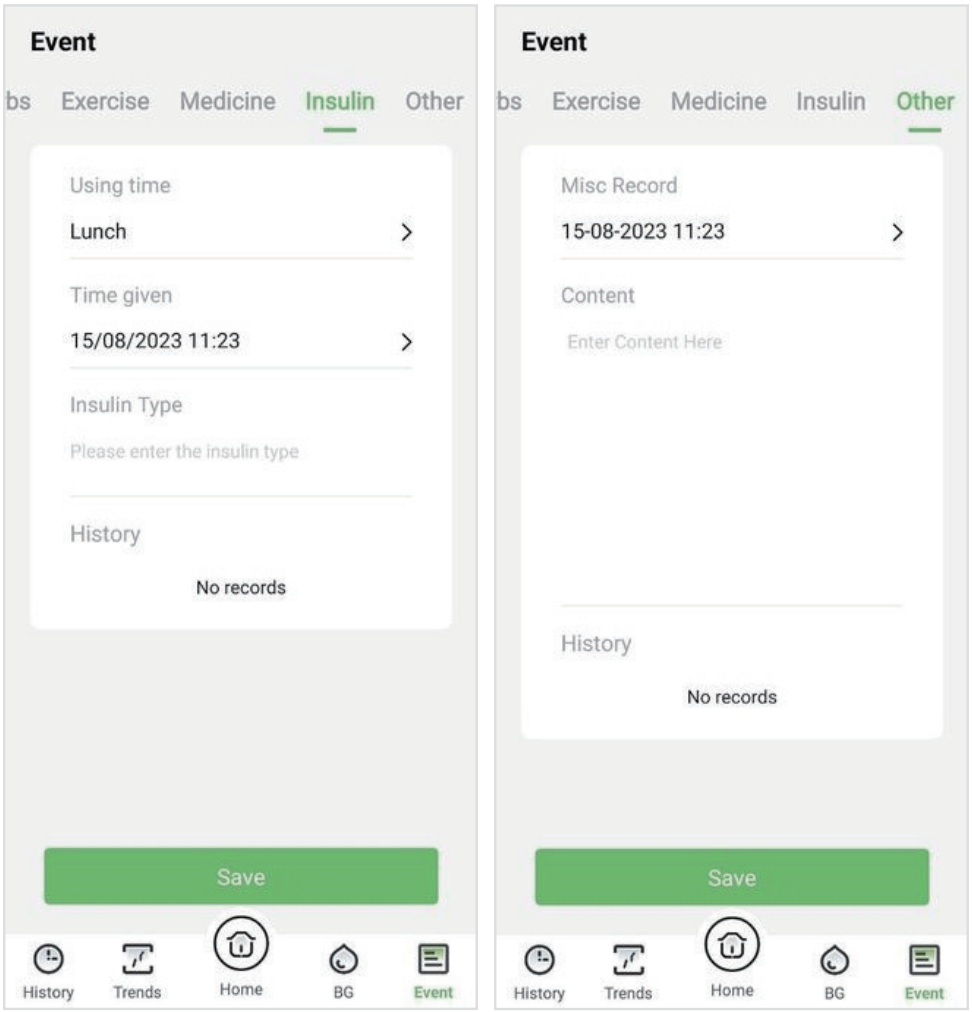
Scroll the slider to input your blood glucose test value. Once you have selected the right value, click “Calibrate” to complete the calibration.

4.3.5 Events

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

1. You can select different types of events including “Carbs”, “Exercise”, “Medicine”, “Insulin” and “Other” at the top of the Event dashboard.
2. You can record the time that the event occurred.
3. The added events will also be displayed in the History dashboard.
4. The recorded events are uploaded to the cloud server. You can access the event history on the Cloud by using your LinX App account.


Event
Carbs
Exercise
Medicine
Insulin
Type of meal
Lunch
Meal time
15/08/2023 11:23
Food name
Please enter the food name
History
No records
Save
History
Trends
Home
BG
Event
Event
Carbs
Exercise
Medicine
Insulin
Exercise Start Time
15-08-2023 11:23
Type of Exercise
Please enter the type of exercise
History
No records
Save
History
Trends
Home
BG
Event
Event
Carbs
Exercise
Medicine
Insulin
Medication time
Lunch
Medication time
15-08-2023 11:23
Medication name
Please enter the medication name
History
No records
Save
History
Trends
Home
BG
Event


Event
bs
Exercise
Medicine
Insulin
Other
Using time
Lunch
Time given
15/08/2023 11:23
Insulin Type
Please enter the insulin type
History
No records
Save
History
Trends
Home
BG
Event
Event
bs
Exercise
Medicine
Insulin
Other
Misc Record
15-08-2023 11:23
Content
Enter Content Here
History
No records
Save
History
Trends
Home
BG
Event

5.Using a New Glucose Sensor

5.1 Inserting a Sensor

Caution

During intense exercise, your sensors may fall off due to excessive sweating or sensor dislodging. If your sensors dislodge, you will not receive any sensor readings or the readings will be unreliable.

Select the appropriate insertion site according to the instructions.

