

**Urgent New Field Safety Notice**  
**Model 500.0100 aura6000<sup>®</sup> Remote Control and Chargers**  
**FSN / FSCA Reference: NM-HOU-2019-005**

**Type of action:** 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 an aura6000<sup>®</sup> Model 500.0100 Remote Control and Charger(s)<sup>1</sup> potentially affected by the issue described below, and/or one or more of these device(s) may remain in your inventory.

**Description of the Issue**

A premature Elective Replacement Indicator (ERI – see **Figure 1**) may occur using the Model 500.0100 Remote Control and Charger (RCC) devices due to an algorithm error in the RCC firmware. This issue may potentially cause the RCC to inaccurately report to the patient that the implant battery is approaching End of Life (EOL), although the implant battery is not nearing EOL.



**Figure 1.** Elective Replacement Indicator (ERI) symbol

**Risk to Health**

The issue described in this Field Safety Notice (FSN) will not impact the performance of the device, including the battery longevity and the ability to safely deliver therapy.

The issue presents a potential risk of unnecessary surgery if the battery status is not confirmed by the clinician. However, no unnecessary surgical interventions or serious injuries have been reported to date as a result of this issue.

As of January 31, 2020, this issue has been reported in 5 distributed RCCs; the observed occurrence rate of this issue within the potentially affected device population is currently 0.27%.

**Which Device(s) are Potentially Affected?**

Any Model 500.0100 RCC device(s) is potentially susceptible to this issue.

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<sup>1</sup> **Primary Clinical Purpose of Device:** The Remote Control and Charger (RCC), Model 500.100 is part of the aura6000™ THN Sleep Therapy System. The device is used in conjunction with the implantable programmable generator (IPG) Model 100.0100 and Charging Antenna (CA) Model 500.0300. The RCC is a handheld device for controlling and recharging the 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.

### **What Actions Should Health Care Professionals Take?**

The following recommendations should be applied:

1. Ensure patient awareness of this issue. Notify patient(s) who currently have a RCC device.
2. Ensure that patient(s) notify you if the ERI symbol is observed on their RCC.
3. At the patient's clinic visit(s):
  - a. Fully charge the implant battery, as described in the User's Manual (see **Attachment 2 and/or Appendix 1**).
  - b. Use the aura Clinical Manager (aCM) Software to check if the implant is delivering therapy as intended, as described in the Operator's Manual (see **Attachment 3 and/or Appendix 2**).
  - c. Charging the implant battery should take between 30 minutes and 2.5 hours. Discuss with the patient if the charging times have noticeably changed over time.
  - d. The implant will need to be charged at least twice a week and possibly daily depending upon the settings. Discuss with the patient if therapy does not last through the night when starting with a fully charged implant battery.

If the patient does not report noticeable changes in charging frequency or time, and therapy lasts through the night, the appearance of the ERI symbol may be premature.

4. If the RCC displays a suspected premature ERI symbol, contact LivaNova<sup>2</sup> 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](mailto:SleepApnea.Support@livanova.com) to report the event and for troubleshooting assistance.
5. If the RCC displays a suspected accurate display of the ERI symbol, follow the information and recommendations of the User's Manual (see **Attachment 2 and/or Appendix 1**) to plan for your next steps and contact LivaNova Customer Quality (contact information provided above) for assistance.
6. Please complete and return the attached Customer Response Form (**Attachment 1**) by e-mail to [LivaNova.FSCA@livanova.com](mailto:LivaNova.FSCA@livanova.com) or by fax to (281) 853-1248 within 2 weeks from receipt of this notification.

### **What Actions Is the Manufacturer Taking?**

1. Notification of the Field Safety Notice via letter to known treating medical professionals that:
  - Have one or more patient(s) who were supplied with an aura6000TM Model 500.0100 RCC(s) potentially affected by the issue described in this Field Safety Notice; and/or
  - Have one or more aura6000TM Model 500.0100 RCC(s) in their inventory potentially affected by the issue described in this Field Safety Notice.
2. Package Insert is being included in all distributed RCC devices to notify new and replacement customers of this issue.

