




PATIENT'S GUIDE
***Proximal Hypoglossal Nerve Stimulation
Therapy for Obstructive Sleep Apnea***

March 2026

This Patient's Guide is a supplement to the physician's manuals. It is not intended to substitute for advice from your doctor. For a complete discussion of indications for use, contraindications, warnings, precautions, and potential side effects, talk to your doctor.

 CAUTION: Your doctor is your first source for health-related questions and information. LivaNova cannot provide healthcare advice or services.

Your doctor's phone number: _____

Rx Only

© 2025 LivaNova USA, Inc., a wholly owned subsidiary of LivaNova PLC. All rights reserved. LivaNova and the LivaNova logo are trademarks or registered trademarks of LivaNova PLC in the U.S., other countries, or both. aura6000™ and related brand marks are trademarks or registered trademarks of LivaNova PLC or its consolidated subsidiaries and are protected under applicable intellectual property laws. All other names are trademarks of their respective companies.

All trademarks and trade names are the property of LivaNova or the property of LivaNova's consolidated subsidiaries and are protected under applicable intellectual property laws. Solely for convenience, LivaNova's trademarks and trade names may appear without the ® or TM symbols, but such references are not intended to indicate in any way that LivaNova will not assert, to the fullest extent under applicable law, LivaNova's rights to these trademarks and trade names. Prior permission from LivaNova is required for the use or reproduction of such intellectual property rights. The *Bluetooth*® word mark and logos are registered trademarks owned by BluetoothSIG and any use of such marks by LivaNova is under license.

Table of Contents

1	INTRODUCTION	5
1.1	Introduction to aura6000™ system	5
1.2	Parts of the aura6000™ System	5
1.2.1.	<i>Implantable Parts</i>	5
1.2.2.	<i>Non-Implantable Parts</i>	6
1.3	Cybersecurity and Safe Use	7
2	WHO USES PROXIMAL HYPOGLOSSAL NERVE STIMULATION?	9
2.1	Indication for Use	9
2.2	Contraindications	9
3	WARNINGS AND PRECAUTIONS	11
3.1	Warnings	11
3.2	Precautions	12
3.3	Essential Performance	13
4	HAZARDS	14
4.1	Environmental Hazards	14
4.2	Medical Hazards	14
5	BENEFITS AND RISKS	15
5.1	Benefits Shown in the Clinical Studies	15
5.2	<i>aura6000™</i> Clinical Study Participants	16
5.3	Risks from Clinical Studies	16
5.3.1.	<i>Common Surgical Risks</i>	16
5.3.2.	<i>Risks After the Device is Turned On</i>	16
5.4	OSPREY Study	17
5.4.1.	<i>Adverse Events (Side Effects) from the OSPREY Study</i>	17
5.5	Results from Earlier Studies	20
6	IMPLANT SURGERY	22
6.1	Generator and Lead Placement	22
6.2	Surgery	22
7	POST-IMPLANT GUIDANCE AND PATIENT MATERIALS	23
7.1	Physician’s Instructions	23
7.2	Patient Materials and Resources	23
7.2.1.	<i>Patient’s Guide</i>	23
7.2.2.	<i>Implant Warranty and Registration Form</i>	23
7.2.3.	<i>Patient Implant Card</i>	23
7.2.4.	<i>Emergency Service Resource</i>	24
7.3	After Treatment Begins	24
8	GETTING STARTED	25
8.1	Charge Your Remote	25
8.2	Turn Your Remote ON and OFF	25
8.3	Understanding the Remote Screen	26
8.4	Charge Your Generator	26
8.5	Start a Sleep Session	28

8.6	Pause or Stops Sleep Session	29
8.7	Adjust Therapy	29
8.8	Set Preferences	30
8.9	More Options	31
8.10	Maintain Your Remote	31
8.11	Handling and Cleaning	31
9	TROUBLESHOOTING	32
9.1	Error Messages	32
9.2	Reset Your Remote	35
9.3	Test Stimulation.....	35
10	DEVICE COMPLICATIONS.....	36
10.1	Surgery	36
10.2	Generator Malfunction (Device Not Working Right).....	36
10.3	Manipulation of the Generator and Lead	36
11	PATIENT REGISTRATION AND SAFETY LISTING	37
12	REMOTE CONTROL AND CHARGING ANTENNA SPECIFICATIONS AND GUIDANCE	38
12.1	Remote Control and Charging Antenna Specifications	38
12.2	Electromagnetic Emissions Guidance for Remote Control	38
12.3	FCC Requirements	40
13	GLOSSARY	41

List of Tables

TABLE 1	DEVICE-RELATED SIDE EFFECTS IN THE TREATMENT GROUP UP TO MONTH 7	18
TABLE 2	DEVICE-RELATED SIDE EFFECTS IN THE TREATMENT GROUP BETWEEN MONTH 7 AND MONTH 13	18
TABLE 3	STIMULATION-RELATED SIDE EFFECTS IN THE TREATMENT GROUP UP TO MONTH 7	19
TABLE 4	STIMULATION-RELATED SIDE EFFECTS IN THE TREATMENT GROUP BETWEEN MONTH 7 AND MONTH 13	19
TABLE 5	STIMULATION-RELATED SIDE EFFECTS IN THE CONTROL GROUP BETWEEN MONTH 7 AND MONTH 13	20
TABLE 6	ERROR MESSAGES.....	32
TABLE 6A	Summary of Serious and Non-Serious Adverse Events Through Month 13.....	21
TABLE 7	REMOTE CONTROL AND CHARGING ANTENNA SPECIFICATIONS.....	38
TABLE 8	ELECTROMAGNETIC EMISSIONS	38
TABLE 9	ELECTROMAGNETIC IMMUNITY	39
TABLE 10	ELECTROMAGNETIC IMMUNITY TO PROXIMITY FIELDS FROM RF WIRELESS COMMUNICATIONS EQUIPMENT	39