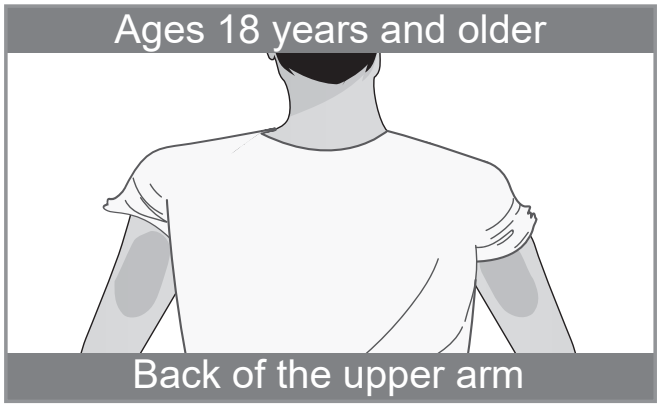
Note

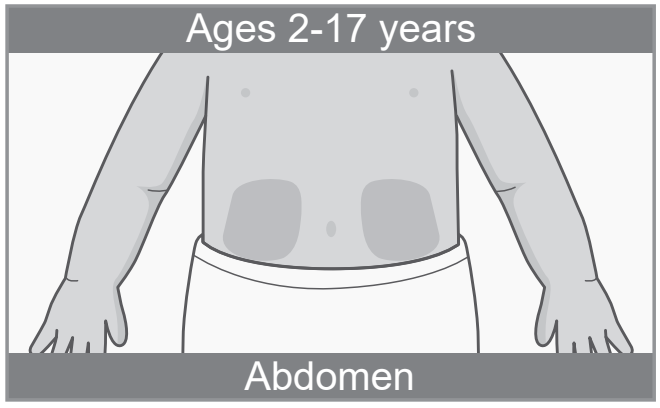
Open the App and enter the Personal Settings screen. Click “Help Centre” in the main menu to enter the User Guide that explains how to insert the sensor.

1. Recommended areas for sensor insertion include the abdomen (age 2-17 years), the outside and the back of the upper arm(age ≥ 18). Avoid areas with scars, moles, stretch marks or lumps. For best performance, avoid excessive motion which may weaken the sensor and its adhesive tape.

2. Choose an insertion site that is normally not affected by your usual daily activities (stretching or compression). Be careful not to bump or knock the sensor off.

3. It should be at least 5-7.5 cm away from any insulin injection site. To avoid discomfort or skin irritation, ensure you rotate sites each time and insert the new sensor into a different site from the previous one.



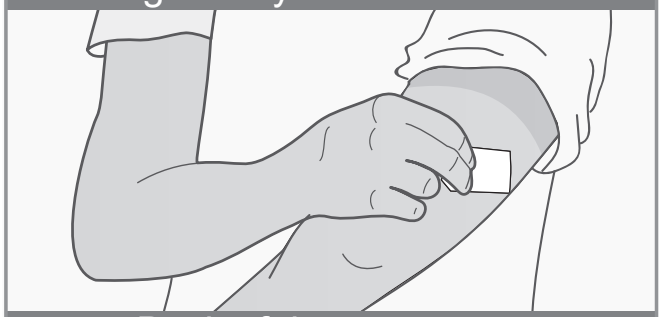


4. Wash the insertion site with soap, dry it, clean it with an alcohol wipe and allow to air dry. Ensure you have removed any oily residue that may affect the adhesion of the sensor.

Note

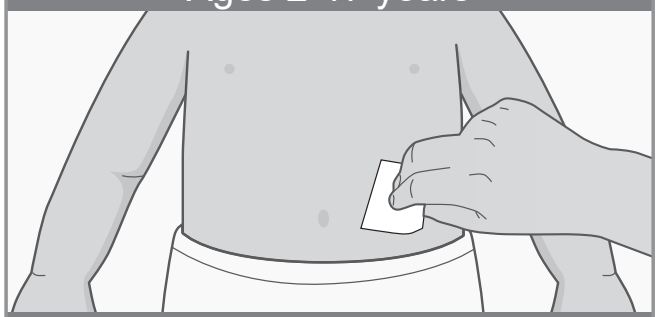
The skin area must be clean and dry. Otherwise, the sensor will not stick to the skin.

Ages 18 years and older



Back of the upper arm

Ages 2-17 years



Abdomen

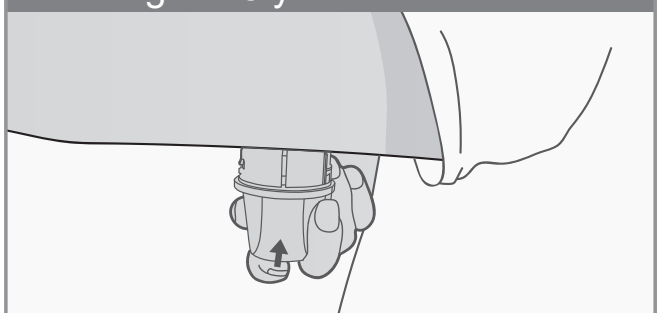
5. Remove the cover from the sensor applicator and set it aside.

Caution

- Do not use the sensor applicator if it is damaged or if the safety seal has been tampered with.
- Do not reattach the sensor applicator, as this will damage the sensor.
- Do not grasp the inside of the sensor applicator, as the introducer needle is exposed.
- Do not use the sensor after the expiration date.

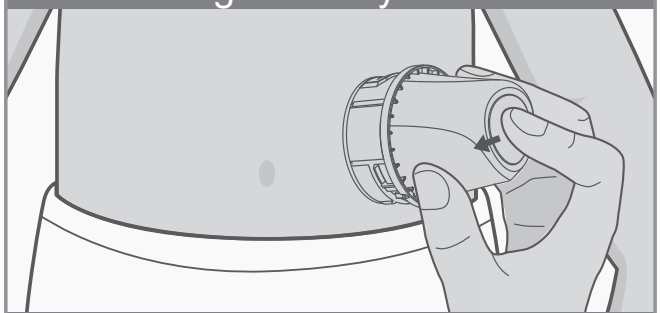
6. Align the opening of the applicator onto the insertion site and press tightly against the skin. Press the insertion button on the top of the applicator. Wait a few seconds after the sensor inserts to ensure it adheres properly to the skin. The introducer needle automatically retracts into the applicator after sensor insertion.

