



THIS IS AN IMPORTANT NOTICE!
PLEASE REVIEW AND RESPOND – 1st Notice
IMMEDIATE RESPONSE REQUESTED

Model 106 Generators: Device Disablement

Dear Doctor,

You are receiving this notification because one or more of your patients is implanted with a Model 106 AspireSR[®] VNS Therapy[®] generator.

What is the issue?

Due to unintended behavior in the Model 106 AspireSR generator software, the generator can stop delivering stimulation unexpectedly. This event can only occur when a rare combination of circumstances are present, one of which is when the AutoStim Output Current is programmed greater than or equal to the Magnet Output Current. Stimulation can be reinitiated at the next office visit by programming stimulation output current on.

How does this affect my patient?

If this event occurs, the patient may be unable to perceive stimulation following the device disablement, and may also experience a loss of efficacy. If the patient cannot feel stimulation, they should inform the physician immediately so the device can be checked for this condition.

How do I identify this event?

The programming computer will display a message (shown in Figure 1), upon interrogation of the generator following this event.

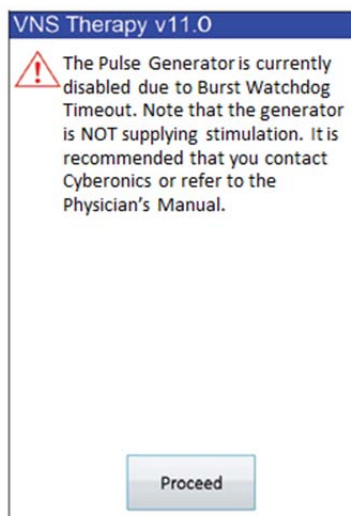


Figure 1 – Error message displayed upon interrogation of M106 Generator after event

What actions should physicians take?

This issue is preventable by following programming recommendations provided in Cyberonics' Physician Training Material (see Figure 2, VNS Therapy Dosing Guidelines). **If a Model 106 generator is programmed with the Magnet Output Current greater than the AutoStim Output Current, this condition will not occur.** No action is needed for those patients already programmed in this manner.

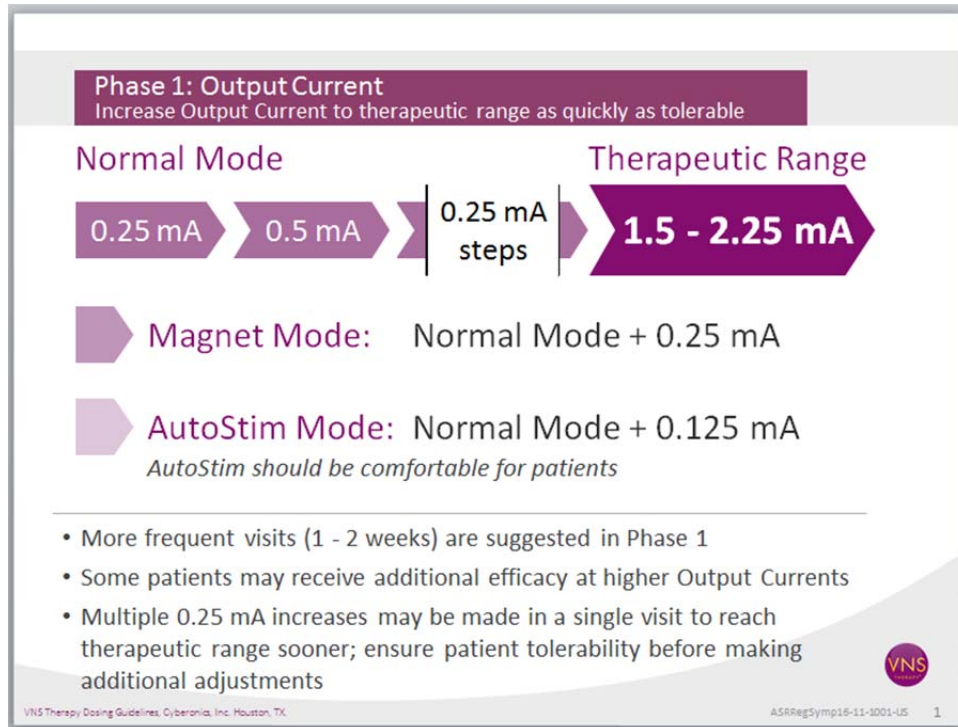


Figure 2 – VNS Therapy Dosing Guidelines

Note: For AspireSR Model 106 generators, programming output current allows 0.125 mA increments up to 2.0 mA and 0.250 mA increments from 2.0-3.5 mA.

If it is identified that a patient's generator has been disabled due to this condition, please contact Clinical Technical Support at 866-882-8804 to report the event. The generator output currents for Normal, Magnet, and AutoStim should be programmed back on (i.e., greater than 0 mA) to resume therapy, following the programming recommendations presented in Figure 2 to prevent recurrence of the issue.

Please complete and return the attached effectiveness card as soon as possible.

By signing and returning the attached Effectiveness Check Form, you acknowledge that you have read and understood this Safety Alert Letter. Returning the Effectiveness Check Form will also prevent repeat notifications of this Safety Alert.



If you need further information, please contact Clinical Technical Support at 866-882-8804 or via email at cservices@livanova.com.

This notification is being made with the knowledge of the US Food and Drug Administration.

We appreciate your assistance in this matter.

Sincerely,

A handwritten signature in black ink that reads "Bryan Olin". The signature is written in a cursive, flowing style.

Bryan Olin, Ph.D.
Vice President, Quality and Regulatory