

# Safety Analysis of a 90-Day Implantable CGM System in the PRECISE Study

Grace Carlson<sup>1</sup>, MD, MBA; Xiaoxiao (Oliver) Chen<sup>2</sup>, PhD; Colleen Mdingi<sup>2</sup>, MS; Andrew Dehennis<sup>2</sup>, PhD; Eric Zijlstra<sup>3</sup>, PhD

<sup>1</sup>Alta Bates Summit Medical Center, California, USA; <sup>2</sup>Senseonics, Inc, Maryland, USA; <sup>3</sup>Profil, Neuss, Germany

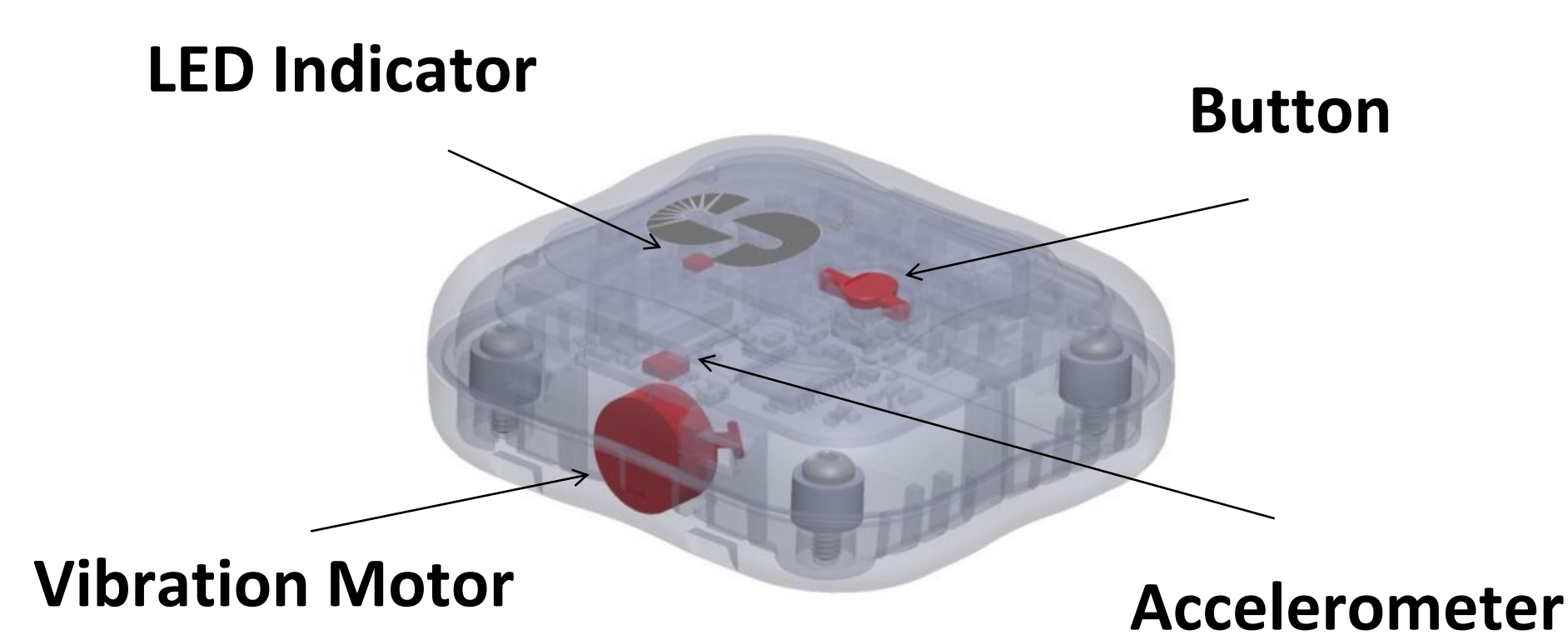
A new implantable CGM system consisting of a fluorescence-based glucose Sensor, body-worn Smart Transmitter and smartphone App has been developed. The small cylindrical Sensor has been designed to be inserted subcutaneously and provides 90 days of continuous measurements. Besides demonstrating functionality of the CGM system, a prospective, multi-center clinical study (PRECISE) was designed to demonstrate safety of the system through 90-day continuous use by measuring incidence of device or procedure related adverse events (AEs).

## Implantable CGM System



The Senseonics CGM system utilizes a long-term implantable glucose Sensor powered by an external, wearable Smart Transmitter through a wireless inductive link. The Sensor is fluorescence-based and developed for subcutaneous implantation in the upper arm. The Smart Transmitter wirelessly communicates with a smartphone App to display real-time glucose readings, trends, and alarms to the users.

