



# SmartWatch®

## Clinical Study Report

### October 2013

#### SmartWatch – Monitoring and Detection of Convulsive Movements Caused by Seizures

*University of California, San Francisco Pediatric Epilepsy Center July 2011 - January 2013  
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# 1. INTRODUCTION

Approximately one in 26 people will develop epilepsy at some point in their lives and more than two million Americans currently have epilepsy.<sup>1</sup> For the families of epilepsy sufferers, a major worry is that their loved one may suffer a seizure while alone, resulting in injury or even death.<sup>2</sup>

SmartWatch, a product designed and developed by Smart Monitor, Inc., is a compact wrist-worn device that detects excessive repetitive movements similar to those caused by generalized tonic-clonic (GTC) seizures and sends alerts to the user's family member(s) or caregiver(s). The SmartWatch records the time, duration and location of these movements and sends this information via Bluetooth to a smartphone. The smartphone, in turn, automatically alerts a designated caretaker that these movements have occurred, allowing for immediate response.<sup>3</sup>

Over a period of 19 months, The University of California, San Francisco (UCSF) conducted a clinical study to determine whether the SmartWatch device could be used to effectively detect abnormal motion patterns associated with GTC seizures. The study concluded that the SmartWatch is effective for this purpose.



## 2. METHODS

### 2.1 Subjects

The Pediatric Epilepsy Center at the UCSF Benioff Children's Hospital monitored 15 patients between July 2011 and January 2013. The patients ranged in age from three to 17 years old. These patients were admitted to the EMU for routine monitoring purposes and opted to participate in the study validating use of the SmartWatch in alerting upon the onset of generalized tonic-clonic seizures. In total, 500 hours of study were conducted. Pediatric neurologist Dr. Joseph Sullivan,<sup>4</sup> who serves as the Director of the Center at UCSF Benioff Children's Hospital, was the clinical study's principal investigator.

### 2.2 Detection

A detection algorithm embedded in the SmartWatch uses pattern recognition and analysis to determine if the motion is caused by a GTC seizure. When the SmartWatch detects sustained abnormal movements, it displays an alert message on its face, vibrates, and issues an audible alert. Within 5-10 seconds of detecting these patterns of abnormal movements, the SmartWatch

sends a text message and/or phone call via Bluetooth link to a computer or smart phone. The event is recorded along with the date, time and duration of the movements.<sup>5</sup>

Users can wear the SmartWatch on their wrist or ankle. The device can be adjusted on a scale of 1-10 to change the sensitivity and specificity of motion detection. For the UCSF study, the sensitivity was set at 9.

While they wore the SmartWatch, patients were monitored by video/EEG for routine monitoring purposes. Detection by the SmartWatch of abnormal motion similar to those caused by GTC seizures was validated, by comparing them to the patients video EEG recordings, which are the gold standard in the EMU for identifying seizures.

### 3. RESULTS

Over nineteen months and more than 500 hours of study, fifteen patients had a total of seven GTC seizures while being monitored. All seven seizures were detected by the SmartWatch and validated by video/EEG. At least two of the seizures occurred while the patient was sleeping, and one patient accounted for three of the seizures. Only one false positive occurred during the testing period.

While monitoring a three-year-old patient, a SmartWatch detected clonus, a condition involving a series of involuntary, rhythmic muscular contractions and relaxations.<sup>6</sup> Clonus can be a sign of certain neurological conditions.<sup>7</sup> The patient, her family and her doctors only became aware she had clonus after the SmartWatch detected it.

Every patient, besides a child with severe Autism, found the SmartWatch easy to set up and use. There were no reports of communication issues between the SmartWatch and the smartphones used. None of the patients used the cancel button.

