Continuous Glucose Monitoring System

Product Usage Guide

No. TJ/CGM-SW-A-084 ROv. A/0

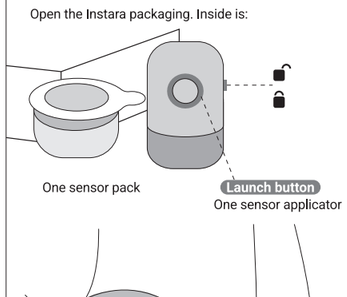
App,
og in

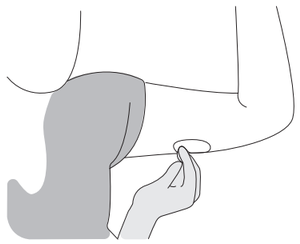
Scan the QR code to download the App and follow the App's prompts to complete registration and information settings.Allow all permissions requested by the App.

Scan the QR code
to watch the wearing tutorial video

2 Preparation before Wearing

Open the Instara packaging. Inside is:

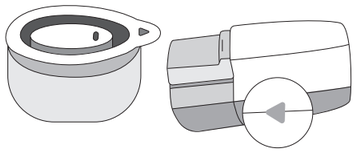


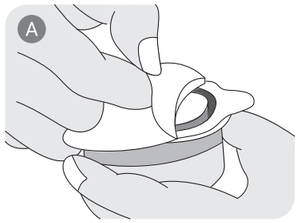


Note
Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding).

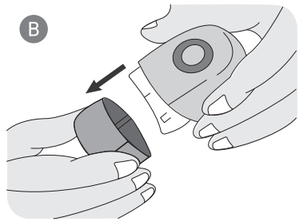
Operation
Choose a softer area on the underneath of the upper arm as the application site.
Clean the skin with an alcohol wipe.

3 Assemble the Sensor





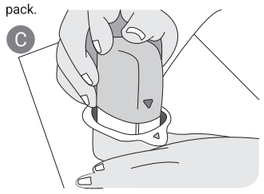
Remove the sealing film from the sensor pack.



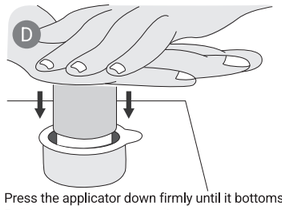
Remove the cap from the sensor applicator.

Alignment marker symbol

Place the sensor pack on a flat surface. Align the
" ▽ " mark on the side of the sensor applicator with the
" ▽ " mark on the sensor pack, and press down.



Make sure the two markings " ▽ " aligned.

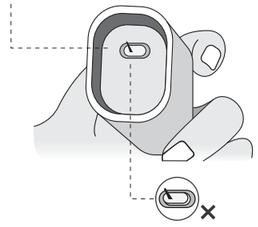


Press the applicator down firmly until it bottoms. Pull it out after you hear a click

4 Check the Assembly Condition

On the same horizontal line, not protruding

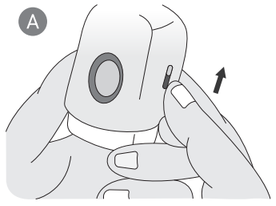
If the internal components and the tape are on the same plane as shown in the left picture, the assembly is correct.



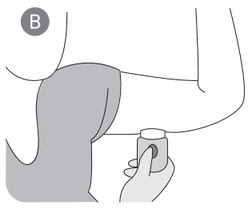
Not on the same horizontal line, protruding

If the internal components are obviously raised, try to repeat the downward pressure operation in steps 3C and 3D.

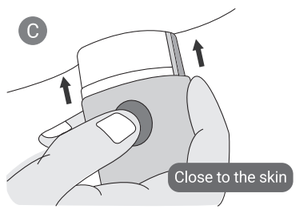
5 Applying the Sensor



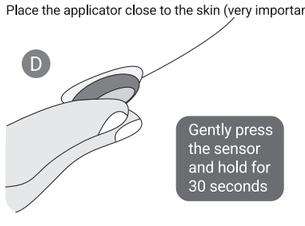
Turn the unlock switch on the side of the applicator to 🔓 position



Place the applicator close to the skin (very important)

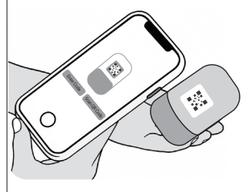


Press the launch button of the applicator.

