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Urgent Field Safety Notice
Model 105 Aspire HC® and 106 AspireSR®
VNS Therapy® Generators

Date: June 30th, 2017

Reference: NM-HOU-2017-001

Attention: Risk Management, Neurology

Reason: Possibility of shorter than expected longevity on certain Model 105 AspireHC and Model 106 AspireSR generators

Details on affected devices:
You are receiving this notification because one or more of your patients has been implanted with a VNS Therapy® Model 105 AspireHC® or Model 106 AspireSR® generator potentially affected by the issue described here below. **Attachment 1** of this letter contains a list of devices potentially impacted by this issue that may be implanted in one of your patients.

Description of the problem:
The manufacturing process used to assemble the circuit board for certain lots of Model 105 AspireHC and Model 106 AspireSR generators manufactured in 2015 may result in some devices experiencing a shorter than expected longevity. Although the device lifetime may be reduced, its functions are not affected by this issue and the delivery of therapy is unaffected until the device reaches end of service (EOS). Similarly, the device's battery status indicators (i.e., IFI, NEOS, and EOS) are also unaffected and will accurately reflect the device battery status.

The manufacturing issue has been corrected and does not affect devices manufactured after September 2015.

This issue presents the following risks:
- Premature replacement of a generator; or
- The patient returning to baseline seizure frequency or depressive symptoms as a result of the device reaching EOS prior to replacement.

The observed occurrence rate of premature EOS within the potentially affected device population is 1.5% for Model 105 and 3.7% for Model 106.

Advise on action to be taken by the user:
1. Monitor patients frequently and continue to perform diagnostic testing at each visit per labeling to evaluate battery status. Information and recommendations regarding battery status indicators can be accessed in the VNS Therapy Programming Software Physician's Manual, found in the manuals section at http://dynamic.cyberonics.com/manuals/index_iframe.asp;
2. Ensure patients (epilepsy only) continue using their magnet regularly to verify that stimulation is felt as described by the labeling;
3. Ensure patients notify their physician if stimulation feels different or is not felt; and
4. Please complete and return the attached Customer Response Form (see Attachment 2) by fax to +32 2 720 60 53 or by email to AspireFieldAction@livanova.com.

Transmission of this Field Safety Notice:
Please complete and return the attached Customer Response Form (see **Attachment 2**) by fax to +32 2 720 60 53 or by email to AspireFieldAction@livanova.com. Please ensure within your organization that this notice is communicated to all personnel who need to be aware of it.

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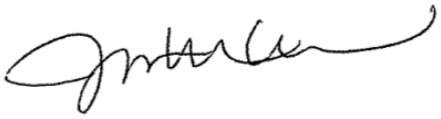
If you believe that any adverse reactions have occurred associated with the use of this product, these issues may be reported to LivaNova at clinicaltechnicalservices@livanova.com.

Contact reference person:
For questions regarding this Field Safety Notice, please contact +32 2 720 95 93 or Noella.Lormans@livanova.com.

This action is being conducted with the knowledge of the competent authority of your country and other applicable regulatory agencies.

Sincerely,



Joan Ceasar
Director, Customer Quality

Enclosed:
Attachment 1: Affected Product List
Attachment 2: Customer Response Form

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Attachment 1: Affected Product List

Affected Product				
Model Number	**Serial Number**	**Patient Initials**	**Year of Birth**	**Implant Date**

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Attachment 2: Customer Response Form

Model 105 Aspire HC® and 106 AspireSR® VNS Therapy® Generators

June 2017

MEDICAL DEVICE CORRECTION RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

By signing and returning this Effectiveness Check Form, you are acknowledging that you have read and understood the notification that contains important information relating to the potentially affected VNS Therapy AspireHC and/or AspireSR Generator discussed in this letter.

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

- **Fax to +32 2 720 60 53; or**
- **Email to** AspireFieldAction@livanova.com.

Medical Professional Signature _____

Print Name: _____

Address: _____

_____

_____

Phone Number: _____