## STUDY RESULTS

Hours Tested	500
# Participants	15
Age Range	3-17
Sensitivity	99%
Specificity	95%
Seizures Detected/Caught	7/7
Validated by Video EEG	100%
False Positives	1

## 4. ADDITIONAL STUDIES

### 4.1 Stanford University Medical Center

The SmartWatch has been clinically validated by a previous study, which was conducted by Stanford University Medical Center and Lucile Packard Children's Hospital(8) from March 2009 to June 2010. Forty patients, ranging in age from 23 to 48, were monitored in the hospital. Six of the patients had a total of eight GTC seizures, seven of which were detected by SmartWatch. The one seizure was missed because an aide accidentally put an uncharged watch on the patient. The convulsive movements consistent with seizures were detected within 4-15 seconds, and alerts were sent out immediately.<sup>9</sup>

Since this study, Smart Monitor has improved the SmartWatch's algorithm accuracy to virtually eliminate false positives. Smart Monitor has made other improvements to reduce the likelihood of a false negative, including extending the SmartWatch battery life to 30 hours and linking the SmartWatch with computers and other devices with built-in Bluetooth capabilities.<sup>10</sup>

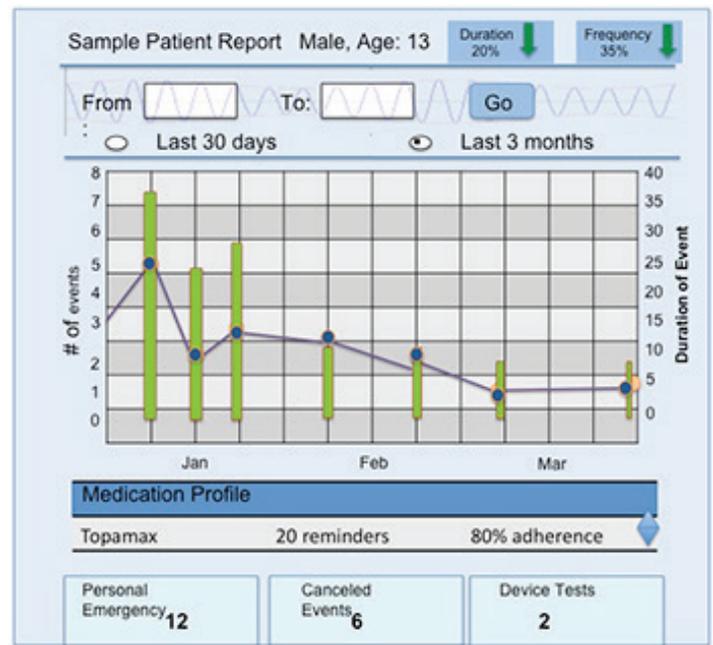
### 4.2 St. Jude's Le Bonheur Children's Hospital

Clinical studies are currently underway at St. Jude's Le Bonheur Children's Hospital in Memphis, TN. The studies are focusing on the SmartWatch's data reporting and aggregating capabilities. The studies began in January 2013 and will be completed by year's end.<sup>11</sup>

## 5. DISCUSSION

The results of the UCSF study show that the SmartWatch is a user-friendly device that can be used to effectively detect abnormal motion patterns associated with GTC seizures. It can help parents monitor the health and safety of the children, particularly during nighttime hours when the child is asleep.

The SmartWatch has several ancillary features that can help improve the safety and treatment of users. The Medication Reminders feature allows users to set customized medication reminders and other useful notifications. For the many people with epilepsy who may find it challenging to stay



on a daily medication routine, Medication Reminders can be valuable and potentially life-saving.

Another useful feature is the “Get Help” button, which allows users to immediately notify parents or caregivers and, if necessary, quickly direct them to their exact location using SmartWatch’s GPS functionality. With this feature, users can also get help when they have non-GTC seizures that the SmartWatch won’t detect.

Finally, the SmartWatch’s data reporting capabilities can provide significant value to both users and clinicians. The device records the date and time, location, duration and intensity of every alerted event. Users can easily share captured data with their physicians, providing valuable information that can lead to more proactive and better-informed care decisions.

## 6. REFERENCES

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