### **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 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.

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<sup>2</sup> ImThera Medical, Inc. was acquired by LivaNova in 2018, and LivaNova is acting on behalf of ImThera Medical, Inc.

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

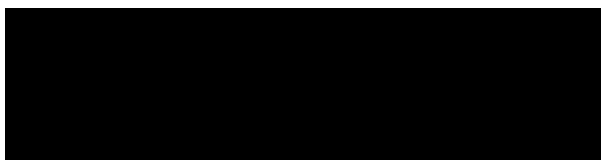
Please report all device-related incidents to LivaNova or your local representative, and the national Competent Authority if appropriate, as this provides important feedback.

**Contact Reference Person**

For questions regarding the information in this letter, please contact your usual representative or LivaNova Customer Quality via e-mail at [SleepApnea.Support@livanova.com](mailto: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:**

**Attachments:**

Attachment 1: Customer Response Form (-005)

Attachment 2: aura6000® THN Sleep Therapy™ System User's Manual [via separate document in e-mail]

Attachment 3: aura6000® Clinical Manager Operator's Manual [via separate document in e-mail]

**Appendices:**

Appendix 1: Excerpts from the aura6000® THN Sleep Therapy™ System User's Manual

Appendix 2: Excerpts from the aura6000® Clinical Manager Operator's Manual

**Attachment 1: Customer Response Form (FSN-005)**

**aura6000® Model 500.0100 Remote Control and Charger(s)  
NM-HOU-2019-005 – February 2020**

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

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 via e-mail to [LivaNova.FSCA@livanova.com](mailto:LivaNova.FSCA@livanova.com) or via fax to (281) 853-1248 within 2 weeks from receipt of this notification.**

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 above table are aware of this issue (or I plan to notify the patient(s)):

☐ YES      ☐ NO

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

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If you have any questions about this Field Safety Notice, please contact your usual representative or 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](mailto:SleepApnea.Support@livanova.com).

Responsible Medical Professional's Signature:

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Print Name of Responsible Medical Professional:

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Hospital / Clinic Name:

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City / Country:

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E-Mail Address:

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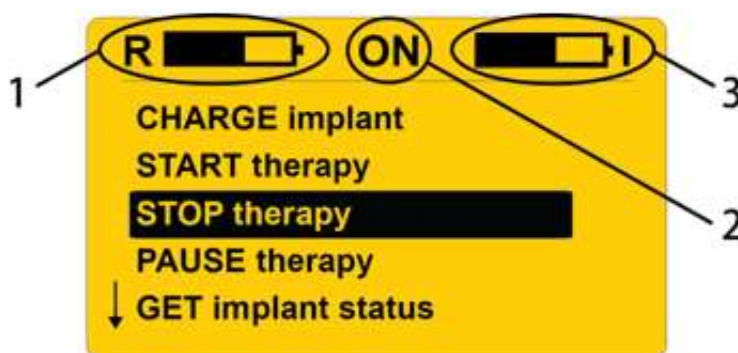
Phone Number:

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**Appendix 1: Excerpts from the aura6000® THN Sleep Therapy™ System User's Manual**

## Understanding the Remote Screen

The remote navigation buttons (UP, DOWN, OK) enable you to control your therapy and manage your system through the remote screen. Below are the screen's main indicators:



**Figure 4**

1. **Remote Control Battery:** The “R” beside this battery icon indicates that it is the remote’s battery. This icon shows your remote’s battery level. A power cord icon will appear to the right of this battery when your remote is being recharged.
2. **Therapy Status:** This shows the current status of your therapy (ON, OFF, or PAUSED).
3. **Implant Battery:** The “I” beside this battery icon indicates it is your implant’s battery. This icon shows your implant’s battery level and flashes when your implant is being charged.

**Note:** If your remote displays only the remote’s battery status (item #1 above) on the top left of the screen and no other information (#2 and #3), it means that the remote does not know your implant’s current status. Select *GET implant status* on the Main Menu to refresh and display this information.



## Charging Your Implant

You will need to charge your implant at least twice a week, and possibly daily depending upon the settings that your doctor has prescribed for you, how old your system is, and how often you use your system.

