

Title: Automated Seizure Onset Detection as a New Method of On-Demand VNS Stimulation: Initial Technical Development and Findings

Keyword 1: Vagus nerve stimulation **Keyword 2:** Seizure detection **Keyword 3:** Ambulatory EEG/monitoring **Keyword 4:** Seizure onset **Keyword 5:** Seizure control

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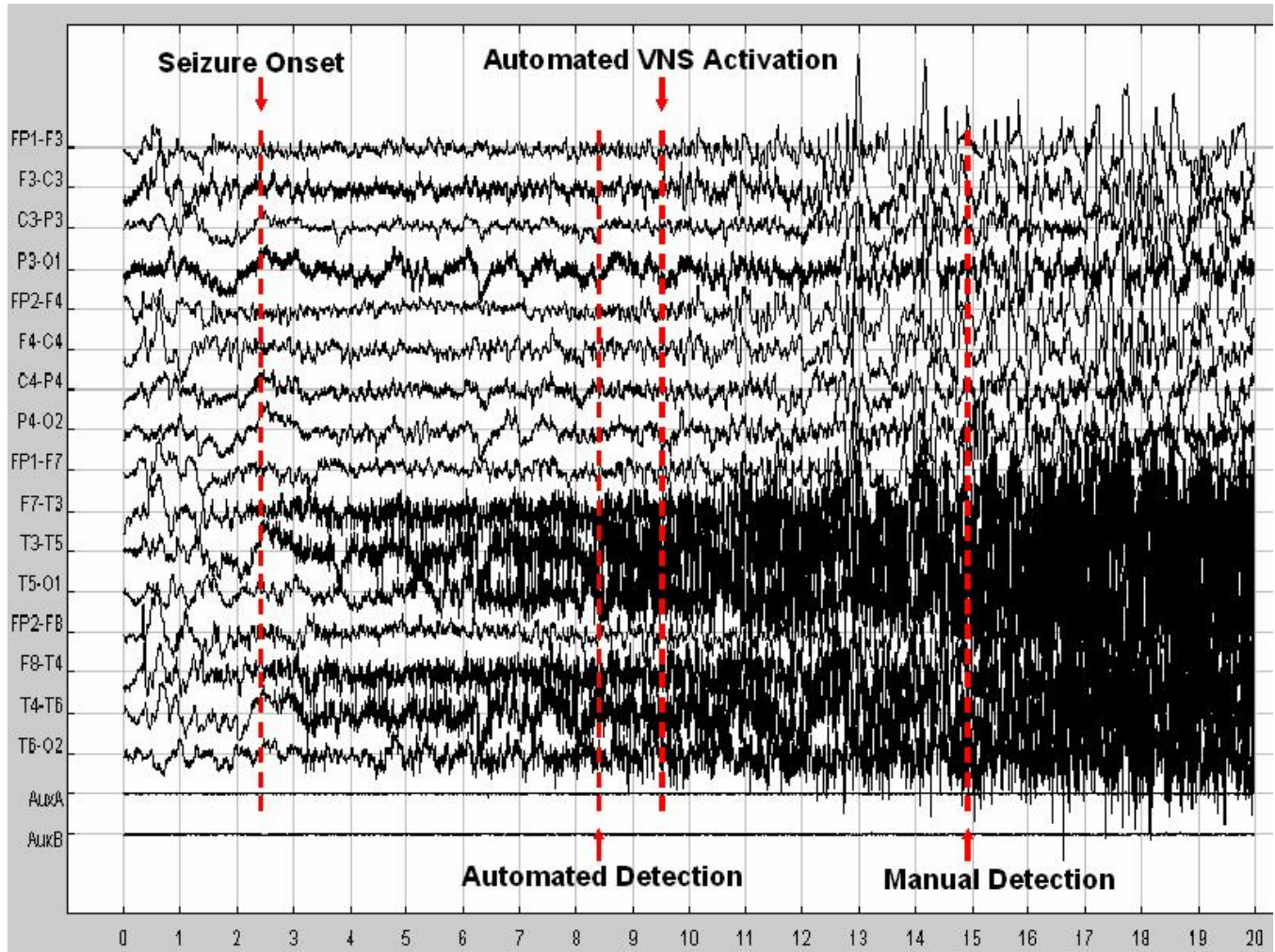
RATIONALE: The VNS Therapy System (Cyberonics, Inc) is programmed to deliver vagus nerve stimulation (VNS) in two modes for the treatment of epilepsy: periodic (automatic) and on-demand (manual). On-demand initiation of VNS, which requires moving a magnet over the generator, may abort or shorten seizure duration, especially if administered at seizure onset (Morris GL *Epilepsy Behav* 2003;4:740-5). Unfortunately, many patients lose consciousness at seizure onset or are physically incapable of using the magnet during a seizure. A method that couples automated detection of seizure onset to on-demand VNS stimulation is desirable.

METHODS: We installed a patient-specific seizure detector algorithm (Shoeb A et al *Epilepsy Behav* 2004;5:483-98) on a small digital signal processor (DSP; TM320C6711, Texas Instruments) and connected the DSP to a 9V battery-powered electromagnet, which when charged produces a magnetic field sufficiently strong at a distance of 0.5 inches from a VNS generator to activate it in the on-demand mode. The system is designed to charge the electromagnet when seizure onset is detected and thereby activate the VNS generator.

RESULTS: An ambulatory EEG study was streamed from a laptop PC to the seizure-detector equipped DSP at 200 samples/sec per channel and the seizure detector trained off 7 seizures. We chose an ambulatory study in which the patient could perceive seizure onset and thereby press an event button. The figure below illustrates the performance of the DSP-electromagnet system on a seizure that was not used for training. The seizure detector recognized the seizure onset, charged the electromagnet and activated the on-demand mode of an external VNS generator six seconds before the patient pushed the event button, which theoretically is when he would have initiated on-demand vagus nerve stimulation had he been treated with VNS.

CONCLUSION: Our preliminary results show the potential for an ambulatory seizure-onset detection system to initiate VNS within seconds of electrographic seizure onset, and even before a patient may be aware of seizure onset.

Further refinement of the system is underway and clinical trials of its efficacy, tolerability and safety are planned.



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