

Urgent New Field Safety Notice

Model 500.0100 aura6000[®] Remote Control and Chargers NM-HOU-2019-006

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

February 10, 2020

To Attention of: Vigilance responsible, Health care professionals involved in patient's follow-up

Dear Madam, dear Sir:

Purpose of this Letter

You are receiving this notification because one or more of your patient(s) was supplied with a version of the aura6000[®] Model 500.0100 Remote Control and Charger(s) potentially affected by the issue described below, and/or one or more of these device(s) may remain in your inventory. LivaNova is coordinating a removal and replacement of potentially affected Remote Control and Charger (RCC) device(s) and their accompanying Model 500.0300 Charging Antenna (CA) device(s).¹

Description of the Issue

Certain hardware versions of the Model 500.0100 RCC devices have been identified to potentially lose functionality due to a component failure. This issue may result in an inability of the RCC to charge the implant, and results in the following RCC charging error: "Charging Implant...Low Efficiency."

Risk to Health

The risk associated with the issue described in this Field Safety Notice is interruption in therapy until a replacement RCC is provided. Therapy will resume upon use of the replacement device.

As of January 31, 2020, this issue has been reported in 53 distributed devices; the observed occurrence rate of this issue within the potentially affected device population is currently 2.89%.

Which Device(s) are Potentially Affected?

Any Model 500.0100 RCC device with hardware revision prior to Revision AW (AA to AR) could potentially be affected by this issue. Revisions AW and later revisions are not affected by this issue. (LivaNova is

¹ **Primary Clinical Purpose of Device:** The Model 500.0100 RCC is part of the aura6000TM THN Sleep Therapy System. The device is used in conjunction with Model 100.0100 Implant and Model 500.0300 CA. The RCC is a handheld device for controlling and recharging the implantable programmable generator (IPG). The RCC consists of an enclosure case, electronic circuitry, a rechargeable battery pack with a wall charger, and software. The patient uses the RCC to communicate wirelessly with the IPG: to turn stimulation ON or OFF; to pause stimulation; to adjust therapy; to charge the IPG; or to get IPG information (IPG's battery level, serial number, hardware version and software version). The RCC battery is recharged by connecting to the medical grade wall charger.

The Model 500.0300 CA is also a non-implantable component which is used with the RCC to recharge the IPG battery. The Model 500.0300 CA versions that are used with the potentially affected 500.0100 RCCs as described in this Field Safety Notice are not compatible with newer versions of the RCC.

currently distributing Revision BA.)

Attachment 4 of this letter contains patient(s) anonymous identification, when available, and associated device(s) serial number that may potentially be impacted by this issue.

What Actions Should Health Care Professionals Take?

Please refer to the list of the potentially affected device(s) in **Attachment 4** to confirm the RCC device(s) that is potentially susceptible to this issue and remains in your or your patient(s)' possession:

1. Please complete and return the attached Customer Response Form (**Attachment 4**) by e-mail to LivaNova.FSCA@livanova.com or by fax to (281) 853-1248 to confirm acknowledgement and distribution of the information to all applicable users and to initiate the replacement process of the RCC and CA device(s).
2. LivaNova will contact you to coordinate replacement of the RCC and CA device(s).

NOTE: The Model 500.0300 Charging Antenna (CA) devices are not impacted by this issue; however, the accompanying CAs for the devices listed in **Attachment 4** will also be replaced due to compatibility reasons with the replacement RCCs. The aura6000 system Implantable Pulse Generator and Lead operate as specified and are not affected by this correction.

For patients currently in possession of a potentially affected RCC device as listed in **Attachment 4**, the following recommendations should be applied:

1. Ensure patient awareness of this issue. Notify patient(s) who currently have a potentially affected RCC device of the need to return their current RCC and CA for a replacement RCC and CA.
2. Ensure that patient(s) notifies you if the "Low Efficiency" error message is observed on their RCC. If observed, contact LivaNova Customer Quality at +1-858-259-2980 (Monday to Friday, 8 AM to 5 PM CST), extension 2 for THN Sleep Therapy, or via e-mail at SleepApnea.Support@livanova.com to report the event and for troubleshooting assistance.
3. After receiving the replacement RCC and CA, schedule a follow-up clinic visit for product replacement and to register the RCC with the implant via the aCM software.