Ages 18 years and older



Back of the upper arm

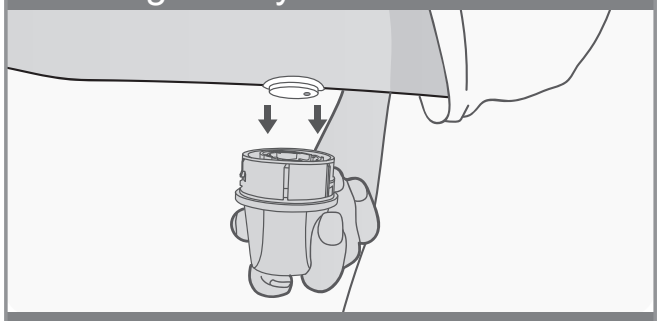
Ages 2-17 years



Abdomen

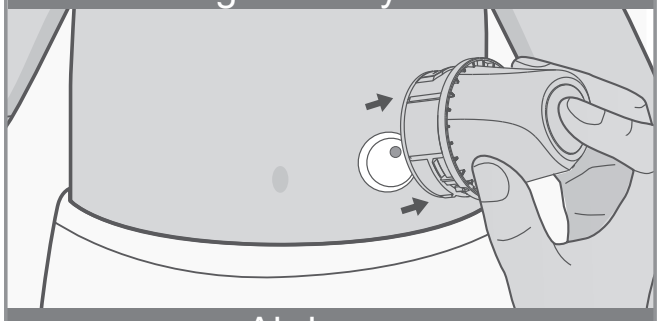
7. Gently pull the sensor applicator away from the body, and the sensor should now be attached to the skin.

Ages 18 years and older



Back of the upper arm

Ages 2-17 years

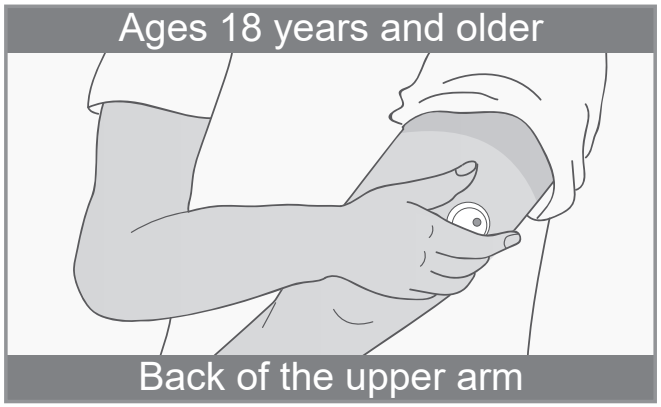


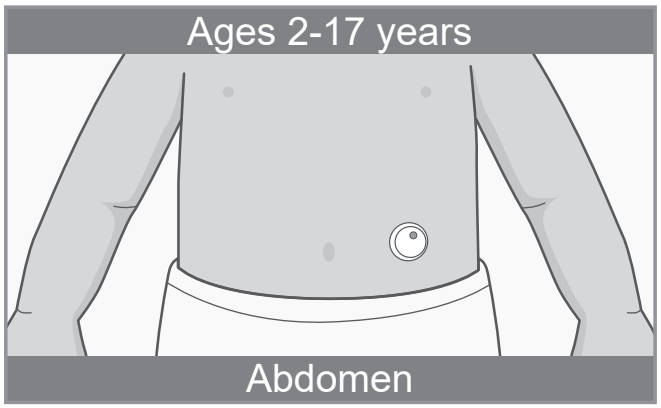
Abdomen

Note

There may be bruising or bleeding after inserting the sensor. If bleeding persists, remove the sensor and insert a new sensor at a different recommended insertion site.

