

# Monthly Safety Notice

February 2019

National Baromedical Services, Inc.

## Implantable Glucose Monitoring Safety for HBO Patients

### Background

The Eversense® Continuous Glucose Monitoring (CGM) System was launched in 2018 and is the first implantable glucose sensor that provides continuous monitoring for up to three months. A physician inserts the sensor just under the skin in the upper arm. The removable electronic transmitter rests on the outside of the skin. Readings are obtained thru the patient's enabled phone or watch.



### The Issue

We contacted the manufacturer to obtain information regarding the safety and efficacy of the product for patients undergoing hyperbaric oxygen therapy. Below was their response:

*"We do not have a controlled test for performance characterization either in the hyperbaric chamber or after exposure to hyperbaric chamber.*

*Following are the three points for consideration,*

- 1. If the customer does not have a sensor, they should talk to their physician to check if they can wait for the insertion, until the treatments are completed.*
- 2. Based on the characteristics of the sensor, at present, there is no known mechanism to cause damage to the sensor such as to result in a safety concern.*

3. We do not have test data, which characterizes the performance after the hyperbaric chamber treatment. Any drop in performance can however be monitored with a fingerstick calibration over a few days after the hyperbaric treatment.

*Since hyperbaric treatment can be vital to certain diabetes patients, the patient should consult with their physician on the risk/benefit trade-off." -Eversense Customer Care*

**Bottom Line**

The implanted sensor can safely enter the chamber. The transmitter must be detached and stay outside. The accuracy of the readings should be verified with finger sticks. See the Eversense website for more details about the product. <https://www.eversensed diabetes.com/products/>