POCTech Corporation

CT-100B_____

Continuous Glucose Monitoring System

User Manual

Doc Number: A4-CGM04-001
Version. V20160725

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CT100B CGM System User Manual

1 Product Information

1.1 Name of Product

Continuous Glucose Monitoring (CGM)System；

1.2 Model Number

CT-100B

1.3 Indication

For Interstitial fluid glucose real time monitoring for diabetes mellitus or other patients who need glucose monitoring.

1.4 Contraindication

Not established

1.5 Composition of Product

CT-100Bsystem consists of three parts, a glucose sensor, an Transmitter, and a receiver. The sensor is a four electrode flexible tiny strip assembled with an inserter, packed in a sterile package for direct use.

* * * * * *

Sensor Model: CT-100

Transmitter Model: CT-100B

Receiver Model: Ct-100BX, X indicates color of the receiver (white-W; Black-D; Blue-B).

1.6 Part List

#	Part	Number
1	Sensor	1
2	Batch Certificate	1
3	Transmitter	1
4	Receiver	1
5	Use Manual	1
6	Product Certificate	1
7	USB (Type C) Cable	1

2 Product Characteristics

2.1 Sensor

2.1.1 dimensions: 10mm x 0.3mm (L x W, approximate)

2.1.2 Sensor use life: 7 days.

2.1.3 Shelf life: 9 months.

2.1.4 Initialization time: 3 hours.

2.2 Transmitter Use Life: 2 years.

2.3 Receiver Use Life: 2 years.

2.4 Storage, Shipping, and Use Conditions

2.4.1 Shipping Conditions

Condition	Data System	Sensor
Temperature/℃	-15~45℃	-10~50℃,
Humidity /RH, %	≤93% RH	≤ 5days

2.4.2 Storage Conditions

Condition	Data System	Sensor
Temperature/℃	-15~45℃	2~8℃
Humidity /RH, %	≤93% RH	NA
Electrostatic	Protected	NA

2.4.2 Use Conditions

Condition	Data System Sensor
Use	Normal Living Environment
Transmitter Battery	DC3.0V, (CR1620, Each Sensor)
Receiver Battery	DC3.7V,
Pressure/kPa	70 ~ 107kPa
Temperature/℃	10~40℃
Humidity(RU)/%	≤93% RH

2.5 Method of Measurement

Continuously detect glucose in the subcutaneous tissue.

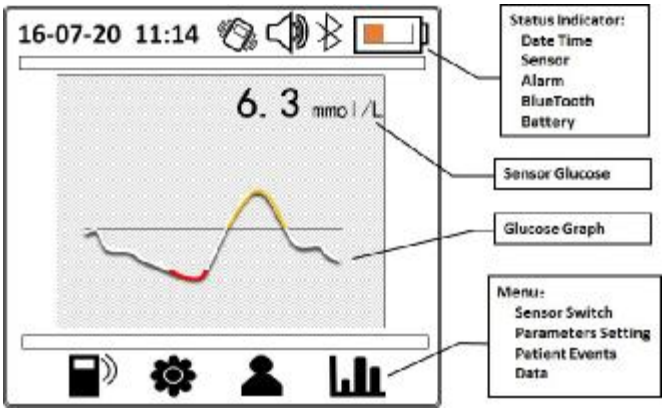
2.6 Principle of Measurement

Real time monitoring of tissue fluid glucose based on amperometric electrochemical enzymatic method.

2.7 Type of Medical Device

Class III, Type 6821 Medical Device Equipment.

3 Receiver Display Content and Menu



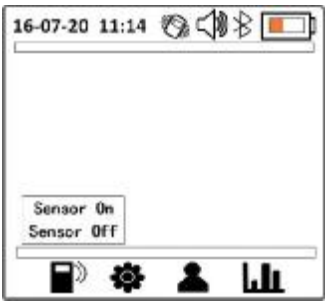
3.1 Top Status Line: Date, Time, Sensor Status, Alarm, Blue Tooth, Battery.

3.2 Middle Glucose Information: Glucose Concentration, Glucose Graph.

3.3 Bottom Menu Line: Sensor ON/OFF ( ), Parameters Setting( ), Patient

Events Input( ), Data ( ).

