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References:

1. *The Dexcom SEVEN Plus User Guide (LBL-010004)*

Brief Safety Statement:

INDICATIONS FOR USE: The SEVEN PLUS Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in **adults (age 18 years and older)** with diabetes. The device is for prescription use only. **CONTRAINDICATIONS:** SEVEN PLUS must be removed prior to Magnetic Resonance Imaging (MRI). Use of acetaminophen-containing medications while the Sensor is inserted may affect the performance of the device. **WARNINGS:** This device is not designed to replace a blood glucose meter. Always confirm with a blood glucose meter. **PRECAUTIONS:** The Sensor has currently only been tested in adult person with Type 1 and Type 2 diabetes. The device has not been tested in children or adolescents, pregnant women, or persons on dialysis. Contact DexCom at 1.888.SEVENGO or www.dexcom.com for detailed instructions for use and safety information. Please note: The Performance Characteristics Section of your new User's Guide has changed to reflect the recent study done. The overall results of the trial showed that this next-generation SEVEN PLUS System will provide you more continuous glucose readings, and you should expect more of your Sensors to provide data for the entire 7-day use period. Note that the data described in the Performance Section also showed a difference from this generation SEVEN PLUS device to the original SEVEN device in performance in the low glucose region (40-80 mg/dL). Our study showed that at 50 mg/dL blood glucose, the device reported glucose to be as high as 64 mg/dL and at 80 mg/dL blood glucose, the device reported glucose to be as high as 90 mg/dL. Because the performance of the Next-Generation SEVEN PLUS System varies from the original, it is important that you assess how the new generation device performs for you, especially in the low range. You should review the performance of this device with your healthcare provider to understand how well the SEVEN PLUS System performs.