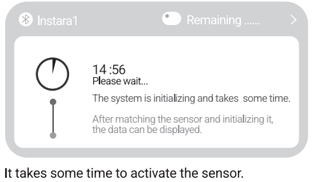


Remove the applicator and gently press the sensor and the edge of the tape to ensure that the tape is firmly attached to the skin.

6 Connect the App and Activate the Sensor

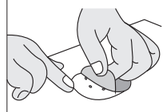


Follow the app's instructions to connect and activate the sensor by scanning the QR code on the back of the applicator. If the scan fails, manually enter the 8-digit connection code.



It takes some time to activate the sensor.

7 Paste Adhesive Patch



Peel off the first protective film of the Adhesive Patch

Stick the patch onto the surface and press it along the edges to ensure completely adhesion.

Note

Some people may be allergic to adhesives. Avoid wearing the sensor twice on the same site.
When finished wearing the sensor, gently pull up the adhesive edge of the sensor and slowly peel it off your skin.

Dowmload the electronic manual

https://service.teljane.com/user_manual/ifu-en.pdf

More information

If you have any questions during use, please contact our online customer service team via email at service@teljane.com.

TELJANE
Instara™-1

Continuous Glucose Monitoring System Mannual

No. TJ/CGM-SMS-002 Rev. A/6

1.Product introduction

1.1 Basic information

Device name: Continuous Glucose Monitoring System (CGM System)
Model and Size: TX-14, TX-21
Device Description: The System consists of the following components:

- Sensor Kit: The Sensor kit is single-use and disposable. It includes two main components:
  Sensor Applicator: This includes an applicator, a transmitter, and medical adhesive tape.
  Sensor Pack: This is a sterile device that includes a sensor electrode assembly and a needle.
  These components are used to assemble and apply the sensor to the back of the user's arm. The sensor continuously measures glucose concentration in interstitial fluid and has a 14-day(TX-14) or 21-day(TX-21) memory capacity. It is factory-calibrated, does not require fingerstick calibration, and can be worn for up to 14 days (TX-14) or 21days(TX-21).
- App: When downloaded to a compatible smartphone, the app uses BLE communication to display glucose data and issue alarms based on the measurements calculated by the sensor.

Sensor kit includes:

SN	Component name	Component model/ specification	Picture (the color is subject to the actual object)	Quanti-ty
1	Sensor Pack	TS001		1
2	Sensor Applicator	TA001		1
3	Manual	/	/	1
4	Product Usage Guide	/	/	1
5	Adhesive Patch	/	/	1
6	Alcohol Wipe	/	/	1

1.2 Indications for Use

The Continuous Glucose Monitoring System (CGM System) is indicated for measuring interstitial fluid glucose levels in people (aged 4 and older) with diabetes mellitus. The CGM System is designed to replace blood glucose testing in the self-management of diabetes. The indication for children (aged 4-12) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the sensor and also for interpreting or assisting the child to interpret sensor glucose readings.

1.3 Contraindications

MRI/CT/Diathermy: The system must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.
Since the sensor of the system needs to be attached to the skin via an adhesive tape, patients with allergic skin or those prone to skin ulcers should use it with caution.
Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Sensor glucose reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
The device does not show a glucose value or a trend arrow, and abnormal value displayed or data transmission delay, the device should be checked, if needed, a fingerstick test is required to confirm sensor reading.

