

Commercialization of Seizure Prediction Technology

Promises and Pitfalls of Biosignal Analysis: Seizure Prediction and Management (A case study);

Mark T. Rise, Ph.D.

Technical Fellow, Neurostimulation Business, Medtronic, Inc.
Minneapolis, MN 55421

Abstract-This presentation will focus on the process of commercializing technology designed to predict/detect seizures. The author will present general design criteria for an implantable device used chronically by an individual with epilepsy to manage their seizures. He will also contrast the requirements of a commercial product with the sophisticated approaches of algorithm developers. Where an implantable product requires low power consumption, small size, and ease of use, the trends of algorithm developers is to make use of increasingly sophisticated mathematical techniques and increasingly affordable, high speed, powerful desktop computers. A discussion of various design approaches will emphasize the trade offs which could be employed to accommodate important advances in algorithm development.

I. INTRODUCTION

Researchers over the past twenty years have devoted their efforts to identifying algorithms which are able to predict or rapidly detect the onset of seizure activity. Appropriately, their efforts have focused on algorithms which improve reliability and increase the prediction time. Making use of the advances in desktop computing power, researchers have succeeded in applying more sophisticated mathematical techniques to develop algorithms capable of predicting seizures rather than simply early detection of their onset. These new algorithms have considerable value when used in a clinical setting where computer size and power requirements are not an issue. However, when considering implementing an algorithm as part of an implantable, chronically used product, restrictions on power consumption and size become critical.

II. Design Criteria

An implantable product to control or manage seizures is ideally, totally implanted as is the case of the Activa® Tremor control system depicted in Fig. 1. It consists of an implantable neurostimulator (INS) containing electronics, a communication antenna and circuitry, and a power source. The INS is connected to an extension tunneled through the neck to an array of electrodes located on or in the cranium. Options for electrodes include screw type electrodes positioned in the bone, arrays of discs placed over the convexity of the brain, and depth electrodes positioned in the brain parenchyma as shown in Fig. 1. A system of this type may simply record ictal and or interictal brain activity. It may warn the patient when a seizure is about to happen. Or it may execute a therapy in response to a detection to abort or prevent the seizure from occurring. The therapy may be electrical stimulation of a portion of the brain or infusion of a drug. The therapeutic and seizure management options

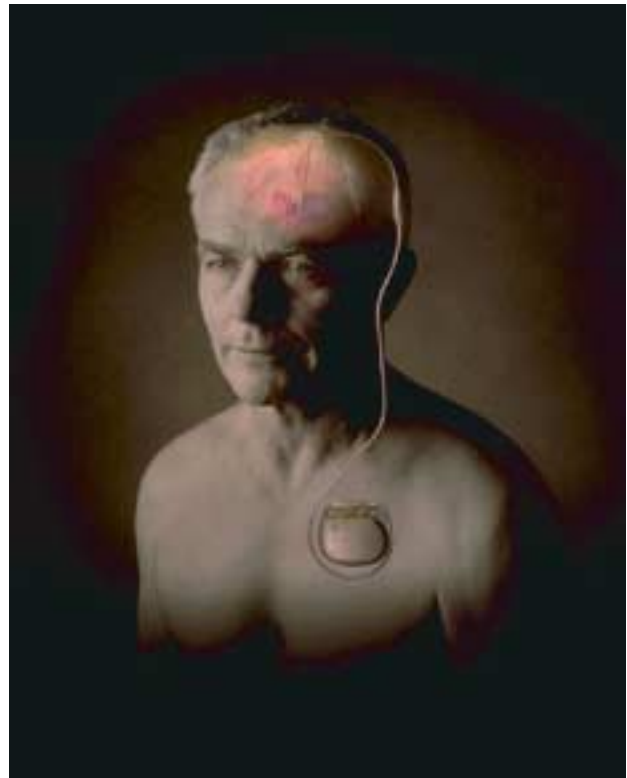


Figure 1; Activa Tremor Control Therapy

will depend on the reliability of the seizure prediction algorithm and the amount of time available to take action. The system will include a physician programmer capable of communicating with the implanted device to make parameter adjustments. Features of the seizure detection algorithm may be adjustable to permit tuning it to individual patient characteristics. The seizure management options may also constitute choices a physician can make depending on the needs of individual patients.

Persons with epilepsy who are sufficiently disabled to be candidates for an implantable system to manage their seizures may have a wide range of disabilities besides seizures. They may be completely dependent upon a caregiver for even the simplest of activities of daily living. In contrast, they may be quite independent and attempting to be self sufficient. As a consequence the user interface of an implantable seizure management system must meet the demands of these two extremes of users. On the one hand it needs to be simple and basic in its operation and on the other, it must be capable of implementing features that would be useful to an active, self sufficient person. Certain other characteristics of the system will be requirements for all users.

