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Health innovation that matters

Urgent Field Safety Notice

Model 1000 SenTiva®
VNS Therapy® Generators
NM-HOU-2018-006

Type of action: advice given by MANUFACTURER regarding the use of the device and/or the follow up of patients

December 6, 2018

Dear Doctor:

Purpose of this Letter

You are receiving this notification because one or more of your patients has been implanted with a Model 1000 generator, a Model 1000 generator was supplied to your hospital/facility, or you have been trained to the product potentially affected by the issue described below.

Reason for the Voluntary Correction

Lead impedance values reported by the Model 1000 generator will be higher compared to those reported by Model 103 - 106 generators. This is due to a change in the timing of when the Model 1000 generator takes the lead impedance measurement during diagnostic testing[1]. As a result, normal impedance ranges for the Model 1000 have shifted relative to the existing thresholds of 600 - 5300 Ohms defined in labeling and as present in the VNS Therapy programming software.

As shown in the following comparison of impedance values recorded at implant, the majority of devices (as represented by the 95th percentile) are expected to remain well below the 5300 ohm 'High' threshold even with the shift toward higher values seen in Model 1000.

	95th percentile values	
	New Implants	**Replacement Implants**
Model 103-Model 106	2487 ohms	3194 ohms
Model 1000	2933 ohms	3922 ohms

As indicated in the Physician's Manual[2], high lead impedance (≥ 5300 Ohms), in the absence of other device-related complications, is not an indication of a lead or generator malfunction. Existing recommendations, as described in the Physician's Manual, should still be followed.

Risk to Health

This will not impact the performance of the device, including the battery longevity and the ability to safely deliver therapy.

The issue presents a risk of unnecessary surgery or unnecessary explant/replacement of implantable product. Surgical interventions where high impedance could not be conclusively identified as being caused by a system malfunction or connector pin insertion issue have occurred in 0.24% of the potentially affected device population.

Which Patients are potentially Impacted?

Any patient implanted with a Model 1000 generator could potentially be affected by this issue. Patients implanted with 2.0 mm electrode leads (i.e. Model 30X-20) have a higher possibility of being affected by this issue than those patients implanted with 3.0 mm electrode leads (i.e. Model 30X-30), as the greater surface area of the 3.0 mm leads generally results in lower overall impedance results.

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1 The impedance is calculated by measuring voltage response to a constant current pulse delivered to the nerve. The actual voltage response monotonically increases over the duration of the pulse, and the Model 1000 performs the measurement later in the pulse compared to other generator models.

2 VNS Therapy System Physician's Manual: http://en.eu.livanova.cyberonics.com/healthcare-professionals/resources/product-training

Actions to be taken by the Physician

1. Patient's management during surgery:

   If high lead impedance (≥ 5300 Ohms) is observed intra-operatively:

   a. Continue to perform troubleshooting steps as described in labeling to assess proper lead pin insertion, proper lead placement on the nerve, proper irrigation of the nerve, and properly functioning generator via generator diagnostics being within normal limits. Detailed information and recommendations regarding the *Implantation Procedure* and troubleshooting can be accessed in the VNS Therapy Physician's Manuals, found in the manuals section: http://en.eu.livanova.cyberonics.com/healthcare-professionals/resources/product-training.

   b. If high lead impedance (≥ 5300 Ohms) is still observed for new implants following all troubleshooting steps being performed as described in labeling in order to sufficiently rule out other causes, consider replacing the M1000 generator or lead with another device. For replacement procedures, compare the last known impedance reading from the prior generator with the M1000 reading if available; differences similar to those shown in the prior table may be observed.

   c. Contact Clinical Technical Support at +1 (281)-228-7330 (Monday to Friday, 8 AM to 5 PM CST) or e-mail at cservices@livanova.com to report the high lead impedance and to obtain a Returns Good Authorization (RGA) number to return the explanted/unused M1000 generator for product analysis.

2. Patient's management during follow-up:

   a. Continue to monitor patients and perform diagnostic testing at each visit. Information and recommendations regarding high and low impedance thresholds can be accessed in the VNS Therapy Physician's Manual, found in the manuals section: http://en.eu.livanova.cyberonics.com/healthcare-professionals/resources/product-training

      If lead impedance is reported at, or above, the high impedance threshold (≥ 5300 Ohms):

      i. **New implant patients**: Perform an anteroposterior (AP) and lateral chest and neck X-ray and mail to Clinical Technical Support for X-ray review to assess proper lead pin insertion.

      ii. **Replacement patients**: Perform an AP and lateral chest and neck X-ray and mail to Clinical Technical Support for X-ray review to assess proper lead pin insertion and for potential lead breaks.

      iii. Contact Clinical Technical Support at +1 (281)-228-7330 (Monday to Friday, 8 AM to 5 PM CST) or e-mail at cservices@livanova.com to report the high lead impedance, and provide X-rays for additional review.

   b. Ensure patients do the following:

      i. (Epilepsy only) Continue using their magnet regularly to verify that stimulation is felt as described by the labeling; and

      ii. Notify their physician if there is a change in perceived clinical symptoms (e.g., increase in seizures/depressive symptoms, painful stimulation, changes in perception of stimulation, etc.)

3. Please complete and return the attached **Customer Response Form** (see **Attachment 1**) by e-mail to LivaNova.FSCA@livanova.com.

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Transmission of this Communication

Please ensure that this notice is communicated to all personnel within your organization who need to be aware of it, and transfer this notice to other organizations on which this action has an impact.

This action is being reported to the Food and Drug Administration and other applicable regulatory agencies.

Contact reference person

For questions regarding the information in this letter, please contact Clinical Technical Support at +1 (281)-228-7330 (Monday to Friday, 8 AM to 5 PM CST) or e-mail at cservices@livanova.com or LivaNova.FSCA@livanova.com.

LivaNova is diligently working to resolve this issue. Patient safety is our top priority, and we remain committed to providing quality products and services to our customers. We apologize for any inconvenience this situation may have caused.

Thank you for your cooperation in this matter.

Sincerely,

Njemile Crawley

Director, Customer Quality, North America

Enclosed: Attachment 1: Customer Response Form

Model 1000 SenTiva® VNS Therapy® Generators
NM-HOU-2018-006

Urgent Field Safety Notice
Acknowledgement and Receipt Form

Response is Required

By signing and returning this Medical Device Correction Acknowledgment and Receipt Form, you are acknowledging that you have read and understood the notification that contains important information relating to the potentially affected VNS Therapy SenTiva Generator discussed in this letter.

To prevent repeat notifications of this notice, please sign form and return by one of the following methods:

- E-mail to LivaNova.FSCA@livanova.com; **or**
- Fax to +1-281-853-1248

If you have any questions about this Field Safety Notice, contact LivaNova at +1 (281)-228-7330 (Monday to Friday, 8 AM to 5 PM CST) or e-mail at cservices@livanova.com or LivaNova.FSCA@livanova.com.

Medical Professional Signature

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Print Name:

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Address:

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E-Mail Address:

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Phone Number:

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