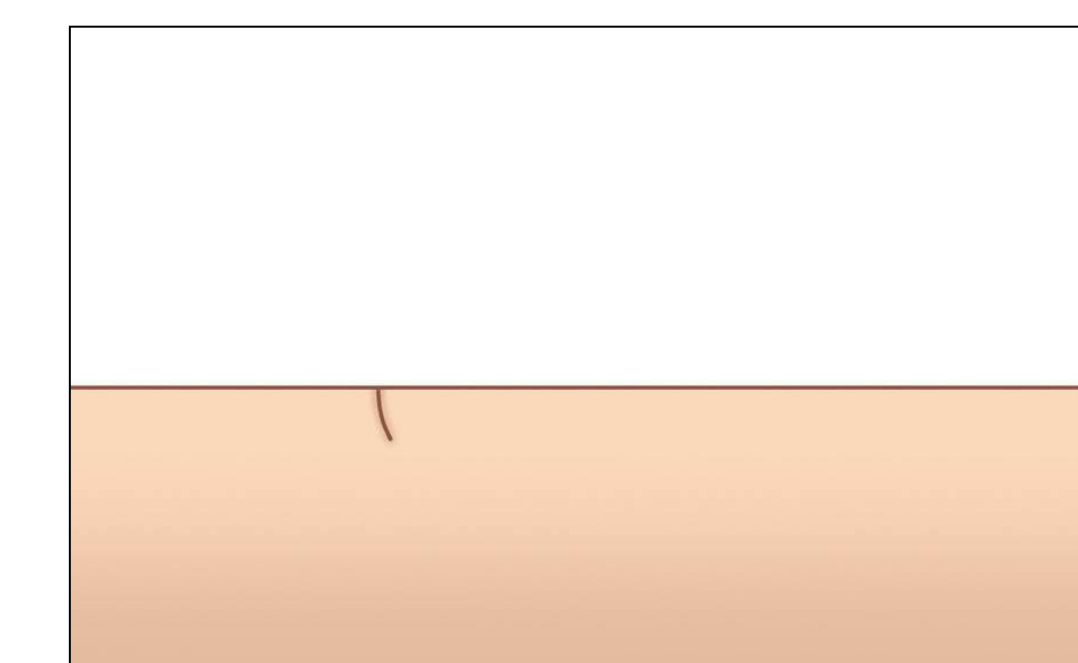
## Wearable Smart Transmitter



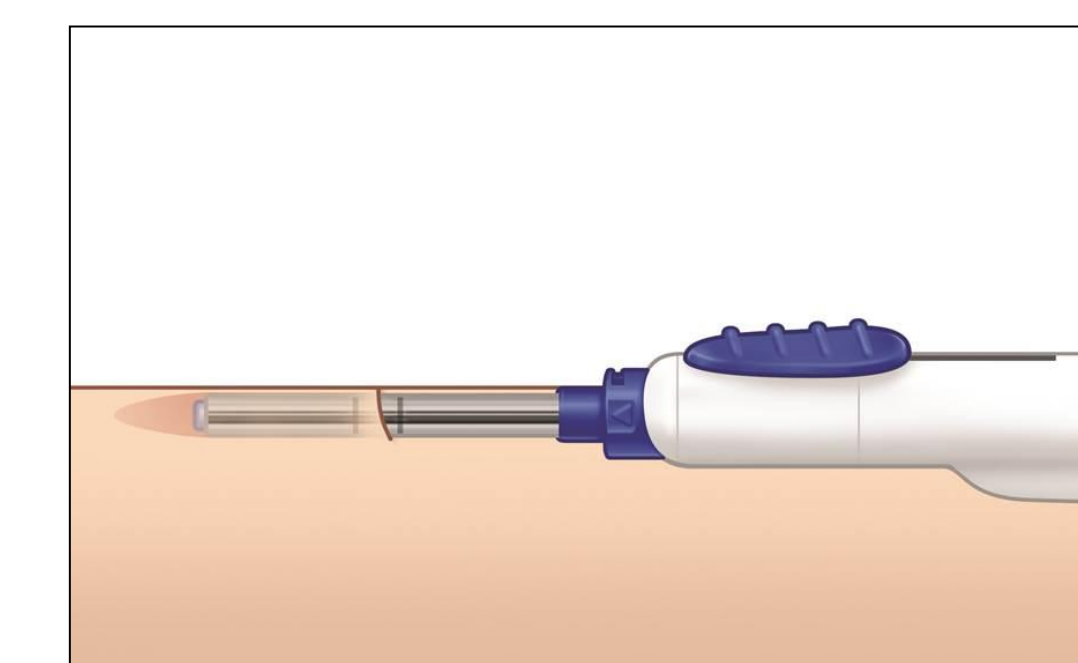
- Transmits information for graphical display on smartphone via a secure, encrypted Bluetooth LE link
- Attached via replaceable adhesive or armband
- Remotely powers Sensor via Near Field Communication (NFC)
- Provides discreet on-body alarms through the vibration motor
- Single button: powering, pairing, alarm suppression

