Clinical Benefit in Glycemic Control Using a Long Term, Implantable Continuous Glucose Monitoring System in a 90 Day Feasibility Study

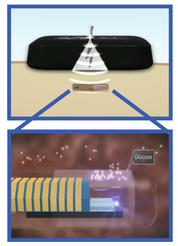
Colleen Mdingi, MS; Ravi Rastogi, PhD; Andrew DeHennis, PhD
Senseonics, Inc., 20451 Seneca Meadows Parkway, Germantown, Maryland 20876, USA

Senseonics CGM System

The Senseonics system utilizes a long term implantable glucose sensor along with a wearable transmitter, which wirelessly communicates with a smartphone-based mobile medical app. The system also enables a web based data management system and a NFC interface for direct sensor measurements.

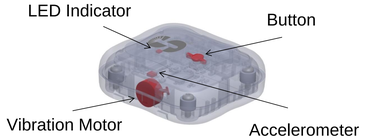
Sensor

A fluorescence-based glucose sensor is developed for long-term subcutaneous implantation in the upper arm or abdomen for up to six months. It is designed to provide an accurate and reliable sensor with no sensor part protruding from the skin. The sensor is an electrically passive device that must be powered by an external, body-worn Transmitter through a wireless inductive link.



Wearable Transmitter

The Transmitter is an autonomous system that incorporates Bluetooth 4.0 capability and continuous interfacing via NFC with the implantable sensor. It also calculates and logs glucose measurements, as well as provides discreet, on-body alerts and alarms through the vibration motor and activity measurement capability.



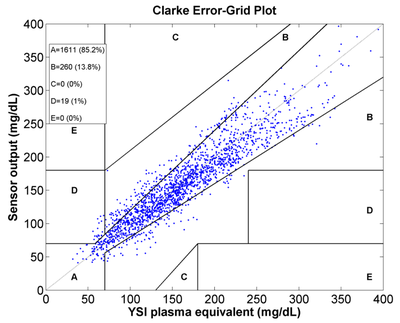
Mobile Medical App

The Mobile Medical App is developed for iOS and Android platforms. The App enables viewing of the real time glucose and history through a touch interface. The smartphone app also allows the user to enter data on daily events, for example, meals, insulin bolus administration, and exercise.

Clinical Study

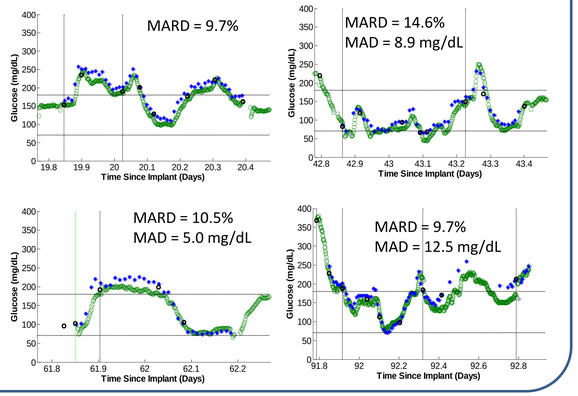
The study was conducted with the system fully blinded during the first half of the sensor wear. For the second half, the transmitter and App were unblinded to enable full access to the real time glucose display and glycemic history of the sensor's measurements. Throughout the study, the subjects managed their therapeutic regimen as prescribed by their doctor. SMBG measurements were taken by the subjects as per the protocol.

Purpose	• Evaluate sensor longevity • Evaluate sensor accuracy • Assess safety of CGM
Number of Subjects	12
Population	• Type 1 and Type 2 MDI • Aged ≥ 18 to ≤ 65 years • HbA1c ≤ 10% before study
Clinic Visits	Every 14 or 28 days for an 8hr session
Insertion Duration	90 days
Days Blinded	45.25±6.7
Days Unblinded	44.75±6.7
Number of Data Points	469,492

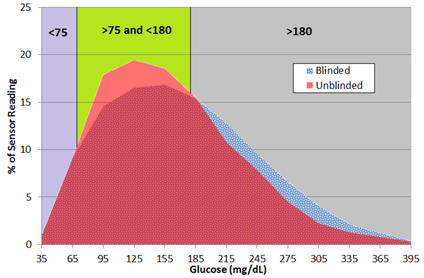


Subject	*MARD (%)*	*MAD (mg/dL)*
1	7.9	10.1
2	9.8	37.0
3	9.1	7.2
4	17.7	29.3
5	7.7	6.8
6	15.0	NaN
7	10.9	3.0
8	8.1	14.9
9	9.4	6.2
10	8.0	2.5
11	12.6	11.0
12	13.1	28.1
Average	11.1 (0.6)	12.8 (0.9)

In-clinic sessions were performed ~ every 14 days throughout the study. During the sessions blood draws were taken every 15 minutes to be measured by a Lab reference.
The Senseonics CGM system measures glucose every 2 minutes and shows an accuracy over a 90 day implant duration that does not diminish.

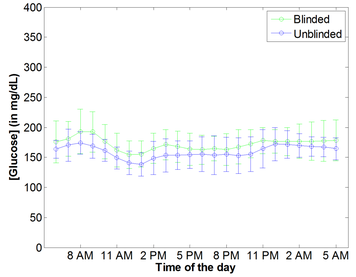


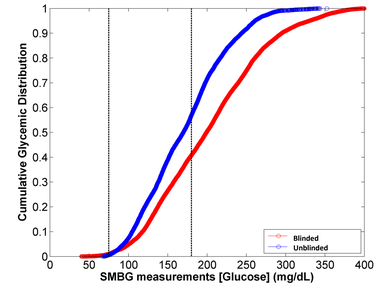
Glycemic Control Benefits



Percentage of time change from Blinded to Unblinded:	
Hypoglycemia	-1.4%
Euglycemia	7.9%
Hyperglycemia	-6.5%
Average Glucose Blinded	174.6 mg/dL
Average Glucose Unblinded	155.9 mg/dL

While subjects used the unblinded system they increased the percentage of time in euglycemia while decreasing time in hyper and hypoglycemia.





The average daily glycemic profile of unblinded system showed smaller variation as well as a lower, more desirable, average glucose level as compared to when using the blinded system.

Glycemic Mean	*Blinded*	*Unblinded*	*Paired T Test*
Day Time	171 mg/dL	156 mg/dL	p<0.001
Night Time	172 mg/dL	162 mg/dL	p<0.001

Conclusions

The results showed an overall increase in glycemic control when the system was unblinded. Data also indicated a statistically significant increase in the percentage of time in euglycemia when the system was unblinded.