USER’S MANUAL

Continuous Glucose Monitoring System

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Contents

1. Product introduction

1.1 Basic information

Device name: Continuous Glucose Monitoring System (CGM System)

Model and Size: TX-14

Device Description: The TX-14 Continuous Glucose Monitoring System (hereinafter referred to as the 'System') is a fully-integrated continuous glucose monitoring system (iCGM) that provides glucose readings every 5 minutes, delivering real-time glucose levels, trends, and alerts.The System comprises two primary components: a sensor kit that transmits data via Bluetooth Low Energy (BLE), and an App for data sharing. The sensor kit consists of two elements: a sensor pack (incorporating a sensor electrode assembly and a needle) and a sensor applicator (comprising an applicator, a transmitter, and adhesive tape).

The Sensor automatically stops working after 14 days of wear and must be replaced.

Sensor kit includes:

SN	Component name	Component model/specification	Picture (the color is subject to the actual object)	Quantity
1	Sensor Pack	TS001		1

2	Sensor Applicator	TA001		1
3	Product insert	/	/	1

1.2 Indications for Use

The device is intended for continuous or periodic monitoring of interstitial fluid glucose levels in adult patients with diabetes (≥18 years of age). The System can provide and store real-time continuous glucose values, enabling users to track the trend of glucose concentration changes. If the glucose readings falls below or rises above a preset value, the companion app will issue an alert. The device is intended for single use and does not require calibration. It should be noted that the glucose readings obtained by the sensor cannot replace blood glucose testing for making diabetes treatment decisions.

1.3 Contraindications

The sensor must be removed prior to the Magnetic Resonance Imaging (MRI), X-ray, CT scan, other examinations that may expose the patient to strong magnetic or electromagnetic radiation fields, and diathermic therapy.

The System is not intended for use in conjunction with the closed-loop insulin infusion system and the insulin infusion suspension system.

The use of this System by pregnant women, dialysis patients, or persons under the age of 18 has not been researched. Unknown risks may arise if they use this product.

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) The measurement results of this product can not replace blood glucose testing for diabetes treatment decisions.

(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 Sensor contains small parts that may be dangerous if swallowed.

(6) Do not use if expiry date.has passed.

(7)Intense exercise may cause your sensor to loosen due to sweat or movement of the sensor. If the sensor is becoming loose or if the sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your sensor if it starts to loosen and follow the instructions to select an appropriate

application site. Do not attempt to reinsert the sensor. Contact our Customer Care Team if your sensor becomes loose or falls off before the end of the wear period.

(8) The sensor shoud not be touched by pets or children to avoid loosening or falling off.

(9) Please keep the terminal equipped with the CGM system software away from children, pets or insects to avoid being misoperation.

(10) Do not clean, resterilize, or try to extract the needle from the applicator. An accidental needlestick or puncture may occur.

(11) A fingerstick test is required to confirm the low or near-low blood glucose readings.

(12) 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.

(13) The effect of the sensor which is used together with other active distribution medical devices such as the heart pacemaker has not been evaluated.

(14) If you have a medical appointment that includes strong magnetic or electromagnetic radiation, for example an X-ray, MRI (Magnetic Resonance Imaging) or CT (Computed Tomography) scan, remove the Sensor you are wearing and apply a new one after the appointment. The effect of these types of procedures on the performance of the Sensor has not been evaluated.

(15) Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for resterilisation. Further exposure to irradiation may cause inaccurate results.

(16) 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.

(17) Your Sensor automatically stops working after 14 days of wear and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if the App reports a problem with the Sensor currently in use.

(18) Don't go near the place with magnetic field when wearing the sensor to avoid the sensor power being turned off and the sensor stop working.

(19) 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 transmitter to the sensor.

c. If bleeding does not stop, do not connect the transmitter to the sensor 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.

(20) Your Sensor has been tested to withstand immersion into one point one meters of water for up to 60 minutes. It is also protected against insertion of objects >12 mm diameter (IP28). Your Sensor is water-resistant and can be worn while bathing, showering or swimming. Do NOT take your Sensor deeper than 1.1 meters or immerse it longer than 60 minutes in water. Note that bluetooth performance may be impacted if using the system while underwater.

(21) 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.

(22) 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.

(23)

2. Overview of software functions

The App is a component of the System and can obtain blood glucose readings from

the sensor applied on you, thereby helping you to monitor the blood glucose level. The App can provide continuous, comprehensive and reliable blood glucose data throughout the day.

