



## **CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT**

### **2.1 INDICATIONS FOR USE**

The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons (**age 18 and older**) with diabetes. The system is intended for single patient use and requires a prescription.

The Dexcom G4 PLATINUM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM System results should be based on the trends and patterns seen with several sequential readings over time.

### **2.2 IMPORTANT USER INFORMATION**




Please review your product instructions before using your continuous glucose monitoring system. Contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

## 2.3 CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM sensor, transmitter, and receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The Dexcom G4 PLATINUM System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

## 2.4 WARNINGS

- Thoroughly review the training materials included with your CGM system before using the Dexcom G4 PLATINUM CGM System. Incorrect use might lead to you misunderstanding the information provided by your system, or might affect system performance, and you might miss a low or high blood glucose value.
- Do not use the Dexcom G4 PLATINUM System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.
- Do not ignore symptoms of high and low glucose. If your sensor glucose readings do not match your symptoms,



measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range, so you do not miss a low or high blood glucose value.


- Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664** or **1.858.200.0200**.
- The Dexcom G4 PLATINUM System is **not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this system in the critically ill population is not recommended.
- Sensor placement and insertion is **not approved** for sites other than the belly (abdomen).
- If your transmitter or receiver case is damaged/cracked, do not use it. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.
- Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor



glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

## 2.5 PRECAUTIONS

- Before opening the sensor package, wash your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.
- Before inserting the sensor, clean the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allow to dry. This may help prevent infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Change the site where you place the sensor with each insertion. Using the same site too often might not allow the skin to heal, and might cause scarring or skin irritation.
- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor performance, and you might miss a low or high blood glucose value.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.
- To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a



carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

- Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.
- The system accuracy may be affected when your glucose is changing at a significant rate (e.g., 2-3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.
- The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and you might miss a low or high blood glucose value.
- Keep the USB port cover on the receiver closed whenever the USB cable is not attached. If water gets into the


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USB port, the receiver could become damaged and stop displaying readings or providing alerts, and you might miss a low or high blood glucose value.

- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also make sure to use the correct version of Dexcom Studio with your system.

## 2.6 CAUTION

U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM System to sale by or on order of a physician.