8. After inserting the sensor, make sure that the sensor is firmly in place. Replace the cover on the sensor applicator.

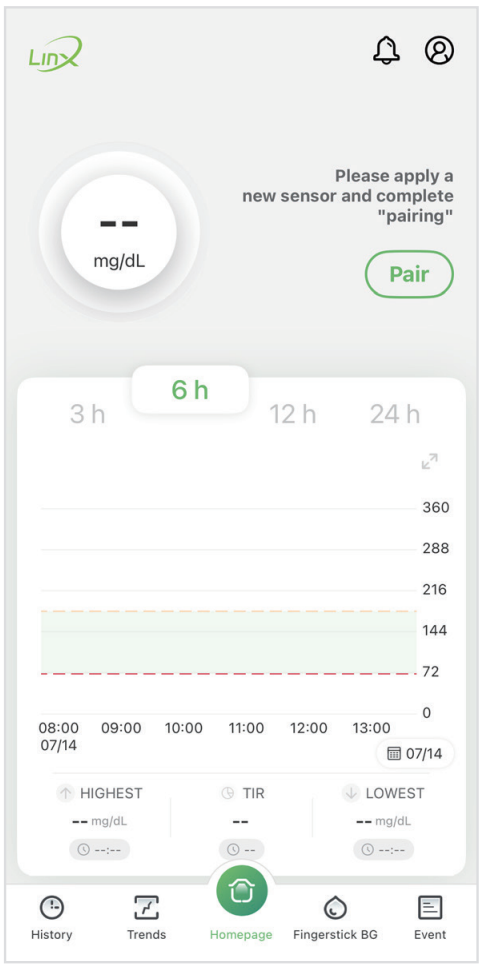




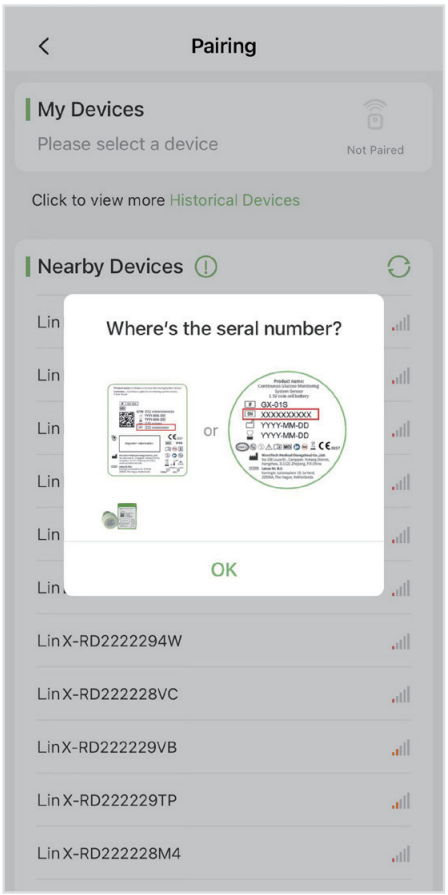
5.2 Starting a Sensor

Pairing a Sensor

- Click “Pair” on the Home screen and select your sensor by searching for the device.



- Select your device, enter the Serial Number (SN) printed on the sensor box label or scan the QR code.



Note

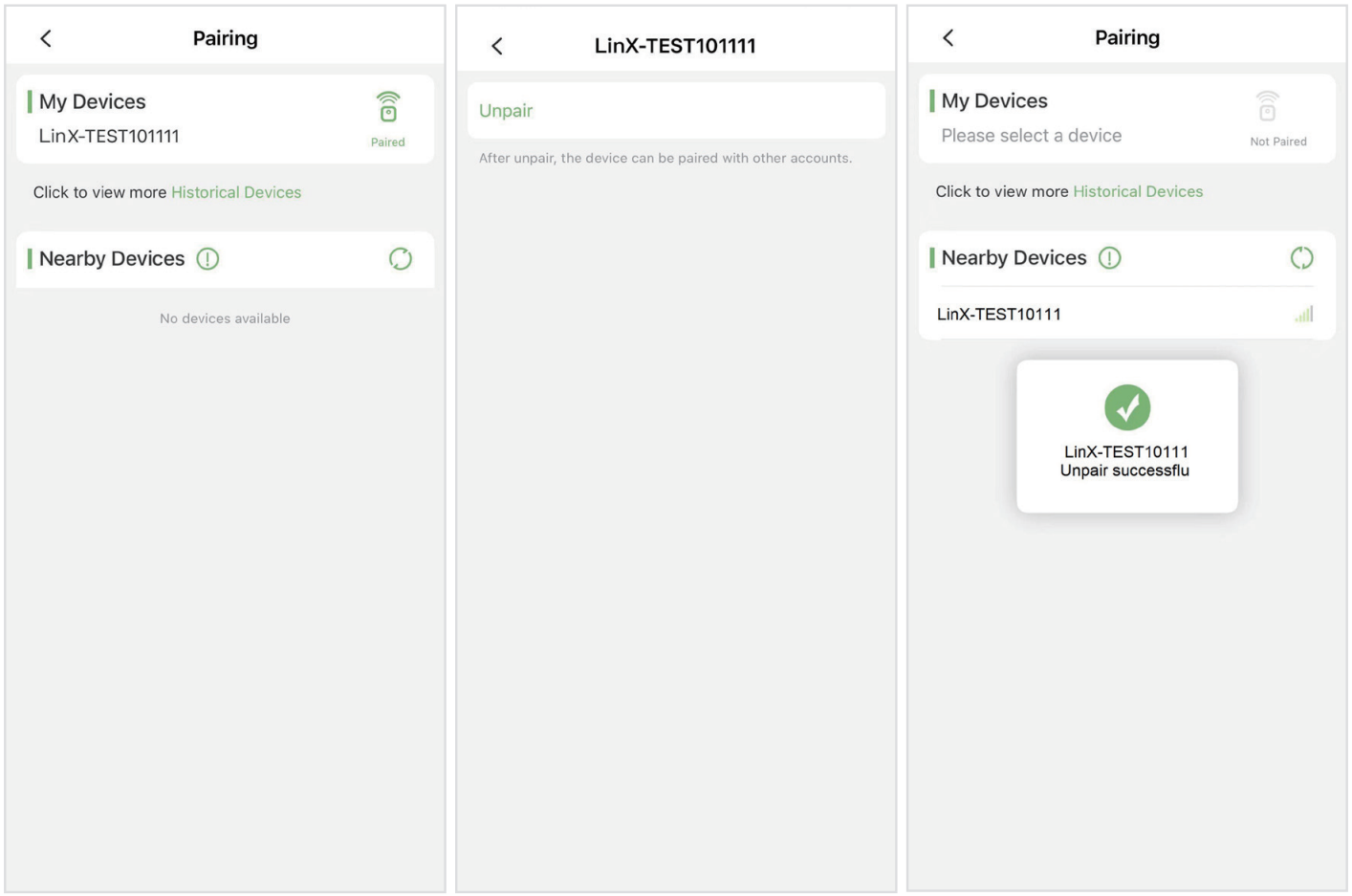
Please enable the Bluetooth function on your mobile device. The communication range between your mobile device and sensor should be no more than 6 metres without any obstacles. If pairing fails, a notification box will appear. Users can choose to retry or input the SN again.

Sensor Warm-up

When you have successfully paired the sensor, please wait one hour for your sensor to warm up. The real-time glucose readings (updated every minute) will be visible 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 LinX 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 insertion site when the App prompts that the sensor has expired or when the user feels any irritation or discomfort at the insertion site during use.
2. Pull up the edge of the adhesive that attaches the sensor to the skin and slowly peel it away in one motion.