Charging your implant will take between 30 minutes and 2.5 hours. You can charge your implant without the remote being plugged into a wall outlet if your remote is fully recharged.

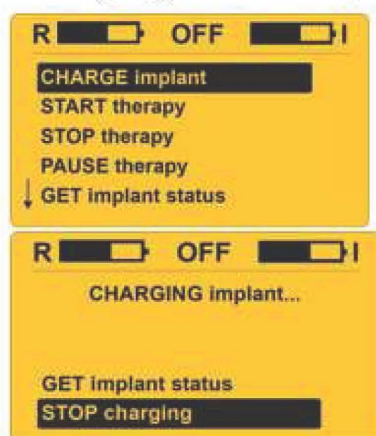
To charge your implant:

1. Connect the antenna to your remote.
2. Orient the antenna so that the ImThera logo is visible as shown in Figure 5, and place the antenna directly on your skin over your implant. The antenna and the implant each have a magnet which is designed to align the antenna with the implant and hold the antenna in place.



**Figure 5**

3. Press any button to turn on your remote.
4. Highlight *CHARGE implant*, and then press OK.



**Figure 6**

5. Continue to charge the implant until the remote beeps, signaling the full replenishment of the implant battery.

TIPS:

- The ImThera logo on the antenna must be facing away from you, or the magnets will not hold the antenna in place.
- Your implant will charge faster if the antenna is placed directly on your skin.
- To inhibit you from charging while sleeping, your remote will not permit you to charge your implant while therapy is on.
- If the antenna is not properly connected to your remote, the message *"Charging not possible. Connect charge antenna"* will be displayed. If this occurs, double check the connection and select *TRY AGAIN*.
- Your implant may not be able to communicate with your remote if your remote is too far away during charging, or if your implant battery is too low. If this happens, your remote will display *"Unable to connect to the implant"* and then continue charging. You will be able to charge the implant, but your implant may not be able to tell your remote when it is fully charged, so charging may appear to take longer.
- If your remote is not sufficiently recharged before attempting to charge the implant, the remote might display the message *"Charging not possible. Insufficient power in remote control."* If this occurs, plug the remote into the wall power cord and try again.
- Checking your implant battery while charging uses implant battery and extends the charging time. Avoid checking the implant battery, except when necessary.


## TROUBLESHOOTING

### Error Messages

Your remote displays messages to communicate minor issues and warnings to you. Contact your doctor if you are unable to solve any problem with your system.

Problem /Message	Reason	What you need to do
Remote display is blank	Button press not detected	<ul style="list-style-type: none"> <li>Press any button</li> </ul>
	No power	<ul style="list-style-type: none"> <li>Recharge your remote.</li> <li>Disconnect and reconnect your remote battery.</li> <li>Replace your remote control battery.</li> </ul>
	Remote needs to be reset	<ul style="list-style-type: none"> <li>Press and hold the "UP" button for 10 seconds, then release it.</li> </ul>
	Display broken	<ul style="list-style-type: none"> <li>Contact your doctor or ImThera to order a replacement device.</li> </ul>
Battery icon does not appear when remote is plugged in.	Power cord not plugged into wall outlet	<ul style="list-style-type: none"> <li>Plug the power cord into the wall outlet.</li> <li>Try a different wall outlet.</li> </ul>
	Power cord not connected to the remote	<ul style="list-style-type: none"> <li>Disconnect and reconnect the power cord to the remote. See <i>Recharging Your Remote</i>.</li> </ul>
"Unable to connect to the implant"	Remote too far from implant	<ul style="list-style-type: none"> <li>Move your remote closer to your implant and try again.</li> </ul>
	Implant battery is low	<ul style="list-style-type: none"> <li>Charge your implant, then try again. Note: Your implant can be charged even when your remote cannot connect to your implant.</li> </ul>
	Wrong remote is being used	<ul style="list-style-type: none"> <li>Use the remote that is registered with your implant.</li> </ul>
	Remote failure	<ul style="list-style-type: none"> <li>Use <i>TEST telemetry</i> to diagnose the problem.</li> <li>If you have tried the other solutions and are still having problems, call your doctor.</li> </ul>



