Benefit of an Implantable Continuous Glucose Monitoring System for Nocturnal Hypoglycemic Alarms in a 90 Day Feasibility Study

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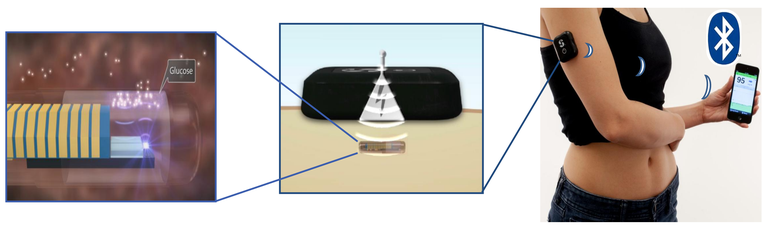
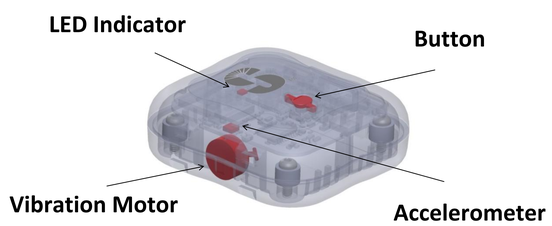
Use of Continuous Glucose Monitoring (CGM) systems provide real-time calculation of glucose, trends, and alarms. Nighttime use also enables detection and potential prevention of episodes of nocturnal hypoglycemia. This study analyses the home use and nocturnal performance of an investigational CGM system which consists of a fully implantable, long term glucose sensor, a wearable smart transmitter, and a smartphone app. This system can prompt for alarms both by on-body vibration alarms via the wearable transmitter and through audible alerts on the smartphone. The objective of this study is to assess the system's overall performance as well as assess the sensing systems susceptibility to Nocturnal Sensor Attenuation (NSA).

Fluorescent Sensor Based CGM System



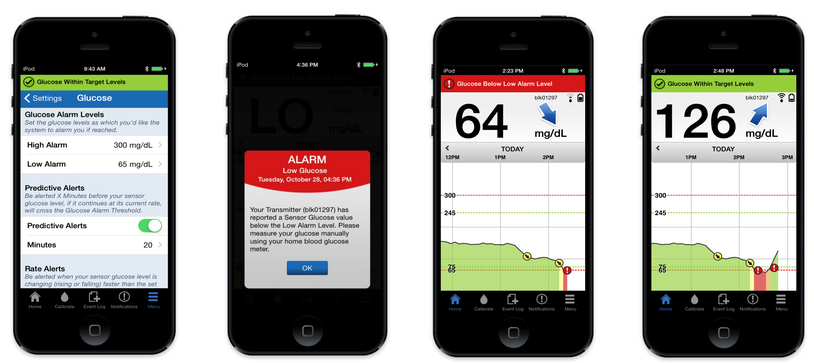
The Senseonics system utilizes a long-term implantable glucose sensor which is powered by an external, body-worn transmitter through a wireless inductive link. The sensor is fluorescence-based and developed for subcutaneous implantation in the upper arm or abdomen. The transmitter wirelessly communicates with a smartphone-based mobile medical app. The system reports real-time glucose , trend information and alarm conditions (Hypo/Hyper) to the users .

Wearable Smart Transmitter



- Transmits information for graphical display on smartphone via a secure, encrypted Bluetooth LE link
- Attached via armband or replaceable adhesive
- Remotely powers sensor via Near Field Communication (NFC)
- ***Provides discreet on-body alarms through the vibration motor. Low glucose alarm is indicated with long buzz repeated 3 times***
- Single button: powering, pairing, alarm suppression

Smartphone App Glucose Alarms



- User can set Alarms levels
- When glucose is below the low alarm level, the alarm becomes active
- When alarm is active, the transmitter vibrates and smartphone prompts user
- Suppress: press OK and alarm is still active on screen

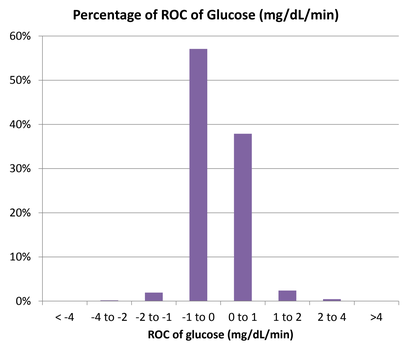
Clinical Study Overview And Conclusions

Study Design

Purpose	• Evaluate *in vivo* stability • Evaluate sensor improvement
Sensors	• 12 sensors
Insertion Site	• Upper Arm
Population	• Age 22 – 52 yrs, 8 males and 4 females • Type 1 Diabetes • HbA1c 7.0 to 9.8% • BMI 19.4 to 29.3 kg / m^2
Sensor Duration	• 90 days

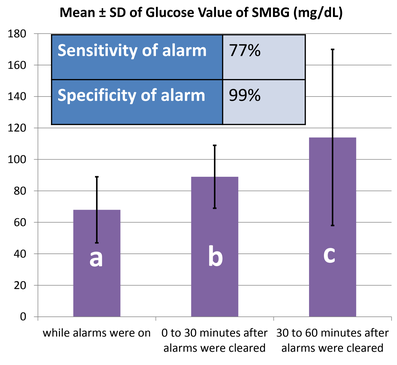
Throughout the study, the system enabled full access to the real time glucose display and glycemic history through the App. The user programmable hypo- and hyper- glycemic alarms were enabled.