The App is a graphical user interface, consisting of windows and function buttons. It has 4 main menus, namely Monitoring, Recording, Analysis, and Mine.

2.1App 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
Monitoring	Sensor information	Number, and Bluetooth connection status	The user can see the transmitter connection status and its information
	Blood glucose monitoring	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
Notes	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 ($eHbA_{1c}$), 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
Mine	Information edition	Head portrait, nickname, gender, diabetes type, date of birth, height, and weight	The user can edit his/her own information

	Report management	Report list: time, device serial number, and report view. Report details: Share to friends, download PDF, time, 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	After the user has used the product for more than 6 days, the user can view the AGP graph and share or download the AGP graph in the PDF format. The graph contains some information about the product use by the user, mainly a summary of blood glucose changes and some indicators.
	Blood glucose alarms	Blood glucose settings: Blood glucose unit, high and low limits, blood glucose alarms, reminder mode (vibration/ringtone), time, blood glucose value, and high or low blood glucose alarms	The user can set the limits for high and low blood glucose alarms and the reminder mode, and view the alarm for blood glucose out of range
	Settings	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: 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 followings	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 followers	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

a. The user has entered the wrong account number or password when logging in:

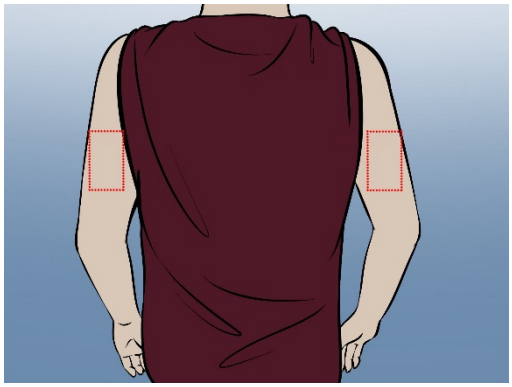
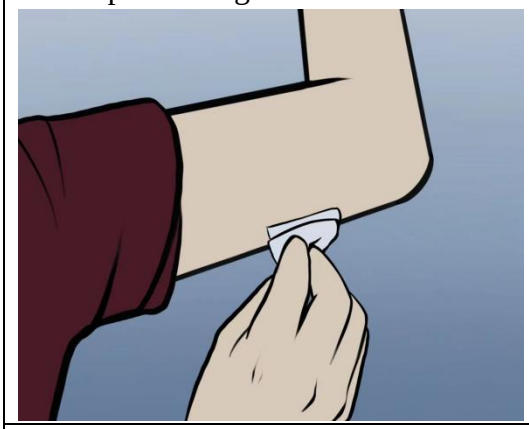
“Sorry, the account number/password is wrong”; “The password length is wrong. It needs to be of 8~14 characters”.

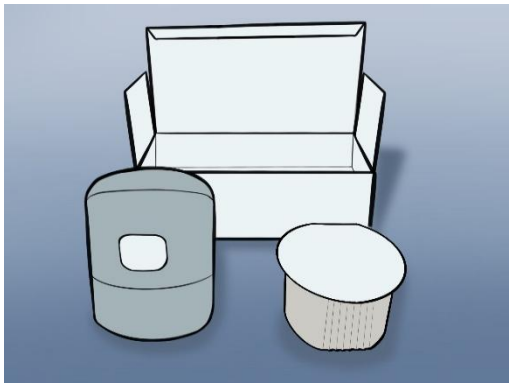
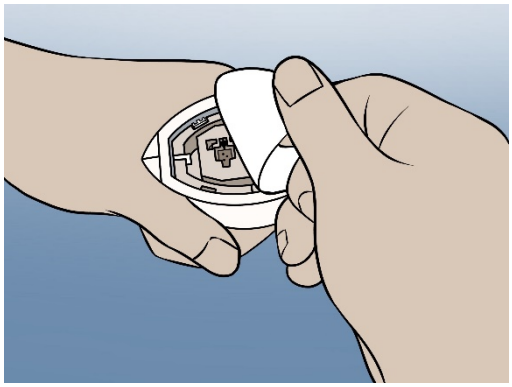
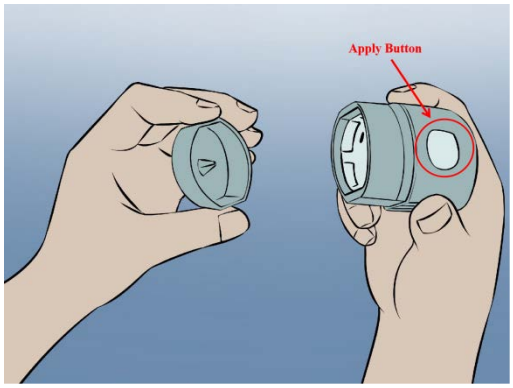
b. The information entered is incomplete: If the user proceeds to the next step without entering the complete information when logging in, recording an event, filling in the personal file, or making system settings, a prompt such as “Please select...!” or “Please enter...!” will pop up at the bottom of the software’s home page to instruct the user to enter the complete information before proceeding to the next step.

