MicroTech Medical

LinX FAQs

Contents

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Operation Notes

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Product Components

Applicator + Sensor

APP

App download and permission settings

Download in Google play store or IOS store

Google Play App Store

Permission Setting

The App can only be used when

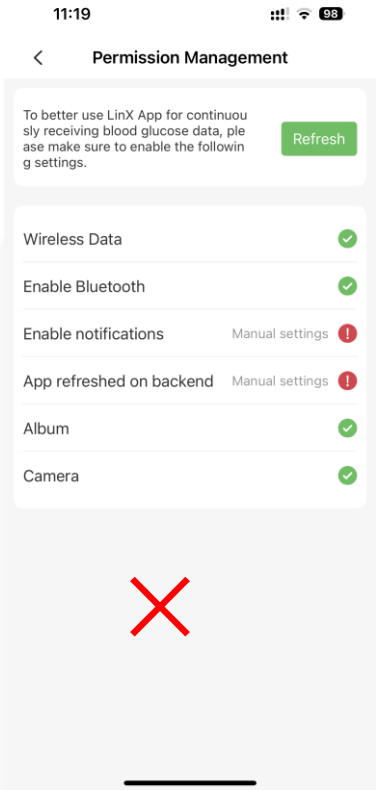
all setting is green and checked in APP .

- Android

(Software Version requires 10.0 or above, HarmonyOS2)

- iOS

(Software Version 14 or above)



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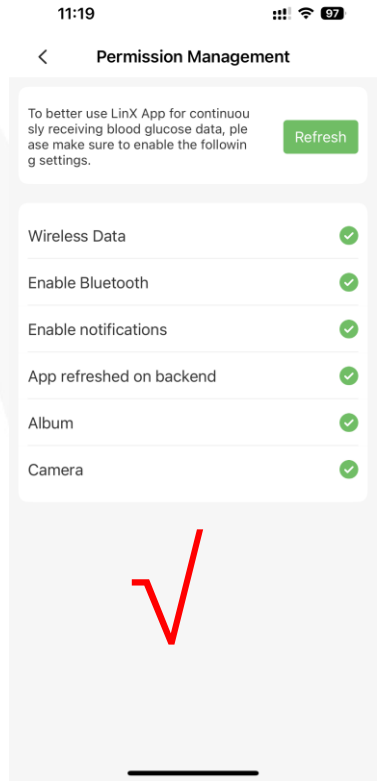

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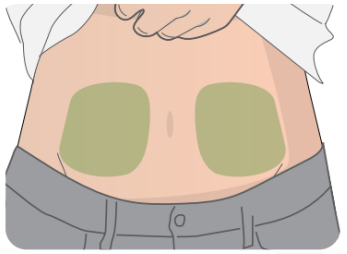
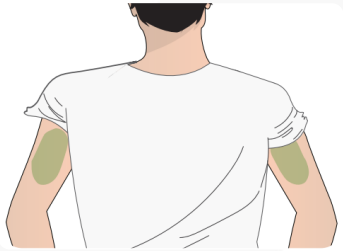
Wear a new sensor

1) Choose the Insertion Area:

-Children and adolescents (age<18):
About 3-10 cm around the belly button of the **abdomen**



-Adults: **upper arm**

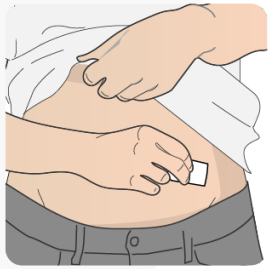


-When you are wearing an insulin pump
More than 2.5 cm from the insertion site of the insulin pump

-When you are using insulin injection
More than 2.5 cm from the injection site

2) Sterilize:

Before the insertion, clean the insertion site with an alcohol wipe and let it dry completely.

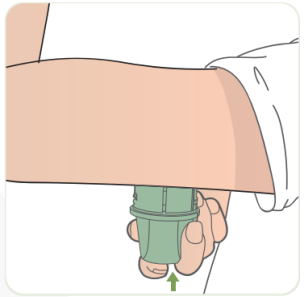


Wear a new sensor

3) Apply sensor:

Open the sterilized package, unscrew the applicator and lift it out of the package

Push the applicator vertically and firmly against the insertion area, and then press the top button to insert the sensor.



4) After insertion:

keep pushing down for about 3 seconds to allow the adhesive patch completely stick to the skin, and then remove the applicator.

Use your fingers to flatten the edge of the patch to avoid wrinkles and warping.

Wear a new sensor

5) Pair with the App:

Tap “Pair“ on the home screen.

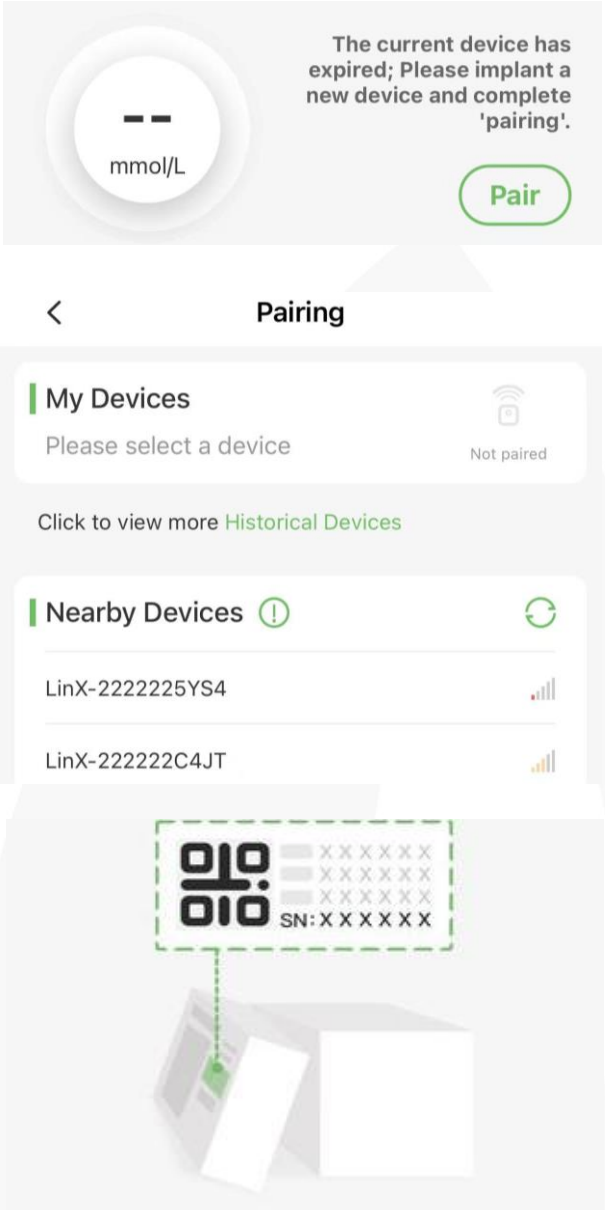
Check the device detected in the list, usually there is only one SN shown on the list.

