

INSTRUCTIONS FOR USE

PLEASE REFER TO THE INSTRUCTIONS FOR USE

CT3 Series Continuous Glucose Monitoring System
For Serial Models: CT3, CT3A, and CT3C
Zhejiang POC Tech Co., Ltd.
Note: See the User Manual for technical instructions

Protective Note

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Violations give rise to a claim for damages and may have criminal consequences. This User Manual is subject to change without notice.
This User Manual may be changed without prior notice, in which case a new version of the User Manual will be issued.

01 Introduction

1-1 Foreword

Dear Users,

Please make sure that you carefully read the User Manual included with your CT3 series real time continuous glucose monitoring (rtCGM) system before use to gain a full understanding of the instructions for use and all indications, contraindications, warnings, precautions and cautions. Always keep the User Manual for future reference. If you have any questions or difficulties regarding the use of your CT3 series, please do not hesitate to contact us. You should report any events of concern to the competent authority of the Member State and us. An event of concern refers to an event that directly or indirectly had, would have, could have, or may have any of the following consequences:

- harm to the user or any other person;
- a serious public health hazard.

2- What the User Manual is for?

The instructions described in the User Manual is for the use of POC Tech's CT3 series (contains CT3, CT3A, CT3C) rtCGM. The contents of the User Manual are subject to change without notice.

3- Limits on POC Tech's liability obligations

POC Tech shall not be liable for any personal injury or damage caused by failure to use the CT3 series rtCGM System and its components according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions, including but not limited to:

- improper use (e.g. use with protective covers removed, use without indications etc.)
- improper maintenance (e.g. intentional damage to cables or electrodes, unauthorized repairs or modifications etc.)

4- Label symbols

Warning

A WARNING provides important information about a potentially hazardous situation that, if not avoided, can have serious consequences.

Caution

A CAUTION provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the medical device or other property.

Note

A NOTE contains additional information to avoid malfunctions during operation.

5- Information of the safety and effectiveness

The instructions described in the User Manual is for the use of POC Tech's You can get the information of the safety and effectiveness of the product on the website at www.poctechcorp.com

6- Software basic information

elFU operating environment requirements table

Processor	1 GHz or faster processor
RAM	1 GB (32 bit) or 2 GB (64 bit)
Hard-disk space	16 GB (32 bit operating) or 32 GB (64 bit operating system)
Graphic card	DirectX 9 or higher (including WDDM 1.0 driver)
Display	1024x768
Internet connection	Need to connect to the Internet for download, and use some functions
Browser	The operating system comes with a browser

elFU operating environment requirements table

	IOS	Android
Typical hardware configuration:		
CPU	2.5GHz	2.0GHz
Memory	3GB	4GB
Hard disk	64GB	64GB
Display	1792*828	1920*1080
Bluetooth	4.0	4.0
Typical server configuration	OS IOS13 compatible version	os Android7 compatible version

02 Safety Statement

1- Read the User Manual

Read the entire User Manual before you use your CT3 real time continuous glucose monitoring (rtCGM) system. In case of any questions regarding the use of your CT3, please contact healthcare professionals (HCP). You will be able to learn the instructions of use, and all indications, contraindications, warnings, precautions, cautions and other important safety information by a careful read of the User Manual.

Warning

CT3 is not a life sustaining device or a life support device. You may remove the sensor in case of device failure. If you are feeling unwell that may be associated with abnormal glycemic levels, use a finger glucose meter to double check. Failure to do so may result in severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) that leads to diabetic complications. Sensors are shipped and stored in sterile packages. Keep the sensor in sterile packaging until you are ready to use it. Early opening may cause microbial contamination.

Do not ignore hyper or hypoglycemia symptoms. When experiencing low/high glucose symptoms, use your blood glucose meter to confirm.

CT3 is used to supplement information for diabetes management, if the CT3 alarms a hyperglycemic event or a hypoglycemic event, you need to test your blood sugar to see if you need to take action to prevent a hypoglycemic or hyperglycemic event or consult the HCP.

If the blood glucose reading exceeds the default value or the set value, the health care professional (HCP) should be consulted when triggering low or high alert.

Skin abnormalities such as wounds, scars, redness, swelling or infection may affect sensor attachment and functioning.

If you have anemia and abnormal hematocrit levels, fingertip blood glucose (BG) measurements may be unreliable.