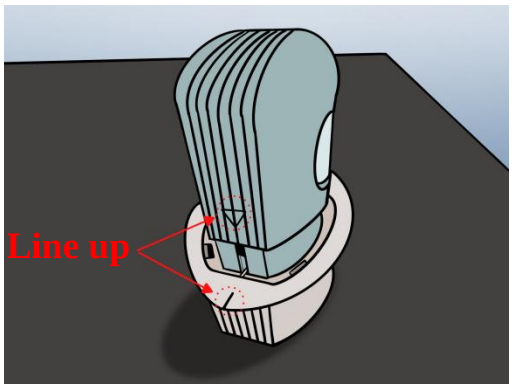
c. The communication is abnormal: If the mobile computing terminal that has been installed with the CGM system software is connected to the transmitter in the sensor via the Bluetooth, and the distance is within 6m, the data can be exchanged. If the distance is more than 6m or the Bluetooth is disconnected, the communication becomes interrupted. At this point, there will be a prompt: “The device is not connected”. The user can click “Connect transmitter” to try to connect this sensor again.

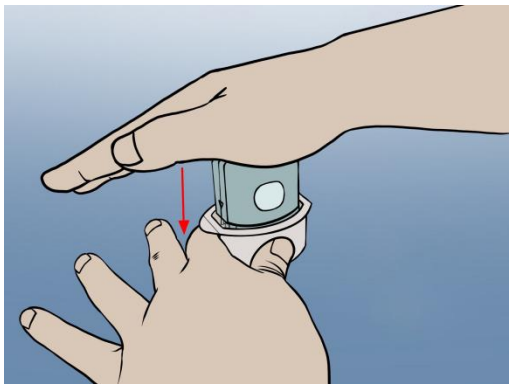
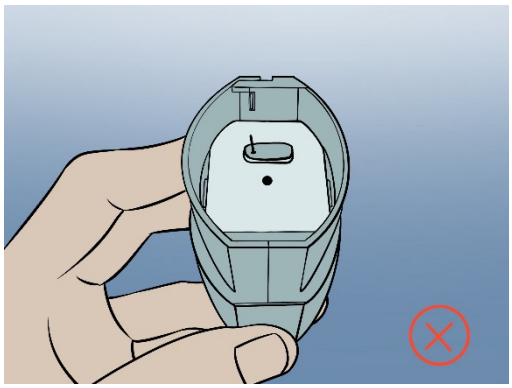
d. Prompts for other situations: If the mobile computing terminal has been installed with the software, but has not been connected to the sensor, there will be a prompt: “The device is not connected”. If the sensor has expired, there will be a prompt: “The current sensor has expired. Please replace the sensor”.

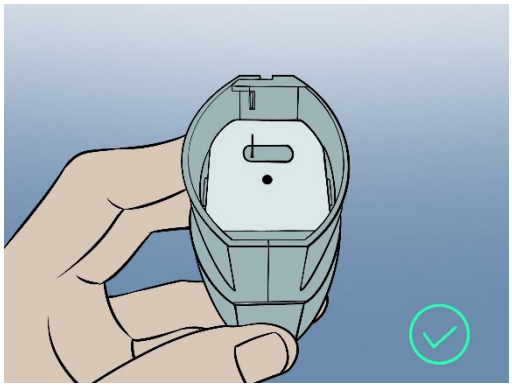
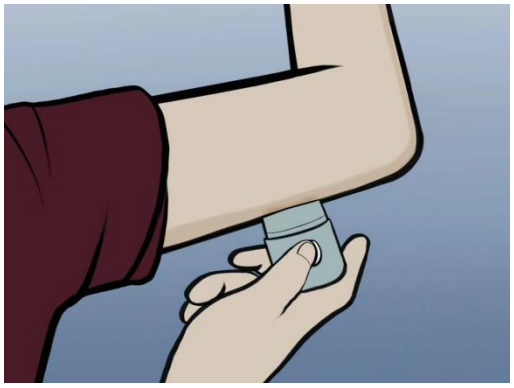
3. Applying Your Sensor

Applying Steps	Notes
1. Selection of application site: Apply the Sensor only on the back of your upper arm. 	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. 	The area you selected must be clean and dry, or the Sensor may not stick to the site.
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 . Unscrew the cap from the Applicator and set the cap aside. (DO NOT touch the apply button.)	Do NOT use if the Sensor Pack damaged or has already been opened. Do NOT use if past expiry date. Sensor pack and sensor applicator codes must match or glucose readings may be inaccurate.