Tap to connect.

If there is more than one SNs detected.

Check if the Sensor SN is the same as show on the sensor package

Tap the correct CGM SN to connect.



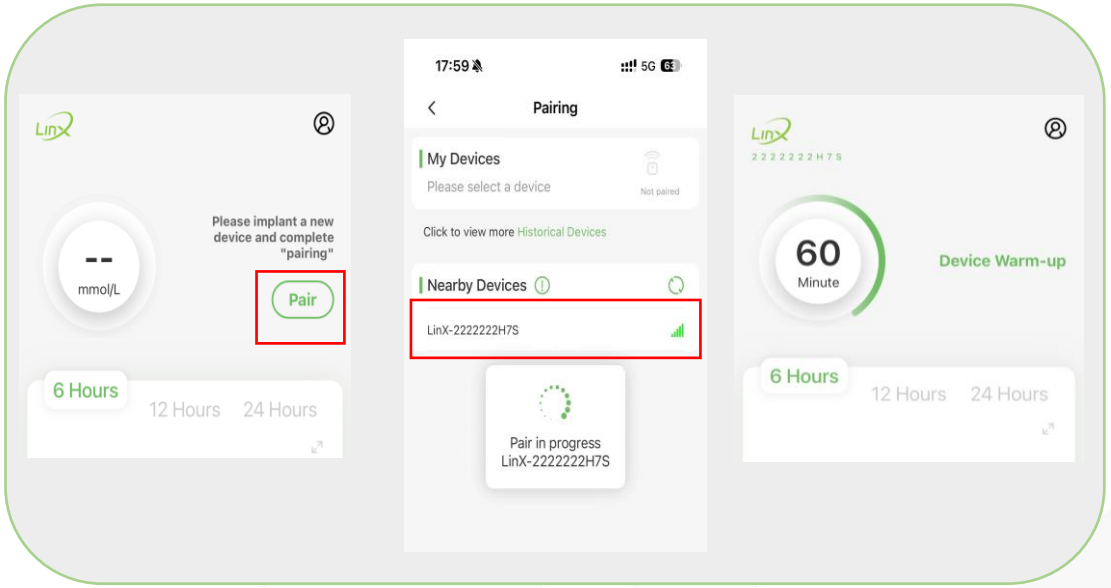
Pairing and Confirming a New Sensor on the App

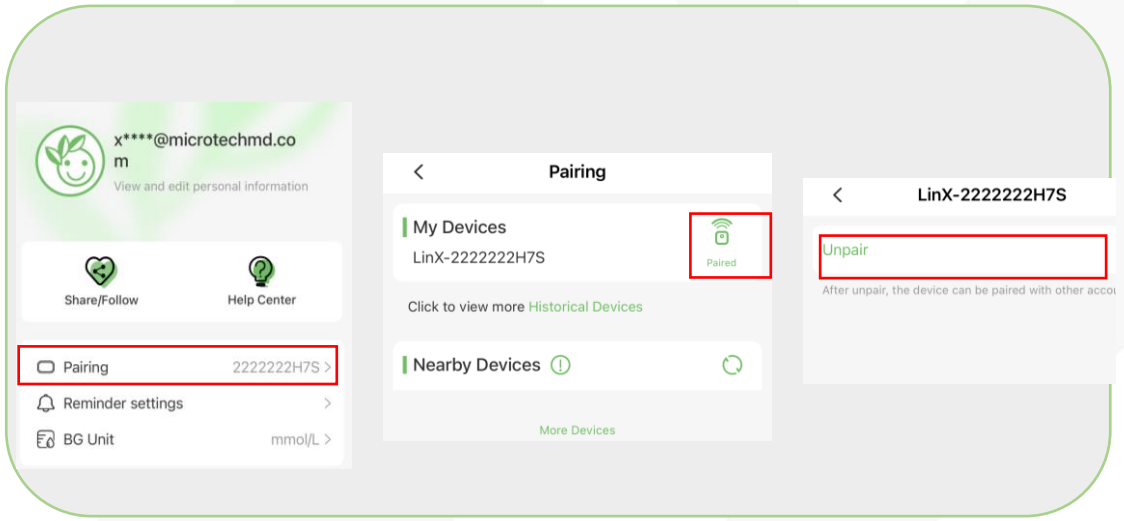
- Click “Pair” and select the SN to connect. You will enter “Warm-up” interface after pairing succesfully.

- The pairing of the Email Account and Sensor is one-to-one. when you want to change a new account to pair, please first tap "Settings-Pairing--to unpair the current Sensor.