Note

1. Any remaining adhesive residue on the skin can be removed with warm soapy water or an alcohol wipe.
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 insert a new sensor, follow the instructions in “5.1 Inserting a Sensor” and “5.2 Starting a Sensor”.

5.5 Replacing a Sensor

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

Note

If the sensor glucose reading does not appear to be consistent with your symptoms, check whether the sensor may be loose.

If the sensor tip is no longer underneath the skin, or if the sensor is loose, remove the sensor and insert a new one.

6. Personal Settings

6.1 Reminder Settings

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

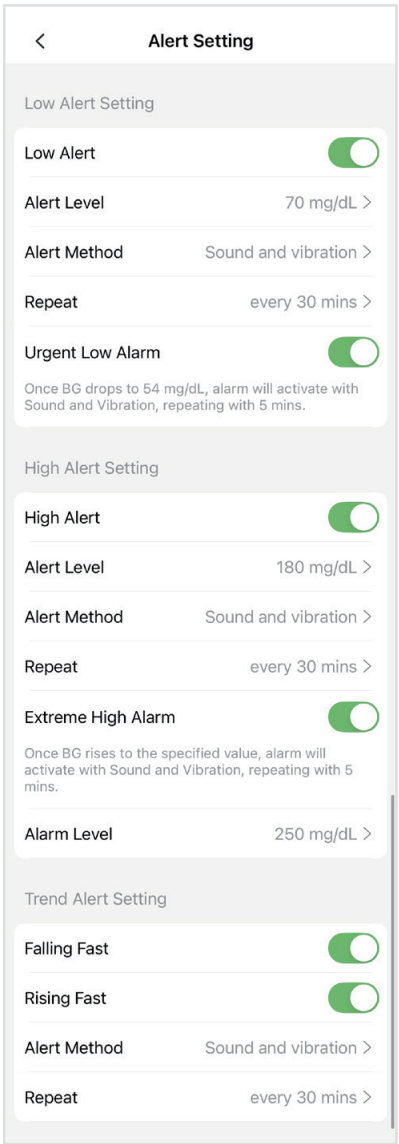
Note

To receive alerts, make sure:

- The alerts are switched on and your mobile device is always within the transmission range of a maximum distance of 6 metres away from you. If you are outside the range, you may not receive the alerts. To receive alerts from the App, ensure your device is connected.
- The App must be running in the background all the time to receive alerts.
- The App will request to activate phone permissions which are needed to receive alerts.

Setting Alerts

The alerts can be set up in the Alerts dashboard. You can set the values for high glucose, low glucose and urgent low glucose 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 and low glucose alerts will also be displayed in the History dashboard.



You will receive a notification alert when:

- Your glucose is too low.
- Your glucose is too high.
- Your glucose is decreasing rapidly.

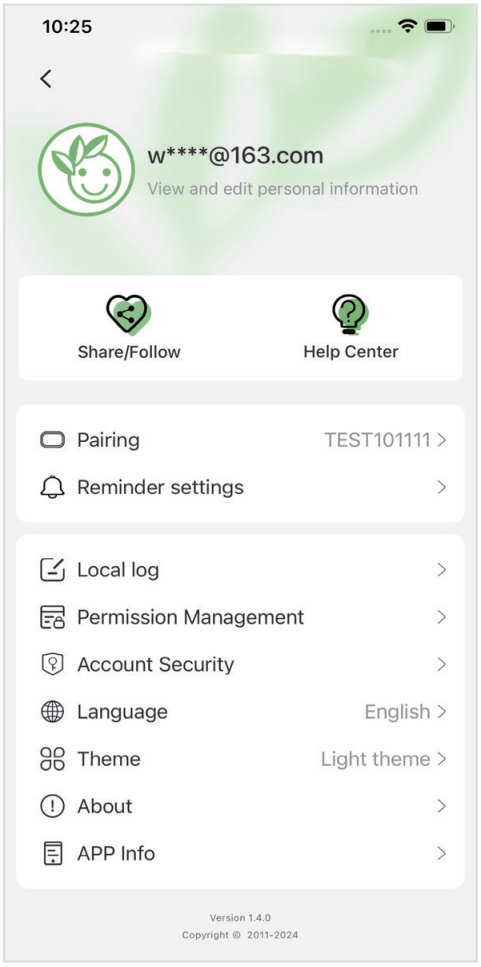
- Your glucose is increasing rapidly.
- Sensor signal is lost.
- Urgent low glucose occurs.

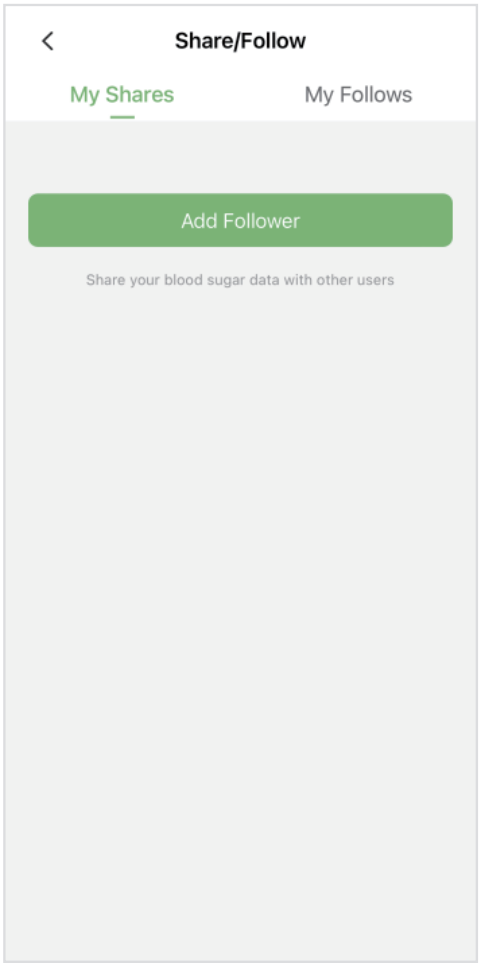
6.2 Sharing/Following

Click the “Personal Settings” icon on the top right-hand corner, then click “Share/Follow” to set up glucose level data sharing.

