Information of the safety and effectiveness

⚠ 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 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.

● 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.

● 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.

1.1 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 14 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 hypoglycemia. It is intended for single patient use.

1.2 Indications

Patients with type 1 diabetes and type 2 diabetes, 14 years and older or other patients in need of glucose trend monitoring.

1.3 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.

1.4 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.

2. Performance Characteristics

2.1 Warm Up Time: 1 hour.

2.2 Sensor Use Life: 14 days.

2.3 Effective Glucose Range: 1.7 - 27.8mmol/L.

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

2.5 The sensor is a single-use medical device, sterilized by E-beam irradiation.

2.6 Laboratory test accuracy: (linear deviation): within ± 20%

2.7 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).

2.8 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