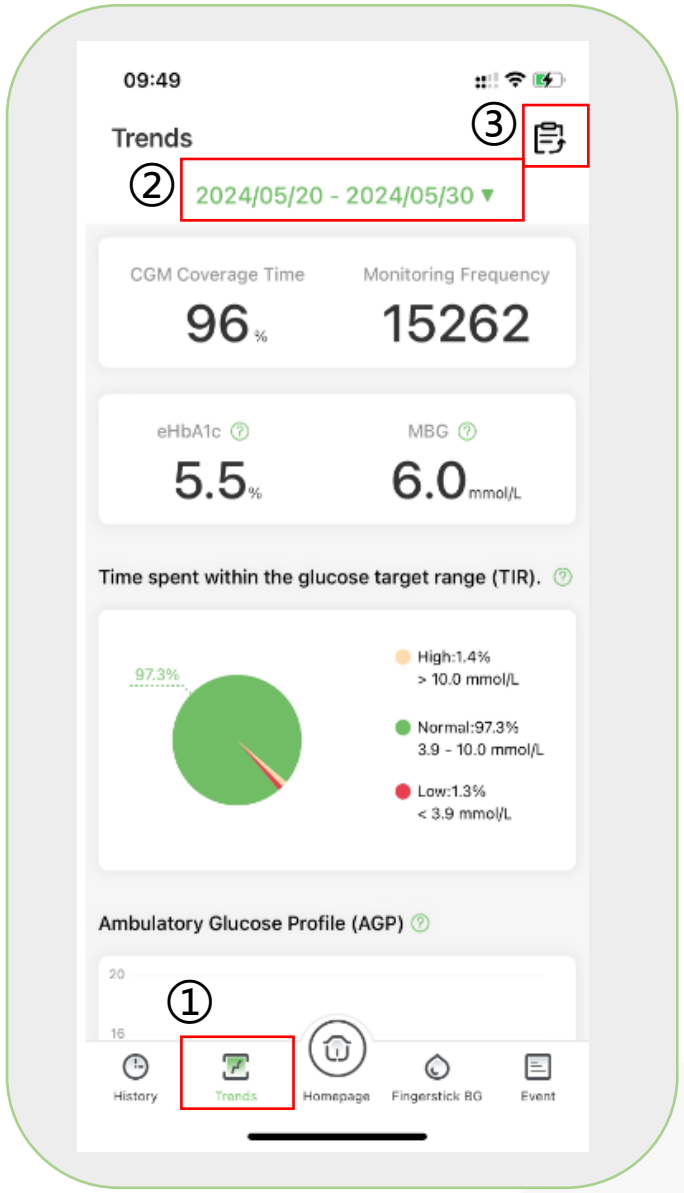
- Please note that one account is not allowed to log in multiple phone devices at the same time.

- When the user wants to change to a new sensor, it can be paired directly by clicking the new sensor SN in nearby device to pair. (No need to unpair)



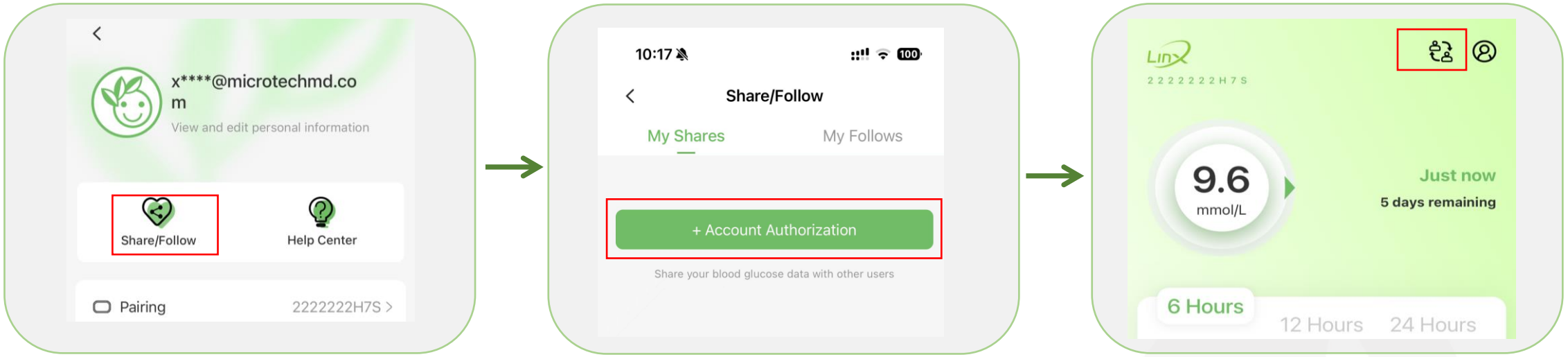


AGP Report



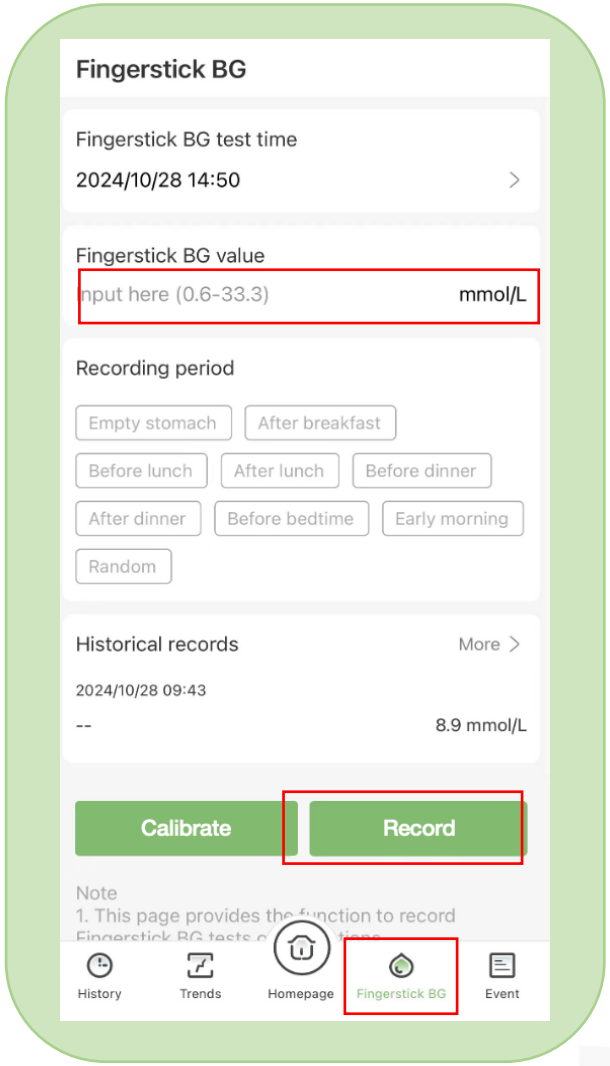
- Enter “Trend” interface and selected the duration of data(5-16 days is required),then click the icon at the right top to export the AGP report
- The AGP report includes three main components of AGP :glucose statistics and targets; the ambulatory glucose profile; daily glucose profiles .