	The ERI has been activated.	<ul style="list-style-type: none"> <li>See the <i>Elective Replacement Indicator</i> section of this document.</li> </ul>
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## Elective Replacement Indicator (ERI)

Over time your implant battery will lose its ability to hold a charge—just like the battery in a mobile phone. As this happens, you will need to charge your implant more frequently. The elective replacement indicator (ERI) symbol shown below will appear on your remote after approximately 11 years of use. When this happens, tell your doctor so that together you can plan for your implant to be surgically replaced. Your implant will reach its functional end of life (EOL) approximately 4 years after the ERI appears, that is, after approximately 15 years of use. The time to ERI and EOL may be longer or shorter than this depending upon how you use and maintain your implant battery.



## Test Stimulation

The test stimulation function allows you to test the stimulation settings that have been programmed for you by delivering one cycle of stimulation at the therapeutic amplitude and duration.

To test stimulation:

1. Scroll to *MORE options* then press the OK button.
2. Scroll to *TEST stimulation* then press the OK button. Stimulation will start in a few seconds, and then automatically stop.

**Appendix 2: Excerpts from the aura6000® Clinical Manager Operator's Manual**

**Common Functions Accessible from Visit Screens**

All visit screens (Surgery, PSG and Follow-Up) have the following common functionalities:


- a. **Home / Exit**—Home takes you back to the Home screen, and Exit takes you out of the application.
- b. **Header**—The header contains the following information about the visit: visit number; current screen type (Surgery, PSG, or Follow-Up); date; IPG serial number; and Patient ID (except on Surgery screen).
- c. **Checklist**—The checklist area (Surgery and Follow-Up screens only) provides a recommendation of the steps that you should take on each screen. As each step is completed, a green check mark will appear to the left of the step. The Checklist function is not utilized on the PSG screen.
- d. **System Status**—The system status area shows: the communication activity between the aCM and RCC, and between the RCC and IPG; the IPG and RCC battery status, and the IPG State (Idle, Sleep, Stim, or Unknown). You should monitor the system status indicators when using the aCM application. The System Status area is located on the right side of the Surgery and Follow-Up screens, and on the upper left side of the PSG screen.

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### Follow-Up Screen

The Follow-Up screen is used for follow-up office visits when the clinician does not intend to do a full titration. This screen offers a subset of the functionality available on the PSG screen.

In addition, the Follow-Up screen provides the ability to demonstrate the stimulation to the patient. Clicking the “Test Stimulation” button enables you to deliver a single cycle of the therapeutic program. This can be helpful in identifying problematic contacts or demonstrating the effects of stimulation for patients or for endoscopic video recording. This is the same stimulation sequence that is delivered when the patient uses their remote to Test Stimulation at home.


IMTHERA™
aura Clinical Manager
Home
Exit

Visit | #00101 | Follow Up | 3/28/2014 | IPG: F1130124001 | Patient: ME1

### Checklist

- Test impedances.
- Demonstrate stimulation.
- Fine tune therapeutic level (µA).
- Set sleep delays and duration.
- Download event log.
- Generate visit report.
- Save and exit.

### 1 - Test Contact Impedances (Ω)

Test Impedances

Test Stimulation

### 2 - Test Stimulation

Test Impedances

Test Stimulation

### 3 - Fine Tune Therapeutic Levels (µA)

Contact Enabled

Therapeutic Level

1000 975 1500 1050 1000 1000

Percentage Update

Select contacts to update

check all

uncheck all

1 2 3 4 5 6

Select percentage

-10% -5% +5% +10%

Update Therapeutics

### 4 - Set Delays and Duration

Startup Delay (m)

40

5 - Download Log

Pulse Delay (m)

15

6 - Generate Report

Sleep Duration (h)

7.00

7 - Save And Exit

Save and Tag

Restore

Advanced Settings

### System Status

IPG Bat.: 70 %

RCC Bat.: 100 %

State: idle

Progress: success

### Message:

Initialize visit command executed successfully!

RCC: 4.35 / IPG: 2.99

Frequency: 3 pps

Cathodic Phase: 200 µs

### Notes

**Figure 5: Follow-Up Screen**