  	
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.	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.

<table>
<tr>
<td> 

 </td>
<td></td>
</tr>
<tr>
<td>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.
  </td>
<td>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.</td>
</tr>
</table>

	
6. Applying the Sensor: Place the sensor applicator over the application site (DO NOT press it hard), and press the apply 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.  	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 (19).

4. Starting Your Sensor

Important:

①When the memory space of the mobile computing terminal(herein taking “mobile phones” as an example) is insufficient, the App may malfunction. At this point, you needs to clear the memory space of the mobile phone. Normal use can be resumed after relauching the application. It is recommended that you clear the memory space of the mobile phone regularly.

②The App occupies about 300M of memory during operation. To guarantee the smooth operation of the software, please allocate a certain amount of system resources for it.

③You should regularly ensure that the System software is running on a mobile phone that is free from viruses or malware and has been updated with the latest security patches.

④The App requires that your phone has the correct date and time for recording your health information. Your phone's date and time should be set to update automatically. You can check this in your phone settings.

⑤If you encounters an unexpected shutdown of the software while using the App, you may try to solve the problem by relaunching the software.

4.1 The operating environment and compatibility for the App

	Android	Harmony OS	iOS
Operating system	Not lower than Android 2.43.0	Not lower than Harmony OS 2.0	Not lower than iOS 11.0
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/m^2	
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 is running at the same time as other software, it will not cause functional loss or operation errors in other software.

No need to configure the environment and parameters in advance when using the App. The actual functions are subject to the last installed version. Multiple versions of the App cannot be installed in the same mobile phone at the same time. Only one version can be retained.

4.2 App Setup

Before using the App for the first time, you must complete the setup.

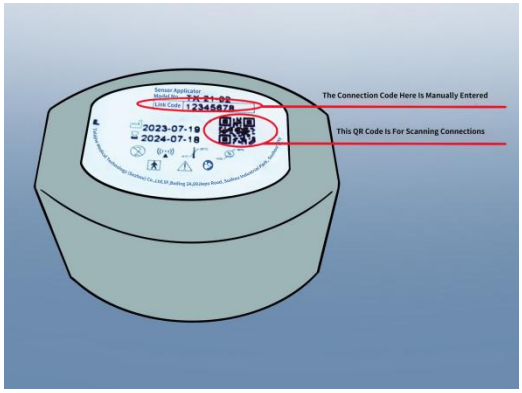
①Check that your phone is connected to a network (Wi-Fi or mobile). You can then install the App from the App Store or Scan the QR code provided in the *Instructions for Use* .

②To obtain blood glucose readings, enable the Bluetooth on your phone and connect it to your blood glucose monitor.Tap the App icon to open the App. If you are a new user, please 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.

There are two ways to log in after registration and you can choose one of them:(1)Log in with account number and password; (2)Log in with mobile phone number and SMS verification code.

③Follow 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 connection code found on the applicator label (see below for reference).



④Accept required notification permissions. The Sensor can be used to check your glucose after 30 minutes. While the Sensor is starting up, you can navigate away from the App.

4.3 Checking Your Glucose

Low or High Glucose Alarms

Sensor Remaining Available Time

Glucose Trend Arrow

Current Glucose

Glucose Graph

Target Glucose Range

↑ 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:

When performing the above operations, the user must ensure that the distance from the mobile phone installed with the App to the sensor is within 6m.

In order for the App to share data with other connected apps, please enable Wi-Fi or mobile service.

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 S~~ensor".

Caution:

Your Sensor automatically stops working after 14 days of wear and must be

replaced. You should also replace your Sensor if you notice 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 with how you feel, check to make sure that your Sensor has not come loose. If the Sensor tip has come out of your skin, or your Sensor is coming loose, remove the Sensor and apply a new one.

5. Cleaning and maintenance

The device is intended for single use and has no components that need to be replaced or repaired.

6. Disposal

Sensor:

Sensors must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste. As Sensors may have been exposed to bodily fluids, you may wipe prior to disposing, such as by 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. Batteries may explode upon incineration.

