LivaNova

Health innovation that matters

January 16, 2025

URGENT MEDICAL DEVICE CORRECTION

Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ Generators

Dear Valued Customer:

Purpose of this Letter

The purpose of this letter is to notify you of an issue that has been identified in a small percentage of LivaNova's Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ generators, which are intended for use in the treatment of epilepsy and depression. As of October 7, 2024, ninety-four (94) out of approximately 70,000 generators distributed worldwide have encountered this problem.

Hospitals are receiving this notification because a Model 1000 or Model 1000-D generator affected by the issue below was supplied to your hospital/facility. All distributed SenTiva Model 1000 and Model 1000-D devices are potentially impacted and have serial numbers less than 500,000.

Physicians are receiving this notification because one or more of your patients is implanted with a Model 1000 or Model 1000-D generator. All distributed Model 1000 and Model 1000-D devices are potentially impacted and have serial numbers less than 500,000.

Reason for the Voluntary Safety Notice

LivaNova issued a voluntary medical device Safety Notification to notify hospitals and treating physicians that a small percentage of implanted Model 1000 and Model 1000-D generators may stop delivering therapy due to a component issue.

The reed switch is a component inside the VNS Therapy™ implantable pulse generator that senses changes in magnetic field in order to provide on-demand stimulation (Epilepsy indication only) or to stop stimulation. LivaNova has identified that the generator may stop delivering therapy in a small percentage of Model 1000 and Model 1000-D generators due to an issue with this internal, mechanically activated component. This component may become stuck in a closed position, resulting in a loss of stimulation.

If this event occurs, the generator will stop delivering stimulation (i.e., the generator will not deliver therapy). As a result, patients may no longer be able to perceive any sensation of Normal Mode, Magnet Mode (Epilepsy only) or AutoStim Mode (Epilepsy only)

stimulation. Please refer to the Instructions for Use for further details on the therapy stimulation modes, if needed.

Which Patients are Potentially Impacted?

Any patient who is currently implanted with or may be implanted with a Model 1000 SenTiva™ or Model 1000-D SenTiva Duo™ VNS Therapy™ generator.

How can Physicians Detect this Event

- For all generators, perform an on-demand System Diagnostic test (using the Diagnostics tab in the programming software) at every clinic visit to confirm proper function of the generator. A generator with a reed switch stuck in the closed position will display “Error Code 254 – Test Interrupted” on a Model 3000 programmer when a diagnostic test is attempted using the VNS Therapy Programming System (see Figure 1).

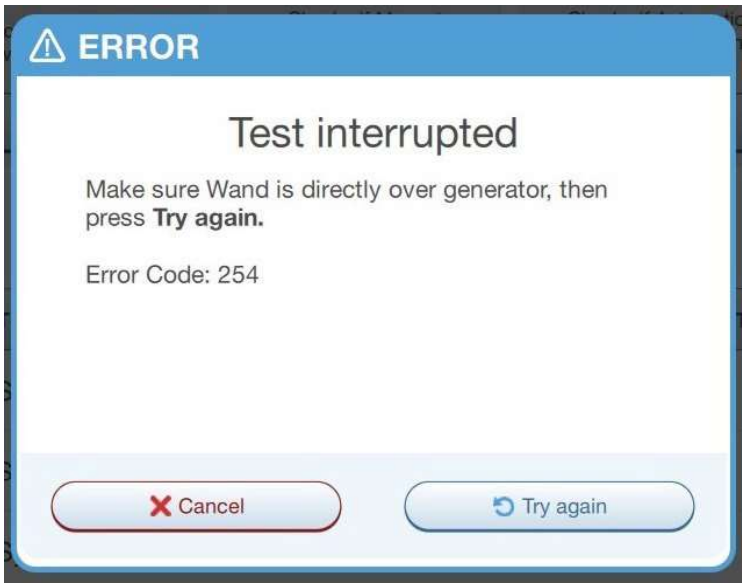

Figure 1: “Error Code 254 – Test Interrupted” message encountered during System Diagnostic Testing

Note: The diagnostic test that is performed as a part of the initial interrogation to enter a session will NOT detect this event.

- A generator with a reed switch stuck in the closed position may also prevent parameter changes from being made with the programming system. The programmer may display “Error Code 254 – Apply Changes Interrupted” (see Figure 2).

Figure 2: "Error Code 254 – Apply Changes Interrupted" message encountered during programming

- An on-demand System Diagnostic test may result in LOW lead impedance for some generators with a reed switch stuck in the closed position (see Figure 3).