List of Figures

FIGURE 1	NON-IMPLANTABLE PARTS	6
FIGURE 2	REMOTE CONTROL COMPONENTS.....	7
FIGURE 3	CHARGING ANTENNA COMPONENTS	7
FIGURE 4	IMPLANT LOCATION	22

FIGURE 5	REMOTE CONTROL WITH CHARGER CONNECTED.....	25
FIGURE 6	REMOTE MAIN MENU SCREEN.....	26
FIGURE 7	ANTENNA ORIENTATION	27F
FIGURE 8	UNSAFE CHARGING CONFIGURATION.....	27
FIGURE 9	CHARGING SCREEN	27
FIGURE 10	GENERATOR BATTERY FULLY CHARGED.....	28
FIGURE 11	START THERAPY	29
FIGURE 12	STOP OR PAUSE THERAPY	29
FIGURE 13	ADJUST THERAPY MENU	30

1 Introduction

See the “Glossary” on page 41 for terms and definitions used in this guide.

1.1 Introduction to *aura6000*[™] System

Many people have obstructive sleep apnea (OSA). Healthcare providers typically treat most patients diagnosed with OSA using positive airway pressure (PAP) therapy. If PAP therapy is not feasible, they often opt for surgical treatment options, oral appliances, or other methods. Despite these efforts, some still have untreated OSA.

The *aura6000*[™] system is an implantable system (generator and lead) that sends a mild electrical pulse to the nerve that controls the tongue. This nerve is called the hypoglossal nerve. The treatment is called proximal hypoglossal nerve stimulation, or pHGNS. The *aura6000*[™] system stimulates the movement of muscles in the tongue, helping to keep your upper airway open while you sleep and allowing you to breathe better.


 **Note:** See the “Glossary” on page 41 for terms and definitions used in this guide.

1.2 Parts of the *aura6000* System

1.2.1 Implantable Parts

1.2.1.1 Generator

The main implantable part is the generator, sometimes called an IPG (implantable pulse generator). The generator is computer-controlled and battery-powered. It sends signals to the hypoglossal nerve through a special type of wire called a lead. The generator battery can last approximately 15 years after implant. Depending on how you use and charge the generator battery, the lifespan of the generator battery may be shorter.

 **Note:** When the battery is nearing its end of life, your generator may not stimulate for the full duration of a night of intended sleep. If you feel your therapy is not lasting the full night, it may be time to consider replacing your generator. Contact your doctor to determine when it is time to replace your generator.

The generator has many settings. Your doctor or a specialist will choose the stimulation settings for your generator. Your doctor can change stimulation settings anytime using the programming system. Most of the time, changing these settings is a painless procedure and occurs during or after a scheduled sleep study. You also can adjust the stimulation level (within the range set by your doctor) on your own with your remote control.

1.2.1.2 Lead

The lead connects the generator to the hypoglossal nerve. The end of the lead that wraps around the nerve has six contact areas that deliver the programmed stimulation settings directly to the nerve.

1.2.2 Non-Implantable Parts

1.2.2.1 Programming system

Figure 1. Non-implantable Parts



The programming system (Figure 1) includes a Remote Control (remote) and Charging Antenna (antenna). The remote (Figure 2) is used to control your therapy, and with the antenna (Figure 3) to charge your generator.

The remote and the generator contain rechargeable batteries. The remote is charged by connecting it to a wall power outlet with the remote power cord. You can charge the generator through the skin by connecting the antenna to the remote and placing the antenna over the generator. Both the antenna and the generator contain a magnet to ensure proper alignment. The remote and antenna should last at least 1 year.

Your remote has three buttons (**UP**, **DOWN**, **OK**) and a LCD display used to control your stimulation therapy and show the status of your generator and remote, as shown in Figure 2.


Warning: Do not use the remote if it has been tampered with. The remote battery compartment  is sealed with a tamper-evident sticker. If the sticker is missing or damaged, return the remote to LivaNova or your healthcare provider.

Figure 2. Remote Control Components

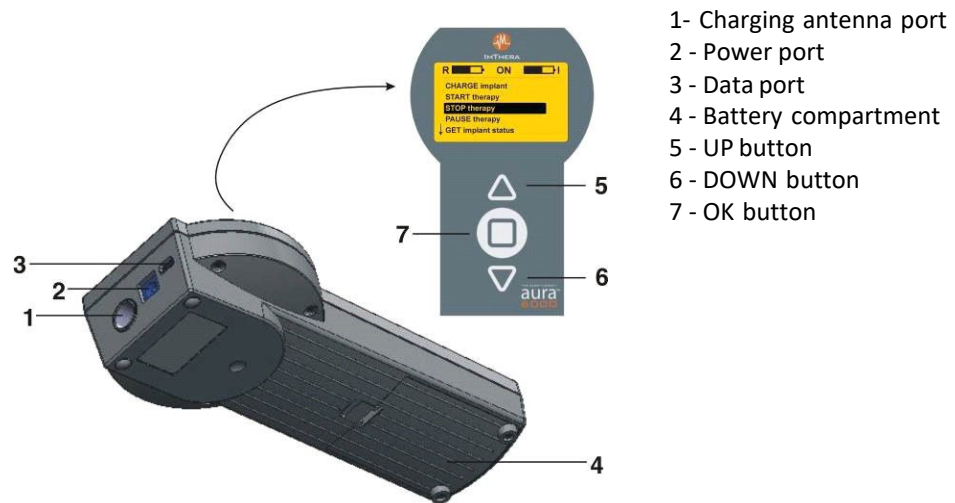


Figure 3. Charging Antenna Components



1.3 Cybersecurity and Safe Use

The aura6000™ system connects wirelessly to your implant and includes security protections. Like any connected device, it can be at risk if not used correctly. You can help protect the system by following these safety instructions:

- Keep your Remote Control and Charger (RCC) secure. Do not let anyone else use it or take it.
- Use only approved accessories. Charge your implant with the cable and parts provided by your clinic. Do not connect the RCC to unknown computers, cables, or devices.
- Do not modify or open the RCC. Do not tamper with screws, install updates, or change the software. Only your clinic or LivaNova staff can perform updates.
- Avoid unauthorized connections. Never plug USB cables or other devices into the RCC.