Note

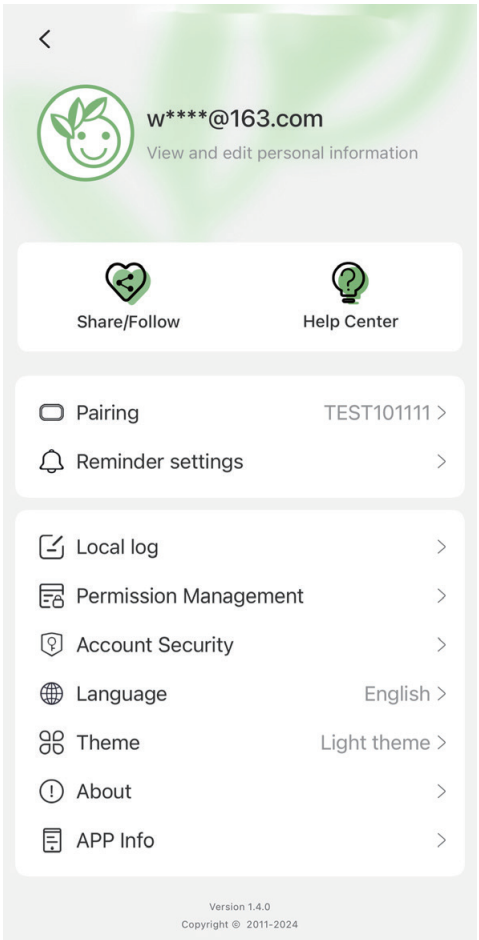
Blood glucose data is for your private use only. Think carefully before sharing your data with other accounts and keep data shared with others confidential.


10:25
w****@163.com
View and edit personal information
Share/Follow
Help Center
Pairing
TEST101111
Reminder settings
Local log
Permission Management
Account Security
Language
English
Theme
Light theme
About
APP Info
Version 1.4.0
Copyright © 2011-2024


Share/Follow
My Shares
My Follows
Add Follower
Share your blood sugar data with other users

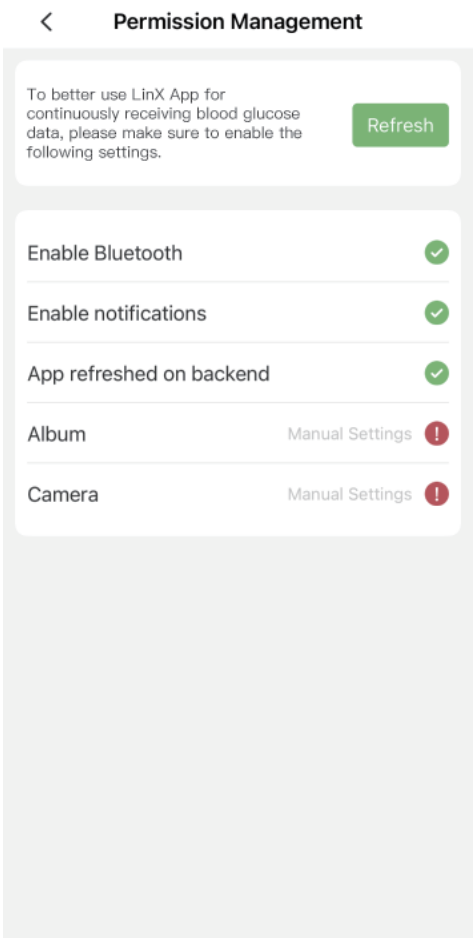
6.3 Local Log

In the event of any errors or software faults, click ‘’Local Log” to provide feedback to technicians for further investigation.



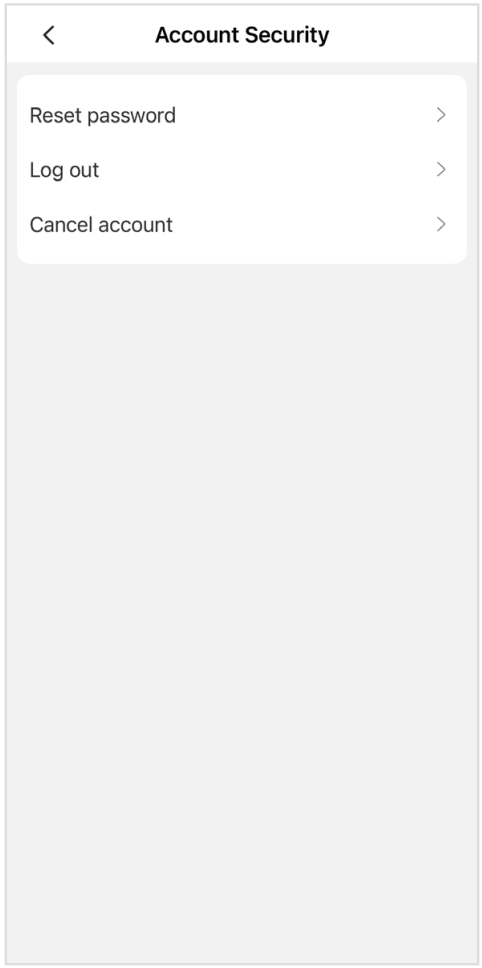
6.4 Permission Management

The App may require certain permissions, such as: Enable Bluetooth, Enable notifications, Refresh App in the background, Access to camera, in order to provide you with corresponding services.