1) *Power consumption and device longevity*: Systems for processing biosignals utilizing computationally intensive algorithms are useful and provide no limitation for clinical

Report Documentation Page

Report Date 25 Oct 2001	Report Type N/A	Dates Covered (from... to) -
Title and Subtitle Commercialization of Seizure Prediction Technology Promises and Pitfalls of Biosignal Analysis: Seizure Prediction and Management (A case study);	Contract Number	
	Grant Number	
	Program Element Number	
Author(s)	Project Number	
	Task Number	
	Work Unit Number	
Performing Organization Name(s) and Address(es) Technical Fellow, Neurostimulation Business, Medtronic, Inc Minneapolis, MN 55421	Performing Organization Report Number	
Sponsoring/Monitoring Agency Name(s) and Address(es) US Army Research, Development & Standardization Group (UK) PSC 802 Box 15 FPO AE 09499-1500	Sponsor/Monitor's Acronym(s)	
	Sponsor/Monitor's Report Number(s)	
Distribution/Availability Statement Approved for public release, distribution unlimited		
Supplementary Notes Papers from 23rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Oct 25-28, 2001, held in Istanbul, Turkey. See also ADM001351 for entire conference on cd-rom, The original document contains color images.		
Abstract		
Subject Terms		
Report Classification unclassified	Classification of this page unclassified	
Classification of Abstract unclassified	Limitation of Abstract UU	
Number of Pages 2		

monitoring systems. However, when incorporated in an implantable device, power consumption becomes a critical issue. Ideally, the device is totally implanted such as is the case with the Aactiva® used to treat movement disorders shown in Figure 1...However, a totally implanted INS may have a battery capacity of only a couple ampere-hours. These devices are designed to be low power, operating in such a way as to only draw tens of microamperes from the battery. At these low levels and with non continuous use, the systems can last three to five years in most applications. However, a system designed to execute a computationally intense algorithm may draw so much current that a primary battery may only last weeks to months. This would be unacceptable from an economic perspective as well as the risk to the patient requiring frequent replacement surgeries which even though they are minor do pose a risk.

2) *Computing speed.*: In order to achieve low power consumption, implantable neurostimulators operate at low clock frequencies. While the desktop computer used to develop a seizure detection/prediction algorithm may operate with megahertz speed, an implantable device will include a microcontroller to implement a seizure prediction algorithm that will typically be clocked with a frequency in the kilohertz range.. Given this clock frequency, it then becomes difficult to execute too many computations and still process signals in real time.

III. Design options

Design engineers have other options apart from a totally implanted device to implement a seizure management system. Rechargeable batteries are theoretically possible, however reliable systems for implanted products have still not been demonstrated. Even rechargeable battery powered devices may not be adequate in some cases. If the power consumption is sufficient to cause frequent recharging cycles, it still may not be an efficient system since rechargeable batteries have a limited number of charge-recharge cycles before they fail.

Neurostimulation devices used to treat chronic pain and cochlear stimulators have made use of what has been referred to as "RF" implantable neurostimulators such as shown in Fig.2. In these systems the implanted electronics package has no battery. Power for the implanted portion is derived from electromagnetic energy transmitted through the skin from an external coil antenna placed over the implanted electronics package. In this instance, power becomes less of an issue since it is contained in the external electronics package. Such a system has the disadvantage that it ceases to work whenever electrical contact between the antenna and the implanted portion is lost. This poses a risk for a person counting on the device to manage their seizure. Often tape is used to maintain appropriate contact which leads to skin irritation. Showers and even sleeping become a problem when an external electronics package is required to deliver the therapy.



Figure 2, RF Neurostimulation Technology.

IV Summary

The commercial implementation of research conducted to predict or detect seizure activity from biosignals as a product useful to persons with epilepsy requires making tradeoffs. The use of more sophisticated mathematical techniques to improve the specificity, reliability and prediction time of seizure prediction algorithms expands the opportunities for therapeutic intervention. However, it also imposes more demanding requirements on the power sources and computing speed of implantable systems. Important trade offs between battery longevity and algorithm sophistication are a critical part of the commercialization process. Options for hybrid systems that include both implanted portions and external portions may provide solutions. Further development of implantable, rechargeable batteries may also be the answer. Some algorithms simply can't be implemented with today's implantable technology.