

**Seven**<sup>™</sup>

CONTINUOUS GLUCOSE  
MONITORING SYSTEM

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**PACKAGE INSERT**

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# INSTRUCTIONS FOR USE

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## Seven™ Continuous Glucose Monitoring System

### STERILE DEVICE

This device is sterile unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged.

### INDICATIONS FOR USE

The Seven Continuous Glucose Monitoring System (Seven System) is a glucose-monitoring device indicated for detecting trends and tracking patterns in adults (age 18 and older) with diabetes. The Seven System is intended for use by patients at home and in health care facilities. The device is for prescription use only.

The Seven Continuous Glucose Monitoring System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Seven Continuous Glucose Monitoring 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 Seven System results should be based on the trends and patterns seen with several sequential readings over time.

### CONTRAINDICATIONS

The Seven System must be removed prior to Magnetic Resonance Imaging (MRI).

Use of acetaminophen-containing medications when the Sensor is inserted may affect the performance of the device.

### WARNINGS

- This device is not designed to replace a blood glucose meter. The Seven System must be used with a blood glucose meter.
- Treatment decisions should not be based solely on results from the Seven System. You must confirm with a blood glucose meter before making therapeutic adjustments.

- Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose, use your blood glucose meter to check the Seven System results.
- You should update the Seven System's calibration every 12 hours at a minimum to ensure device performance. The performance of the Seven System when calibrated less frequently than the recommendation to calibrate a minimum of every 12 hours has not been studied.

### PRECAUTIONS

- Always wash hands with soap and water before opening the Sensor package. After opening the package, avoid touching the adhesive area.
- Before inserting the Sensor, always clean the skin at the Sensor insertion location with a topical antimicrobial solution such as isopropyl alcohol. Do not apply the Sensor until the cleaned area is dry.
- Establish a rotation schedule for choosing each new Sensor location. Avoid Sensor locations that are constrained by clothing, accessories, or subjected to rigorous movement during exercise.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of a Sensor.
- The Sensor is sterile in its unopened, undamaged package. Do not use any Sensor if its sterile package has been previously damaged or opened.
- The Sensor has currently only been tested in adult persons with type 1 and type 2 diabetes. The device has not been tested in children or adolescents, pregnant women, or persons on dialysis.

### PRINCIPLE OF OPERATION

The Sensor works through an electrochemical reaction with glucose. The Sensor enzyme, glucose oxidase, converts the glucose into an electronic signal. The Transmitter measures the glucose signal and continuously sends the signal to the Receiver wirelessly via radio frequency (RF). The Receiver converts the Sensor signal to a glucose reading that is displayed to the user.

## REAGENTS

Glucose oxidase. The enzyme glucose oxidase is derived from a microorganism *Aspergillus niger* purified and dried according to Type VII-S guidelines. Less than 0.6 µg of glucose oxidase is used to manufacture each Sensor. Direct tissue contact with the glucose oxidase is prevented by an outer Sensor membrane layer. Therefore the risk of tissue reactions from glucose oxidase is considered to be minimal.

## STORAGE AND HANDLING

The Sensor must be stored within a temperature range of 2-25 degrees Celsius (36-77 degrees Fahrenheit). Do not freeze.

Use the Sensor before the expiration date shown on the package. Discard and do not use any Sensors in which the packaging is torn or the seal is broken or when the Sensor has been exposed to storage conditions outside of the specified temperature range.

## ADVERSE REACTIONS

Blistering, Redness, mild swelling at the insertion site may occur with use of the device.

## PRESCRIPTION DEVICE

Caution: U.S. federal law restricts the sale of the DexCom Seven System to sale by, or on order of, a physician.

## SEVEN SYSTEM COMPONENTS

The Seven System consists of three (3) major components.

- 1. Sensor** – Contains the Applicator, Sensor Probe, and Sensor Pod.
  - **Applicator** – A disposable piece of the Sensor that you use to insert the Sensor Probe. There is a needle inside that Applicator that you remove once you have inserted the Sensor Probe underneath your skin.
  - **Sensor Probe** – The portion of the Sensor that is inserted under your skin using the Applicator. Measures glucose levels in your surrounding tissue fluid.
  - **Sensor Pod** – The small base adhered to your abdomen and holds the Transmitter in place. The Sensor Pod and Transmitter are all that remain on your skin during each Sensor wear period.

