

# Senseonics Eversense CGM Sensor Receives Indication for MRI



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*Now patients who need to have an MRI\* do not need to remove the Eversense Sensor*

GERMANTOWN, Md.--(BUSINESS WIRE)-- Senseonics Holdings, Inc. (NYSE American: SENS) a medical technology company focused on the development and commercialization of a long-term, implantable continuous glucose monitoring (CGM) system for people with diabetes, today has announced that they received notice from FDA that the Eversense Sensor is no longer contraindicated for MRI scanning\*.

“Based on our testing, we have demonstrated that it is safe for patients to leave the Eversense Sensor in place, even when they need to have an MRI,” said Tim Goodnow, President and CEO of Senseonics. “Now patients using Eversense CGM do not need to worry about an emergency MRI or delay getting a scheduled MRI based on their glucose sensor. All other CGMs currently on the market are required to be removed before an MRI scan, according to their FDA indications. This is a first for the CGM category.”

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

The Eversense CGM System consists of a fluorescence-based sensor, a smart transmitter worn over the sensor to facilitate data communication, and a mobile app for displaying glucose values, trends and alerts. In addition to featuring the first long-term and first implantable CGM sensor, the system is also first to feature a smart transmitter that provides wearers with discreet on-body vibratory alerts for high and low glucose and that can be removed, recharged and re-adhered without discarding the sensor. The sensor is inserted subcutaneously in the upper arm by a health care provider via a

brief in-office procedure. Now patients can safely get an MRI\* while still wearing the Eversense Sensor – the only CGM sensor that is indicated by the FDA for this use.

Patients who are interested in getting started on Eversense can sign up at [www.eversensediababetes.com/get-started-today](http://www.eversensediababetes.com/get-started-today). Physicians, nurse practitioners or physician assistants interested in offering the Eversense CGM System for their patients can contact 844-SENSE4U (844-736-7348).

## About Eversense

The Eversense® Continuous Glucose Monitoring (CGM) System is indicated for continually measuring glucose levels in persons age 18 and older with diabetes for up to 90 days. It is intended to complement, not replace, fingerstick blood glucose monitoring. The sensor insertion and removal is performed by a health care provider. The Eversense CGM System is a prescription device; patients should talk to their health care provider to learn more. For important safety information, see <https://eversensediababetes.com/safety-info/>.

## About Senseonics

Senseonics Holdings, Inc. is a medical technology company focused on the design, development and commercialization of transformational glucose monitoring products designed to help people with diabetes confidently live their lives with ease. Senseonics' CGM systems, Eversense® and Eversense® XL, include a small sensor inserted completely under the skin that communicates with a smart transmitter worn over the sensor. The glucose data are automatically sent every 5 minutes to a mobile app on the user's smartphone.

**\*MRI Safety Information** Non-clinical testing has demonstrated the Eversense Sensor is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the Eversense Sensor is expected to produce a maximum temperature rise of less than 5.4 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 2.83 inches (72 mm) from the Eversense Sensor when imaged with a gradient echo pulse sequence and a 3T MR system. The Eversense Smart Transmitter is MR Unsafe and **MUST BE REMOVED** before undergoing an MRI procedure. Share this information with your imaging facility while

scheduling your MRI so that they can determine if the MRI equipment in their facility is safe to use with the Eversense Sensor.

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