Carry your mobile phone at all times to maintain a smooth data communication. You won't be able to receive real time alerts when communication link is lost.

The transmitter and sensor combined is IP58 certified (immersion in water at 2.5m for 1 hour).

However, due to variation in the adhesion level in different people, it is strongly recommended that you do not expose the transmitter-sensor in water for extended periods of time.

Avoid vigorous physical activities or bumps. It may cause complete or partial detachment of the sensor, resulting in unreliable readings.

Remove the transmitter and sensor when you have to undergo MRI examinations. Avoid strong interruptions to other medical electrical equipment under extreme circumstances. Avoid strong magnetic field. See details in the Electromagnetic Compatibility (EMC) Statement.

Place the sensor not less than 5cm from your insulin pump infusion set or injection site.

Do not misuse CT3 components with components of other systems. Do not connect your CT3 to other devices or networks. Refer to manufacturer's declaration of sensor compatibility.

Used sensors should be handled according to local regulations for disposal of blood-contacting components to avoid cross-infection.

Pay attention to whether the needle shrinks and retracts after use. Wrap it in paper towels in time to avoid scatters.

The transmitter, charger and power adapter are electronic devices. Do not wash with water. Do not use them in humid environment or in strong electromagnetic field.

Medical devices that do not belong to the specific POC Tech CGM should not be connected to the system.

Do not let children have access to your CT3 without adult supervision. Do not swallow the small components that may pose a choking hazard.

3- Working Principle

Glucose in the interstitial fluid reacts with glucose oxidase in the sensor membrane, producing hydrogen peroxide which in turn reacts at the sensor electrode to generate electrochemical current signal. The current is proportional to the tissue glucose concentration. The electric signal is converted to numerical values to represent glucose levels.

4- Product Components

Table 1- Components for CT3 serial Models

Model	Hardware Components	App-Software Components	Accessories
CT3	Sensor CT-302 Transmitter CT-300D	AnytimeWell	Transmitter Charger Type-C USB Cable Power Adapter (optional) User Manual
CT3A	Sensor CT-312 Transmitter CT-301D	AnytimeFollow	
CT3C	Sensor CT-312C Transmitter CT-301DC		

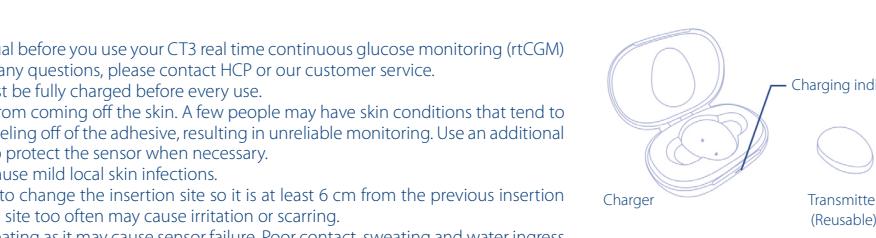


Figure 1 CT3 Components

04 Performance Characteristics

Warm Up Time: 1 hour.

Sensor Use Life: 14 days.

Effective Glucose Range: 1.7 - 27.8mmol/L (30.6mg/dL-500.4mg/dL).

Number of 24-hour glucose data points: 480 (1 data point / 3 minutes).

The sensor is a single-use medical device, sterilized by γ -Beam irradiation.

Laboratory test accuracy: (linearity deviation): within $\pm 20\%$.

The sensor can automatically monitor and correct electrochemical interference. Lab test recovery ranges 80% - 120% (n = 12, with 20mg / L acetaminophen and 60mg / L ascorbic acid).

Transmitter Power Supply: DC 3.7V rechargeable battery. Use power adapter provided by the manufacturer or users can purchase by themselves for charging.

Requirements and specification of power adapter provided by the manufacturer

- Comply with the IEC 60601-1 standard

- Adapter Input: 200-240VAC, 50 / 60Hz, 0.35A, Output: 5.0V, 1.0A

- Requirements and specification of power adapter purchased by users

- Comply with the IEC 60601-1 standard

- Output: 5.0V, 1.0A

Operating Conditions:

- Transmitter, charger and power adapter operate at temperatures between 5°C to 40°C

- Humidity $\leq 93\%$ RH. If the transmitter has been stored at a temperature lower than 5°C, warm up to room temperature before using.