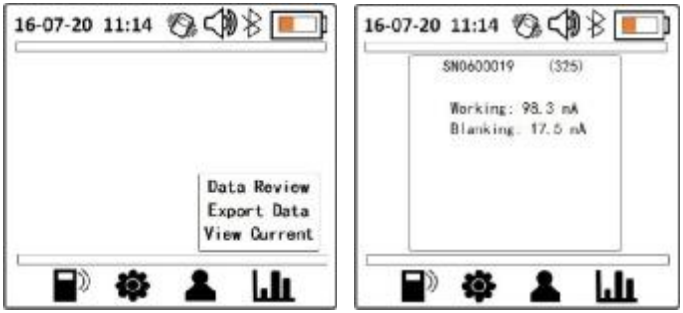
Sensor Switch: Turns sensor-Transmitter data communication link ON/OFF.



Parameters Setting: Sets Date/Time; Hyperglycemia/Hypoglycemia thresholds, Alarms ON/OFF; BG interval; Language (Chinese/English).

Patient Events: Enters Blood glucose, logs exercise, diet, medication, rest.

Data Review or Upload Sensor Data: Review current or historical data. Upload data files to a computer.



4 Implantation Procedure

4.1 Prepare the Receiver data set:

Turn-on power of the Receiver by pressing the ON/OFF switch for more than 3 seconds. The receiver searches for all nearby Transmitters and displays a list of Transmitters.

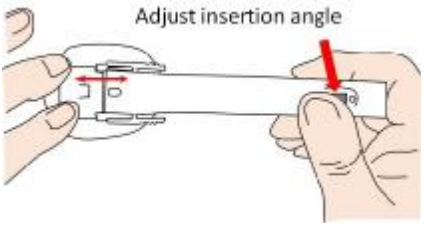
Check receiver battery. Charge the battery if necessary.

Set Date and Time, Alarms, Ref BG Interval, Language.

4.2 Prepare the skin: Choose one upper arm or middle abdomen for sensor insertion. Use alcohol swaps(or pads) to clean the skin.

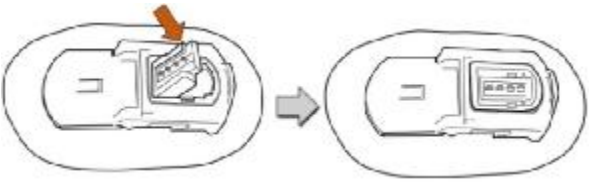
4.3 Prepare the sensor: Take a sensor pack out of refrigerator and allow sufficient time for it to warm to room temperature. Tear open the sterile package to take out the sensor assembly. Remove the protection film on the sensor base adhesive tape.

4.4 Implant the sensor: Remove the protection cap on the release button. Remove the inserter lock pin. Place the sensor on the cleaned skin, make sure it adheres to the skin firmly. Bend down the inserter handle to the designed 45° angle. Push the release button to insert the sensor.

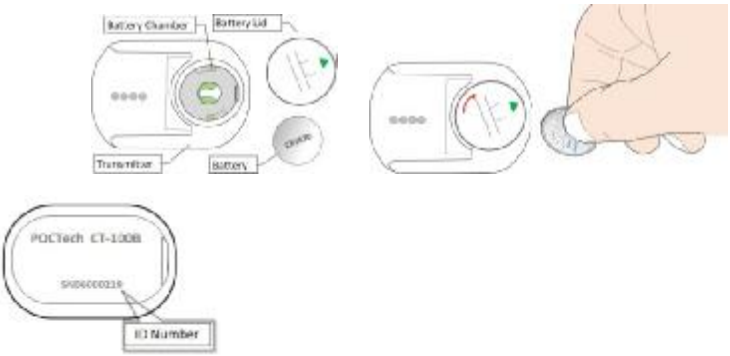


4.5 Separate the inserter: Press the arms on the sides of the inserter to disengage the sensor. Discard the inserter.

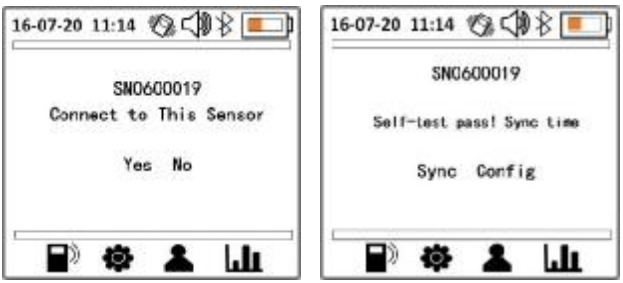
4.6 Press down the sensor connection block: Push the sensor connection block down to lock in the base.