Sensor Applicator:

Please consult your local waste management authority for instructions on how to dispose Sensor Applicators at a designated sharps collection site. Ensure the cap is 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 a new sensor.
Skin irritation at the Sensor application 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 reader 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	IP28
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-permanently installed equipment	Non-permanently installed equipment - portable equipment

9. System specifications

Sensor detection range of blood glucose concentration	2mmol/L~26.0mmol/L
Transmitter size	27 mm height and 20 mm width
Transmitter power supply	DC 3.0V (one lithium manganese button battery)
Sensor service life	Up to 14 days (TX-14)
Shelf life of sensor assembly and applicator assembly	1 year
Date of manufacture and expiration date	See the label for details
Transmitter memory	Up to 14 days (glucose readings stored every 5 minutes)
Operating conditions	Temperature: 5℃~40℃; Humidity: 10%~90%RH;

	Atmospheric pressure: 600hPa~1060hPa
Storage and transportation conditions	Temperature: 2℃~30℃; Humidity: 10%~90%RH; Atmospheric pressure: 600hPa~1060hPa
Sensor water resistance and ingress protection	IP28
Sensor assembly sterilization method	Electron beam sterilization
Radio Frequency	2402MHz~2480MHz
Transmitter modulation type	GFSK (gaussian frequency-shift keying) modulation
Effective radiated power of transmitter	4dBm
Sensor transmission range:	6 metres unobstructed
FCC ID	2BFX7-0044

10. Electromagnetic compatibility

★Warnings:

(1) The Sensor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

(2) Portable and mobile RF communications equipment can affect the Sensor.

(3) The Sensor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Sensor should be observed to verify normal operation in the configuration in which it will be used.

(4) All potential hazards of this system have been reduced to acceptable risk levels, and the overall assessment of benefits and risks shows that the user’s benefits outweigh the risks during the use of this system.

(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 Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. 2. This equipment 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 equipment 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 equipment 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 equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Radiated emissions CISPR11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>Conducted emissions CISPR11</td><td>Class B</td><td rowspan="3">The CGM system is suitable for use in all establishments, including the domestic environment.</td></tr>
<tr><td>Harmonic emissions IEC61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC61000-3-3</td><td>N/A</td></tr>
</table>

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	Compliance 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 transient/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	<5% U_T (>95% dip in U_T)	N/A	Mains power

interruptions and voltage variations on power supply input lines IEC61000-4-11	for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s		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.

10.3 Guidance and manufacturer’s declaration - electromagnetic immunity - for non-life-supporting 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	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150kHz~80MHz 3V/m 80MHz~2.5GHz	N/A 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: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz~800MHz $d=2.3\sqrt{P}$ 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

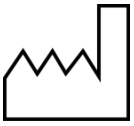
Recommended separation distances between portable and mobile RF communications equipment and the CGM system
The CGM system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CGM system can help prevent electromagnetic 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$\sqrt{P}$	800MHz~2.5GHz; d=2.3$\sqrt{P}$
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. Performance Characteristics

Performance of the Sensor was evaluated in a controlled clinical study. The study was conducted in 3 centers and a total of 70 subjects ages 18 years and older with diabetes were included in the effectiveness analysis. Each subject wore up to two Sensors for up to 14 days on the back of the upper arm.

12. Labelling Symbols and Definitions

	Consult instructions for use		Use by date
	Temperature 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		Serial number
	Keep away from sunlight		Keep dry
	Do not reuse		Non-ionizing electromagnetic radiation
	Warning		Sterilized using irradiation

	Batch code		Environmentally friendly use period is 10 years
FCC ID	Federal Communications Commission Identification Number	IP28	Can withstand immersion into 1.1 metres (3.6 ft) of water for up to 60 minutes. Protected against insertion of objects≥ 12.5 mm diameter.
	CE Mark		

13. Manufacturer information

Registrant/manufacturer name	Teljane Medical Technology (Suzhou) Co., Ltd.
Registrant/manufacturer domicile	5F, Building 2A, 69 Jiepu Road, Suzhou Industrial Park, Suzhou City
Registrant/manufacturer contact information	
Manufacturer production address	5F, Building 2A, 69 Jiepu Road, Suzhou Industrial Park, Suzhou City
Production License No.	
Medical Device Registration Certificate	

No./Product Technical Requirements No.	
After-sales service hotline	
After-sales service provider	Teljane Medical Technology (Suzhou) Co., Ltd.
Customer service hotline	
Company website	
Version number	
Revision date	