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Field Safety Notice

Model 105AspireHC® and Model 106 AspireSR® VNS Therapy® Generators

Affected Devices:	Specific Model 105 and 106 Generators manufactured by Cyberonics, Inc.[1]
Date:	June 27th, 2017
Reference:	NM-HOU-2017-001
Attention:	LivaNova Distribution Partners
Reason:	LivaNova is issuing a Field Safety Notice associated with specific Model 105 and Model 106 Generators due to the potential for reduced device longevity

Dear LivaNova Distributor:

You are receiving this notification because you have purchased and received VNS Therapy® Model 105 AspireHC® or Model 106 AspireSR® generators potentially affected by the issue described here below.**Attachment 2** of this letter contains a list of devices potentially impacted by this issue that may be implanted implanted in your country.

Description of the problem:
The manufacturing process used to assemble the circuit board for certain Model 105 AspireHC® and Model 106 AspireSR® generators may result in some devices experiencing a faster than expected reduction in device longevity. Although battery life may be reduced, battery function is not affected by this issue and the delivery of therapy is unaffected until the device reaches 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.

If these devices are implanted, the issue presents the following risks:

- Premature replacement of a generator; or
- Failure to replace the generator before the battery depletes, causing the patient to return to baseline seizure frequency or depressive symptoms.

This specific communication is to provide you with information to be sent to physicians who have patients that are implanted with potentially affected devices.

Advise on action to be taken by the distributor:
Please follow the instructions provided on the next page(s) in detail to assure timely and compliant implementation of this Field Safety Notice.

Transmission of this Field Safety Notice:
Please assure that this notice is passed on to all personnel within your organization who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please pass this information on to them and also inform the below mentioned contact person.

Contact reference person:
For questions regarding this Field Safety Notice, please contact LivaNova at AspireFieldAction@livanova.com.

Sincerely,

Ger Kamminga
Director, Commercial Quality
LivaNova, PLC.

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

[1] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including Cyberonics, Inc., the manufacturer of the product addressed in this notice. In this document, we refer to all entities using the brand name LivaNova.

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Action to be taken by the Distributor:

1. **Confirm receipt and understanding** of this Field Safety Notice Update using the Distributor Response Form (Attachment 1).

2. If local regulations so require, **inform your local health authority** by June 29th2017 at the latest, of your intent to initiate this communication. Provide the date on which you informed your health authority using the Distributor Response Form (Attachment 1). In case you have not informed your local health authority about this FSN, indicate "Not Required".

3. **Return the completed Distributor Response Form** toAspireFieldAction@livanova.comby July 2nd2017 at the latest.

4. **Identify any customers** in receipt of the affected products covered by this Field Safety Notice. See Attachment 2, Affected Product List. Document and track the customers **using the Customer Notification Log**.

5. It is your responsibility to contact each of your customers in writing about this Field Safety Notice. If no objections are received from your Health Authority, **initiate the customer communication** by June 30th2017 at the latest.

6. **Use the provided Customer Letter** including its attachments to inform your customers.**Translate** to local language if so required.

7. After all customers have confirmed receipt of this Field Safety Notice by returning the signed Customer Response Form (attachment 2 of the Customer Letter), **complete the Customer Notification Log** and return toAspireFieldAction@livanova.com.

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Attachment 1: Distributor Response Form

DISTRIBUTOR RESPONSE FORM

FIELD SAFETY NOTICE	Model 105 Aspire HC® and 106 AspireSR® VNS Therapy® Generators **NM-HOU-2017-001**

Please return and complete the attached form by e-mail to M106FieldAction@cyberonics.com

Section 1: Confirmation - Please complete		YES	NO
1	We HAVE reviewed and understand the attached FSN	YES ☑	☐
2	We HAVE/WILL complete all required actions	YES ☑	☐

Section 2: Health Authority Communication - Please complete		
1	Date Health Authority was informed	3/7/2017
2	Language in which FSN was translated	ENGLISH

Section 3: Impacted customers - Please complete		
1	Number of final customers to inform	14

Section 4: Distributor Information – please complete	
Country	SAUDI ARABIA
Distributor Name	CIGALAH GROUP
Contact Name	Abdualrazaq Al shebib
Email	a-naif9@hotmail.com
Telephone number	0507666809

Section 4: Please complete and sign	
Submitted by	Abdualrazaq Al shebib
Date	3/7/2017
Signature	[redacted]

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Attachment 2: Affected Product List

Affected Product			
Model Number	**Serial Number**	**Hospital (if known)**	**Patient initials (if known)**
106	39433		**NHA**
106	38073	**KFSH**	**LN**
106	38193	**NGH**	**HA**
106	37947	**KFSH**	**AA**
106	37971	**KFSH**	**SKA**
106	38057		**WQ**
106	38080		**TWK**
106	39267		**HSA**
106	39291		**TYZ**
106	39311		**KFA**
106	39380		**HAZ**
106	38006	**PSMMC**	**AO**
106	38019	**PSMMC**	**AK**
106	38028	**PSMMC**	**HAJ**