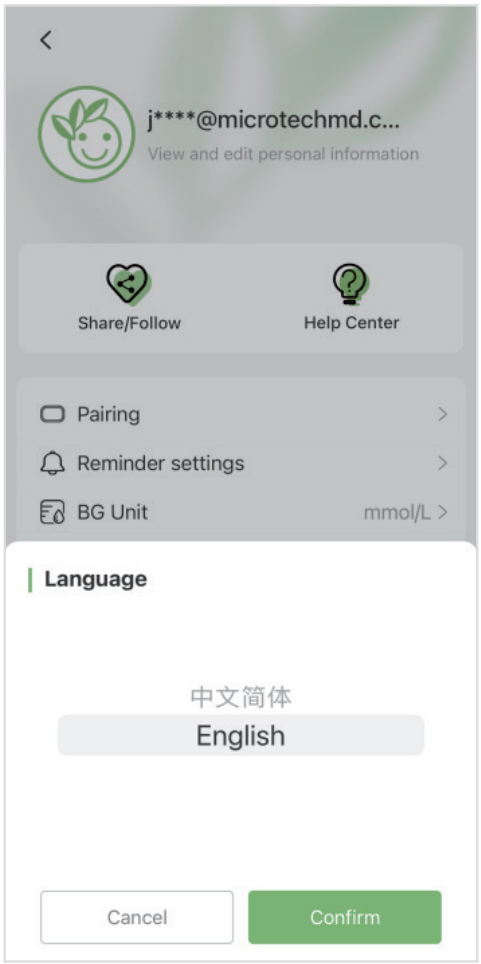
6.5 Account Security

On the Personal Settings screen, click “Account Security” to access Reset Password, Log Out, and Delete Account functions.



6.6 Language

Click the “Personal Settings” icon on the top right-hand corner of the Home screen, then click “Language” to select the App language.

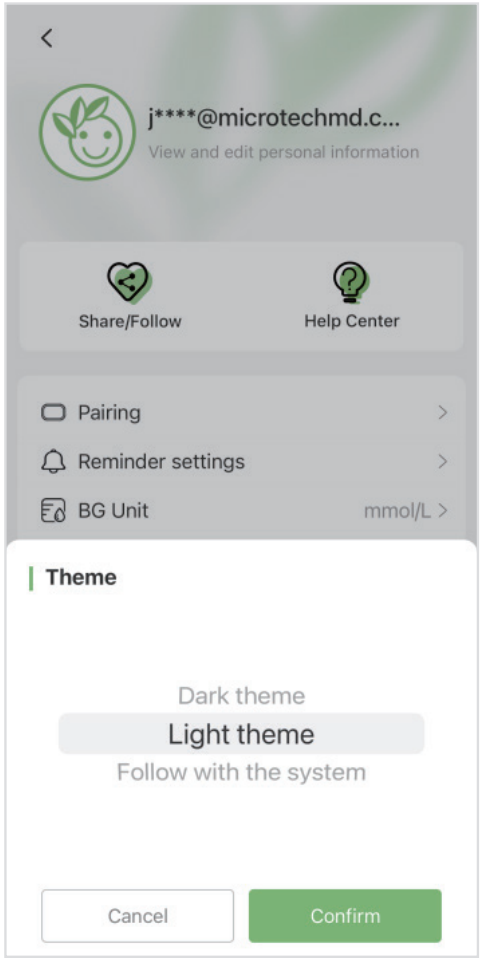


6.7 Theme

On the Personal Settings screen, you can select a light or dark style under “Theme”.

Note

For iOS, there is an additional option “Follow with the system”, which allows you to follow the system’s theme.



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**:

- The sensor is a precision device. If failure is not serviceable, third-party individuals or institutions are not permitted to disassemble and repair the device. Circuit diagrams and component lists are not provided in the instructions.
- Mobile device applications continue to improve to meet new requirements or problem resolution.
- If the App update fails, uninstall the original App and install the latest version.

7.1 Cleaning

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

7.2 Disposal

Sensor:

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 them 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

The sterile sensor packaging should not be exposed to heavy pressure, direct sunlight or moisture during transportation. It shall be transported in accordance with the storage and transportation conditions specified for the product.

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, first check if the Bluetooth function on your mobile device has been switched on. If so, the pairing will be restored automatically. If the problem persists, restart the App.

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 Bluetooth and re-pair the App and the corresponding sensor or contact your local distributor.

Sensor Signal Lost

When the “Sensor Signal Lost” notification pops up, please check if you have switched your Bluetooth off.

After switching your Bluetooth function back on, the signal connection between the App and the sensor will be restored automatically. If the “Error” notification pops up, please restart the App or Bluetooth. The blood glucose data is temporarily stored in the sensor during signal loss. When the connection between the App and the sensor is restored, all relevant data will be transmitted to the App.

Failure to Read Data

Data reading failure can be caused by signal interference. Users are required to stay away from environments with strong electromagnetic interference. You may contact your local distributor for assistance.

Note

Should a software fault occur, the user can click “Feedback” to upload the software log to the cloud, and the technical support staff will analyse and solve the problem.

9. Performance Characteristics

Note

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

To demonstrate the accuracy performance of the LinX CGM System, two prospective clinical studies were conducted at seven centers in China.

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 analysed over up to three separate visits to the clinical center using the Glucose and lactate measuring Instruments manufactured by EKF-diagnostic GmbH.

- Accuracy results obtained from the adult study

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 value.	94.6%
Results within a deviation range of ±2.22 mmol/L from the reference value.	100.0%
The percentage of data points that fall within Clarke error grid zones A+B	99.7%
The percentage of data points that fall within Consensus error grid zones A+B	100.0%

- Alert rate

The success rate of hyperglycaemic alert: 89.4% (hyperglycaemic alert threshold set at 11.1mmol/L);

The success rate of hypoglycaemic alert: 89.3% (hypoglycaemic alert threshold set at 4.4mmol/L).

