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yuwell

# INSTRUCTIONS FOR USE

## PLEASE REFER TO THE INSTRUCTIONS FOR USE



CT3 Series Continuous Glucose Monitoring System

For Serial Models: CT3, CT3A, and CT3C

Zhejiang POCTech Co., Ltd.
Note: See the User Manual for technical instructions

**Protective Note**

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- 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- 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 POCTech's CT3 series (contains CT3, CT3A, CT3C) rtCGM. The contents of the User Manual are subject to change without notice.

**3- Limits on POCTech's liability obligations**

POCTech 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 POCTech'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 |

- Software name: AnytimeWell, AnytimeFollow
- Software operating environment

| 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 treat or 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. As it may cause 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 scratches.
- 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 POCTech 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.

**Precaution**

- Read the User Manual before you use your CT3 real time continuous glucose monitoring (rtCGM) system. If you have any questions, please contact HCP or our customer service.
- The transmitter must be fully charged before every use.
- Protect the sensor from coming off the skin. A few people may have skin conditions that tend to cause premature peeling off of the adhesive, resulting in unreliable monitoring. Use an additional medical adhesive to protect the sensor when necessary.
- This product may cause mild local skin infections.
- It is recommended to change the insertion site so it is at least 6 cm from the previous insertion site. Using the same site too often may cause irritation or scarring.
- Avoid excessive sweating as it may cause sensor failure. Poor contact, sweating and water ingress may lead to abnormal readings. Remove the sensor if sustained abnormal readings are observed associated directly with physical activities or sweating.
- There are no special requirements regarding the maintenance of the transmitter, charger and power adapter. Clean them with alcohol pads if the surface becomes dirty. Dry completely before use.
- Charge your transmitter using Type-C USB cable and either the adapter included with your CT3 or any IEC 60601-1 certified adapters.
- The CT3 rtCGM system contains no parts that require user repair. Please contact the manufacturer or your agent for any problem. Do not open the device, replace or modify parts.

**2- Label symbols**

| | | | |
|---|---|---|---|
| | Refer to instruction manual | ⎓ | DC current |
| | Sterilized using Irradiation | | Consult instructions |
| | Non-ionizing irradiation | | Type BF applied part |
| | Do not dispose in unsorted municipal waste stream | | Do not re-use |
| | Do not use if package is damaged | | Temperature limits |
| IP58 | Water proof level IP58 | | USB port |
| | Do not re-sterilize | | Class II equipment |
| | Keep away from sunlight | | Keep dry |
| | Transmitter stacking limit | | This side up |
| | Date of manufacture | | Warning |
| | Manufacturer | | Use-by date |
| LOT | Batch code | SN | Serial number |
| | Single sterile barrier system with protective packaging outside | # | Model number |
| | Authorized representative in the European Community/European Union | | Humidity limitation |
| UDI | Unique device identifier | | Not compatible with magnetic resonance |
| | Does not contains or no natural latex rubber | MD | Medical Device |
| CE | Symbol of compliance with REGULATION (EU) 2017/745 | | |

**3- Intended Use**

The CT3 Series Continuous Glucose Monitoring System (CT3 System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in in persons age 18 years and older. Interpretation of the CT3 System results should be based on the glucose trends and several sequential readings over time. The CT3 System also aids in the detection of episodes of hyperglycemia and hy poglycemia. 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

**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<br>Transmitter CT-300D | AnytimeWell<br>AnytimeFollow | Transmitter Charger<br>Type-C USB Cable<br>Power Adapter (optional)<br>User Manual |
| CT3A | Sensor CT-312<br>Transmitter CT-301D | | |
| CT3C | Sensor CT-312C<br>Transmitter CT-301DC | | |

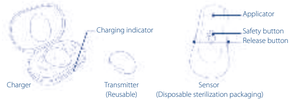



Figure 1 CT3 Components

## 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 E-beam irradiation.
Laboratory test accuracy: (linear deviation): within ± 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: 100-240VAC, 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°Chumidity ≤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
- 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 (Figure 2) and the surface of the transmitter.




Figure 2 Transmitter Contact Pins

- Charge your transmitter: Place the transmitter into the charger to start charging; Flashes white when charging, a blue color indicates charging completion. Make sure that your transmitter is fully charged before every use.

**2- 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.

***• Log in***

Install AnytimeWell and open the App. If it is the first time, follow the on-screen prompt to create your account. Use your email address as your account number and create a password to complete registration (Figure3). For normal use, log in your account by entering your email address and password. Then click Login to log into your account.