1.4 Precautions

Read this entire user guide before attempting to insert the sensor:
(1) Failure to follow the directions may result in improper insertion, pain or injury. If there is anything you don't understand or you have any doubts, please contact your local representative for assistance.
(2) It is designed to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.
(3) Do not use the sensor if the sterile package has been opened or damaged. The sensor pack is sterile, unless the package has been opened or damaged. Use of an unsterile sensor can cause site infection.
(4) Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. The Company does not assume any responsibility for any consequence caused by unauthorized modification.
(5) The device contains small parts that may be dangerous if swallowed.
(6) After use, the sensor and applicator may be contaminated with blood stains, body fluids and other biohazardous materials. To minimize the risk of infection, please ensure their disposal in accordance with local laws and regulations.
(7) Do not use if expiry date has passed.
(8) Your sensor may become loose if you bump onto it, engage in contact sports, or sweat excessively. If the sensor becomes loose or if the sensor tip starts to come out of your skin, you may receive no readings or unreliable readings. If your sensor begins to loosen, remove it and replace it with a new one, and follow the instructions to select an appropriate application site. Do not attempt to reinsert the sensor. If your sensor becomes loose or falls off before the end of the wear period, contact Customer Service for assistance.
(9) Keep the sensor away from scratch by pets and children to prevent it from loosening or falling off.
(10) Please keep the terminal equipped with the CGM system software away from children, pets or insects to avoid being misoperation.
(11) Do not clean, resterilize, or try to extract the needle from the applicator. An accidental needle stick or puncture may occur.
(12) A fingerstick test is required to confirm the low or near-low blood glucose readings.
(13) A fingerstick test is required to confirm the sensor readings when the user's symptoms do not match the glucose values displayed by the device.
(14) The effect of the sensor which is used together with other active distribution medical devices such as the heart pacemaker has not been evaluated.
(15) If the user is severely dehydrated or experiencing hyperhydration, the readings obtained by the sensor may be inaccurate.
(16) Do not reuse sensors. Both the sensor and the sensor applicator are designed for single use only. Reusing them may result in no glucose readings and potential infection. They are not suitable for resterilization. Further exposure to irradiation may cause inaccurate results.
(17) Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in Sensor glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin or exercising.
(18) If this product is not used according to the instructions, its effectiveness may be reduced.
(19) Your Sensor should be replaced after 14 days(TX-14) or 21 days(TX-21) of wear. Additionally, you should replace your Sensor if you experience any irritation or discomfort at the application site, or if the app indicates a problem with the current Sensor.
(20) Don't go near a place with strong magnetic field when wearing the sensor to avoid the sensor power being turned off and the sensor ceasing to function.
(21) If bleeding occurs, do the following :
a. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
b. If bleeding stops, connect the sensor to app.
c. If bleeding does not stop, do not connect the sensor to app because blood may lead to inaccurate readings.
d. If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:
①Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.
②Check the site for redness, swelling, bleeding, irritation, pain, tenderness or inflammation. Treat based on instructions from your healthcare professional.
(22) The product is designed to withstand immersion in water up to 1.1 meters deep for a maximum of 60 minutes (IP58 rating) and is protected against bumping onto objects larger than 12 mm in diameter. It is water-resistant, allowing you to wear it while bathing, showering, or swimming. However, you should avoid submerging your Sensor deeper than 1.1 meters or for longer than 60 minutes. Please note that Bluetooth performance may be compromised when using the system underwater.
(23) Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. The error depends on the effective amount of potential interferents such as ascorbic acid in the body. If you notice that your current physical condition does not match the blood glucose readings obtained, or if you suspect that the blood glucose readings may be inaccurate after using potential interfering substances such as ascorbic acid, you should perform a fingerstick test to confirm the sensor readings.
(24) Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the Sensor. Contact your healthcare professional before continuing to use the Sensor.
(25) If a serious incident has occurred in relation to this device, it should be reported to Customer Service. In European Union Member States and Switzerland/UK, serious incidents should also be reported to the competent authority (the government department responsible for medical devices) in your country.
Please refer to your government website for details of how to contact your competent authority.
A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to:
the death of a patient, user or other person,
the temporary or permanent serious deterioration of a patient's, user's or other person's state of health.
(26) Work with your healthcare professional to figure out what's the best way for you when making treatment decisions, such as dosing of insulin, food and exercise. Always use their instructions to manage your diabetes. You should use your blood glucose meter until you're familiar with product to manage your glucose reading.

