Cyberonics

THIS IS AN IMPORTANT SAFETY NOTICE! PLEASE READ IT CAREFULLY

IMMEDIATE RESPONSE REQUESTED

VNS Therapy® Model 103 and 104
Use of Electrosurgical Equipment or Exposure to Static Electricity

Why am I receiving this alert?
You are receiving this notification because your name was supplied to Cyberonics, Inc. on a patient registration form as a surgeon who has implanted a VNS Therapy Demipulse® Generator (Model 103) or Demipulse Duo® Generator (Model 104) (collectively the "Demipulse Generators") and the situation being discussed relates to implantation of these devices.

What is the issue?
As indicated in the Demipulse Physicians Manual[1], various environmental and medical hazards have the potential to damage Demipulse Generators. An investigation of 11 recent complaints has determined that exposure of Demipulse Generators to the following specific conditions can temporarily drain the generator battery excessively and shorten battery life of the device by approximately 50%:

- Electrosurgical equipment (e.g. electrocautery) used during implantation or other surgical procedure near the pulse generator; and
- Static electricity (also known as electrostatic discharge or ESD) imparted to the device during a surgical procedure.

Of the 11 complaints investigated, 6 occurred during initial implants, 4 occurred during re-implant procedures, and 1 occurred during an explant of a device.

How do I know if my patient is affected?
When performing a System Diagnostics test on the device, an End of Service indicator during surgery may be an indication that the device has been damaged in this manner. Applicable indicators include any of the following:

- *"The Pulse Generator battery is within 6 months of projected end of service (EOS). If you have questions, please consult the Physician's Manual or contact Cyberonics."*
- *"The Pulse Generator battery is PAST projected end of service (EOS). If VNS therapy is to be continued, it is suggested that the Pulse Generator be replaced as soon as possible. If you have questions, consult the Physician's Manual or contact Cyberonics."* and
- *"The Pulse Generator is currently disabled due to a Vbat < EOS threshold. Note that the generator is NOT supplying stimulation. It is recommended that you contact Cyberonics or refer to the Physician's Manual."*
- *"End of Service <10 years"* (new devices only)

[1] Section 5.4.1 of 26-0006-8000/4, *Introduction*, Indications, Warnings, and Precautions

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What actions should physicians take?
To minimize the potential for this event to occur, the following precautions should be taken during any new implant or re-implant procedure:

- Do not use electrosurgical equipment once the Demipulse Generator has been introduced to the sterile field to prevent damage to the device;
- Care should be taken when using the hex screwdriver to avoid touching the metal shaft when the wrench is engaged with the setscrew of the Pulse Generator. This shaft can serve as a path to conduct static electricity into the device circuitry;
- Have a backup generator available during an implant procedure; and
- Perform a System Diagnostics test after the device has been secured in the pocket (as prescribed in the implantation procedure).

If any of the End of Service indicators are observed during the surgical procedure, perform a System Diagnostics test to update the longevity estimate. If the battery longevity estimate indicates that there is less than 10 years remaining until End of Service, or if any other End of Service warning message appears, the device should be removed and returned to Cyberonics and the backup device should be used.

For other surgical procedures involving a device that is already implanted (i.e. repositioning a device that has migrated), the following should be performed:

- Perform a System Diagnostics test prior to surgery and note the estimated battery longevity;
- Take the same precautions as indicated above in regards to refraining from use of electrosurgical equipment near the device, avoiding contact with the metal shaft of the hex screwdriver, and having backup product available; and
- Perform another System Diagnostics test after the device has been secured in the pocket (as indicated in the Implantation Procedure[2]).

If the battery longevity estimate following surgery is significantly lower than the initial measurement prior to surgery, or if any other End of Service warning messages are observed, the device should be removed and returned to Cyberonics and the backup device should be used. Note that a significant change in the lead impedance or a change in programmed device settings may also affect the battery longevity estimate as described in the Physicians Manual[3]. If any other error messages are obtained, refer to the Troubleshooting section of the Physician's Manual[4] for assistance.

Physicians may contact Clinical Technical Support at the phone numbers and email addresses provided below if assistance is needed in the identification of a device that may have a decreased longevity due to exposure to electrosurgical equipment or static electricity.

We have requested that this event and the resolution options be addressed in our FDA-approved labeling. Once approved, you will be notified and the modified labeling will be posted at www.VNSTherapy.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

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[2] Section 9 of 26-00006-6900/6, *Implantation Procedure,* VNS Therapy™ System

[3] Section 4.2.7 of 26-0006-5600/7, *Technical Information*, VNS Therapy™ Demipulse Model 103 Generator and Demipulse Duo Model 104 Generator

[4] Section 5 of 26-0006-5600/7, *Technical Information*, VNS Therapy™ Demipulse Model 103 Generator and Demipulse Duo Model 104 Generator

understood 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: Clinical Technical Support at 866-882-8804 or via email at clinicaltechnicalservices@cyberonics.com

International customers: 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,

Bryan Olin

Bryan Olin, Ph.D.
Vice President, Quality