4.7 Prepare the Transmitter (Install the Transmitter battery): Install aCR1620 battery in the Transmitter. Tighten the battery chamber lid. The Transmitter starts wireless communication. Its ID number will be displayed on the nearby receiver.



4.8 On the Receiver, when the Transmitter has been successfully started, its ID number will be displayed on the receiver. Verify the serial number of the Transmitter for its last 4 digits. Select “Yes” to select the Transmitter (sensor). The antenna icon appears on the receiver screen, indicating the data communication has been established. Then choose “Sync” to start synchronizing the Transmitter and the receiver.



4.9 The screen then displays “Open this Sensor? Yes/No". When choosing “Yes”, the system enters next “Initialization” Mode and begins to store sensor data.

4.10 Install the Transmitter to the sensor: Slide the Transmitter onto the sensor base and lock.

4.11 Place medical adhesive tape (3x4")to cover the entire Transmitter/sensor assembly if necessary.

5 Sensor Initialization

5.1 The sensor requires a 3-hour initialization period. The counting down displayed on the screen.

6 Reference Blood Glucose Input

6.1 Once the initialization is complete, a reference finger blood glucose (BG) is required. Select "👤", and then "Ref BG Input" to enter the finger GB.

6.2 The sensor glucose value and a continuous glucose graph will be displayed after the BG entry.

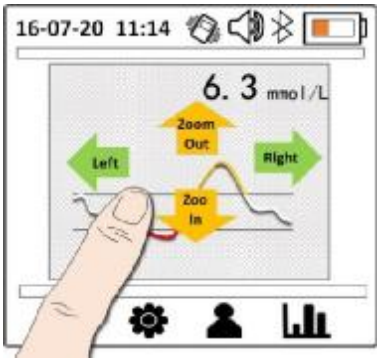
6.3 A second BG is required within 6-10 hours after the first BG calibration on the first day.

6.4 From the second day on, only one calibration per day is needed, preferably, using the fasting finger BG before breakfast.

6.5 Special Note: The sensor signal may experience certain drift during the first 24 hour period due to interactions between tissue fluid and the implanted sensor. To assure accuracy, one or two additional BG calibration may be needed for the second day, especially when a hypoglycemia event is indicated.

7 Receiver Touch-Screen Operation

7.1 Use the touch-screen feature, swipe a finger down to zoom-in, swipe up to zoom out. Or move right or left to scroll the graph right or left.



8 During Normal Sensor Use

8.1 Keeping Data Transfer Smooth: The nominal Blue-Tooth wireless communication distance is 4 meters. The communication may be affected by environmental conditions. Human body dampens the signal. In case the communication is interrupted, the system can retrieve the data in a later time but the real time display will be unavailable during the miscommunication period. And alarm functions will be affected.

8.2 Daily Reference BG: The default setting requires a reference blood glucose every 24 hours, preferably before breakfast (fasting glucose). However, during the first day, two finger BGs are needed.

8.3 Patient Event Input: The user should maintain a full activity log by entering all meals, exercise, medicine (including insulin), and resting during the entire sensor wearing period.

- Pink mark for diet.
- Green mark for exercise.
- Blue mark for medicine.
- Yellow mark for resting.

8.4 Alarm Setting: The alarm function can be set from Setting Menu "⚙".The alarm responds to the glucose thresholds based on the pre-set values for Hyper Alarm and Hypo Alarm. It may be set to beep, vibrate, or flasher any combination of the three forms when the pre-set threshold is triggered.

9 Precaution

9.1 Read the User Manual before using and operating the system.

9.2 Monitor the receiver battery indicator. Charge the battery whenever needed.

9.3 Showering: Do not tub bathe or swim. When showering, try not to wet the sensor.

9.4 Sweating: Excessive sweating should be avoided. It may cause short circuit between sensor connections and adhesive tape to become lose.