1.5 The measuring range of the sensor on the glucose solution concentration is 2.0mmol/L~26.0mmol/L, linear deviation is not exceed ±0.83mmol/l or ±15%, take the larger one.

1.6 Skin allergy and skin lesion may occur in few cases.

2. Overview of APP Functions

The app is an integral part of the System designed to communicate with the implanted sensor and to display glucose reading continuously.
The app features a graphical user interface with windows and function buttons, comprising four main menus: Monitoring, Record, Analysis, and Profile.

2.1 App Functions

The App mainly has the following functions

Description of software functions			
Product name: Continuous Glucose Monitoring System (CGM System)			Release Version : V1
Menus	Function		Description
Moni-toring	Sensor informa-tion	Number, and Bluetooth connection status	User can see sensor connection status and its information
	Blood glucose monitor-ing	Current blood glucose value, time in range (TIR), and remaining day(s) of sensor use	Display the information related to the blood glucose and sensor
	Blood glucose trend	Blood glucose trend, and glucose target range value set	Display the blood glucose change curve and the glucose target range value set
	Blood glucose interval	Highest and lowest blood glucose values during the selected period	Display the highest and lowest blood glucose values during the selected period
Record	Item list	Picture and name	Choose the corresponding items (exercise, diet, medication, insulin, finger blood, sleep, and physical condition)
	Record details	Record items	Record the relevant information of the selected items (exercise, diet, medication, insulin, finger blood, sleep, and physical condition)
Analysis	Date selection	Calendar list	Scroll down to select the previous date of product use
	Daily blood glucose	Overview of daily blood glucose: Mean blood glucose level (MG), daily time in range (TIR), largest amplitude of glycemic excursions (LAGE), and number of recorded events daily	The user can view the information related to blood glucose
		Blood glucose trend, and daily highest and lowest blood glucose values	The user can view the information related to blood glucose trend
		Blood glucose fluctuation: Standard deviation of mean blood glucose level (SD), coefficient of variation (CV), mean amplitude of glycemic excursions (MAGE), and mean of daily differences (MODD)	The user can view the information related to blood glucose
	Historical blood glucose analysis	Overview of historical blood glucose: Mean blood glucose level (MG), estimated glycosylated hemoglobin (eHbA1c), glucose time in range (TIR), and coefficient of variation (CV)	The user can view the information related to blood glucose
		AGP graph and graph interpretation	The user can view the information related to blood glucose
Profile	Edit Infor-mation	Head portrait, nickname, gender, diabetes type, date of birth, height, and weight	The user can edit his/her own information

Profile	Report	generation date, basic information, blood glucose data, AGP graph, daily overview, daily glucose curve, multi-day comparison curve, and multi-day period-specific glucose details	download the AGP graph in PDF format. The graph depicts how blood glucose changes over the period and also contains other useful information.
	Alarms	Blood glucose settings: Blood glucose unit, high and low limits, blood glucose alarms, reminder mode (vibration/ring-tone), time, blood glucose value, and high or low blood glucose alarms	The user can set limits for high and low blood glucose alarms and the reminder mode, and view the alarms for out-of-range blood glucose readings
	Setting	Blood glucose settings: Blood glucose unit, high and low limits, blood glucose reminder, reminder mode (vibration/ringtone)	The user can set the high and low limits of blood glucose reminder and the reminder mode
		Clear cache	The user can clear the blood glucose data of the previous transmitters, but the data of transmitter in use cannot be cleared
		Account and security: Mobile phone number, change password, and cancel account	The user can cancel the account or change the password through a verification code
		Software name: Instara Continuous Glucose Monitoring System software	The user can view the software name
		Version number	The user can view the version number
		Issue version number	The user can view the issued version number
		User agreement	The user can view the service agreement
		Privacy policy	The user can view the privacy policy
		Log out	After clicking, the user can log out of the system
	Blood glucose sharing	My follow-ings: Add relatives and friends to be followed	The user can submit applications by filling in the mobile phone numbers, nicknames, and other relevant information of their relatives and friends. Once their relatives and friends agree, the user can access their blood glucose information
		My follow-ers: Invite relatives and friends to follow	The user can invite their relatives and friends to follow them by filling in their mobile phone numbers, nicknames, and other information. Once the relatives and friends agree, they can view the blood glucose information of the user.
	Help center	How to enable the APP protection	The user can view the approach to enable the APP protection
		Precautions for using the APP	The user can view the precautions for using the APP
		How to enable the APP application lock	The user can view the approach to enable the APP application lock
		Causes and recovery of data interruptions	The user can view the causes and recovery methods of data interruptions