- Bring your RCC to doctor visits for programming or check-ups.
- Report problems immediately. Contact your doctor or LivaNova Technical Support if:
 - ◆ The RCC is lost or stolen.
 - ◆ It shows strange messages or stops working.
- Pairing is secure. Your RCC is paired to your implant by your healthcare provider in a controlled setting. Do not attempt pairing yourself.

If you have questions or concerns about safe use of the *aura6000™* system, contact your healthcare provider or LivaNova Technical Support.

2 Who Uses Proximal Hypoglossal Nerve Stimulation?

Doctors prescribe proximal hypoglossal nerve stimulation (pHGNS) therapy with the *aura6000™* system for people with OSA; however, it is not right for everyone. You and your doctor will decide if pHGNS therapy is right for you and if you have any other medical conditions that might be affected by it.

2.1 Indication for Use

The *aura6000™* system is indicated for the reduction of apneas, hypopneas, or both in adult patients with moderate to severe obstructive sleep apnea (OSA), defined as an apnea-hypopnea index (AHI) of ≥ 15 and ≤ 65 .



The *aura6000™* system is intended for patients who failed, do not tolerate, or are ineligible to be treated with current standard of care treatments such as positive airway pressure (PAP), oral appliances (e.g., mandibular advancement device), or pharmacotherapy.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

- Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or
- Unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it).

2.2 Contraindications

THN Sleep Therapy with the *aura6000™* system should not be used (is contraindicated) in the following situations or procedures:

- Patients with combined central and mixed apnea-hypopnea index (AHI) greater than or equal to 25% of the total AHI.
- Patients with any functional or structural problem, medical illness or condition that would prevent or interfere with implantation, activation or continued use of the *aura6000™* system.
- Patients with an implantable device which may be susceptible to unintended interaction with the *aura6000™* system. Consult the device manufacturer to assess the possibility of interaction.
- Women who are pregnant, planning to become pregnant or breastfeeding.
- Patients with any condition or procedure that has compromised neurological control of the upper airway.
- Patients who require magnetic resonance imaging (MRI):
 -  The generator and lead are **MR Unsafe** devices. MRI exposure may result in dislodgement of implanted components and heating of the generator, lead, and/or electrodes, which may cause tissue damage, damage to the device electronics, and/or voltage induction through the lead and generator. The *aura6000™* generator and lead must be explanted if an MRI is required.
 -  The remote and antenna are **MR Unsafe** devices. These devices are projectile hazards and must not be brought into the MR scanner room.

- Patients who require diathermy:

Shortwave, microwave, and therapeutic ultrasound (hereafter referred to as diathermy) energy can be transferred through the stimulation system, causing damage to the implant and tissue damage, resulting in severe injury or death. Diathermy can also damage system components, resulting in loss of therapy and requiring additional surgery for explantation and replacement. Advise your patient to inform all their healthcare professionals that they must not be exposed to diathermy treatment. Injury to the patient or damage to the system components can occur during diathermy treatment:

- ◆ Whether the system is on or off
- ◆ Wherever diathermy is used on the body (not just over the system component)
- ◆ Whether diathermy delivers heat or not

3 Warnings and Precautions

As with all types of treatment for OSA, THN Sleep Therapy with the *aura6000™* system carries some risks. Talk to your doctor about the following warnings, precautions, side effects, and hazards. Ask about other risks not covered in this guide that you should know about.

3.1 Warnings

- **Do not modify** — *Do not modify* the remote or antenna. This includes the power cord supplied with your remote.
- **Do not use if tampered with** — *Do not use* the remote if it has been tampered with. The remote battery compartment is sealed with a tamper-evident sticker. If the sticker is missing or damaged, return the remote to LivaNova.
- **Device malfunction** — Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage and other associated problems. Contact your doctor immediately if you experience painful stimulation so they can evaluate the device's performance. Additional surgery may be required if a malfunction occurs.
- **Device manipulation** — Do not manipulate the generator and lead through the skin, as this may damage or disconnect the lead from the generator and/or possibly damage the hypoglossal nerve.
- **Device trauma** — Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted (such as firing shoulder firearms, contact sports, accidental impact) could cause damage to the lead.
- **Elevated pressure conditions** — Do not scuba dive below 15 meters (49 feet) of water or enter a hyperbaric chamber above 150 kPa. Pressures caused by SCUBA diving deeper than 15 meters (49 feet) of water or exposing the system to pressures greater than 150 kPa can damage the generator. Contact your doctor before you scuba dive or use a hyperbaric chamber.
- **Other hospital or medical equipment and procedures** — Always tell your healthcare provider, such as your personal physician, consulting physicians, dentist, or other healthcare provider that you have an implanted medical device before undergoing any medical procedure or exam. The following medical therapies or procedures may interfere with stimulation, cause permanent damage to your generator or lead (particularly if used near your generator or lead), or inadvertently concentrate energy and cause harm: radiation therapy, lithotripsy (high-output ultrasound), magnetic stimulation, TENS, FES, or any other form of electrical stimulation not covered above. No testing has been done to date. The effect of these therapies on the device is not known. Talk with your doctor if you plan to have any of these treatments.
- **Portable RF communications equipment** — Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *aura6000™* system, including cables specified by LivaNova. Otherwise, degradation of the performance of this equipment could result.