***• Set up your profile***

If it is the first time you log in, you will see the profile screen, as shown in Figure 4. Fill in the information as guided to set up your profile. Or you can skip it and complete your profile later.

**3- Connect the transmitter to your phone**

- Take the fully charged transmitter out of the charger. This will turn the Bluetooth of the transmitter into broadcast/search mode.

Place you phone next to the transmitter. On the App screen, Tap Next Step (as shown in Figure 5). The App will start searching for the transmitter. A list of available transmitters in the vicinity of your phone will be listed.
- Choose the SN of your transmitter, tap Confirm to connect your transmitter to your phone, as shown in Figure 6.

**4- Warm up your sensor**

- Once the connection between your App and the transmitter is successful, you will come to a screen that prompts you to scan or enter the QR code of the sensor. Scan the QR code on the sensor base with your phone as shown in Figure 7. You can manually input sensor information if the code is invalid after scanning for several times. The system enters into the warm up mode after the sensor information is captured.

***• Sensor warmup***

After a successful connection, the sensor will start its 1-hour warmup, as shown in Figure 8.

**5- Prepare your skin**

- Check the sterile package of the sensor. Do not use the sensor if its sterile package has been damaged or opened.
- Check the sensor package for expiration date before opening. Do not use if expired.
- Choose either the abdomen or arm as the sensor site (Figure 6):
  1. Avoid part of skin that has scars, wounds, redness, swelling or infection.
  2. Place the sensor not less than 5cm from your insulin pump infusion set or injection site.
  3. When choosing abdomen, the sensor should be at least 5 cm from the belly button.
  4. Avoid strong muscular movement parts.
  5. Avoid parts that are likely to be bumped, pushed or laid on while sleeping.
  6. Avoid sites where sensor can be rubbed, for example, by your belt.
- First, clean and disinfect the insertion site with alcohol pads or by other proper means.



Figure 3 Login



Figure 4 Set Up Your Profile



Figure 5 Tap Next Step



Figure 6 Connect to transmitter



Figure 7 Scan the QR code on the Sensor Base



Figure 8 Sensor Warmup



Figure 9 Sensor Sites

**6- 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).

**7- 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.




Figure 10 Pull off the Adhesive's Backing



Figure 11 Firmly press the sensor



Figure 12 Unlock the Safety Pin and Insert the Sensor



Figure 13 Remove the Applicator



Figure 14 Sensor in place and Align the transmitter

**8- The AnytimeWell main user interface is shown in Figure 15**

- After the 1-hour warmup period, Anytime begins to display CGM glucose monitoring information.

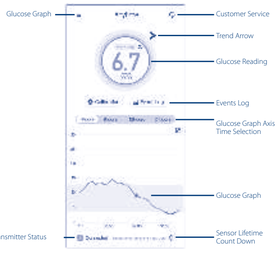



Figure 15 The User Interface of the App

- The CT3 glucose monitoring user interface:
  1. The App displays the most recent CGM reading together with the time. The reading is updated every 3 minutes.
  2. It also displays glucose trend arrows and a graph.
  3. Different colors represent different glucose ranges.
  4. You can choose to view the glucose curve for 4/8/12/24 hours periods.
  5. Information such as data link status and remaining sensor life is also displayed.
  6. If the Bluetooth communication with the transmitter becomes inactive after a period of non-active time, AnytimeWell is capable of reconnecting the data link automatically when you tap the App to activate it again.
  7. The meanings of the trend arrows are shown in Figure 16.

**Warning**

⚠ Enter wrong values will result in large error.

**9- Log events**

To log an event, tap 'Events' on the home screen to open the event log page. Make sure you enter all events in real time. Your CGM lets you keep track of four types of events, diet, medicine, exercise and insulin. Tap ⊕ at lower part of the screen to enter your event. To delete an event, highlight the event and tap 🗑 to delete , as shown in Figure 17.

**10- End a monitoring session**

- During your 14-day sensor session, AnytimeWell displays sensor time countdown. The system will automatically terminate the monitoring at the end of the sensor session and await your confirmation.
- Remove your sensor: Start from one edge of the adhesive, carefully pull off the sensor and transmitter together.
- Check the skin of the sensor site. If bruises, infection, redness and swelling etc. are observed, take a photo for a healthcare professional (HCP) to view, or ask a healthcare professional (HCP) to check.
- The transmitter is reusable. Separate the transmitter from the sensor: push the clip and turn the transmitter to separate, as shown in Figure 18. Clean the transmitter with an alcohol pad and place it in the charger for next use.