2.2 App Prompt Messages

(1) Login Errors:
"Sorry, the account number/password is incorrect."
"The password length is incorrect. It must be 8-14 characters long."
(2) Incomplete Information:
If the user proceeds to the next step without entering complete information during login, event recording, personal file completion, or system settings, a prompt such as "Please select...!" or "Please enter...!" will appear at the bottom of the software's home page, instructing the user to complete the information before continuing.
(3) Communication Issues:
The mobile computing terminal with the CGM system

sensor's
e. If the
nnection is
point, a
ed." The
t to the
during the

sensor, and the status will show "Connecting" process.
(4) Other Prompts:
If the mobile computing terminal has the software installed but is not connected to the sensor, a prompt will appear: "The device is not connected." If the sensor has expired, a prompt will appear: "The current sensor has expired. Please replace the sensor."

3.Applying Your Sensor

Applying Steps	Notes
1.Selection of application site: Apply the Sensor only on the back of your upper arm. **As Figure 2**	Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
2.Skin cleaning: Clean the application site with an alcohol wipe. Allow site to air-dry before proceeding. **As Figure 2**	The area you selected must be clean and dry, or the Sensor may not stick to the site or may fall off prematurely before the sensor usage period ends.
3.Check the contents in kit When opening your kit, check that the contents are undamaged and that you have all parts listed. Completely tear off the sealing film of the sensor pack. Twist the cap from the applicator and set the cap aside. (Caution: DO NOT press the Apply button on the side at this point.) **As Figure 3**	Do NOT use if the Sensor Pack damaged or has already been opened. Do NOT use if past expiry date.
4.Preparing the Sensor Line up marks on the sensor applicator and pack. Press down firmly on the sensor applicator until it comes to a stop. Lift the sensor applicator out of the sensor pack. **As Figure 3**	Do NOT touch inside Sensor Applicator as it contains a needle. Do NOT put cap back on or place back inside sensor pack as it may damage the Sensor.
5.Check the assembly condition Check the needle-containing part's position is in the same plane as the other parts. If not, repeat the operation in step 4. The sensor applicator is now ready to apply the sensor. **As Figure 4**	Do NOT touch inside Sensor Applicator as it contains a needle. Do NOT put cap back on or place back inside sensor pack as it may damage the Sensor.
6.Applying the Sensor: Slide the unlock switch on the side of the patch applicator to the 🔒. Place the sensor applicator over the application site (DO NOT press it hard), and press the launch button of the applicator. Hold for a few seconds then pull the sensor applicator away from your body gently. Make sure the sensor is secure by pressing the sensor down and running your finger along the sensor adhesive. **As Figure 5**	Do NOT press the button of the applicator before placing the applicator on the application site, so as to avoid unexpected damage. If bleeding occurs, please follow the information in 1.4.
7.Application of Adhesive Patch Remove the first protective layer from the adhesive patch. Align the patch with the sensor and apply it securely, ensuring the ventilation hole remains unobstructed. Remove the second protective layer and press firmly around the edges of the patch to ensure complete adhesion. **As Figure 7**	The adhesive patch may be used optionally for auxiliary fixation under specific extreme conditions, such as prolonged water activities, excessive sweating, or abnormally high skin oil secretion, or if slight lifting of the sensor edges due to accidental abrasion is observed.