## 5-minute Office Procedure of Sensor Insertion

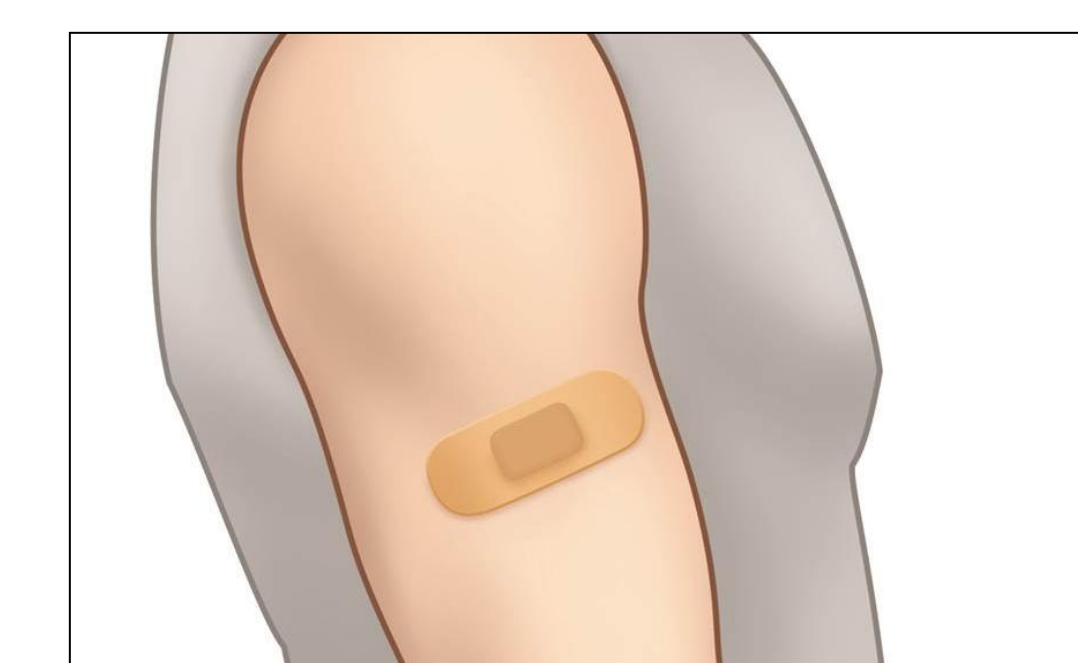
1. 5 to 8 mm incision in upper arm under local anesthetic



2. Sensor inserted with custom inserter



3. Steri-strips to close



## Clinical Study Overview and Results

### Study Design

<b>Objective</b>	• To demonstrate safety of the Senseonics CGM system over successive periods of 30 days for up to 6 months
<b>Total Subjects Enrolled</b>	• 81
<b>Insertion Site</b>	• 2 Sensors were inserted bilaterally in the upper arm for each subject
<b>Population</b>	<ul style="list-style-type: none"> <li>• Age 20 to 68 years</li> <li>• 50 (61.7%) males and 31 females</li> <li>• 76 (93.8%) Type 1 Diabetes and 5 Type 2 Diabetes</li> <li>• HbA1c 5.1 to 10.6%</li> <li>• BMI 19.2 to 41.1 kg/m<sup>2</sup></li> </ul>
<b>Calibration</b>	• 2 SMBG per day for daily calibration
<b>Evaluation Cohort</b>	• 81 subjects after the first 44 crossing the 90-day timepoint since sensor insertion