Share and Follow (up to 20 sharers/followers)



- Click the “Personal Settings” icon on the top right-hand corner, then click “Share/Follow” to set up glucose level data sharing.
- After authorization is completed, we can switch to view the blood glucose data of the followed users by clicking the icon at the right top part of the home page.
- When sharing data, please ensure that the App keeps running in the background and the network is enabled and stable at both ends to receive the data in a time.

Blood Glucose Record as an Event



- Take a fingerstick blood test.
- Open the Linx App, tap "BG" on the bottom bar, input finger BG test result, and tap "Record".
- Go back to the Home page, you can see an icon on the blood sugar curve, and you can check the time and value of the blood sugar record by pressing your finger on this icon.

Calibration

Make sure the following before you use a BGM value to calibrate the CGM:

- the Blood Glucose Meter test result is relatively accurate
- the trend arrow of your CGM value is flat at least for the last 15 minutes:

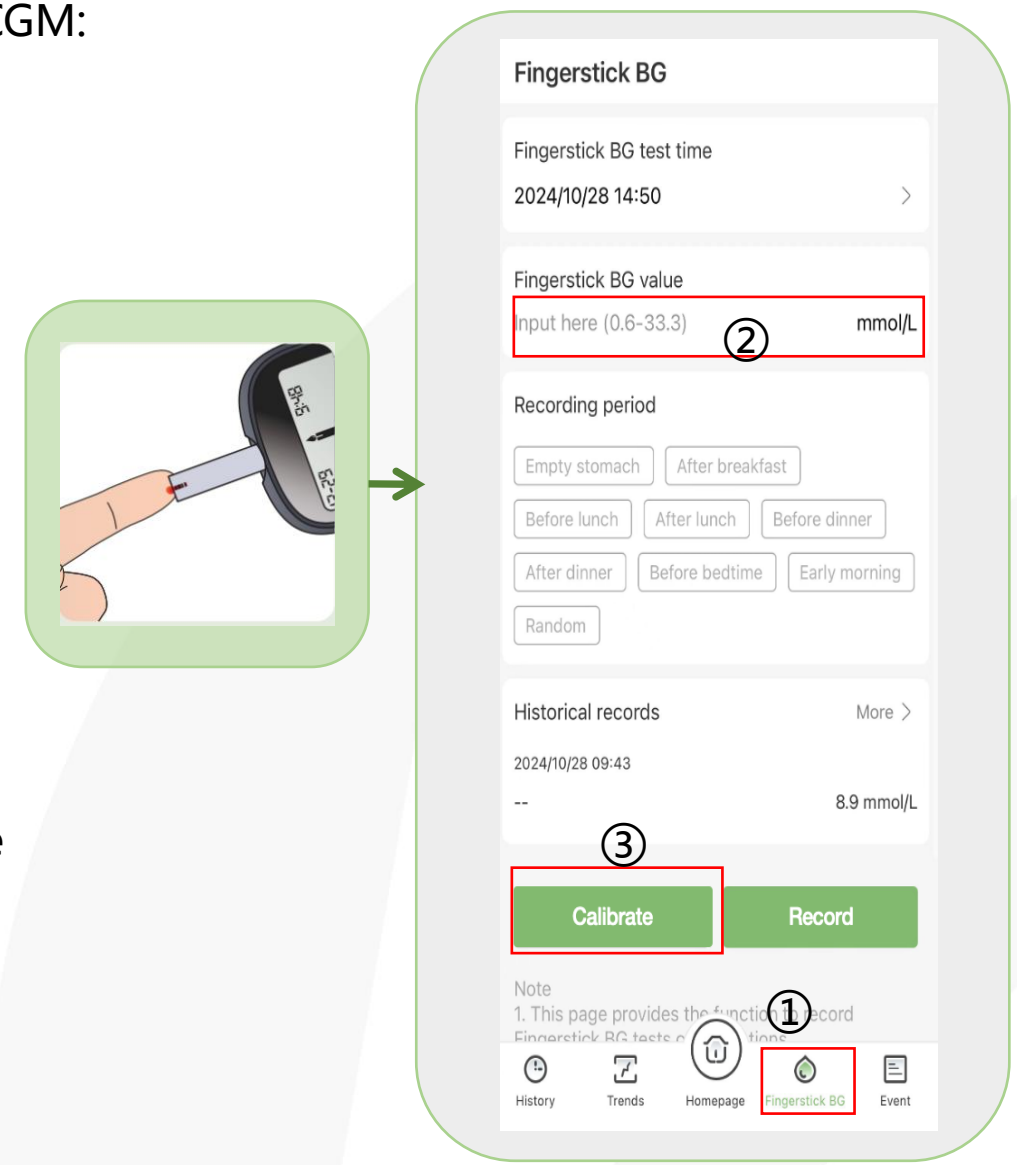
When to calibaration

the LinX CGM is factory-calibrated, you do not need to do calibration unless:

- The difference between BGM and CGM are more than **20%**. or the CGM readings does not match your actual feelings and symptons

It is **not recommended** to do any calibrations on the CGMs during the first 24 hours.