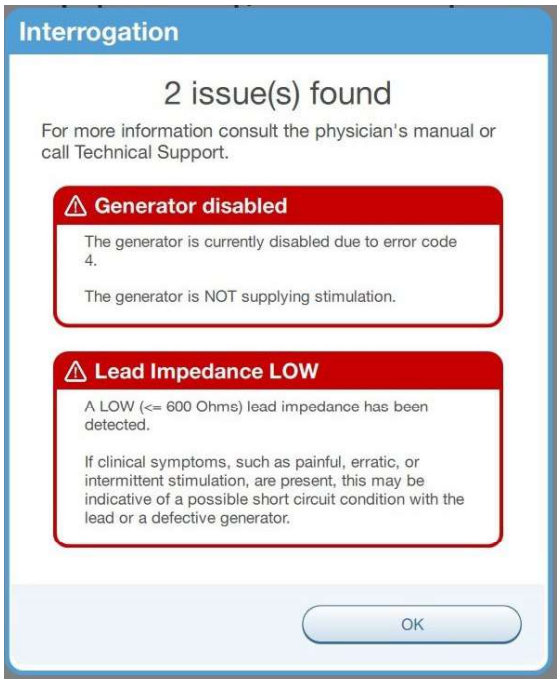

Figure 3: Low lead impedance error message

Risk to Health

If the issue occurs, patients may return to baseline seizure frequency or depressive symptoms as a result of the device no longer delivering stimulation. Such patients may require generator replacement surgery if their device cannot deliver stimulation.

As of October 7, 2024, ninety-four (94) out of approximately 70,000 generators distributed worldwide have encountered this problem, with 34 serious injuries and no deaths reported as a result of loss of therapy due to this issue. The reported serious injuries are associated with increased seizures and other adverse events (e.g., emotional changes and sleep disturbances) occurring due to a loss of therapy. 70 of 94 devices with this issue have been explanted.

What Actions Should Hospitals Take?

1. The current version of the device in your inventory may continue to be implanted, provided the instructions in the physician medical device correction letter are followed. LivaNova is issuing notices to treating physicians that, among other things, recommend testing patients' devices. Hospital Risk Management should ensure that their treating physicians have received and are aware of these notices.

What Actions Should Physicians Take?

Patient Management

1. Monitor the patient for changes in clinical symptoms or if the patient loses perception of stimulation (e.g., the typical cadence for patient visits range from every 3-12 months). Perform an on-demand System Diagnostic test at each visit in accordance with the device labeling. Note that the diagnostic test that is performed as a part of the initial interrogation to enter a session will NOT detect this event. Information and recommendations regarding device checks and monitoring of clinical symptoms can be found in the VNS Therapy Physician's Manual. Access your approved labeling from the LivaNova VNS Therapy website or contact LivaNova for assistance.

2. Contact LivaNova Customer Quality by phone at +1-281-228-7330 or by e-mail at cservices@livanova.com if communication with the generator using the VNS Therapy Programming System indicates that:
    i. Diagnostic tests cannot be performed ("Error Code 254 – Test Interrupted" error message)
    ii. Programming changes cannot be made ("Error Code 254 – Apply Changes Interrupted" error message); or
    iii. System Diagnostic test displays a "LOW" lead impedance result.

3. Encourage patients to do the following:
    i. Notify you if they perceive a change in clinical symptoms (e.g., increase in seizures or depressive symptoms).

ii. Notify you if they no longer perceive any form of stimulation.

LivaNova is updating the VNS Therapy Instructions for Use (IFU) to reflect the patient management recommendations relevant to this issue.

Notification Acknowledgement

Follow the instructions below to acknowledge receipt of this notification:

1. Sign and return the attached Customer Response Form (**Attachment 1**) [insert country specific information].

LivaNova will continue to send communications to you via physical mail, email, and phone until your response has been received.

Communication of this Medical Device Correction

Please ensure that this notice is communicated to all personnel within your organization who need to be aware of it.

This action is being reported to the US Food and Drug Administration (FDA), [insert country specific information], and other applicable regulatory agencies.

Contact Reference Person

For questions regarding the information in this letter, please contact [insert local contact details].

Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova at cservices@livanova.com.

Thank you for your cooperation in this matter. LivaNova is committed to providing quality products and service to its customers, and we apologize for any inconvenience this situation may have caused.

Sincerely,

Casey Haley
Vice President, Quality – Neuromodulation
LivaNova USA, Inc.

Attachment 1 – Customer Response Form

LivaNova
Health innovation that matters

Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™
VNS Therapy™ Generators

January 2025

URGENT MEDICAL DEVICE CORRECTION

Customer Response Form for Reed Switch FSN

Response Required

By signing and returning this Medical Device Correction Customer Response Form, you are acknowledging that you have read and understood the notification that contains important information relating to the potentially affected VNS Therapy™ SenTiva™ and SenTiva Duo™ generators discussed in this letter, and that all staff who are trained to the use of VNS Therapy have also understood the information within this letter.

Please acknowledge receipt of the Medical Device Correction by signing and returning this Customer Response Form [insert country specific information].

If you have any questions about this notification, please contact [insert local contact details].

☐ **HOSPITAL ACKNOWLEDGEMENT (check if applicable)**

☐ **PHYSICIAN ACKNOWLEDGEMENT (check if applicable)**

Recipient Information

Signature	
Print Name / Title	
Facility	
Address	
Telephone	
E-Mail address	
Comments / Additional Information	