9.5 Sensor falling off: Very few people experience difficulty keeping the adhesive on the skin firmly. Additional means such as arm band may be needed to protect the Transmitter /sensor.

9.6 Accidental loss of sensor. In case the sensor came off by accident, do not try to re-use. Report the incident or hand it into your doctor.

9.7 Outdoor activities: Try to avoid strong activities that may involve physical bumps.

9.8 Itchiness: Adhesive tape usually causes skin itch. This can be handled by changing the cover tape every few days. When changing tape, pay attention not to disturb the sensor.

9.9 Avoiding Extreme Temperature: Try not to enter or stay in

9.10 Strong Electromagnetic Fields: Avoid strong electromagnetic fields.

9.11 CT Scan or NMR: When must be examine with CT or NMR imaging, remove the Transmitter for the processes and place it back afterword. The interruption will cause the sensor signal to re-stabilize. An additional BG calibration is required.

9.12 Effect on other medical equipment: Under extreme circumstances, nearby medical equipment may be affected. Refer to IEC declaration.

9.13 Communication Distance: Keep the Transmitter and the receiver within the required distance at all times during monitoring. Try to keep the receiver on the same side of the body to avoid signal interruption.

9.14 Abnormal Signal: System malfunction, short circuit, sweating, water ingression, etc., may cause signal abnormality. Take down the sensor and report the incident.

9.15 The receiver should not be placed overlapping with other similar system to avoid interferences. For example, insulin pump user should not place the sensor on the same side with the insulin infusion line.

9.16 The data system only functions with the designated sensors. Refer to related

announcement by the manufacturer regarding sensor compatibility in the future.

9.17 The sensor is a single-use device. Do not use if damage to the packaging has been discovered.

9.18 The information displayed by the receiver is intended to supplement instead of replacing a registered blood glucose measurement device or instrument. It is intended to provide information of continuous changing concentration or trend of change.

10 Termination of a Sensor

10.1 The system is programmed to collect data for up to 7 full days. It terminates the data collection automatically when a 7-days acquisition is complete.

10.2 Turn off the sensor from the Sensor Menu "  " and remove the sensor together with the Transmitter. When removing the sensor from the skin, peel and lift the sensor base adhesive from one edge and pull up it firmly until the entire sensor/Transmitter assembly is separated from the skin.

10.3 Examine the skin site for sign of infection, redness, bleeding, etc. Report abnormalities if so find. Take photos of the site if necessary. Consult a medical professional if necessary.

11 Data Review or Upload

11.1 During a sensor lifetime, the sensor signal (currents) can be viewed by selecting "View Currents" from the "  ." Menu. On normal glucose graph display, simply use the touch screen feature to zoom-in or zoom-out, by sliding finger DOWN or UP. To scroll the glucose graph horizontally, touch the screen and slide right or left.

11.2 Select "Data Review" enables viewing any historical sensor data that have been stored in the receiver.

11.3 After the end of a sensor, data can be uploaded to a computer (Type-C USB cable is supplied) with the POCTech sensor software and viewed. Report can be generated and printed.

12 Alarm Handling and Trouble Shooting

12.1 Abnormal Sensor Signal

When sensor signal is out of the expected range, the receiver will sound an alarm. The glucose display may be turned off. This usually occurs when water causes short circuit. A partial pulling off of the sensor may be another reason for alarm for abnormal signal.

Check the sensor and the Transmitter. If they both look normal, wait for one to two hours to see if the signal recovers. Water ingression can disappear after a short time. If problem persists, turn off the sensor and remove it from the skin.

12.2 Transmitter Low Battery

The receiver receives the Transmitter battery information on a regular basis. An alarm will sound if the Transmitter battery is low. Simply replace the CR1620 battery and reconnect. In such a case, the system will re-initiate and results in a loss of a three-hour use time period.

12.3 Receiver Low Battery

The receiver has a rechargeable battery pack and does not need replacing. The battery indicator on the upper right corner changes color when the battery is low. Make sure to check it regularly and charge the battery in time. The battery normally has a remaining operational time of more than 10 hours even when the indicator color turns orange, allowing enough time to find a chance to charge.

