Cyberonics®

Important Safety Alert – 2nd Notice

VNS Therapy™ Demipulse Generator and VNS Therapy™ Demipulse Duo Generator Reset

Cyberonics, Inc. is notifying VNS Therapy practitioners about the possibility that in certain situations the VNS Therapy Demipulse Generator (Model 103) and the VNS Therapy Demipulse Duo Generator (Model 104) may inadvertently be disabled or shut off.

Cyberonics has identified situations in which, during a magnet-initiated stimulation, inhibition, or in the presence of a strong magnetic field, the software may report an error even though no such error occurred. This error causes the generator to reset, which disables the generator (i.e. no stimulation delivered).

As of March 23, 2008, approximately 364 Model 103 and Model 104 generators have been implanted worldwide, and four (4) incidents have been reported involving a generator found to be disabled. In all cases, the handheld programming computer displayed an error message indicating that the system was not stimulating. No patient injuries or deaths have been reported to Cyberonics as the result of a device being disabled. Patients who are not programmed to magnet settings are at less risk for this event.

Physicians should inform any potential and currently implanted patients of the possibility of this event. Patients should continue with their regularly scheduled visits as determined by their physician.

If this event is suspected, physicians should interrogate the device as described in the Physicians Manual to confirm the generator has been reset and Cyberonics should be contacted for any additional instruction. Should the device be programmed back to the patient's normal settings, the patient will then again receive the programmed therapy.

The FDA has approved our labeling updates that include the resolution options to address this event. The modified labeling is posted at www.VNStherapy.com.

100 Cyberonics Blvd • Houston, TX 77058 • Tel: (800) 332-1375 • Fax: (281) 218-9332
Belgicastraat 9 • 1930 Zaventem • Belgium • Tel: 32 2 720 95 93 • Fax: 32 2 720 60 53
www.cyberonics.com

Please complete and return the effectiveness card as soon as possible. By signing and returning this Effectiveness Check Card, you are acknowledging that you have read and understand this Safety Alert Letter. Returning the Effectiveness Check Card will also prevent repeat notifications of this Safety Alert.

If you need further information, please contact us at the following numbers:

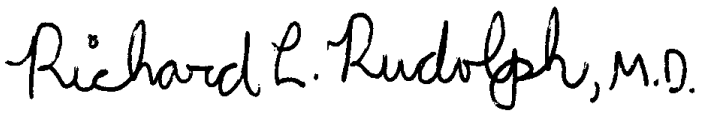
United States customers may contact Clinical Technical Support at 866-882-8804 or via email at clinicaltechnicalservices@cyberonics.com

International customers may contact Clinical Technical Support at +32 - 2 - 720 95 93 or via email at europeclintechservices@cyberonics.com

The Safety Alert is being made with the knowledge of the US Food and Drug Administration.

We appreciate your assistance in this matter.

Sincerely,



Richard L. Rudolph, MD
Special Safety Advisor