3.2 Precautions

- **Patient identification card** — Carry the *aura6000™* patient identification card at all times.
- **Patient remote control** — Always bring your remote to every office visit for therapy adjustments. Your doctor will use your remote to pair with your generator, as it is specifically designated for your device.
- **Uncomfortable or painful sensation** — Report uncomfortable or painful sensations to your doctor immediately.
- **Generator charging** — Your generator battery must be charged regularly (every other day) to prevent it from losing all its charge. A fully depleted battery can permanently damage your generator.



Caution: Do not go more than 2 days without charging your generator battery.

- **Heat due to charging** — Your remote, antenna, or generator may become warm during the charging process. If it feels uncomfortable, stop the charging process until it cools down, or try charging it more frequently and for shorter periods. If the heating persists, contact your doctor.



Caution: Do not charge your generator battery while you sleep.

- **Device failure** — If your system stops working, turn off stimulation therapy and contact your doctor to evaluate your system.
- **Use of the *aura6000™* system while awake** — Do not use the device when you are awake (for example, if you leave it turned on during the day) because you might feel pulling, tingling, or other sensations. While these sensations are normal, the device has not undergone testing for treating OSA while awake.
- **Handling** — Handle your remote and antenna with care, as they are sensitive medical devices. Do not drop them on hard surfaces, expose them to water, or treat them roughly, which may cause permanent damage.




Caution: Keep the remote and antenna in the carrying case when not in use.

- **Temperature** — If your remote or antenna is exposed to temperatures outside the operating range wait 1 hour to start therapy.



Note: The remote and antenna operating conditions are in the “Remote Control and Charging Antenna Specifications” on page 38.

- **Exposure to sunlight** — Do not expose your remote or antenna to direct sunlight. Doing so may degrade the plastic material on your remote or antenna.
- **Post-operative activities** — After implantation (during and after the recommended 4-week recovery period), you should avoid the following:

- ◆ Disturbance of the implant location, the lifting of heavy objects, and extreme head or neck movements, all of which can change the position of the electrode cuff on the nerve
 - ◆ Activities that could damage the generator or lead by mechanical force or direct impact
 - ◆ Placement of the antenna on an unhealed wound/incision
 - **Driving and Operating Equipment** — You should not attempt to use the system while you drive or operate equipment.
 - **Travel** — To avoid damage to the remote and antenna or accidental activation of therapy during travel, disconnect the antenna from the remote, turn off the remote, and store both devices in the carrying case.
-  **Note:** The generator is not expected to trigger airport metal detectors.
- **EAS system and RFID** — The *aura6000™* generator and remote systems are not affected by exposure to Radio Frequency Identification (RFID) or Electronic Article Surveillance (EAS) systems in general public environments. These systems may be used for anti-theft and security in retail stores and libraries and may not be readily visible.
 - **Hospital or Medical Environment** — Always inform all healthcare personnel that you have an implanted medical device before you undergo a medical procedure or exam.
 - **Other components** — LivaNova provides your remote, antenna and accessories (e.g., power adapter, power cord), which are meant solely for use with components supplied by LivaNova. The use of non-*aura6000™* system components may damage LivaNova components, result in loss of therapy, cause patient injury, and void the product warranty.

3.3 Essential Performance

The *aura6000™* system components do not have any essential performance.

4 Hazards

4.1 Environmental Hazards

Being close to certain types of equipment can affect the generator, remote control, and charging antenna. Move away from or avoid equipment such as transmitting antennas.

- **Devices with strong electromagnetic fields** — The *aura6000™* system is tested to show it is immune to the reasonably foreseeable maximum electromagnetic disturbance levels in the general public environment. Electrical or electromechanical devices with a strong electromagnetic field could affect system performance. These fields may be from an object that is not readily visible. Keep this type of equipment away from the *aura6000™* system components, as they can cause a change in stimulation, which you could perceive as tingling or shocking. If you suspect interference with any electrical device, avoid using your system near that electrical device or turn off the equipment.
- **Pacemaker warning signs** — Talk to your doctor before entering places with Pacemaker Warning signs.

4.2 Medical Hazards

Medical equipment, procedures, and surgery using certain electrical instruments can affect the *aura6000™* system's operation and sometimes damage the generator or lead.



Caution: Ensure medical personnel know you have a device implanted in your chest.



Caution: Always call your doctor before you have any medical tests that may affect, or be affected by, the *aura6000™* system as described. Precautions may be needed.

- **Routine diagnostic procedures** — Most routine diagnostic procedures, such as diagnostic ultrasound and radiography (x-rays), should not affect the *aura6000™* system.
- **Mammography** — Because the generator is in your chest, you may need to be specially positioned for a mammogram. Otherwise, the device may be seen as a shadow on the mammogram. It could make a lesion or lump hard or even impossible to detect in that area. Make sure that your doctor and the mammography technician are aware of the implanted device.
- **Radiation treatment** — Treatment with radiation, cobalt machines, and linear accelerators *may damage* the generator. No testing has been done to date. The effect of radiation on the device is not known. Talk with your doctor if you plan to have radiation treatment.
- **Other procedures** — External cardiac defibrillation and other procedures for heart problems, as well as extracorporeal shockwave lithotripsy and electrocautery, *may damage* the generator and temporarily or permanently damage the nerve. If you had any of these procedures and your doctor did not know about them, have the generator checked. While diagnostic ultrasound should not affect the *aura6000™* system, *therapeutic* ultrasound therapy *could damage* the generator or inadvertently harm you.

5 Benefits and Risks

Treating obstructive sleep apnea (OSA) offers well-documented benefits for physical health, mental well-being, and daily functioning. These benefits include reduced snoring, fewer nighttime awakenings, less daytime sleepiness, and a lower risk of motor vehicle and workplace accidents. Proper treatment of OSA can also reduce the risk of serious health conditions such as heart disease, heart failure, insulin sensitivity (type 2 diabetes) and early death.