**11- Set up your AnytimeWell**

***• Set High and Low Alerts***

Tap the icon ☰ on the top left corner of the home screen or swipe the home screen from left to right to go to the menu. Tap High and Low Targets. Scroll the numbers to select the set levels, tap Save to confirm, as shown in Figure 19.

***• Notifications***

Tap the icon ☰ on the top left corner of the home screen or swipe the home screen from left to right to go to the menu. Tap Notifications as shown in Figure 20. You can set up or change your notification settings following the instructions on the screen.

***• CGM Sub-menus***

1. Tap the icon on the top left corner of the home screen or swipe the home screen from left to right to go to the menu. Tap CGM and see the SN of the transmitter when it is in normal connection status to the AnytimeWell, as shown in Figure 21.
2. To end the sensor session during a regular monitoring session, tap Forced termination. There will be a pop-up window for you to confirm, as shown in Figure 22 If the monitoring session is terminated from AnytimeWell, it will show "No device connected". This results in permanent detachment between the transmitter and the phone App. The system is ready to start a new link for a new sensor.
3. When the transmitter and AnytimeWell are unbound, it will show "No device connected". This means the system is available to start the next sensor, as shown in Figure 23.



Figure 16 Trend Arrows



Figure 17 Events



Figure 18 Separate the Transmitter from the Sensor



Figure 19 Set Your High and Low Alerts



Figure 22 Confirm End Session



Figure 20 Notification Settings



Figure 21 CGM Interface Diagram



Figure 23 No Device Connected

**12- View Glucose Report**

**• Daily View**

Tap the icon ☰ on the top left corner of the home screen or swipe the home screen from left to right to go to the menu. Tap Daily View and see the CT3 readings of the day. You can also choose the date to see historical CT3 data: the glucose curve and main indicators, as shown in Figure 24.

**• Data Report**

Tap Data Report on the menu, scroll up to view the data report generated for a sensor session.
1. Select sensor session, as shown in Figure 25.
2. Device information as shown in Figure 26.
3. Monitoring results as shown in Figure 27.
4. Blood glucose panorama, as shown in Figure 28.
5. 24-hour Overlay Graph, as shown in Figure 29.
6. 24 hourly trend graph representing daily glucose trend, as shown in Figure 30.
7. Daily Highs and Lows graph showing your highs and lows, as shown in Figure 31.
8. Time percentages of your highs and lows as shown in Figure 32.
9. Distribution of glucose levels as shown in Figure 33.
10. Tap ⎙ on the top right corner of the screen to share data reports and data lists, as shown in Figure 34.

**• AGP Report**

Tap AGP Report on the menu to view and share the AGP (Ambulatory Glucose Profile) report generated for a sensor session.



Figure 24 Daily View



Figure 25 Select Sensor Session



Figure 26 Device Information

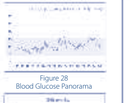


Figure 28 Blood Glucose Panorama

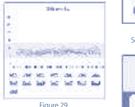


Figure 27 Monitoring Results



Figure 29 24-hour Overlay Graph

**13- Other Sub-menus**

***• Personal Data***

Tap ☰ on the top left corner of the home screen to go to the menu. Tap Nickname to enter the profile setting screen where you can set up and change your profile picture, nickname, gender, birthday, height and weight, as shown in Figure 35.

***• Help Center***

Tap Help Center on the menu to view supporting materials, as shown in Figure 36.

***• Settings***

Tap Settings on the menu to view About, Synchronize Data to Apple Health, Account Management to learn about software updates, user license agreement and terms of use, legal statements and privacy policies, instructions on synchronizing data to Apple Health, and to change the password in Account Management, as shown in Figure 37.

***• Logout***

Tap icon on the top left corner of the home screen to go to the Menu. Tap Logout at the bottom to log out your current account. You will have to re-login next time to enter your account, as shown in Figure 38.

***• Glucose Unit Settings***

Tap Unit Settings on the menu to enter the unit settings, as shown in Figure 39.

***• Share your monitoring data with Followers***

You can share your real time monitoring results with your HCP, guardians, and family members via the AnytimeFollow App. After you send your invitation to people (Followers), they will be able to follow the invitation to download the Follow App on their smartphones and setup their Follower's page to view your glucose monitoring information.