What Actions Is the Manufacturer Taking?

1. Notification of the Field Safety Notice via letter to known treating medical professionals of:
 - One or more of your patient(s) was supplied with an aura6000TM Model 500.0100 Remote Control and Charger(s) potentially affected by the Field Safety Notice described in attached documentation;
 - One or more aura6000TM Model 500.0100 Remote Control and Charger(s) potentially affected by the Field Safety Notice may remain in your inventory.
2. Removal and replacement of the potentially affected RCC(s) and accompanying CA(s).

Transmission of this Communication

Please ensure that this notice is communicated to all personnel within your organization who need to be aware and transfer this notice to other organizations on which this action has an impact or where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers, and this action is being reported to other applicable regulatory agencies. Follow-up FSN is not planned for this issue.

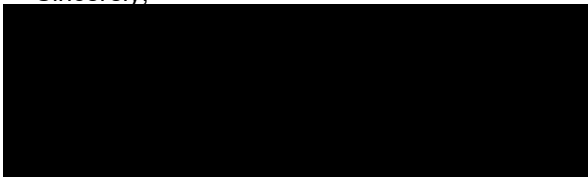
Please report all device-related incidents to LivaNova or your local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Contact reference person

For questions regarding the information in this letter or regarding the device return and replacement, please contact your usual representative or LivaNova Customer Quality via e-mail at SleepApnea.Support@livanova.com or phone at +1-858-259-2980 (Monday to Friday, 8 AM to 5 PM CST), extension 2 for THN Sleep Therapy.

Thank you for your cooperation in this matter. LivaNova is diligently working to resolve this issue. We remain committed to providing quality devices and service to our customers, and we apologize for any inconvenience this situation may have caused.

Sincerely,



LivaNova

Enclosed:

Attachment 4: Potentially Affected Device(s) & Customer Response Form (FSN-006)

CONFIDENTIAL

Attachment 4: Potentially Affected Device(s) & Customer Response Form (FSN-006)

**aura6000® Model 500.0100 Remote Control and Charger(s)
NM-HOU-2019-006 – February 2020**

**Urgent New Field Safety Notice
Customer Response Form - RESPONSE REQUIRED**

Physician / Site: [INSERT NAME]

By signing and returning this Customer Response Form, you are acknowledging that you have read and understood the notification that contains important information relating to the aura6000® Model 500.0100 Remote Control and Charger(s) discussed in this letter.

To prevent repeat notifications of this notice, please complete all pages, sign on the next page, and return the form within 2 weeks from receipt of this notification:

- Via e-mail to LivaNova.FSCA@livanova.com or;
- Via fax to (281) 853-1248.

1. Please refer to **Table 1** below to check the disposition of each potentially affected device supplied to you and/or your patient(s). **Please complete the Table 1 information (Columns 5 and 6) and Contact Information in Question 3 for replacement RCC and CA delivery.**

Table 1: Potentially Affected Device(s)

Patient Anonymous Identification	Potentially Affected RCC Serial Number	Associated CA Serial Number	Associated Implant Serial Number	Do the device(s) remain in the patient's possession? (Yes/No/Unknown)	Comments, As Applicable

2. Please answer the below questions:

- a. I confirm all actions described in the letter have been understood and all patient(s) supplied with a RCC device listed in **Table 1** are aware of this issue (or I plan to notify the patient(s) as soon as possible):

YES NO

b. In case question 2.a. is answered as NO, please share details below:

3. Please fill in all Contact Information below: LivaNova will use this contact to initiate the replacement for the potentially affected RCC(s) and accompanying CA(s) as detailed in **Table 1**.

Provider / Partner Name: _____

Provider / Partner Contact Person: _____

Provider / Partner Full Address: _____

Provider / Partner Phone Number: _____

Provider / Partner E-mail: _____

Other Relevant Information: _____

4. Please sign the form: _____

Responsible Medical Professional's Signature: _____

Print Name of Responsible Medical Professional: _____

Hospital / Clinic Name: _____

City / Country: _____

E-Mail Address: _____

Phone Number: _____

If you have any questions about this Field Safety Notice, please contact LivaNova Customer Quality at +1-858-259-2980 (Monday to Friday, 8 AM to 5 PM CST) or via e-mail at SleepApnea.Support@livanova.com.