The *aura6000™* therapy has been shown to help patients manage OSA and reduce the impact of excessive sleepiness on their quality of life. While *aura6000™* therapy has been beneficial for many patients, it may not be effective for everyone. Additional treatments might be necessary to fully manage OSA. If the implanted device needs to be removed, another surgical procedure will be required. As with any surgical procedure, this procedure carries certain risks.

Talk to your doctor if you want more information about treating OSA.

5.1 Benefits Shown in the Clinical Studies

The OSPREY study showed that *aura6000™* therapy helped patients with moderate to severe obstructive sleep apnea (OSA) in several important ways after 6 months of treatment:

- **Better Breathing During Sleep** — The therapy improved how often people stopped breathing during sleep. This was measured by the apnea hypopnea index (AHI), which counts the number of times a person's airway is blocked each hour of sleep.
 - ◆ Treatment was considered successful if AHI dropped by more than half and stayed below 20 events per hour.
 - ◆ In the OSPREY study 58.2% (39 out of 67 patients) in the treatment group achieved treatment success, compared to only 13.5% (5 out of 37 patients) in the control group. With 12 months of treatment in the OSPREY study, this success rate in the treatment group improved to 65%.
- **Improved Blood Oxygen Levels** — The OSPREY study also looked at how well oxygen levels were maintained during sleep, using the oxygen desaturation index (ODI).
 - ◆ 56.7% of treated patients had a greater than half reduction in their oxygen desaturation index (ODI), compared to 16.2% of control patients.
 - ◆ With 12 months of treatment in the OSPREY study, this success rate in the treatment group improved to 63%.
- **Less Daytime Sleepiness and Better Daily Life** — Patients were also asked to complete questionnaires to see how sleepiness affected their lives. These questionnaires included the following:
 - ◆ Epworth Sleep Scale (ESS) – Measures how sleepy you feel during the day, a major symptom that affects daily functioning and increases risks such as impaired driving. A clinically meaningful improvement was observed in 63.6% of treated patients, increasing to 71.4% after 12 months of treatment.
 - ◆ Functional Outcomes of Sleep Questionnaire (FOSQ) – Measures how sleepiness affects your daily activities, productivity, and social life. A clinically meaningful improvement was observed in 36.4% of treated patients, increasing to 54.0% after 12 months of treatment.
 - ◆ Sleep Disturbance Index (SDI) – Measures how often your sleep is interrupted, a factor that contributes to cognitive impairment and poor sleep quality. The early benefit was maintained through 12 months of treatment.

- ◆ Sleep-Related Impairment (SRI) – Measures how sleep problems affect emotions, energy, and social life. The early benefit was maintained through 12 months of treatment.

In the OSPREY study, patients in the treatment group who received *aura6000™* system showed greater improvements in all measured areas compared to patients in the control group. This demonstrates how treatment with the *aura6000™* system helped patients' breathing during sleep, which in turn led to better daily functioning and overall well-being. Additionally, the study examined patients' blood oxygenation, an important factor linked to heart health and other long-term health consequences, which also showed notably greater improvements in patients in the treatment group as compared to patients in the control group.

5.2 *aura6000* Clinical Study Participants

More than 300 men and women took part in four studies to test how safe and helpful *aura6000™* therapy is. Two of the studies compared people who got the therapy to those who didn't. Two smaller studies only included people who received the therapy. All participants had moderate to severe OSA who had failed, could not tolerate, or were unwilling to use positive airway pressure (PAP) treatment. The most recent study of the *aura6000™* system is called OSPREY and is described in detail in this document.

The typical person in the studies was about 55 years old (ages ranged from 27 to 74). On average they had OSA for approximately 7 years before trying *aura6000™* therapy.

If you want to learn more about these research studies, talk to your doctor.

5.3 Risks from Clinical Studies

As with any device that's placed inside the body, the *aura6000™* system has some risks. These include:

5.3.1 Common Surgical Risks

- Infection where the device is placed
- Bleeding
- Pain around the surgery area, including pain in the back of the mouth and the throat area, headaches, neck pain, and ear pain
- Swelling or bruising near the head, chin, or neck
- Difficulty swallowing (dysphagia)

5.3.2 Risks After the Device is Turned On

Once the therapy begins, some people may experience:

- Painful stimulation (medical device pain was the most frequent stimulation-related risk)
- Weakness or trouble moving the tongue, which may impact your speech (speech disorder)
- Tingling, a burning sensation, or discomfort in the tongue and mouth (glossodynia), including tongue paralysis
- Pain around the surgery area, including pain in the back of the mouth and the throat area, headaches, neck pain, ear pain, pain in the mouth or jaw, and tooth pain
- Difficulty swallowing (dysphagia)

- Excessive drooling (salivary hypersecretion)
- Difficulty falling or staying asleep (insomnia)

It is possible that the lead could get dislodged, malfunction, or migrate from its original location. You may also need to have your generator repositioned or replaced. If any of these events happen to your lead or generator, another surgery may be needed (see "Common Surgical Risks" on page 16).

The following section explains the adverse events (or side effects) patients experienced in the most recent clinical study, called OSPREY.

5.4 OSPREY Study

The OSPREY study was a clinical trial that tested how well the *aura6000™* therapy works. People in the study were randomly placed into one of two groups:

Treatment group (67 people): These participants had the *aura6000™* therapy system implanted and turned on 1 month after the surgical procedure to deliver therapy.

Control group (37 people): These participants had the *aura6000™* system implanted, but it was not turned on until 7 months after the surgical procedure.

Both groups were followed for 13 months.

