Quick Start Guide

Get started with LinX quickly and easily with this Quick Start Guide.

READ THIS INSERT AND ALL OF THE LABELLING PROVIDED WITH THE CGM APP BEFORE HANDLING THE SENSOR KIT.

Product name: Continuous Glucose Monitoring System Sensor
Product Model: GX-01, GX-02, GX-01S, GX-02S
For use with:
RC2107, RC2109 CGM app

Indication 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 adults (age 18 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 hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustment.

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.

For use with LinX App

Google Play App Store

SEARCH LinX

The electronic manual should be accessible for viewing using a smartphone or computer with a web browser and PDF viewing capability.If you choose to view the electronic manual on the LinX App, make sure to download the application on the compatible device models listed in our equipment list.

Description:

The Sensor is located inside the Sensor Applicator. Follow the instructions to prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 15 days.
For more specific operations, please refer to the instruction for use in electric form through LinX App.

Step 1 **Select Insertion Area**
Upper arm: the back of the upper arm (Don't insert into the muscles on the outer side of the upper arm.)

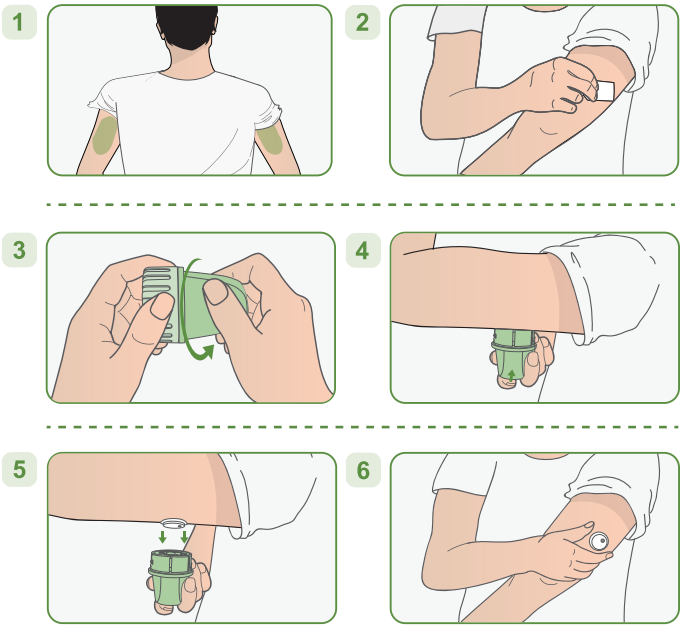
Step 2 **Disinfect:** Before the insertion, clean the insertion site with an alcohol wipe and let it dry completely.

Step 3 Unscrew the cover from the sensor applicator and set it aside.

Step 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.

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

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



Precautions

- Only MicroTech Medical consumables should be used with the CGMS.
- No modifications to the Continuous Glucose Monitoring System 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 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. In these cases, the sensor's reading is checked by a fingertip blood test using a glucose meter.
- When it is necessary to confirm hypoglycemia or near-hypoglycemia as measured by a glucose sensor, a fingertip blood test should be performed using a 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 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 the water more than 2 meters deep for longer than 1 hour.
- CGMS readings should only be used as a reference for the supplemental monitoring of diabetes mellitus and should not be used as a basis for clinical diagnosis.
- While extensive user testing was done on LinX CGMS in Type 1 and Type 2 diabetic patients, 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.
- For user safety, storage, disposal and handling, plese refer to the system instruction for use.

Symbols

Refer to Instruction Manual	
Atmospheric pressure limitation	
Type BF Applied Part	
Single sterile barrier system with protective packaging outside using irradiation	
Manufacturer	
Do not use if package is damaged and consult instructions for use	
Batch code	LOT
Importer	
MR unsafe	
Authorised Representative in the European Community	EC REP
Temperature limit	
Humidity limitation	
Do not re-use	
Caution	
Date of manufacture	
Use-by date	
Serial number	SN
Unique device identifier	UDI
Waste Electrical and Electronic Equipment (WEEE) – Follow local requirements for proper disposal	
CE Mark	CE 0197
Medical device	MD
Instructions for use	
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

MicroTech Medical

MicroTech Medical (Hangzhou) Co., Ltd.
No.108 Liuze St., Cangqian, Yuhang District,
Hangzhou,311121 Zhejiang, P.R.China

EC REP Lotus NL B.V.
Koningin Julianaplein 10, Ie Verd,
2595AA, The Hague, Netherlands.

CE 0197

1034-PMTL-406.V03
Effective date:2024-08-14