- 2. Transmitter** – Device that snaps into the Sensor Pod and wirelessly sends glucose data to your Receiver.
- 3. Receiver** – A cell-phone sized device programmed to collect and process data from the Sensor and to display the results as a glucose values.



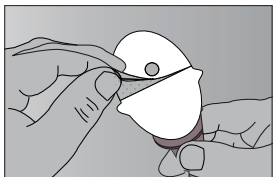
## BEFORE YOU BEGIN

1. Wash your hands thoroughly.
2. Find a flat area on your abdomen (belly) where there isn't any scarring or rough patches of skin and clean that area with an isopropyl alcohol swab. Allow site to dry.
3. Make sure your Receiver is fully charged and that your Receiver and Transmitter are communicating (Antenna Icon "Y" is visible on Receiver Screen).

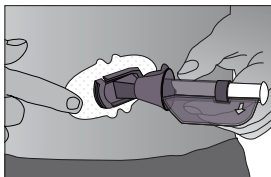
## INSTRUCTIONS

These instructions describe how to insert the Sensor into the abdomen. Please refer to the accompanying illustrations for further assistance. The process is the same regardless of the abdominal insertion site.

**Step 1.** Remove the two pieces of adhesive backing from the bottom of the Sensor Pod and stick (adhere) the Sensor Pod onto the selected skin site.

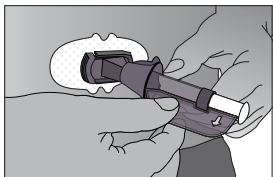


Remove the Adhesive backing

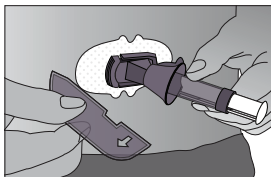


Adhere the Sensor on the skin

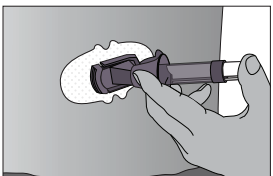
**Step 2.** Remove the Applicator Safety Lock/Transmitter Release by pulling it straight out and away from your body (using the arrow as a guide). The Safety Lock also serves as the Transmitter Release at the end of a continuous monitoring session. Keep the Safety Lock/Transmitter Release to later remove the Transmitter at the end your continuous monitoring session



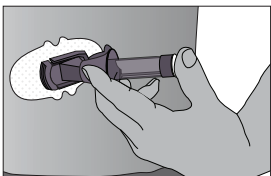
Remove the Safety Lock/Transmitter Release



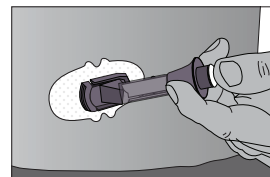
**Step 3.** Holding the Pod with one hand and using your other hand, place two fingers under the collar and use your thumb to push the Applicator plunger down. This action inserts the needle and sensor probe.



Push down the Plunger- Insert the Needle and Sensor Probe

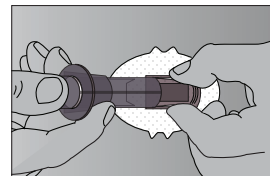


**Step 4.** Still holding the Sensor Pod with one hand, use the other hand to pull the collar of the Applicator back completely until you hear a “click”. This action pulls back (retracts) the needle and leaves the Sensor Probe underneath your skin.



Pull back the collar- Retract the Needle

**Step 5.** Pressing the tabs on the Sensor Pod, pull the Applicator away from your body. The Sensor Pod will stay adhered to your skin. You can throw away the Applicator once it is removed.



Release the Applicator

**Step 6.** To start the continuous sensing period you must install attach your Transmitter in the Sensor Pod and notify the Receiver of your new Sensor insertion period. Detailed instructions on how to do this are located in your Seven Quick Start Guide and Seven User’s Guide.



If you require additional information regarding use of the Seven™ System, contact DexCom Technical Support at 877-DEXCOM4 (877-339-2664).

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Other U.S. and/or foreign patents may be pending.

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