12.4 Hyperglycemia Alarm

The high glucose alarm is triggered when the sensor glucose is over the pre-set threshold value. It is advisable not to set the hyper threshold below 10 mmol/L to avoid frequent annoyance. It is strongly recommended that a physician's advice is sought.

12.5 Hypoglycemia Alarm

Hypoglycemia alarm is the most important feature of the CGM device for patients who may have hypoglycemic unawareness. The low glucose alarm is triggered when the sensor glucose is lower than the hypoglycemia threshold. *However, the registration condition of this device requires a finger BG*

measurement to confirm the situation when a hypoglycemia event is detected by the sensor.

12.6 Blue-Tooth Communication Interruption

There are two situations where an interruption to the wireless communication may happen:

The receiver fails to locate the Transmitter. It occurs at the beginning of establishing communication. Most likely the reason is a failed battery on the Transmitter. Replace or re-install the CR1620 battery and try again.

The receiver alarms for lost communication. It is mainly due to an out-of-range condition between the receiver and the Transmitter. Bring them together to re-connect.

12.7 Unexpected Sensor Removal

Although unlikely, the sensor gets accidental falling off mostly due to excessive sweating, or for few people who have oily skin that makes it difficult for the sensor adhesive to adhere firmly. Do not re-use the sensor. Start a new sensor.

12.8 Sensor glucose obviously different from experienced judgment

When the sensor reading appears erroneous based on personal experience. One finger BG measurement is recommended to confirm.

12.9 Water Ingression

See Abnormal Sensor Signal.

12.10 Receiver Time Difference

One may notice that the time on the receiver is different from that of the actual clock. It is normal as long as the time difference is within 2-3 minutes. *Do not try to adjust the time in the middle of a sensor monitoring period even when the time difference is more significant.* It may cause a data integrity issue, and sometimes, makes the result inaccurate.

12.11 Other Problems

Telephone the customer service.

13 Waste Disposal

13.1 Sensor:

13.2 Data System

13.2.1 Battery

13.2.2 Transmitter

13.2.3 Receiver

14 Cleaning and Maintenance

14.1 The system components must be cleaned according to the User Manual. Incorrect cleaning may damage the device.

14.2 The Transmitter and receiver are delicate electronic instruments. Wet and electromagnetic situations should be avoided.

14.3 Alcohol wide may be used to clean the surface of the Transmitter and receiver. Reuse after completely dry.

14.4 Contact the manufacturer or designated representatives for malfunction. Do not try to open or repair.

14.5 Only the manufacturer should examine and provide parts and repair.

15 Electronics and Part List

Only the manufacturer or designated personnel may provide repair and electronic maintenance.

16 Declaration of Electromagnetic Compatibility

Guidance and Manufacturer's Declaration-Electromagnetic emission		
CT-100B Continuous Glucose Monitoring System is expected to be used in the following environment. Buyers and users should ensure that such electronic conditions are met.		
Emission Test	Conformity	Electromagnetic Environment——Guidance
RF emission GB4824	Group 1	CT-100B system adopts emission only for its internal communication. The energy level is very low and is not expected to cause any interference to surrounding electronic

		equipment.
RF emission GB4824	Type B	/

Guidance and Manufacturer's Declaration - Electromagnetic Interference(EMI)			
CT-100B Continuous Glucose Monitoring System is expected to be used in the following environment. Buyers and users should ensure that such electronic conditions are met.			
Immunity Test	IEC60601Electrical Level Test	Met Electrical Level	Electromagnetic Environment——Guidance
Electrostatic discharge GB/T17626.2	±6KV contact discharge ±8KV air discharge	±6KVcontact discharge ±8KVair discharge	The ground surface should be wood, concrete, or ceramic. If the ground is of synthetic materials, the relative humidity should be at least 30%.
Power frequency magnetic field （ 50Hz ） GB/T17626.8	3A/m	3A/m	Power frequency magnetic field should be of the typical levels of business or hospital environment.
RF emission GB/T12626.3	3V/m 80MHz-2.5GHz	[3] V/m	Portable and mobile RF communication equipment (including any part of the CT-100B system) should be no closer than that of recommendation below. Recommended distance calculation: $d=1.167\times\sqrt{P}$ 80MHz-800MHz $d=2.333\times\sqrt{P}$ 800MHz-2.5GHz

			P——The maximum output power level of the Transmitter based on the manufacturer, unit (W). d——Recommended distance，Unit（m）。 The field intensity of an immobilized RF Transmitter is determined by the a factor. It should be below the electrical level at each b level. Interference may occur near equipment with such label. 

