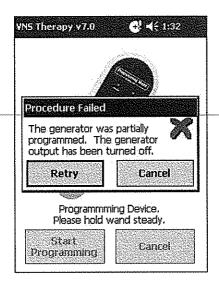


Important Safety Alert 4/09/07 – 3rd Notice

VNS Therapy[™] Programming Software 8.0 milliamp Anomaly

Cyberonics, Inc. is notifying VNS Therapy practitioners of an anomaly associated with the Model 250 programming software used to program the implanted VNS Therapy generator. Through reports from field experience, Cyberonics has become aware of a rare event in which patients' VNS Therapy generators were inadvertently programmed to 8.0 milliamps (mA). The event has been observed in only six patients from among over 45,000 patients implanted with the VNS Therapy System. Five of the six patients reported experiencing pain, and one of these patients also reported coughing and shortness of breath during the stimulation; the sixth patient was asymptomatic. This programming event may occur with all Models 100 and 101 NCP Pulse Generators, and Model 102 and 102R VNS Therapy Pulse Generators, using any version of software on the programming system. This letter addresses the circumstances under which the event can occur, and the steps you should take to avoid its occurrence.

The event can occur if there is an interruption of communication during a programming parameter change sequence. An interruption of communication prompts a pop-up instruction screen requesting the user to "Retry" or "Cancel."



If the retry button is pushed within two seconds of the communication error, the software code sent to the generator can, on rare occasions, cause the generator to be programmed to 8.0 mA.

If the 8.0 mA programming anomaly occurs, placing the magnet over the generator immediately disables the generator. The magnet must stay in place for a minimum of 65 seconds to ensure that the device will begin with an OFF time cycle. After at least 65 seconds have elapsed, remove the magnet and interrogate the generator and reprogram it to the desired settings. After removing the magnet, you must establish programming communication with the generator during the first OFF time cycle. If you do not, an ON time cycle with an 8 mA setting will ensue.

To prevent the 8.0 mA programming anomaly from occurring: if a communication error occurs and the pop-up instruction screen appears, wait at least three seconds and press "Retry" to repeat the programming communication.

The final step for any VNS Therapy programming or diagnostic session should always include an interrogation of the VNS Pulse Generator to ensure the device is set to the appropriate settings.

As mentioned above, you may use a Cyberonics magnet to disable the device by placing it over the VNS Therapy generator. You may request a free patient kit, which includes two magnets, by contacting Cyberonics Clinical Technical Support.

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

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

Sincerely,

Richard L. Rudolph, MD Vice President, Clinical & Medical Affairs and Chief Medical Officer

Name (printed)

Richard L. Rudolph, MD

Please confirm that you have read this letter by signing below and faxing this page to Cyberonics at the number below or by returning the Effectiveness Card included in the envelope.

rvame (primeu)	, Sign	atare Date	
Return Fax to:	281-853-1209	+32-2-720 60 53	
	United States	Europe	

Signatura

Data