"Calibrate" cannot be performed within 6 hours
the calibration button is grey after sensor insertion.



Understand how to calibrate the CGM via BGM value

- For real-time CGMS, when the BG input is of huge difference than the SG, the calibration maybe rejected or not calibrated according to the input blood glucose value. If so, please calibrate in another time:

1) Calibration rejected:
It’s recognized by the algorithm that the blood glucose value is not suitable for calibration. It may be because the user's blood sugar changes rapidly at this time or is very different from blood sugar by finger stick blood test.

2) Not calibrated according to input blood sugar value:
The algorithm uses a progressive calibration approach and limits the adjustment range of a single calibration. The CGM readings may not be the same as the input calibration BG values. This is normal and the user needs not to be concerned.

- If it still doesn’t work after one calibration or “calibration rejected” prompt pops out, then we need to judge by the comparisons between blood meter glucose and CGM sensor glucose.

Precaution - During the Wearing

For users with less subcutaneous fat in the upper arm and abdomen, the probe may be implanted into muscle tissue, causing bleeding, pain, and early damage to the sensor. In this case, the appropriate implantation position should be selected.

Pay attention to wearing on your arm, and avoid bumping into the door frame or scratching it off when wiping with a towel.

Try to avoid strenuous exercise and frequent squeezing or twisting of the skin near the sensor during sleep, which may cause the sensor to fall off or be damaged.

Precaution – Bathing (tub) and Swimming

Its waterproof level is IP68. They can be placed 2 meters underwater for 60 minutes.

It is not recommended to take a bath , swim for a long time, or apply the bath cream to the adhesive patch, which is to avoid affecting the adhesiveness of the patch. An overpatch can be used for extra support if necessary.

Precaution - Magnetic Resonance Imaging (MRI)

This product cannot be exposed in strong magnetic fields. Before doing MRI, please remove sensor from the body together. Do not bring them into the examination room. (see in the User Guide)

FAQs

MicroTech Medical

Pairing Fails

Confirm that Bluetooth on your phone is on and there could be 3 situations.

◆ **Situation 1: the serial number is occupied by others or other devices**

Solution

1. If you want pair with new device, please **unpair with the last device and pair again**

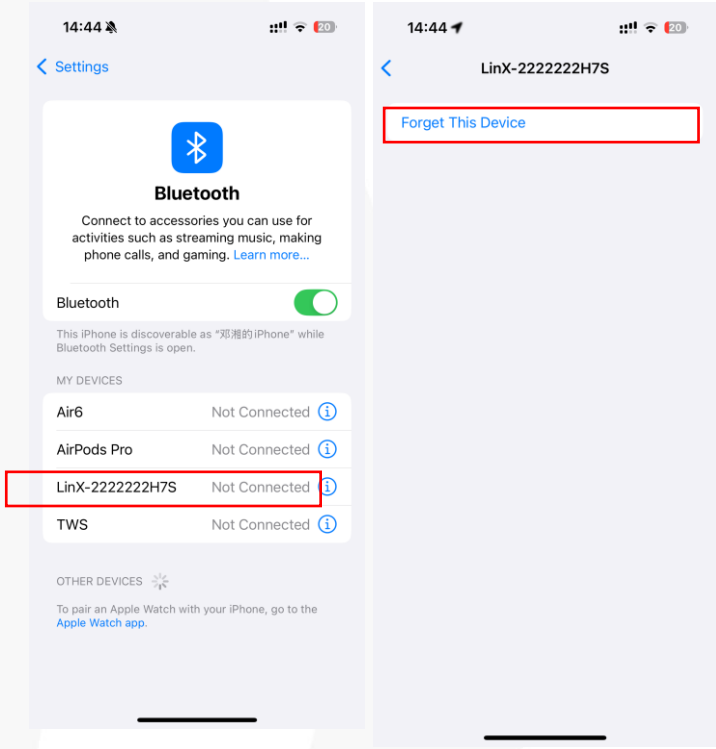
2. The prompt will appear when you just unpaire sensor with the App and historical pairing information still exists. You could **try pairing several times** and then it will show that the pairing is successful.

◆ **Situation 2: Bluetooth Connection Failed**

Solution

1.Reopen the phone Bluetooth and Airplane Mode

2.Enter the Bluetooth settings and find the serial number of the sensor, click "forget this device", and then pair it again.



Pairing Fails

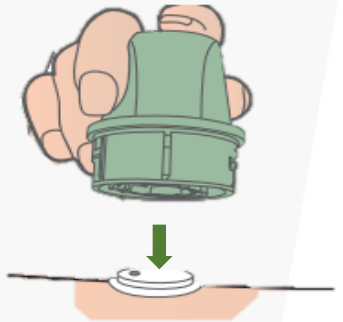
◆ **Situation 3: If your SN was not found by the App at all**

Solution

1. Try to reopen the phone Bluetooth or restart your mobile phone.

2. Or use the applicator to cover the sensor on your body for 3-5 seconds and reconnect.

(There is a magnet in the applicator that can be used to reboot the Bluetooth in the sensor).



Reading

Bluetooth

Internet Connection

Server

- The Sensor stores and sends the data **via bluetooth to APP,** after the data was obtained by bluetooth. It will be uploaded **to the server via internet connection,** data will be stored in the cloud server under the user accont. Users can download the AGP report based on the data from the server.

- If the Bluetooth connection with sensor fails, the data will be stored temporarily on the sensor and all the data will be uploaded to the server once connection is back on.

