



THIS IS AN IMPORTANT SAFETY NOTICE! PLEASE READ IT CAREFULLY

IMMEDIATE RESPONSE REQUESTED

**VNS Therapy Model 250 Programming System
(Version 7.1 and Earlier Versions)**

Why am I receiving this alert?

Cyberonics, Inc. is notifying VNS Therapy practitioners about the possibility that, in rare instances, a system diagnostic test using Model 250 Programming Software (versions 7.1 and earlier) may report “Lead Impedance: OK” when, in fact, normal wear or trauma has resulted in a short-circuit condition that prevents the lead from delivering therapy to the vagus nerve.

A short-circuit condition in a lead results in a low lead impedance. In VNS Therapy Pulse and Pulse Duo Generators (Models 100, 101, 102, and 102R), a device diagnostic test that reports a DC-DC Converter Code of 0 may indicate a short-circuit condition. In VNS Therapy Demipulse and Demipulse Duo Generators (Models 103 and 104), an impedance value of less than or equal to 600 ohms likely indicates the existence of a short-circuit condition, although an impedance value of greater than 600 ohms does not exclude the possibility of a short-circuit condition.

How do I know if my patient is affected?

Patients affected by this event may experience one or more of the following conditions:

- Loss of efficacy;
- Painful stimulation;
- Feeling of erratic stimulation or no stimulation; or
- Feeling stimulation in an atypical anatomical location.

In the absence of these adverse events or device-related complications, a DC-DC Converter Code of 0 or low impedance value likely does not indicate a lead malfunction. A sudden decrease in impedance value or reduction of the DC-DC Converter Code to 0, in combination with the patient’s perception of feeling erratic, limited, or no stimulation, may indicate a short-circuit condition in the lead.

What actions should physicians take?

For your patients:

- Continue with their regularly scheduled visits;
- Ensure patients (epilepsy only) continue using their magnet regularly to verify that stimulation is felt as described by the labeling; and
- Ensure patients notify their physician if stimulation feels different or is not felt.

Page 1 of 2

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

Physicians should:

- Perform regular system diagnostic testing to ensure proper device functionality.
- Note any significant decreases in the DC-DC Converter Code or impedance value since the patient's last visit and whether the patient has presented with adverse events typically associated with a broken lead or short circuit (e.g. no sensation at maximum output stimulation, loss of efficacy, or painful stimulation).
- Use additional diagnostic tools to assist in identifying short circuits in the lead such as:
 - X-rays;
 - Evoked potential monitoring or monitoring with an oscilloscope as described in the Physician's Manual¹; or
 - Laryngoscopy to determine if the vocal folds are affected by vagus nerve stimulation. The effect of vagus nerve stimulation on vocal folds has been well-characterized in scientific literature². Lack of vocal fold movement during stimulation periods may indicate that stimulation is not reaching the vagus nerve.
- Evaluate the patient for possible lead replacement if a short-circuit condition is suspected.

Physicians may contact Clinical Technical Support at the phone numbers and email addresses provided below if assistance is needed in the identification of a short circuit condition in the lead.

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:

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 europaclintechservices@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, Ph.D.
Vice President, Quality

¹ Section 12.1.3.5.1. of 26-0006-0900, *Physician's Manual*, NeuroCybernetic Prosthesis System, NCP Pulse Generator Models 100 and 101 and Section 4.2.4.1 of 26-0006-3900, *Technical Information*, VNS Therapy™ Pulse Model 102 Generator and VNS Therapy™ Pulse Duo Model 102R Generator

² Charous SJ, Kempster G, Manders E, Ristanovic R. The effect of vagal nerve stimulation on voice. *Laryngoscope* 2001; 111:2028-31.