5.4.1 Adverse Events (Side Effects) from the OSPREY Study

5.4.1.1 Surgical Procedure-Related Side Effects

Out of 104 participants in the study, 44 experienced at least one adverse event (also known as side effects) related to the surgical procedure.

Side effects that happened in at least 2% of patients (in other words, 2 out of 100 patients) during the first 7 months are listed in Table 1. You can ask your doctor about the full list of side effects seen in the OSPREY study.

None of these side effects were considered serious. Most (about 90%) happened within the first 30 days after surgery. Around 95% of participants fully recovered from their side effects. The side effects are listed in order of most common to least common.

Table 1. Non-Serious Surgical Procedure-Related Side Effects in at Least 2% of Patients

Non-Serious Surgical Procedure-Related Side Effects In at Least 2% of Patients	
Side Effects	Number of Participants
Implant site pain	10 of 104 participants (9.6%)
Pain in the mouth and throat area (Oropharyngeal pain)	8 of 104 participants (7.7%)
Headache	7 of 104 participants (6.7%)
Trouble swallowing (Dysphagia)	5 of 104 participants (4.8%)
Neck pain	5 of 104 participants (4.8%)
Reduced feeling (Hypoesthesia)	4 of 104 participants (3.8%)

Non-Serious Surgical Procedure-Related Side Effects In at Least 2% of Patients	
Side Effects	Number of Participants
Implant site swelling	4 of 104 participants (3.8%)
Ear pain	3 of 104 participants (2.9%)
Tongue movement disturbance	3 of 104 participants (2.9%)

5.4.1.2 Device-Related Side Effects

From the time of the surgical procedure up to 7 months of study follow-up, 10 participants of 104 (9.6%) reported a side effect related to the *aura6000™* device. This includes 4 participants who had a part of their system revised or removed prior to month 7 (see Section 5.4.1.4). In the treatment group, all device-related side effects through month 7 are listed in Table 2.

Table 2. Device-Related Side Effects in the Treatment Group Up to Month 7

Device-Related Side Effects in the Treatment Group Up to 7 Months	
Side Effects	Number of Participants
Surgical intervention	4 of 67 participants (6.0%)
Headache	2 of 67 participants (3.0%)
Trouble swallowing (Dysphagia)	1 of 67 participants (1.5%)
Inflamed skin (Dermatitis)	1 of 67 participants (1.5%)
Feeling hot	1 of 67 participants (1.5%)
Burning sensation	1 of 67 participants (1.5%)

Additionally, one participant in the control group reported abnormal scarring and tissue fibrosis around the lead cuff prior to their 7-month visit.

After the month 7 visit, eight device-related events occurred among five unique participants randomized to the treatment group. These are listed in Table 3. Including both the treatment and control groups, 8 participants had a part of their system revised or removed between month 7 and month 13 (see Section 5.4.1.4).

Table 3. Device-Related Side Effects in the Treatment Group Between Month 7 and Month 13

Device-Related Side Effects in the Treatment Group Between Month 7 and Month 13	
Side Effects	Number of Participants
Surgical intervention	5 of 67 participants (7.5%)
Medical device discomfort	1 of 67 participants (1.5%)
Obstructive sleep apnea syndrome	1 of 67 participants (1.5%)

About 64% of these adverse events occurred after the device stimulation was turned ON. All participants fully recovered.

5.4.1.3 Stimulation-Related Side Effects

From the time of the surgical procedure up to 7 months of study follow-up, 13 out of 67 participants (19.4%) reported at least one adverse event related to aura6000™ stimulation therapy, with a total of 19 stimulation-related events reported. All of these occurred in the treatment group. The stimulation-related events are listed in Table 4.

Table 4. Stimulation-Related Side Effects in the Treatment Group Up to Month 7

Stimulation-Related Side Effects in the Treatment Group Up to Month 7	
Side Effects	Number of Participants
Tongue pain (glossodynia)	2 of 67 participants (3.0%)
Medical device discomfort	2 of 67 participants (3.0%)
Medical device pain	2 of 67 participants (3.0%)
Neck pain	2 of 67 participants (3.0%)
Speech disorder	2 of 67 participants (3.0%)
Ear pain	1 of 67 participants (1.5%)
Trouble swallowing (Dysphagia)	1 of 67 participants (1.5%)
Drooling (Salivary hypersecretion)	1 of 67 participants (1.5%)
Tongue discomfort	1 of 67 participants (1.5%)
Toothache	1 of 67 participants (1.5%)
Burning sensation	1 of 67 participants (1.5%)
Headache	1 of 67 participants (1.5%)
Tongue-movement disturbance	1 of 67 participants (1.5%)
Dermatitis	1 of 67 participants (1.5%)

Four participants experienced 7 additional stimulation-related events before their 13-month follow-up visit. These are listed in Table 5.

Table 5. Stimulation-Related Side Effects in the Treatment Group Between Month 7 and Month 13

Stimulation-Related Side Effects in the Treatment Group Between Month 7 and Month 13	
Side Effects	Number of Participants
Tongue pain (glossodynia)	1 of 67 participants (1.5%)
Trouble swallowing (Dysphagia)	1 of 67 participants (1.5%)
Oral pain	1 of 67 participants (1.5%)
Medical device discomfort	1 of 67 participants (1.5%)
Jaw pain	1 of 67 participants (1.5%)
Trouble sleeping (Insomnia)	1 of 67 participants (1.5%)
Tongue paralysis	1 of 67 participants (1.5%)

The control group had their therapy turned on after their 7-month follow-up visit. In this group, 7 stimulation-related events were reported before the 13-month follow-up visit. These are shown in Table 6.