4. Starting Your Sensor

Important:

(1)When the memory space of the mobile computing terminal (i.e., your smart phone) is insufficient, the app may malfunction. In this case, you need to clear the memory space on the mobile phone. Normal use can be resumed after relaunching the application. It is recommended that you clear the memory space on your mobile phone regularly.
(2)The app takes up about 300MB of memory during operation. To ensure smooth software operation, please allocate sufficient system resources to it.
(3)Ensure that your mobile phone be free of viruses or malware and have the latest security patches installed. This helps maintain the smooth operation of the system software.
(4) For accurate health information recording, the app requires your phone to have the correct date and time. Ensure that your phone date and time are set to update automatically. You can check this in your phone settings.
(5) If the software unexpectedly shuts down while using the app, try relaunching it to resolve the issue.

4.1 The operating environment and compatibility for the App

	Android	iOS
Operating system	Not lower than Android 9.1	Not lower than iOS 15.6
CPU	The frequency is not less than 1.6 GHz	The frequency is not less than 1.4 GHz
Memory	Not less than 1 GB	
Storage	Not less than 16 GB	
Bluetooth	Not lower than Bluetooth 4.0	
Network bandwidth	Not less than 5 Mbps	
Screen size	Not less than 5.65 inches	Not less than 4.7 inches
Screen resolution	Not less than 1920*1080	Not less than 1334*750
Maximum screen brightness	Not less than 150 cd/m²	
Ambient light	It should have functions such as ambient light detection, display screen brightness correction, and automatic and manual adjustment of screen brightness	
Battery capacity	Not less than 3000 mAh	Not less than 1810 mAh

When the app runs concurrently with other software, it will not cause functional loss or operational errors in those applications. There is no need to configure the environment or parameters in advance when using the app. The app's functionality is determined by the most recently installed version. It is not possible to install multiple versions of the app on the same mobile phone simultaneously; only one version can be retained.

4.2 App Setup

Before using the app for the first time, you must complete the setup process:
(1) Ensure your phone is connected to a network (Wi-Fi or mobile data). You can then install the app from the App Store or scan the QR code provided in the Instructions for Use.
(2) To obtain blood glucose readings, enable Bluetooth on your phone and connect it to the sensor. Tap the app icon to open the app. If you are a new user, enter your mobile phone number to receive the verification code for logging in. Your unregistered mobile phone number will be automatically registered after successfully passing the verification. After registration, you can log in using one of the following two methods:
● Log in with your account number and password.
● Log in with your mobile phone number and SMS verification code.
(3) Follow the on-screen instructions to complete the basic settings. To connect to the sensor, either scan the QR code on the applicator label or enter the 8-digit link code (refer to the instructions below for more details).

As Figure 6

(4)Accept the required notification permissions. The sensor can be used to check your glucose after 15 minutes. While the sensor is starting up, you can navigate away from the app.

4.3 Checking your glucose value

Trend arrows:

↑ Glucose is rising quickly (more than 2.2 mmol/L per 5minutes)
↗ Glucose is rising (between 1.1 and 2.2 mmol/L per 5minutes)
→ Glucose is changing slowly (less than 1.1 mmol/L per 5minutes)
↘ Glucose is falling (between 1.1 and 2.2 mmol/L per 5minutes)
↓ Glucose is falling quickly (more than 2.2 mmol/L per 5minutes)

Caution:

Trend arrows indicating which way your glucose is going. Talk to your healthcare professional about using the trend arrows to determine, such as how much and when insulin to take.

4.4 Removing your Sensor

Step1: Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.
Step2: Discard the used Sensor. See "6.Disposal".
Step3: When you are ready to apply a new Sensor, follow the instructions in "3.Applying Your Sensor" and " 4.Starting Your Sensor".