Paediatric 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 analysed 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.

- Accuracy results obtained from the paediatric 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 value.	90.2%
Results within a deviation range of ±2.22 mmol/L from the reference value.	100.0%
The percentage of data points that fall within Clarke error grid zones A+B	99.8%
The percentage of data points that fall within Consensus error grid zones A+B	99.9%

- Alert rate

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

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

- Accuracy results obtained from the paediatric 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 value.	90.9%
Results within a deviation range of ±2.22 mmol/L from the reference value.	100.0%
The percentage of data points that fall within Clarke error grid zones A+B	99.7%
The percentage of data points that fall within Consensus error grid zones A+B	100.0%

- Alert rate

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

The success rate of hypoglycaemic alert: 100.0% (hypoglycaemic 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 paediatric trial) were recorded.

10. Specifications

Continuous Glucose Monitoring System Sensor	
Item	**Specification**
Model number	GX-01S
Operating temperature	5-40°C
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	15 days
Shelf life	16 months
Detection range	2.0mmol/L-25.0 mmol/L
Wireless frequency and bandwidth	Frequency: 2.402GHz ~ 2.48 GHz Bandwidth: 1Mbps
Wireless modulation	GFSK
Radiated power	-2dBm

Continuous Glucose Monitoring System 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 cellular network and 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 recognised 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 of this product is that within the measurement range, the glucose concentration measurement should meet the technical requirements for linearity and repeatability.

Guidance and Manufacturer'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 function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 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.

Immunity test	Compliance Level	Electromagnetic environment - guidance
Electromagnetic discharge(ESD) (IEC61000-4-2)	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Floors should be made of wood, concrete or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz, PM, 2.1 kHz, 65 A/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)	10 V/m 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 metres (m). Field strengths from fixed RF sensor, 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.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
3. To establish the proximity threshold of 0.15 for Proximity magnetic fields, the IEC Subcommittee (SC) 62A considered the types of proximity 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 kHz.

   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.
4. Field strengths from fixed sensor, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF sensor, an electromagnetic site survey should be considered. If the 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.
5. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note

1. The continuous glucose monitoring system is 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.

2. The performance in relation to the intended use of continuous glucose monitoring systems is within the measurement range, the repeatability of glucose concentration measurements should meet the specified requirements.

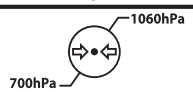
Recommended minimum separation distances:

RF wireless equipment is used in various healthcare locations where medical equipment and/or systems are used. When they are used near 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 meets 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 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

12. Appendix

12.1 Symbols

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).	IP68
Consult the Electronic Instructions for Use at microtechmd.com	

Manufacturer	
Importer	
Authorised Representative in the European Community	EU REP
MR unsafe	
Do not use if package is broken	
Date of manufacture	
Use-by date	
Batch code	LOT
Serial number	SN
Waste Electrical and Electronic Equipment (WEEE)	
Caution	
Unique device identifier	UDI
Medical device	MD
CE Mark	CE 0197

12.2 Potential Interference Information

Studies have shown that when users take standard doses of ascorbic acid or acetaminophen (ascorbic acid blood concentration < 6 mg/dL, acetaminophen blood concentration < 20 mg/dL), the drug does not interfere with the sensor's glucose measurement. However, if the user's blood uric acid levels are significantly higher than normal (blood uric acid concentration > 10 mg/dL or 600 μmol/L), the uric acid in the body may generate an interference current on the sensor electrode surface, reducing the accuracy of the final glucose reading. Additionally, hydroxyurea has a notable impact on Continuous Glucose Monitoring (CGM) values, with the size of the error depending on the actual blood uric acid concentration. If a user feels that their physical condition does not align with the

glucose readings from the CGM or suspects that the measurements may be inaccurate, they should perform a blood glucose test using a fingerstick glucose meter. Based on the test results, appropriate management actions can then be taken. It is important to record the blood glucose values promptly after using the fingerstick meter to avoid forgetting or inaccuracies.

Any serious injury or death related to the device should be reported to the manufacturer and the relevant authority where the user and/or patient is located.

12.3 Potential Risks

- **Inaccurate glucose values**

  Exposure to heat for a 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.

- **Hyperglycaemia or hypoglycaemia**

  Hypo- and hyperglycaemia events stemming from missed alerts or sensor inaccuracies.

12.4 Potential Clinical Benefit

The potential clinical benefits of the CGMS are:

- Improved management of A1C and TIR for tighter glycaemic control
- Reduced time spent in hypoglycaemia and hyperglycaemia
- Reduction in hypo and hyperglycaemic events in diabetes patients

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 decilitre of blood (mg/dL) or millimoles of glucose per litre 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 fluid in your skin, called interstitial fluid. Those glucose results are then sent to an App, where they are displayed as glucose levels and long-term glucose trends.

Hyperglycaemia (high blood glucose)

High levels of glucose in the blood, also known as high blood glucose. When left untreated, hyperglycaemia

can lead to serious complications. Talk to your health-care professional to determine your high glucose level.

Hypoglycaemia (low blood glucose)

Low levels of glucose in the blood, also known as low blood glucose. When left untreated, hypoglycaemia 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 specific situations in which the LinX CGM should not be used because it may be harmful to you or damage the system.

mg/dL

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

mmol/L

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

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E: diabetes@homemed.co.za
www.linxcgm.co.za

You can request this IFU in paper form from your local dealer with no additional cost. You will receive it within 7 calender days.

1034-IFU-008. V03
1034-PMTL-610. V03
Effective Date: 2026-07-16
Support Software Version
V2.4.0 and older