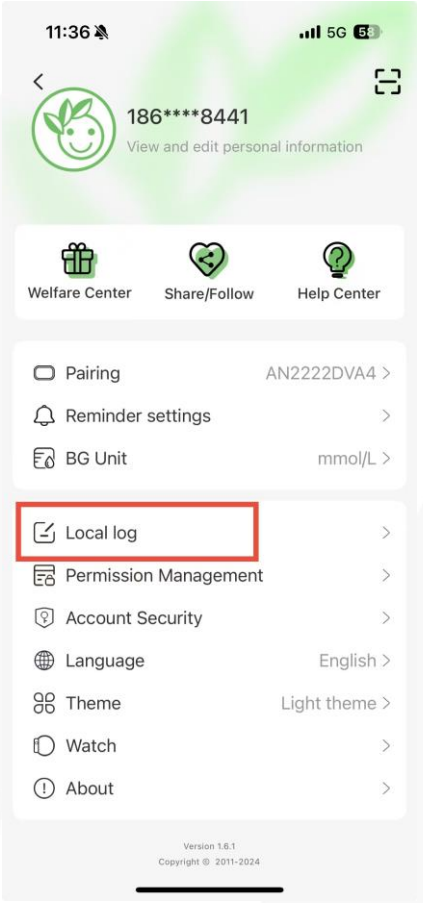
APP shows no readings

Checking

1. Check the distance between the paired mobile device and the sensor (keep the distance within two meters).
2. Check the settings of the user's mobile phone and the app.

Try the 5 steps if the above does not work:

1. Completely close the app on the backend.
2. Restart Bluetooth function
3. Restart the phone.
4. log out the account and log in again.



If the user tried all of there methords but none of them worked.

- Click the “local Log”and report to customer service

(This is to help the engineer identify if there is bluetooth compatibility with the phone brand in a certain country and other issues.)

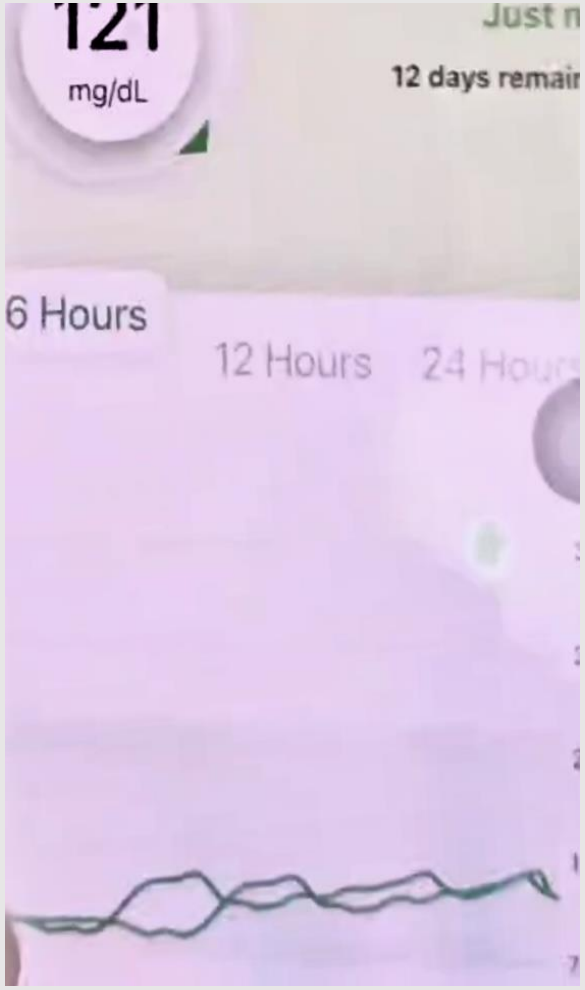
- Collect the mobile phone brand and version, feedback to customer service

Errors

In case of device errors,the system shows “device errors” as it detects the readings may not be accurate for that moment so the mechanism is designed not to show the readings for that period. Please wait patiently for the data to show up lafter after stablization.

- The App will determine whether the insertion is successful within 22 minutes to 4 hours after confirming the insertion of the new sensor.
- The prompt "Device error" appears within a few days after inserting the sensor. This is usually because the selection of insertion area (with little or no fat) or the insertion procedure is improper, or the sensor is hit, causing the root of the sensor electrode to be repeatedly squeezed and damaged. You can contact us for help
- If this prompt appears later in the wearing period (e.g. one week), it is mostly because the adhesive patch is not sticky or the sensor is scratched, which causes the sensor to become loose.
- **In General, if “Device error” appears, you can wait for the error meassage to disappeear and the system gets back to normal readings. If the error message lasts for more than 4 hours, remove the sensor and use a new sensor.**

Across time zones data



- When users cross time zones, the data recording mechanisms of devices and LinX app need to take time zone differences into account. As a result, there may be overlapping glucose curves or broken curve showned on the main page.

- This design is to ensure the authenticity of the data: the time stamps of the data will be kept at actual the local time when the CGM value is measured, so as to accurately reflect the actual chronological order of data collection.

For example, a hypo event happened in the evening in time zone A at 18:00.
When the phone change to time zone B which is time zone A - 6 hours, then the CGM curve during time zone A will be kept at time zone A but the CGM curve started in time zone B will be shifted 6 hours backwards compared to time in zone A. So we see overlapping.
If we changed the time of the data happened in zone A to zone B, the hypo event that happened at 18:00 in the evening would be displayed as a hypo event at 12:00 at noon. This would be misleading.

Low Reading in first 1~2 days

Sensor cannula under the skin is an alien object, it will trigger minor inflammation and immunoreaction of the body.
When such traumatic stress response was caused in implantation process, it activates a large number of macrophages to gather at the site of the trauma, resulting the glucose reading in the local subcutaneous tissue fluid near the sensor is lower than the actual blood glucose reading. So the glucose reading measured by CGMs could be lower.