Caution:

Your Sensor will automatically stop working after 14 days(TX-14) or 21 days(TX-21) of use and must be replaced. You should also replace your sensor if you experience any irritation or discomfort at the application site, or if the app reports a problem with the sensor currently in use.
If the glucose readings from the sensor do not seem to match how you feel, check to ensure that the sensor has not come loose. If the sensor tip has come out of your skin, or if the sensor is becoming loose, remove the sensor and apply a new one.

5. Cleaning and maintenance

The device is designed for single-use only and contains no replaceable or repairable components.

6. Disposal

Sensor:

Sensors must not be disposed of through municipal waste collection. Instead, use the separate collection for electrical and electronic equipment waste. Since sensors may have been exposed to bodily fluids, you may choose to wipe them before disposal using a cloth dampened with a mixture of 1 part household bleach to 9 parts water.
Note: Sensors contain non-removable batteries and must not be incinerated, as the batteries may explode upon incineration.

Sensor applicator:

Please consult your local waste management authority for instructions on disposing of sensor applicators at a designated sharps collection site. Ensure that the cap is securely on the Sensor applicator, as it contains a needle.

7. Troubleshooting

Problem	Cause analysis	Solution
The Sensor is not sticking to your skin.	The site is not free of dirt, oil, hair or sweat.	Step 1: Remove the Sensor. Step 2: Consider shaving and/or cleaning the site with soap and water. Step 3: Replace with a new sensor.
Skin irritation at the Sensor applica-tion site.	Seams or other constrictive clothing or accessories causing friction at the site OR you may be sensitive to the adhesive material.	Ensure that nothing rubs on the site. If the irritation is where the adhesive touches skin, contact your healthcare professional to identify the best solution.
The blood glucose readings displayed by the software is not updated in time.	The Bluetooth is not turned on;	You need to confirm whether the Bluetooth is turned on.
	The distance between the mobile phone and the sensor exceeds 6m;	You need to place the smartphone less than 6m from the sensor.
	The sensor is in an environment that is too cold or too hot.	During wearing of the sensor, you need to need to keep the sensor in an environment with a temperature of 5℃~40℃.

8.Electrical safety

Safety features of sensor kit

Classification by type of protection against electric shock	Internal power unit
Sensor water resistance and ingress protection	IP58
Classification by degree of protection against electric shock	BF Type applied part
Classification by degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Equipment that cannot be used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Classification by operation mode	Continuously operating equipment
Rated voltage and frequency	Powered by disposable lithium manganese battery, DC3.0V
Input power	N/A
Whether this device has applied parts for protection against defibrillation discharge effect	No
Whether this device has signal output or input parts	No
Permanently installed equipment or non-permanent-ly installed equipment	Non-permanently installed equipment - portable equipment

9. System specifications

Sensor detection range of blood glucose concentration	2.0mmol/L~26.0mmol/L
Sensor size	27.5mm*20mm
Sensor power supply	DC 3.0V (one lithium manganese button battery)
Sensor useful life	14 days (TX-14), 21days(TX-21)
Shelf life of Sensor Pack and Applicator	1 year
Date of manufacture and expiration date	See label for details
Sensor memory	Up to 14 days (TX-14) or 21days(TX-21) (glucose readings stored every 5 minutes)
Operating conditions	Temperature: 5℃~40℃; Humidity: 10%~90%RH; Atmospheric pressure: 600hPa~1060hPa
Storage conditions	Temperature: 2℃~30℃; Humidity: 10%~90%RH; Atmospheric pressure: 600hPa~1060hPa
Sensor water resistance and ingress protection	IP58
Sensor assembly sterilization method	Electron beam irradiation sterilization
Frequency band	2402MHz~2480MHz
Modulation type	GFSK (gaussian frequency-shift keying) modulation
Effective radiated power of Sensor	4dBm
Data communica-tion range	6 meters unobstructed
FCC ID	2BFX7-0044

10.Electromagnetic compatibility

Warnings:

(1) Sensor installation and operation must follow EMC guideline provided in this manual.
(2) Portable and mobile RF communication devices can interfere with sensor performance.
(3) Sensor should not be used in proximity to or stacked with other equipment. If such placement is unavoidable, the sensor should be monitored to ensure normal operation in its intended configuration.
(4) All potential hazards associated with this system have been mitigated to acceptable risk levels. The overall assessment of benefits and risks indicates that user's benefits outweigh the risks during the system's operation.
(5) This system has the wireless communication function, with a radio frequency range of 2.402 - 2.480 GHz, a bandwidth of 2Mhz, a modulation type of GFSK, and an effective radiated power of 4dBm. However, this product may be interfered with by other equipment, even if the other equipment meets the emission requirements of the corresponding national standards.
(6) This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. this device must accept any interference received, including interference that may cause undesired operation.
(7) FCC RF Radiation Exposure Statement: 1. This device must not be co-located or operating in conjunction with any other antenna or transmitter. 2. This device complies with RF radiation exposure limits set forth for an uncontrolled environment. 3. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.
(8) This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

10.1 Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems

Guidance and manufacturer's declaration - electromagnetic emissions		
The CGM system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
Radiated emissions CISPR11	Group 1	The CGM system 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.
Conducted emissions CISPR11	Class B	The CGM system is suitable for use in all establishments, including typical domestic environment.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/-flicker emissions IEC61000-3-3	N/A	

10.2 Guidance and manufacturer's declaration - electromagnetic immunity - for all equipment and systems

Guidance and manufacturer's declaration - electromagnetic immunity			
The CGM system is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compli-ance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast tran-sient/burst IEC61000-4-4	±2KV for power supply lines ±1KV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1KV line(s) to line(s) ±2KV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CGM system requires continued operation during power mains interruptions, it is recommended that the CGM system be powered from an uninterruptible power supply or a battery.
Power frequency magnetic fields (50Hz/60Hz) IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC61000-4-3	3V/m 80MHz ~2.5GHz	3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CGM system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=1.2√p d=1.2√p 80MHz~800MHz d=2.3√p 800MHz~2.5GHz where: P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CGM system is used exceeds the applicable RF compliance level above, the CGM system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CGM system.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

10.4 Guidance and manufacturer's declaration - recommended separation distances between portable and mobile RF communications equipment and the ME equipment or ME system - for non-life-supporting equipment and systems

Recommended separation distances between portable and mobile RF communications equipment and the CGM system		
The CGM system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CGM system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CGM system as recommended below, according to the rated maximum output power of the communications equipment.		
Rated power of transmitter (W)	Safe distance according to the transmitter power (m)	
	80MHz~800MHz; d=1.2√P	800MHz~2.5GHz; d=2.3√P
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		

11. Labeling Symbols and Definitions

	Consult instructions for use		Use by date
	Tempera-ture limit		Do not use if package is damaged
	Humidity limit		Do not throw this device away and recycle it in accordance with local disposal requirements
	Date of manufacture		Recyclable
	Alternating current		Manufacturer
	BF Type applied part	SN	Serial number
	Keep away from sunlight		Keep dry
	Do not reuse		Non-ionizing electromag-netic radiation
	Warning	STERILE R	Sterilized using irradiation
LOT	Batch code		Environmentally friendly use period is 10 years
FCC ID	Federal Communica-tions Commission Identification Number	IP58	Can withstand immersion into 1.1 metres (3.6 ft) of water for up to 60 minutes. Dust-protected.
CE 2797	CE Mark		Single sterile barrier system
MD	Medical device	UDI	Unique device identifier

12.Manufacturer information

Registrant/manufac-turer name	Teljane Medical Technology (Suzhou) Co., Ltd.
Manufacturer production address	5F, Building 2A, 69 Jiepu Road, Suzhou Industrial Park, Suzhou City
Company website	www.teljane-instara.com
Version number	A/6
Revision date	2026.02.06