Table 6. Stimulation-Related Side Effects in the Control Group Between Month 7 and Month 13

Stimulation-Related Side Effects in the Control Group Between Month 7 and Month 13	
Side Effects Related to Stimulation	Number of Participants with Event
Dry mouth	3 of 37 participants (8.1%)
Drooling (salivary hypersecretion)	1 of 37 participants (2.7%)
Tongue discomfort	1 of 37 participants (2.7%)
Protrusion of the tongue	1 of 37 participants (2.7%)
Obstructive sleep apnea syndrome	1 of 37 participants (2.7%)

None of these adverse events were considered serious.

5.4.1.4 System Revisions Requiring Surgery

In the OSPREY study, a total of 11 participants (10.6%) underwent revision surgery through the month 13 visit. Four (4) participants experienced issues with insufficient charging or feeling the stimulation therapy in the initial 7-month follow-up period, which required surgery to fix.

Additionally, eight (8) participants had a part of their system revised or removed between their 7-month follow-up visit and their 13-month follow-up visit (One of these participants already had revision surgery during the initial 7-month follow-up period).

The number of participants and the reason for removal or revision between month 7 and month 13 are listed below:

- Two of these patients needed to have their generator moved closer to the surface of the skin to allow for better charging of the device.
- Two patients had issues with stimulation which led to a system replacement in one case and a removal in the other case.
- One patient had an underlying neurological condition which impacted their tolerance of the device.
- One patient had their generator moved to resolve pain in their neck under the jaw at the site of the lead attachment.
- Two patients had excessive scarring which led to the system being removed, however one of these patients had a new system implanted when the scarring was resolved.

5.4.1.5 Serious and Non-Serious Adverse Events Summary

Table 6A below summarizes the number of non-serious and serious adverse events through

Table 6A. Summary of Serious and Non-Serious Adverse Events Through Month 13

Adverse Events	Events Not Related to Device or Procedure	Events Related to Device or Procedure
Non-serious	289 events (88 participants, 84.6% of all participants)	106 events (47 participants, 45.2% of all participants)
Serious	6 events (5 participants, 4.8% of all participants)	14 events* (11 participants, 10.6% of all participants)
Note: A subject can have more than one event. *: All 14 events were due to surgical revisions requiring surgery (see Section 5.4.1.4) and originally were not classified as “serious” by the study investigator or the study clinical events committee.		

5.5 Results from Earlier Studies

The three earlier studies also provided data on the risks of the aura6000™ therapy. The risks related to the aura6000™ surgical procedure, device or stimulation therapy seen in these studies were similar to that seen in the OSPREY study through 6 months of therapy.

Similar positive results were also seen in the three earlier clinical studies. One of these studies followed patients for over 60 months (5 years) and found that most patients maintained their positive results.

These earlier clinical studies also collected the Epworth Sleepiness Scale (ESS), the Functional Outcomes of Sleep Questionnaire (FOSQ), and a generic quality of life questionnaire (EQ-5D), which assesses mobility, self-care, usual activities, pain / discomfort, and anxiety / depression. Patients in these studies who received targeted hypoglossal nerve stimulation therapy reported meaningful improvements across all of these surveys.

In one previous study, patients were also asked about their snoring. Patients in the treatment group showed greater improvement than those in the control group.

If you want to learn more about these earlier research studies, talk to your doctor.

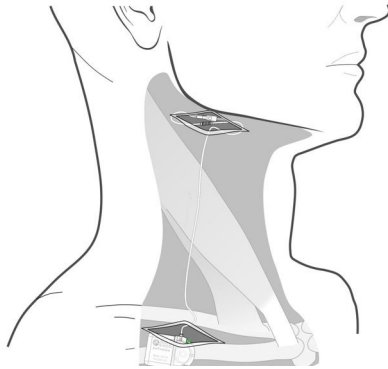
6 Implant Surgery

The *aura6000™* system requires the surgical placement of the generator and lead by a surgeon. At follow-up office visits, your doctor or specialist checks and changes the settings as needed.

6.1 Generator and Lead Placement

The generator is placed under the skin of the upper chest. The lead is typically attached to the right hypoglossal nerve in the neck. It runs under the skin to connect to the generator (see Figure 4).

Figure 4. Implant Location



6.2 Surgery

The implant surgery lasts about 1 hour, and typically involves general anesthesia or sometimes local anesthesia. Most surgeries take place in an outpatient surgery center.

The surgery is minimally invasive. The surgeon makes a small incision on the neck and a second incision below the collarbone in the chest. The lead is passed under the skin between the two incisions. The surgeon attaches the lead to the hypoglossal nerve in the neck and plugs the other end of the lead into the generator, then places the generator in the “pocket” created at the incision site below the collarbone. Finally, the surgeon closes the incisions (see Figure 4). The operation can be reversed if you and your doctor decide to have the *aura6000™* system removed. Removal of the generator and lead requires another surgical procedure.

⚠ Caution: Sometimes, when a surgeon removes an *aura6000™* system, the surgeon leaves a portion of the lead behind to avoid damage to the hypoglossal nerve. This may pose certain risks (see “Medical Hazards” on page 14).

You should exercise caution during the first month after the implant. Do not perform sports, muscular exercises, or lift heavy items for 3-4 weeks after implant. It is best to avoid bending, twisting, and large arm movements for several weeks after the implant procedure, as such movements could impair the healing process. This time period allows the lead and generator to heal more securely in place.

i Note: Recovery from a revision surgery is expected to be similar to the initial implantation. If you undergo a revision surgery, follow the same cautions and guidance as you would after a new implant.

7 **Post-Implant Guidance and Patient Materials**

The generator is usually turned on 4 weeks after the implant surgery. Bring your remote with you to the sleep studies and all other doctor office visits. Your therapy may be adjusted to the proper settings for you during a sleep study. Your doctor or sleep study staff will make sure that it is working well, and that the treatment is comfortable for you. Your doctor or sleep study staff may decide to change your settings periodically as needed.



Caution: It is recommended that you talk with your doctor (in person or by telephone) **every 6 months. Your doctor will check the *aura6000™* system for safe and effective operation.** If stimulation becomes painful, contact your doctor right away.

