Cyberonics

THIS IS AN IMPORTANT SAFETY NOTICE!
PLEASE READ IT CAREFULLY
IMMEDIATE RESPONSE REQUESTED

VNS Therapy® Mode103 and 104 EOS Indicator

Why am I receiving this alert?
You are receiving this notification because your name was supplied to Cyberonics, Inc. on a patient device registration form for a VNS Therapy Demipulse® Generator (Model 103) or Demipulse Duo® Generator (Model 104) (collectively the "Demipulse Generators") and the situation being discussed relates to 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?
Display of the following message during the first interrogation following any surgical procedure, including implantation of the device, may be an indication that the device was damaged during the surgery:

> *"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."*

Additionally, a sudden and unexpected decrease in the estimated battery longevity between two patient visits may be an indication that the device was affected by this condition.

What actions should physicians take?
If the *"Vbat < EOS"* message is displayed during the first interrogation following implantation of the device or other surgical procedure, physicians should:

1. Select "Proceed" at the bottom of the error message.

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

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2. The next screen that appears is the screen where the desired device settings can be programmed into the device. Enter the desired device settings in the right-hand column and select "Program" at the bottom of the screen.
3. Perform a System Diagnostics test. If the following acceptable results are obtained, the device is functioning normally however the battery life will be shortened and the longevity estimate will no longer be accurate:
    - Output Current: OK
    - Lead Impedance: OK
    - End of Service greater than 6 months
4. If "End of Service" is 6 months or less, generator replacement is recommended.
5. If any other error messages are obtained, refer to the Troubleshooting section of the Physician's Manual[2] for assistance.

Physician follow-up activities should include:

- Continuing with regularly scheduled patient visits;
- Ensuring patients (epilepsy only) continue using their magnet regularly to verify that stimulation is felt as described by the labeling;
- Ensuring that patients notify their physician if stimulation is not felt or feels different; and
- Performing regular system diagnostic testing to ensure proper device function. If the battery has been affected, you may observe an abrupt and substantial decrease in the longevity estimate well before expected.

If a sudden and unexpected decrease in the estimated device longevity is detected, this is a possible indication that the battery life of the device has been reduced. In this case, physicians should:

- Check for changes in programmed settings or significant lead impedance changes since the patient's last appointment that may have caused the decrease in estimated device longevity;
- Monitor the patient closely for the pulse generator approaching its end of service. When the device has reached its end of service, this status will still be correctly displayed upon interrogation of the device.

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 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:

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

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