- Sensor operating conditions: normal ambient temperature

- Sensor operating conditions: normal ambient temperature

- Pressure: 700-1060hPa

Transmitter, sensor, transmitter charger and power adapter are all suitable for patient use. The patient can be the intended operator.

CT3 Clinical data

- Main performance data

GlucoseRange

Percent within 20/20% EKF(%)

A+B area ratio of Clarke error grid

A+B area ratio of Consensus error grid

MARD%

Full Glucose Range

91.49%

99.74%

99.95%

9.07%

05 Operating Procedures

1- Prepare your transmitter

- Clean your transmitter (if needed): Clean the electrode contact pins

- Then push down the transmitter and turn it clockwise until you hear a clear click sound. That indicates a secure locking between the transmitter and the sensor.

2- Attach the transmitter

- Attach the transmitter to the sensor (Figure 14). First, mate the transmitter slot onto the sensor block.

- Then push down the transmitter and turn it clockwise until you hear a clear click sound. That indicates a secure locking between the transmitter and the sensor.

3- Insert the sensor and separate the applicator

- Open the sterile package, take out the sensor, pull off the adhesive's backing (Figure 10)

- Firmly press the sensor down to the cleaned and dried skin site. (Figure 11)

- Move the safety pin to the unlock position. Hold the applicator steady and push the release buttons to insert the sensor. After sensor insertion, carefully remove the applicator from the sensor. Dispose the applicator in a medical waste bin (Figure 12 and Figure 13).

4- Prepare your mobile phone

For first time users, scan the QR code on the product packaging, search the App Store on your phone, locate AnytimeWell and download it.

5- Log in

Install AnytimeWell and open the App. If it is the first time, follow the on-screen prompt to create

several sequential readings over time. The CT3 System also aids in the detection of episodes of hypoglycemia and hyperglycemia. It is intended for single patient use.

4- Indications

Patients with type 1 diabetes and type 2 diabetes, 18 years and older or other patients in need of glucose trend monitoring.

5- Limitation

It is not intended to replace fingerstick blood glucose testing for diabetes treatment decisions. It is not intended for use in conjunction with the digitally connected medical devices including automated insulin dosing (AID) systems for the purpose of managing diabetes.

6- Contraindications

Remove the system for magnetic resonance imaging (MRI)

If you are at risk of bleeding or skin ulcers, allergic to disinfectants or medical adhesives, or have sensitive skin, talk with your HCP and use your CT3 under his or her guidance.

03 Basic Product Information

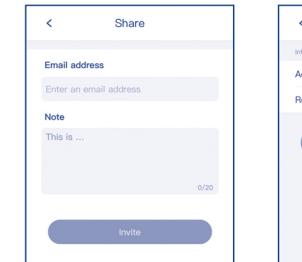
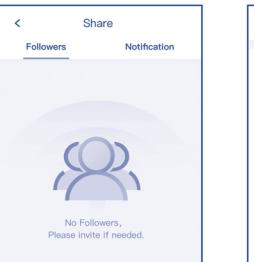
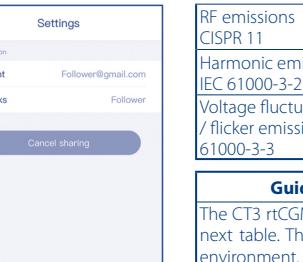
1- Product Name

Continuous Glucose Monitoring System

2- Models

CT3/CT3A/CT3C

your account. Use your email address as your account number and create a password to complete registration (Figure 3). For normal use, log in your account by entering your email address and password. Then click Login to log into your account

Figure 40
Invite FollowersFigure 42
Followers Settings

RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Conforming

The CT3 is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer' declaration - electromagnetic immunity

The CT3 rtCGM system is intended for use in the electromagnetic environment specified in the next table. The customer or user of the CT3 rtCGM system shall ensure it is used in such an environment.

Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment - guidance
ElectroStatic Discharge (ESD) IEC 61000-4-2	± 8kV Contact ± 15kV Air	± 8kV Contact ± 15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be at least 30%.
Electrical fast transient / burst IEC61000-4-4	± 2kV for power supply lines ± 1kV for input / output lines	2kV for power supply lines Not applicable	Main power quality shall be that of a typical commercial or hospital environment.