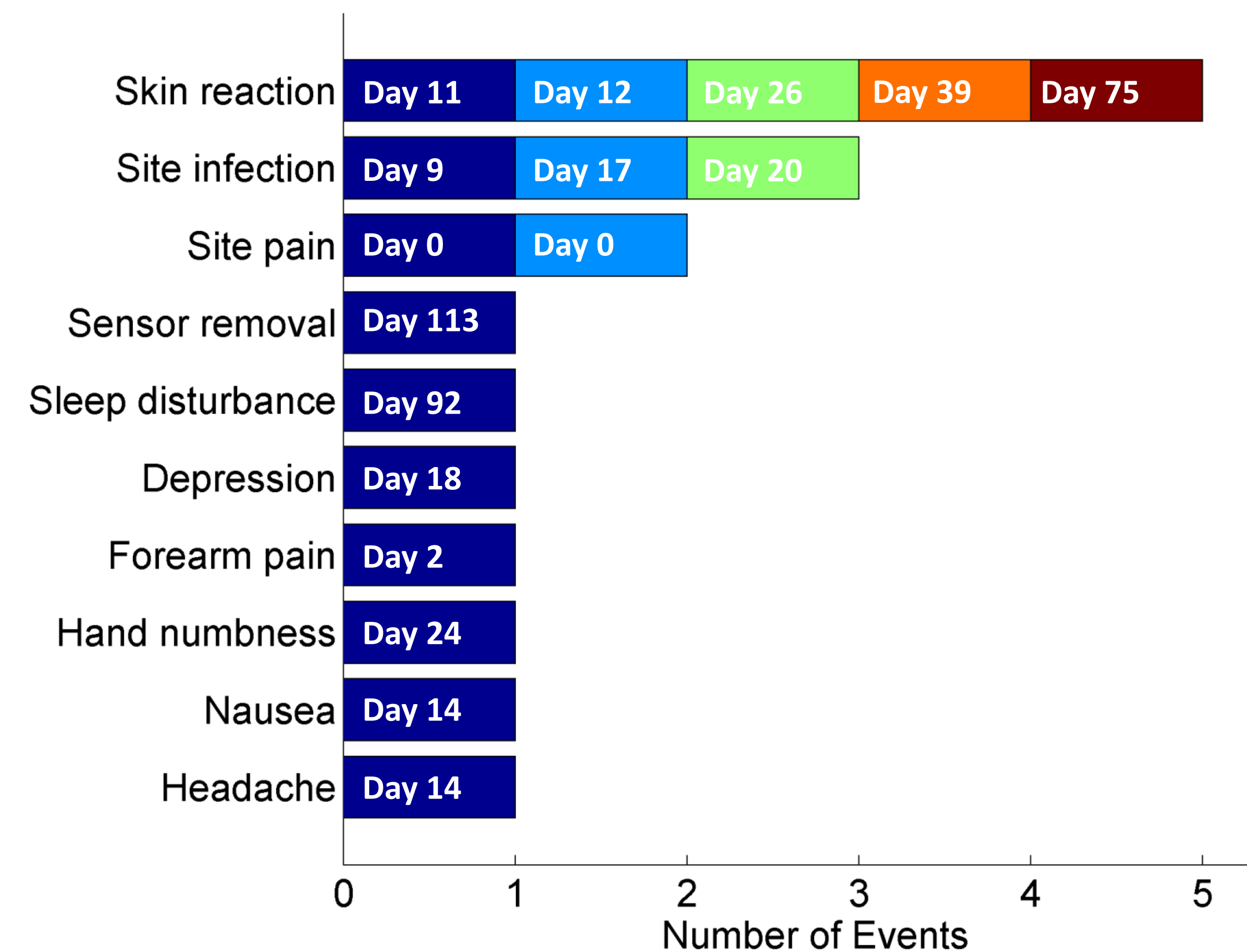
### Methods

- During the investigation, AEs in the clinic and during home use were documented.
- An AE was defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device.
- The primary investigator and the medical monitor independently evaluated each AE for its relation to the device or procedure, seriousness, and whether it was anticipated.
- When discrepancy occurred, the decision made by the medical monitor was used for the analysis.

### Results

- A total of 17 AEs in 12 (14.8%) out of 81 subjects with bilateral sensor insertion for the 90 days of continuous sensor wear were identified as device or procedure related by the medical monitor.
- None of these AEs were serious or unanticipated.
- All AEs were resolved or stable at the study analysis point.

Number of AEs in each event category and their onset day relative to sensor insertion date



### Conclusion

Clinical data from a 90-day pivotal study of an implantable fluorescence-based CGM system has demonstrated that the system is safe for use in subjects with type 1 or type 2 diabetes mellitus.

#### Contact:

Grace Carlson, MD, MBA  
carlson@sutterhealth.org



Oliver Chen, PhD  
oliver.chen@senseonics.com

