LivaNova

Health innovation that matters

January 16, 2025

URGENT MEDICAL DEVICE REMOVAL

Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ Generators – Premature End of Service (PEOS)

Dear Valued Customer:

Purpose of this letter

The purpose of this letter is to notify you of an issue that has been identified with 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 December 2, 2024, twenty-three (23) out of 8,335 generators distributed worldwide have encountered this problem, with 3 serious injuries and no deaths reported due to this issue. The reported serious injuries are associated with increased seizures that may be related to a loss of therapy.

This specific communication is to provide information about the affected devices (**Attachment 1**) that may be in hospital inventory and how to return that product to LivaNova.

Treating Physicians are receiving this notification because one or more of your patients may be implanted with a Model 1000 or Model 1000-D that was produced using an internal component from a particular manufacturing lot (**Attachment 1**), and is therefore potentially impacted.

Reason for the Voluntary Safety Notice

LivaNova issued a voluntary safety notification to hospitals and treating physicians that implanted Model 1000 and Model 1000-D generators may stop delivering therapy due to an internal component issue.

The microcontroller is a component inside the VNS Therapy™ implantable pulse generator that is responsible for controlling the functions of the generator. LivaNova has identified that generators produced using microcontrollers from certain supplier manufacturing lots may experience shorter than expected device longevity. Although the device lifetime may be reduced, generator functions are not affected by this issue and the delivery of therapy is unaffected until the device reaches end of service (EOS). Similarly, the generator battery status indicators (i.e., IFI, NEOS, and EOS) are also unaffected and will accurately reflect the generator's battery status throughout the generator's lifetime.

Risk to Health

The issue presents the following risks:

- Patients may experience a change in clinical symptoms (e.g., increase in seizures or depressive symptoms) as a result of premature battery depletion and loss of therapy.
- Patients will be required to undergo generator replacement surgery to resume therapy.

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Which Devices are Potentially Impacted?

Attachment 1 of this letter contains a list of the devices and serial numbers that may potentially be impacted by this issue and will help identify the patients associated with these serial numbers.

What Actions Should Hospitals Take?

1. The generators included in the **Affected Product List in Attachment 1** are devices that should be removed from inventory, if available.

2. Contact your local Sales Representative or [insert local contact details]to arrange for the return of the affected product, and to order replacement product.

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).

2. Perform system diagnostic testing at each patient office visit to monitor generator battery status. This guidance matches the standard instructions provided in product labeling for a patient follow-up visit. The generator battery status indicators shown on the programming system are accurate (even if the microcontroller issue identified in this letter is present). 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.

3. Counsel patients with devices listed in **Attachment 1** to do the following:

- Notify you if there is a change in perceived clinical symptoms (e.g., increase in seizures or depressive symptoms).
- Notify you if they no longer perceive any form of stimulation.
- Patients with epilepsy who have Magnet Mode enabled should be reminded to use the patient magnet daily to check for the sensation of stimulation to confirm proper generator function, in alignment with recommendations in product labeling for all VNS generator models.

Notification Acknowledgement

Follow the instructions below to acknowledge receipt of this notification:

1. Sign and return the attached Customer Response Form (**Attachment 2**) [insert country specific information].

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

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

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 [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 provide 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 – Affected Product List
Attachment 2 – Customer Response Form

Attachment 1:
Affected Product List

The following is the list of Model 1000 SenTiva™ and/or Model 1000-D SenTiva Duo™ VNS Therapy™ generators potentially affected by this issue specific to your facility / practice.

Model	Device Description	Serial Number
[complete table]	[complete table]	[complete table]

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VNS Therapy™ Generators

January 2025

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Customer Response Form for PEOS 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].

Contact your local Sales Representative or [insert local contact details] to arrange for the return of the affected product, and to order replacement product.

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

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

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

Affected Product Information (for Hospitals Only)

	Quantity in Inventory	Serial Numbers	Date
Model 1000 SenTiva™ Generator			
Model 1000-D SenTiva DUO™ Generator			

Recipient Information

Signature	
Print Name / Title	
Facility	

Address	
Telephone	
E-Mail address	
Comments / Additional Information	