Surge IEC61000-4-5

± 1kV line(s) to line(s) ± 2kV line(s) to earth

± 1kV line(s) to line(s) Not applicable

Main 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

0% UT for 1 cycle
0% UT for 0.5 cycle at 8 phase angles

70% UT for 25/30 cycles
70% UT for 25/30 cycles

0% UT for 250/300 cycles
0% UT for 250/300 cycles

Main power quality should be that of a typical commercial or hospital environment.

If you experience any problems when using your transmitter, transmitter charger and power adapter, please contact the manufacturer or agent. Do not open your device by yourself for repair, replacement or modification.

Transmitter is powered by rechargeable lithium battery (not replaceable). Put your transmitter on its charger when you are not using it and charge it every half year as maintenance. The charger does comply with the IEC 60601-1 standard.

2-Transport conditions

Environmental factors	Transmitter (including charger), power adapter	Sensor
Temperature / °C	-15~45°C	2 ~ 45, no longer than 20 days
Relative humidity (RH) % ratio:	±93%	No special requirements
Pressure	700-1060hPa	700-1060hPa

Note: UT is the AC main voltage prior to application of the test level.

Guidance and manufacturer' declaration - electromagnetic immunity

The CT3 rtCGM system is intended for use in the electromagnetic environment specified in the next table. The customer or user of the CT3 rtCGM system should ensure it is used in such an environment.

Immunity test	IEC60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 V 0.15MHz-80 MHz 6V in ISM bands between 0.15MHz and 80 MHz	3 V 0.15MHz-80 MHz 6V in ISM bands between 0.15MHz and 80 MHz	Portable and mobile RF communications equipment should not be placed closer to any part of the equipment than the recommended separation distance, including cables. The recommended separation distance can be estimated using the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 √P 150kHz-80MHz d = 1.2 √P 80MHz-800MHz d = 2.3 √P 800MHz-2.5GHz
RF radiation IEC 61000-4-3	10V/m 80MHz - 2.7GHz	10V/m	In the equation, 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, shall be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from building structures, objects and people.

11 Accessories, Peripherals and Consumables

Quick Start Guide in the sensor package of the CT-302.

Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.

Inside the transmitter package of the CT-300D: 1 charger, 1 Type-C data cable, power adapter(optional), User Manual. You can purchase your own power adaptor or contact after-sales for that. Check your power adaptor against specifications required and change it if it is not working properly.

12 Product Classification

1- Transmitter

Classification by type of protection against electric shock: internal power supply (operating), class II (charging)

Classification by degree of protection against electric shock: Type BF applied (operating), type BF not applied (charging)

Classification by degree of protection against liquid ingress: IP58 (transmitter)

Classification by safety of use in environment where there is a mixture of flammable anesthetic gases with air or oxygen or nitrous oxide: Not AP/APG

Classified by operation mode: continuous

Transmitter rated voltage and frequency: DC 3.7V (operating), 100-240VAC, 50 / 60Hz (charging)

Transmitter input power: 0.35A (charging)

Defibrillation-proof applied parts: none

Signal output or input applied parts: none

Permanent or non-permanent installation: non-permanent

If you have any other questions, please contact our customer service.

Caution

To receive alerts/notifications timely, please carry the phone with you at all times and make sure the Bluetooth remains connected. The sound volume of app should be loud enough to be heard. Try to turn off other apps as many as you can while making sure that AnytimeWell App remains running in the background. Do not clear cache of AnytimeWell, for this may cause serious operating errors such as rebooting and data wiping-out.

08 EMC Declaration

The CT3 rtCGM system is intended for use under specific EMC standard. It shall only be installed and put into service according to the EMC information specified in this User Manual.

Portable and mobile RF communications equipment can affect the function of medical electrical equipment.

Make sure you use cables as specified in the following table to meet requirements in electromagnetic emissions and immunity:

Type	Length
USB data cable	1.2m

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity.

Do not place CT3 in the vicinity of other equipment or stack the CT3 with other equipment. If adjacent use inevitable, CT3 shall be observed to verify normal operation.

Performance characteristics.

Charging	Normal charging under interference.
Operating	Reading changes should not exceed ± 1mmol / L (18mg/dL) under interference.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and CT3

CT3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CT3 can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CT3 as recommended in the next table, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	separation distance according to frequency of transmitter / m
150kHz to 80MHz d=1.2 √P	80MHz to 800MHz d=1.2 √P
0.01	0.12
0.1	0.38
1	1.2
10	3.8
100	12

The CT3 rtCGM system is intended for use in the electromagnetic environment specified in the next table. The customer or user of the CT3 rtCGM system should ensure it is used in such an environment.