- This phenomenon have a chance to occur in CGM and it is related to many factors such as the condition of the human immune system and the choice of the implantation site.
- Generally, it will gradually subside or disappear after 48 to 72 hours. Therefore, the accuracy of CGM sensors is relatively stable during the period from 3 to 10 days.
- It is **not recommended** to do any calibrations on the CGMs during the first 24 hours.

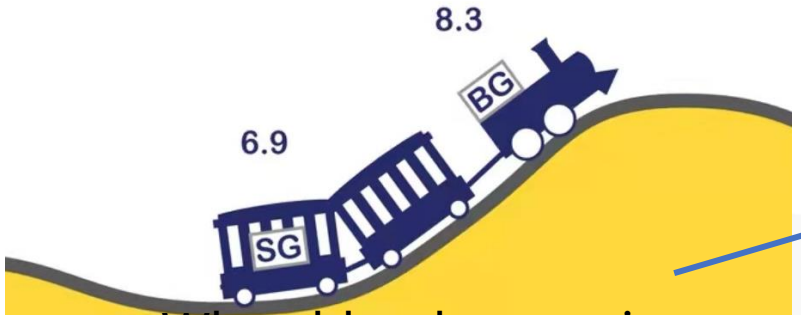
Note:
If the user calibrate when blood glucose is in low reading in the first 1-2 days after wearing the device, it should be noted that after the phenomenon disappears, the readings will become higher again.
At this time, calibrate once more when CGM glucose is stable.

Is there a difference between CGM and BGM ?

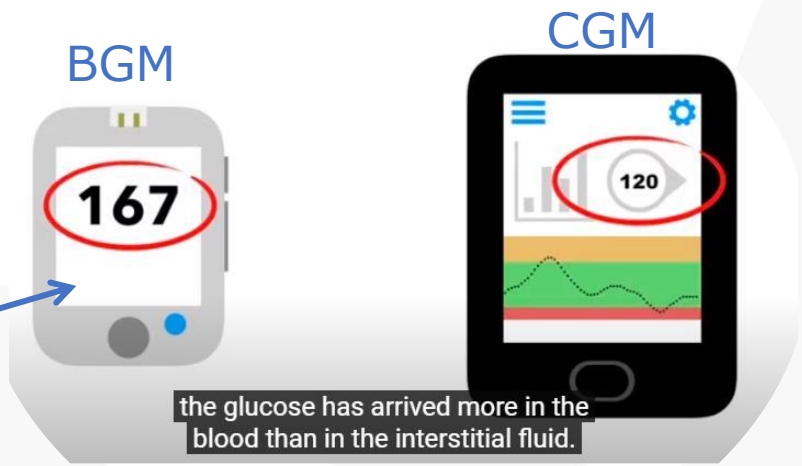
- CGM measures the glucose in interstitial fluid, BGM measures glucose in capillary whole blood. There is surely a difference between the two measurements, it is called a time-lag.
- When the blood glucose levels are largely stable, there is little difference between BG (blood glucose) and SG (sensor glucose) readings
- When the blood glucose levels are changing rapidly (after taking a meal, injecting insulin, exercising, etc.), there is a greater difference between BG and SG readings

When blood sugar is stable

When blood sugar drops



When blood sugar rises



What should I do if the CGM readings are different from BGM?

- **It is normal for the CGM readings to occasionally deviate from the blood glucose meter measurement.**
  - Incorrect fingerstick blood test (finger is not clean, residual alcohol or food juice on the finger, etc.)
  - The test results of the blood glucose meter and test strip fluctuate (the average value can be obtained by repeating the fingerstick blood test multiple times)
  - There is a 5-15 minutes delay in CGM readings when blood glucose rises or falls rapidly
  - Inaccurate readings may occur when the wearing area was affected by external factors like rub, bump against or scratched during daily activities that resulted loosening of the adhesive and being pressed (e.g. the product is pressed when sleeping at night)
- **You can calibrate CGM if its readings are consistently high or low compared to the results of multiple finger stick blood tests.**
  - Only calibrate when blood sugar is stable; When blood sugar rises or falls rapidly after a meal or after medication, calibration can result in incorrect CGM readings

The adhesive is not sticky

The stickiness of adhesive patch meets the needs as part of medical device in general .

In addition, the following factors should be considered. Comparing and dealing with them accordingly:

- **The disinfection and cleaning of the insertion site are not thorough**
- **Wearing the CGM after taking a bath and having used lubricating body wash or other products**
- **Whether the user has oily skin or is easy to sweat, or the skin at the insertion site is too flabby**
- **There are situations such as accidental scratching when putting on and taking off clothes**
- **The adhesive patch is loose or not sticky later in the wear session**