Nocturnal Rate of Change of Glucose



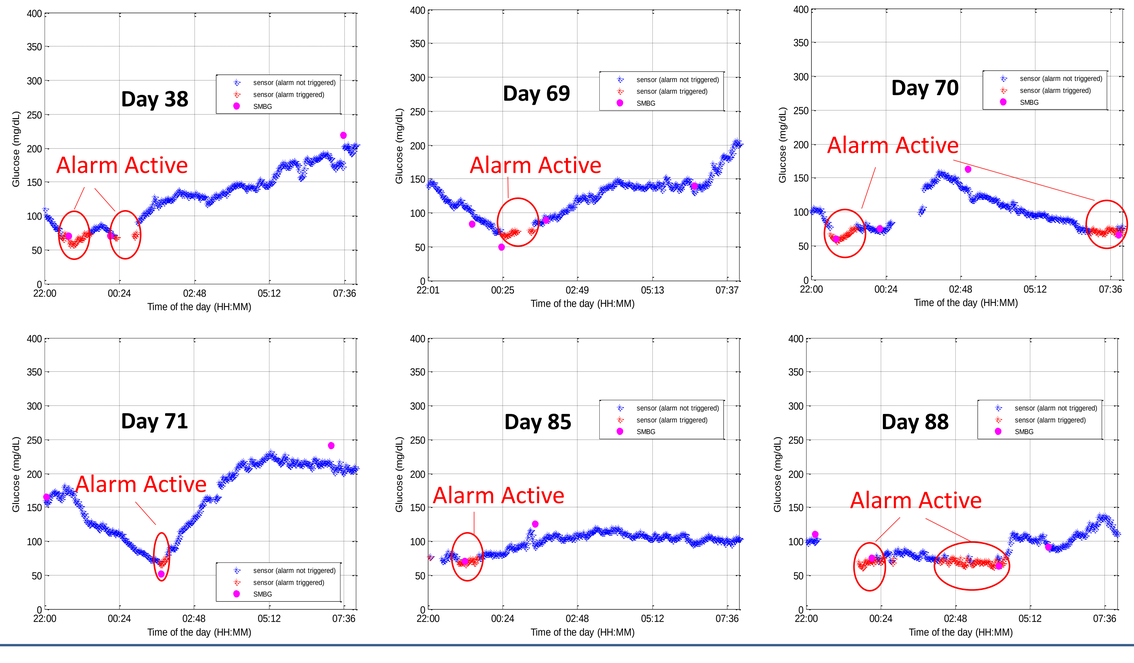
The glucose rate of change was checked to detect any NSA and all the glucose rate of change was within physiological limits.

Mean Glucose Value of SMBG taken after onset of alarms



The SMBG shows the users recovered into euglycemia after confirmation with SMBG when alarms were triggered. *p* value is 0.002 for a and b, 0.0003 for a and c.

Example of Nocturnal Hypoglycemia Alarm of One Subject



Statistical data

Patient ID	number of nights with hypoglycemic alarms active for >10Min	SMBG taken while alarms were active for >10Min		SMBG taken 0 to 30 minutes after alarms were cleared		SMBG taken 30 to 60 minutes after alarms were cleared	
		Number of SMBG	Number of SMBG below 70mg/dL	Number of SMBG	Number of SMBG above 70mg/dL	Number of SMBG	Number of SMBG above 70mg/dL
1	2	1	1	0	0	1	1
2	4	2	2	1	1	0	0
3	6	5	5	3	1	3	2
4	14	8	5	8	7	5	4
5	12	2	1	0	0	5	5
6	1	1	1	0	0	0	0
7	4	0	0	0	0	1	1
8	15	0	0	3	3	2	2
9	7	0	0	3	2	0	0
10	8	1	0	1	0	3	3
11	14	2	1	0	0	0	0
12	13	4	4	0	0	1	1
combined	100	26	20	19	14	21	19

The analysis shows that the average percentage of the nights with hypoglycemic alarms being active for at least 10 minutes was 13.6%. After confirmation with an SMBG, an average of 74% of the time the subjects showed a recovery into euglycemia within 30 minutes from the timestamp of the SMBG. The analysis of the data in this study also shows that the system does not exhibit the high rate of change, which is greater than 4mg/dL/min that is typically associated with NSA of CGM systems.

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