**Share with Followers**

Tap the top left corner of the home screen or swipe the home screen from left to right to go to the menu. Tap Share.
1. Tap Add to invite your Followers. Enter the Follower's email address and add notes as shown in Figure 40. Your Followers open your email invitation on their smartphones that they'll use to follow you. They can then download, install and set up their AnytimeFollow or log in their existing AnytimeFollow account to see your monitoring information.
2. You may check Followers you have invited and notifications on the lists under Followers and Notifications, as shown in Figure 41.
3. Set up your Followers. Tap the arrow on the right of the Follower to enter settings where you can set up notes, and not Share, as shown in Figure 42.



Figure 30 Hourly Trend Graph within 24 hours



Figure 31 Highs and lows



Figure 32 Time percentages of highs and lows



Figure 33 Distribution of Glucose Levels



Figure 34 Data lists



Figure 35 Set Up Your Personal Data



Figure 36 Help Center



Figure 37 Settings



Figure 38 Logout



Figure 39 Unit Settings



Figure 41 Followers and Notifications Lists



Figure 40
Invite Followers



Figure 42
Follower Settings

## 06 Waste Disposal

- Sensor: Used sensors should be handled according to local medical waste regulations for disposal.
- Transmitter, transmitter charger and power adapter: Transmitter, transmitter charger and power adapter are reusable after cleaning. It is recommended to use alcohol pad for surface cleaning. Expired device should be handled according to local electronic medical waste regulations for disposal.

## 07 Notifications and Troubleshooting

- Current abnormality: Your AnytimeWell will send notifications and may stop displaying glucose information if your sensor current becomes out of the normal range. Water ingress or excessive sweating are the most common causes for high currents. Low currents are likely due to sensor coming off. You can continue finishing the sensor session if the current recovers from a short period of abnormal status. If problem persists, you should terminate the monitoring and remove the sensor.
- Transmitter battery low: Your AnytimeWell will send notifications when it fails to establish the initial connect with a transmitter when transmitter battery is low. In such situation, you must fully charge the transmitter before trying to connect.
- High Alert: The High Alert level is 11.1mmol/L (199.8mg/dL) by default and you can reset the High Alert level according to HCP'S recommendation.
- Low Alert: Low Alert is the most important feature for real time glucose monitoring, in particular for patients with hypoglycemia unawareness. When your CT3 readings are below the Low Alert level (default setting is 3.9mmol/L (70.2mg/dL)), you will receive Low Alerts. You may customize the Low Alert level according to physician's advice.
- There are two possible scenarios where a loss of Bluetooth connection occurs: 1. AnytimeWell fails to find the transmitter during initial search. It is most likely due to a low transmitter battery. 2. The communication becomes lost during a regular monitoring session. The cause is mostly out of Bluetooth range. Bringing the phone closer to the transmitter generally restores the link. In cases, you may be in an environment where strong interference exists, e.g., you are at train station, airport or exhibition hall, etc. Under such circumstances, you cannot receive real time alerts. Once the Bluetooth data link is recovered, the delayed data will be retrieved. There is no loss of data in general.
- Urgent Low Alert: The Urgent Low Alert is set at 3.1mmol/L (55.8mg/dL) and it cannot be changed or the sound muted. When your CT3 readings is below 3.1mmol/L (55.8mg/dL), you will receive sound and message alerts. You may confirm the situation by using a blood glucose meter.
- Low Soon Alert: You will receive sound and message notifications when your CT3 forecasts an upcoming Low Alert level within 20 min.
- High Soon Alert: You will receive sound and message notifications when your CT3 forecasts a High Alert level within 30 min.
- Rapid Rise Alert: You will receive sound and message notifications when your CT3 is experiencing rapid rising.You can customize your Rapid Rise Alert.
- Rapid Fall Alert: You will receive sound and message notifications when your CT3 is experiencing rapid falling. You can customize your Rapid Fall Alert.
- Sensor coming off: Your sensor comes off due to adhesive detachment caused by sweating, exercise or oily skin. This may force you to end the current sensor session, remove the sensor and start a new sensor.
- Insufficient adhesion of the adhesive patch: If the adhesive shows early peeling off, use an additional medical tape to protect it.
- Glucose readings delay: Make sure your phone's Bluetooth is connected. It indicates a disconnection if the Bluetooth icon on AnytimeWell turns red. You may restart Bluetooth to reconnect.
- 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. |