Frequent High and Low Alert

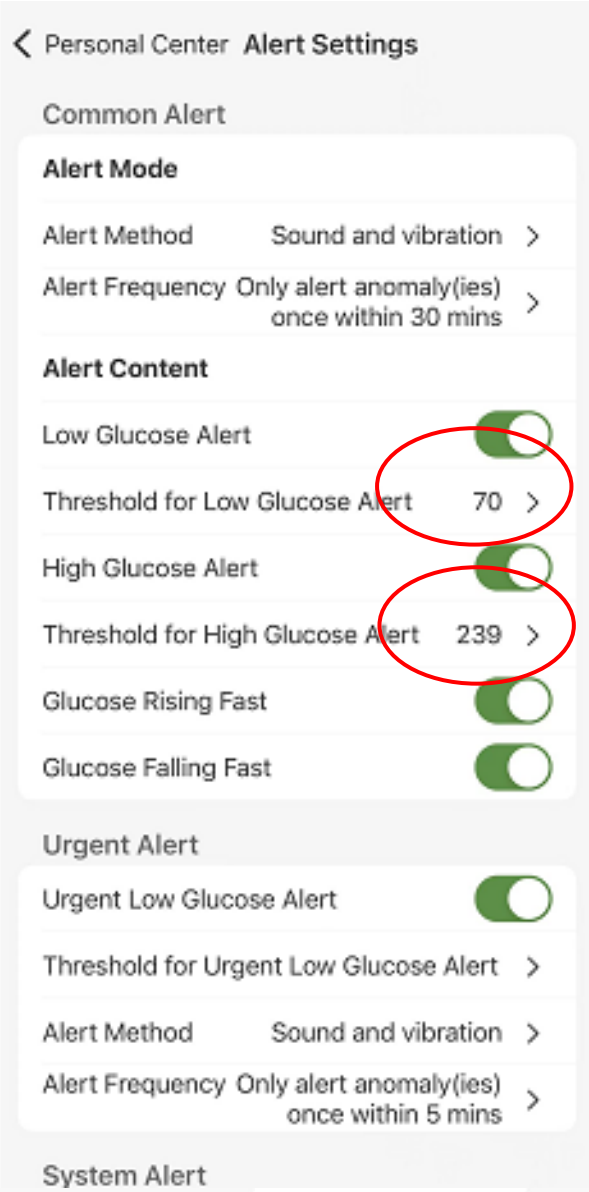
Cause:

Individualized alert interval or threshold is not set according to actual need.

If the alert value is set too low, it will frequently trigger the alert, when someone has high blood glucose.

Solution:

The alert settings can be adjusted according to personal needs and advises from healthcare professionals.



What kind of situation is suitable for using CGM?

Compared with traditional monitoring methods, the main advantage of CGM is that it can detect **hidden** high and low blood sugar that are not easily detected by traditional monitoring methods, especially postprandial hyperglycemia, and nocturnal asymptomatic hypoglycemia.

Examples include:

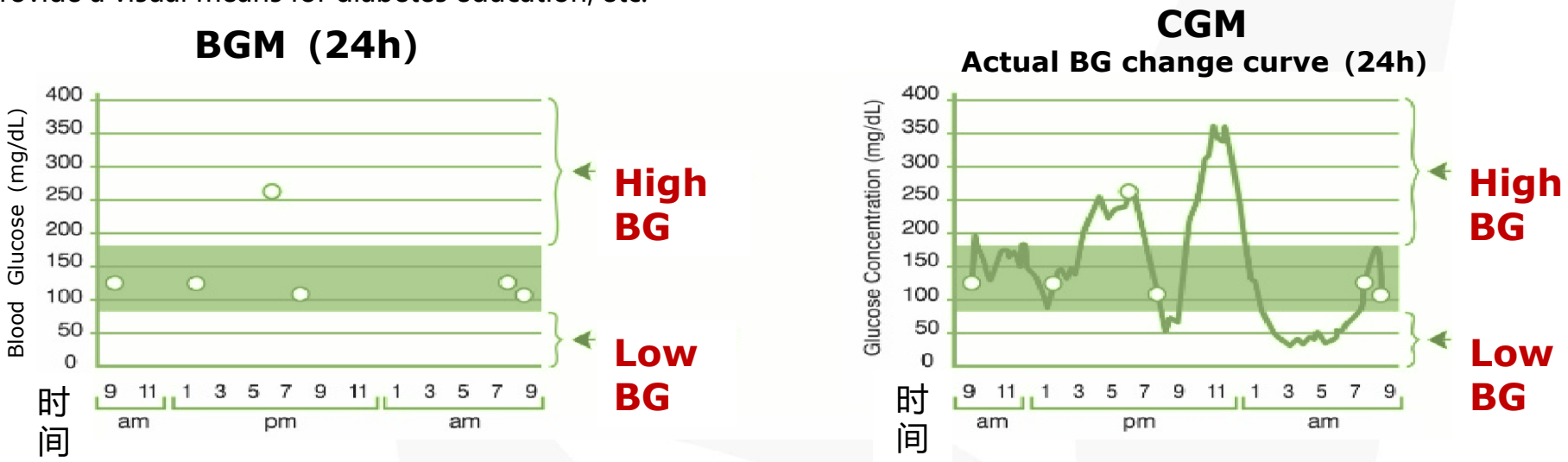
(1) Blood sugar changes related to the following factors can be detected, such as food types, exercise types, treatment plans, mental factors, etc.;

(2) Get to know postprandial hyperglycemia, nocturnal hypoglycemia, Dawn Phenomenon, Somogyi Effect, etc., which are difficult to detect by traditional blood glucose monitoring methods;

(3) Help to formulate individualized treatment plans;

(4) Improve treatment compliance;

(5) Provide a visual means for diabetes education, etc.



What kind of people are not suitable for using CGM?

Patients:

- Who Suffer from **alcoholism, drug use, severe mental disorders** (e.g. depression, schizophrenia).
- Who are **unconscious**.
- Who **cannot understand** or master the operation of the product.
- Who are with **severe hearing or vision impairment**.
- Who are with **severe edema or severe circulatory disturbance**.
- Who are **allergic** to the adhesive patch.
- Who are **too young or old** to take care of themselves and have no guardians.

You can find this list in the IFU

Materials+Disposal

Materials:

The material of adhesive and overpatch is medical tape with no latex and
The material of plastic pack for overpatch is CPE bag (Ethylene-Propylene Copolymer)

The sensor probe includes mental-platinum.

Disposal:

This should be based on local regulations

1. Sensor: Biohazard + battery(Depands on the certain rules of each country, usally consider as biohazard

2. Applicator: Contains needle-Biohazard

After-sales Service

If you encounter problems in the use of the product or malfunctions that cannot be coped with, please contact Microtech.

- We can set up a WhatsApp group for daily issue resolution.
- Email:

cs@microtechmd.com

Thanks!

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