Emission	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CT3 system emits low RF energy only for its internal function, therefore nearby electronic equipment unlikely will be affected.

For transmitters rated at a maximum output power not listed above, the recommended separation distance (m) in meter 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 separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from building structures, objects and people.

What is covered

This warranty applies only to the person who purchased the products plus accessories from an authorized dealer of Zhejiang POC Tech Co., Ltd. or directly from Zhejiang POC Tech Co., Ltd. The independent and limited warranty is neither assignable nor transferable.

For how long

This warranty covers the products for a period of 2 years from the date of purchase for a transmitter, transmitter charger and power adapter and 1 year for a sensor. Sensors intended for single use are covered by a limited warranty lasting until they are used or until their expiration date - whichever occurs first. For all other accessories, the statutory regulations apply. Sensors intended for single use are covered by a limited warranty until they are used or until the expiration date - whichever comes first. For all other accessories, the statutory regulations apply.

What is not covered

Not covered under warranty is damage of any kind resulting from, among other things: Accidents, improper storage, improper operation, modifications, unauthorized repair, improper maintenance, tampering, abuse, neglect, fire, water damage, war or acts of God. In addition, damage of any kind to the Product or its accessories resulting from the use of the Product with non-original accessories or the use of accessories with unapproved medical devices is excluded from this warranty. There is no warranty for the compatibility of the product or its associated accessories with other medical devices.

The warranty remains valid only if the products including accessories are properly maintained, repaired and instructed by Zhejiang POC Tech Co., Ltd. or by the companies or persons authorized by it.

The warranty shall not be valid if the products are used with one or more accessories not approved or authorized by Zhejiang POC Tech Co., Ltd. or an unauthorized product or the products including accessories are not used in accordance with the instructions released by Zhejiang POC Tech Co., Ltd.

No person (including any agent, dealer or representative of Zhejiang POC Tech Co., Ltd.) is authorized to make any representation or warranty with respect to the products or related accessories, other than a reference to the limited warranty. The exclusive remedy with respect to any loss or damage as a result of any cause is set forth below. In no event shall Zhejiang POC Tech Co., Ltd. be liable for any special, indirect or consequential damages of any kind, including but not limited to compensatory damages, punitive damages, economic loss of any kind, loss of business of any kind, loss of profits or personal injury, even if Zhejiang POC Tech Co., Ltd. has been advised of the possibility of such damages, caused by negligence or otherwise. Unless applicable state law does not allow such exclusion or limitation.

Zhejiang POC Tech Co.'s Obligations under limited warranty

Zhejiang POC Tech Co., Ltd. will, at its sole discretion, repair, replace or refund the purchase price of the product on a pro-rata basis. In the event of a replacement, Zhejiang POC Tech Co., Ltd. reserves the right, at its sole discretion, to replace the product with a new, refurbished, identical or similar product. The decision on a similar product is at the sole discretion of Zhejiang POC Tech Co., Ltd. In the event of a replacement, the replacement product will reflect at least the pro-rated remaining period for the product based on the remaining warranty period. In the case of a refund, the refund will reflect the pro-rated value of the product based on the original price of the same or similar product, whichever is less, and the remaining warranty period. In no event will the warranty period of a replacement Product exceed the warranty period of the original Product.

Make a warranty claim

To make a warranty claim, contact the dealer from whom the product was purchased. The product must be returned - at the original end user's expense - to a location designated by the dealer or Zhejiang POC Tech Co., Ltd.

*Valid for equipment from date of shipment to buyer. Please attach invoice copy from Zhejiang POC Tech Co., Ltd. or the dealer. Legal warranty applies to all other products.

Zhejiang POC Tech Co., Ltd. reserves the right to declare on the above terms and conditions.

15 Annex : AnytimeFollow setting-up guide

1. Login

Your Follower downloads, installs and opens AnytimeFollow. They create their AnytimeFollow account with their email address, set password and log in AnytimeFollow, as shown in Figure 1.

2. Add Sharer

Your Followers can also add you on their AnytimeFollow.

Your Followers can tap Add to add Sharer, enter Sharer's email address, add notes and send invitation, as shown in Figure 2. The Sharer will receive request notifications on their