**Guidance and manufacturer's declaration - electromagnetic emissions**

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

**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 0% UT for 250/300 cycles | 0% UT for 1 cycle 0% UT for 0.5 cycle at 8 phase angles 70 % UT for 25/30 cycles 0% UT for 250/300 cycles | Main power quality should be that of a typical commercial or hospital environment. If the user requires the equipment to keep operating during a power cut, uninterruptible power supply or battery is recommended. |
| Power frequency and magnetic field (50 / 60Hz) IEC61000-4-8 | 30 A/m | 30 A/m | Power frequency and magnetic field should be that of a typical commercial or hospital environment. |

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 RF radiation IEC 61000 -4-3 | 3 V 0.15MHz-80 MHz 6V in ISM bands between 0.15MHz and 80 MHz 10V/m 80MHZ - 2.7GHZ | 3 V 0.15MHz-80 MHz 6V in ISM bands between 0.15MHz and 80 MHz 10V/m | 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 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 surveya, shall be less than the compliance level in each frequency rangeb. 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.

a) Theoretically 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 accurately predicted. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey shall be considered. If the measured field strength in the location where the CT3 is used exceeds the applicable RF compliance level, the CT3 shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CT3.
b) In the frequency range 150 kHz to 80 MHz, field strengths should be less than 10V/m.

**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 | 800MHz to 2.5GHz d=2.3 √P |
| 0,01 | 0.12 | 0.12 | 0.23 |
| 0,1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

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.

## 09 Product code / batch number, manufacturing date and service life

**1- Transmitter**
- Transmitter SN.: see the label on the transmitter
- Transmitter manufacturing date: see the package label
- Transmitter service life: 2 years

**2- Transmitter charger and power adapter**
- Manufacturing date: see the package label
- Service life: 2 years
- Sensor
- See the package label on the sensor's parafilm to view its batch number, manufacturing date and expiration date.
- Sensor service life : 12 months

## 10 Maintenance, Storage and Shipping

**1- Maintenance**
- Transmitter, transmitter charger and power adapter are precision electronic instruments that should be kept away from humidity and electromagnetic field.
- Transmitter, transmitter charger and power adapter do not need special maintenance. Wipe it with alcohol pads and let it dry if you see contamination on its surface.
- 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 / ℃ | -15~45℃ | 2 ~ 45, no longer than 20 days |
| Relative humidity (RH)% ration: | ±93% | No special requirements |
| Pressure | 700-1060hPa | 700-1060hPa |

**3- Storage conditions**

| Environmental factors | Transmitter (including charger), power adapter | Sensor |
|---|---|---|
| Temperature / ℃ | -15~45℃ | 12 months (2 ~ 30℃) |
| Relative humidity (RH)% ration: | ±93% | No special requirements |
| Pressure | 700-1060hPa | 700-1060hPa |

## 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

## 13 EU Radio Equipment Directive (RED)

Hereby, POCTech Co, LTD declares that the transmitter of the CT3 system is in compliance with Directive 2014/53/EU.

Hereby, Jiangsu Yuyue Medical Equipment & Supply Co., Ltd. Declares that the radio equipment Transmitter model CT300D, according to Regulation (EU) no. 2017/745 (MDR) of the European Parliament and of the Council of 5 April 2017 complies with the General Safety and Performance Requirements of Annex I, the provisions and the obligations requested by Annexes of the above mentioned Regulation. In addition, the product meets the requirements of European Directive RoHS 2011/65/EU of 08/06/2011 (implemented by Legislative Decree no. 27 of 04/03/2014), amended by Directive 2015/863/EU of 31/03/2015 (implemented by Ministerial Decree of the Ministry for the Environment and Protection of Land and Sea of 06/08/2015).
The product also complies with the essential requirements for radio equipment set forth in article 3 of European Directive 2014/53/EU (RED) (implemented by Legislative Decree no. 128 of 22/06/2016), complemented by Regulation (EU) no. 2022/30 of 29/10/2021. The full text of the EU declaration of conformity according to RED Directive 2014/53/EU is available at the following internet address: https://www.poctechcorp.com/en/contents/268/568203.html

## 14 Warranty

**1- Warranty**
WARRANTY DESCRIPTION Zhejiang POCTech Co., Ltd. independently warrants that the products supplied, including accessories, will be substantially free from defects in material and workmanship. It is irrelevant whether the accessories (for example power adapter) were purchased together with the product or separately.