Note 1：At 80MHz and 800MHz frequencies，use higher frequency formula.

Note 2：The guidance may not be suitable for all circumstances. Electromagnetic transmission is affected by buildings, objects and human bodies.

- Fixed position Transmitters, such as cordless phone, hub for wireless broadcast, amateur radio, FM,/AM radio, and TV, etc., whose intensity may not be accurately determined. To evaluate the intensity of such fields, observation should be done regarding such environment. If higher than the above tested electric levels are observed, and the equipment interferences are confirmed, supplemental measures may be necessary, such adjusting direction or location.
- The field intensity should be below [V1]V/m in the entire range.

Recommended Distances for Portable or Mobile Communication Equipment and Systems ---Non-Life Supporting Equipment and Systems.

Recommended Distances for Portable RF Equipment with CT-100B system
CT-100B CGM system is expected to be used in an environment where RF interferences are controlled. Based on the maximum output power levels, buyers or users may use the below calculation to estimate the minimum distances from an Rf equipment for using the CT-100B system.

The maximum nominal output power level W	d=1.167× $\sqrt{P}$ （80MHz-800MHz）	d=2.333× $\sqrt{P}$ （800MHz-2.5GHz）
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For equipment whose output levels not listed in the above table, an estimate can be made using the equation, where the unit for d is meter (m), and p (the max power) is watt (W).

Note 1：At 80MHz and 800MHz frequencies，use higher frequency formula.

Note 2：The guidance may not be suitable for all circumstances. Electromagnetic transmission is affected by buildings, objects and human bodies.

Basic properties tested in the electromagnetic tests:

DC current measurement in the range of 0~50nA, within±1nA。

DC current measurement in the range of 50～370nA, within ≤2.0%。

17 Biological Safety

There is bovine serum albumin (BSA) from human consumable bovine plasma in the sensing element of this product.

18 Symbols and Definitions

Icon	Definition	Icon	Definition
	Refer to user manual		BF application

Icon	Definition	Icon	Definition
	Read use manual		DC current
	Sterilized by irradiation （sensor）		Non-ionization irradiation
	Do not re-use (sensor)		Do not dispose in household trash.
	Lot number		Temperature range（2℃ ~8℃）
	Use by Date		Do not use if packaging is damaged.

19 Product Code, Batch, and Expiration Dates

19.1 Product Code and Batch

Transmitter Code：See Transmitter labeling.

Receiver Code：See receiver labeling。

Sensor Manufacturing Batch: See sensor labeling.

19.2 Dates of Manufacturing and Expiration：

Transmitter/Receiver: See certificate； Sensor: See individual packaging.

Expiration：

Data system: See certificates;

Sensor: See individual packaging (storage life 9 months; use life 7 days).

Sensor Package Sterility: 9 months.

20 Manufacturer and EU Representative Information

20.1 Manufacturer

Name of Manufacturer	Zhejiang POCTech Corporation
Manufacturer Phone	86-572-2167258

Manufacturer Address	Building 11 Hongfeng Road. Huzhou, Zhejiang Province China, 313000
Manufacturer Permit	浙食药监械生产许 20120026 号
Product Registration No.	
Technical Specification No.	
Customer Service	Zhejiang POCTech Corporation
Phone	86-400-1188-528
Web	www.poctechcorp.com

20.2 EU Authorized Representative

EU Representative		Renault-Petersen Limited
Phone		Tel:+441993 882799
FAX		Fax:+44 1993 880110
Address		5Bankside,Hanborough Business Park,Witney OX29 8LJ UK

21 Dates For Editing and Revision

History of version changes

Edition	Change description	Data	Author