



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

**VNS Therapy<sup>®</sup> Model 250 Programming Software (Version 7.1)  
Affecting VNS Therapy Models 103 and 104**

**Why am I receiving this alert?**

You are receiving this notification because you have been identified as a physician who uses Model 250 Programming Software to monitor patients implanted with the Demipulse<sup>®</sup> Generator (Model 103) or Demipulse Duo<sup>®</sup> Generator (Model 104) and the situation being discussed relates to these devices.

**What is the issue?**

Cyberonics identified two issues in the handheld programmer software and one correctable issue in the generator, all of which affect the accuracy of the battery life projection for the Demipulse Generators. No other generator models are affected.

Delivery of therapy and actual battery performance are not affected.

The inaccurate battery longevity projection has not resulted in any adverse events, nor does Cyberonics expect that it will result in any adverse events in the future. Based on the company's risk assessment, the issues present the following risks if clinical symptoms are not taken into account when considering replacement:

- Premature replacement of a generator; or
- Failure to replace the generator before the battery depletes, causing the patient to return to baseline seizure frequency or depressive symptoms.

**What action should be taken?**

- Physicians should not rely on the battery longevity projection displayed on the handheld as an accurate estimate of the time to end of service (EOS) until Cyberonics provides corrected software to address the anomalies late in 2010.
- Cyberonics recommends careful clinical follow-up to observe patients for clinical signs or symptoms suggesting EOS. Patients with observations or reports consistent with EOS should be thoroughly evaluated and considered for generator replacement. Epilepsy patients can use the magnet daily to confirm that the device is functioning<sup>1</sup>. Inability to interrogate the generator may also indicate EOS<sup>2</sup>.

<sup>1</sup> Sections 10.2 and 13 of Epilepsy Patient's Manual, Cyberonics 26-0007-0900/1 (U.S.)

<sup>2</sup> Sections 4.2.7 and 4.5 of Technical Information VNS Therapy Demipulse Model 103 Generator and VNS Therapy Demipulse Duo Model 104 Generator, Cyberonics 26-0006-5600/7 (Worldwide)

- For questions about whether or not EOS is approaching, you may contact Clinical Technical Support via telephone or email as described below. They can provide instructions on how to collect data to send to Cyberonics that can help assess the generator battery status.
- The generator issue can be corrected by you or your staff the next time your patient is seen in the clinic. All you need to do is re-program the Demipulse Generator signal frequency following the steps below:<sup>3</sup>
  1. Interrogate the generator.
  2. Select “New” next to the signal frequency parameter.
  3. Select the frequency of choice.  
**Note:** If no change in signal frequency is desired, select the currently programmed signal frequency.
  4. Select “Program” at the bottom right corner of the screen and select “Start Programming” on the following screen once the wand is secure over the generator.
  5. After Step #4 is complete, interrogate the generator again to confirm that it has been programmed to the intended settings.

**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:

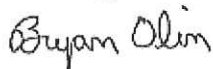
United States customers: Clinical Technical Support at 866-882-8804 or via email at [clinicaltechnicalservices@cyberonics.com](mailto:clinicaltechnicalservices@cyberonics.com)

International customers: Clinical Technical Support at +32 - 2 - 720 95 93 or via email at [europelintechservices@cyberonics.com](mailto:europelintechservices@cyberonics.com)

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

We appreciate your assistance in this matter.

Sincerely,



Bryan Olin, Ph.D.  
Vice President, Clinical Affairs and Quality

2010-Apr, 1st Mailing-Physician

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<sup>3</sup> Section 4.1 and 4.2 of Physician’s Manual VNS Therapy Programming Software Model 250 Version 7.1 Handheld Computer, Cyberonics 26-0007-0700/1 (Worldwide).