*What is covered*
This warranty applies only to the person who purchased the products plus accessories from an authorized dealer of Zhejiang POCTech Co., Ltd. Ltd. or directly from Zhejiang POCTech 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 work, 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 POCTech Co., Ltd. itself or by the companies or persons authorized by it.
The warranty shall not survive if the products are used with one or more accessories not approved or authorized by Zhejiang POCTech Co., Ltd. or an authorized accessory is used with an unauthorized product or the products including accessories are not used in accordance with the instructions released by Zhejiang POCTech Co., Ltd.
No person (including any agent, dealer or representative of Zhejiang POCTech 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 POCTech 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 POCTech 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 POCTech's Obligations under limited warranty*
Zhejiang POCTech 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 POCTech 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 POCTech 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 POCTech Co, Ltd.
*Valid for equipment from date of shipment to buyer. Please attach invoice copy from Zhejiang POCTech Co., Ltd. or the dealer. Legal warranty applies to all other products.
POCTech 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 AnytimeWell.

**3. Sharers list**
Your Followers will see Sharers' list on their home screen, including the Sharer and the Sharer's glucose readings, as shown in Figure 3. They can tap specific Sharer to go to details and swipe to go to Notifications list.
**4. Notifications list**
Notifications list shows both invitations received and sent, as shown in Figure 4.
**5. Details**
*• Real-time Follow*
Your Followers can select a Sharer to go to detailed real-time monitoring results, i.e., trend graph, glucose readings, notifications, diagram, events logs and daily view, as shown in Figure 5.
*• Daily View*
Your Followers will see your readings of the day and choose date to look at your diagram, events records and daily view, as shown in Figure 6.
*• Settings*
Your Followers can tap the top right corner of the Real-time Follow screen to enter Settings to view information, set note, customize notifications and stop following. If they stopped following a Sharer, a notification would be synchronized to Sharer's AnytimeWell, as shown in Figure 7.
*1. Urgent Low Alert*
Urgent Low Alert level is set at 3.1mmol/L (55.8mg/dL). Your Followers cannot change it on their AnytimeFollow. When your CT3 readings go below 3.1mmol/L (55.8mg/dL), they will receive sound and message alerts and can tell you to take necessary measures.
*2. Low Alert*
Low Alert level is set at 3.9mmol/L (70.2mg/dL). When your CT3 readings go below 3.9 mmol/L (70.2mg/dL), alerts will be sent. Your Followers can change Low Alert level, switch off Low Alert, set alert intervals on their AnytimeFollow as advised by HCP or as needed, as shown in Figure 8.
*3. High Alert*
The default High Alert level is set at 11.1mmol/L (199.8mg/dL). When your CT3 readings go above 11.1mmol/L (199.8mg/dL), alerts will be sent. Your Followers can change High Alert level, switch off High Alert, set alert intervals as advised by HCP or as needed on their AnytimeFollow.
**6. Set up profile on AnytimeFollow**
Your Followers can tap the icon on the top left corner of the home screen or swipe the home screen from left to right to go to the menu. Tap Profile to view or edit information, as shown in Figure 9.
**7. Unit Settings**
Your Followers can tap Unit Settings on the menu to go to unit settings, as shown in Figure 10.
**8. Help Center**
Your Followers can tap Help Center on the menu to view supporting materials, as shown in Figure 11.
**9. About**
Your Followers can tap About on the menu to view details as shown in Figure 12, i.e., software updates, user license agreement and terms of use, legal statements and privacy policies.
**10. Account management**
Your Followers can tap Account Management on the menu to manage their account and change their password, as shown in Figure 13.
**11. Log out**
Your Followers can enter the menu and tap Logout to log out the current account. Your Followers will have to re-login next time to enter their account, as shown in Figure 14.



Figure 1
Login AnytimeFollow



Figure 2
Add Sharer





Figure 3
Sharers list



Figure 4
Notifications list on AnytimeFollow



Figure 9
Profile Settings on AnytimeFollow



Figure 6
Daily View on AnytimeFollow



Figure 7
AnytimeFollow Settings



Figure 10
Unit Settings

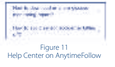


Figure 11
Help Center on AnytimeFollow



Figure 12
About





Figure 8
Low Alert settings on AnytimeFollow



Figure 13
Account Management on AnytimeFollow



Figure 14
Logout on AnytimeFollow

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