7.1 **Physician's Instructions**

Your doctor should provide the following guidance after your surgery:

Review the Patient's Guide thoroughly. Read all sections of your patient guide and ask your doctor if you have any questions about warnings, precautions, hazards, or instructions.

Restrict physical activity for 3–4 weeks. Avoid strenuous exercise, sports, and heavy lifting. Also limit bending, twisting, and large arm movements during this time to support proper healing and allow the lead and generator to settle securely in place.

Inform all healthcare providers about your implant. Notify your personal physician, consulting specialists, dentist, or any other healthcare provider about your implanted device before undergoing any medical procedure or diagnostic exam.

Report any unusual or painful stimulation immediately. If you experience painful or irregular stimulation, contact your doctor right away so the device can be evaluated.

Always carry the implant card with you. Keep your implant identification card with you at all times, in case of an emergency or when receiving medical care.

Ensure no metal objects are near the charging antenna while charging. Remove metal objects such as jewelry, body piercings, and other metal materials while charging the device.

7.2 **Patient Materials and Resources**

7.2.1 **Patient's Guide**

Your doctor should give you the Patient's Guide along with your patient magnet. Be sure to read it, and if anything is unclear, ask your doctor to explain it.


7.2.2 **Implant Warranty and Registration Form**

The generator includes an Implant Warranty and Registration Form that a healthcare provider or representative *must* complete and give to you. Space is provided to record generator and lead information. All local privacy laws should be followed when this form is completed. This information is required by some government agencies. Completed forms returned to LivaNova are entered into the registry and used as a permanent record of implant recipient information. All applicable privacy laws are followed to securely maintain this information.

7.2.3 Patient Implant Card

You will receive a Patient Implant Card.

The implant card contains information needed in case of a device related emergency. Your healthcare provider will give it to you after your implant. Complete the card with your device information (if not already included), your name, other identifying information (e.g., patient number), and your treating physician's name and phone number.

 **Caution:** Carry the Patient Implant Card at all times.

7.2.4 Emergency Service Resource

Consider registering with an emergency service such as MedicAlert® Foundation (www.medicalert.org) so information about the *aura6000™* system will be available to hospital and emergency response personnel when needed. If you have questions about the MedicAlert Foundation, discuss it with your doctor.

7.3 After Treatment Begins

Call your doctor right away if any of the following occur:


- Stimulation becomes painful.
- Stimulation causes any choking, trouble with breathing, or trouble with swallowing.
- You notice anything new or unusual that you relate to the stimulation.

 **Note:** See “Device Complications” on page 36.


- Your OSA symptoms increase.

Call your doctor before you have any of the following:


- **Medical tests** that might affect, or be affected by, the *aura6000™* system (e.g., magnetic resonance imaging (MRI) scans).

 **Note:** See “Medical Hazards” on page 14.

- **An MRI scan.** Because you have an *aura6000™* system, you **cannot** have an MRI scan. The *aura6000™* generator and lead must be explanted, if an MRI is required. **Call your doctor before you have an MRI scan.**

 **Note:** See “Contraindications” on page 9.

- **Other medical devices implanted.**

 **Note:** See “Warnings” on page 11.


8 Getting Started

You must charge the battery in your remote before you can use it. See “Charge Your Remote” below for information on how to do this.

8.1 Charge Your Remote

A rechargeable battery powers the remote.

Use the power cord provided to charge the remote before using it for the first time. It can take longer than 60 minutes to charge the remote fully.

 **Caution:** DO NOT plug the power cord into an outlet behind a large object (such as a dresser or desk) to allow quick disconnection from the outlet.

To charge the remote:

1. Connect the power cord as shown in Figure 5.
2. Plug the power cord into a wall outlet.


The battery and power cord icons will appear on the remote to indicate that the remote battery is charging. When the remote is fully charged, the battery icon will appear full.

Figure 5. Remote Control with Charger Connected



8.2 Turn Your Remote ON and OFF

You must turn the remote on before it can control or charge your generator. To turn on the remote, press the **OK** button (center). When the remote is activated, it will display the MAIN MENU.

 **Note:** If you do not press any buttons, the screen will dim after 30 seconds. The remote will power off within 5 minutes of inactivity.

To turn the remote off immediately, scroll down to **POWER OFF** and press the **OK** button.

8.3 Understanding the Remote Screen

The remote buttons (**UP**, **DOWN**, **OK**) allow you to control your therapy and manage your system through the remote screen. Figure 6 provides the remote screen's main indicators:

Figure 6. Remote Main Menu Screen



- i** **Note:** The “R” beside the battery icon means it is the battery in the remote and shows the remote battery level. A power cord icon will appear to the right of the icon when your remote is charging.
- i** **Note:** If your remote displays only the remote battery level (Figure 6) on the top left of the screen and no other information, the remote does not know your generator's current status. Highlight **GET implant status** on the Main Menu to refresh and display generator status.
- i** **Note:** Press and hold the **OK** button to cancel any action, even if there is no on-screen option to cancel.

8.4 Charge Your Generator

You will need to charge your generator every other day and possibly daily, depending on the settings that your doctor has prescribed for you, how old your system is, and how often you use it.

- ⚠** **Caution:** DO NOT charge your generator battery while sleeping.
- ⚠** **Caution:** DO NOT go more than 2 days without charging your generator battery.
- ⚠** **Caution:** DO NOT wear jewelry while you charge your generator battery. Jewelry may interfere with charging.


Your generator will take between 30 minutes and 1.5 hours to charge. If your remote is charged, you can charge your generator without plugging the remote into a wall outlet.

- i** **Note:** Charging will not start or restart if the internal temperature of the charging antenna is above 30°C (86°F). Allow the antenna to cool down before you try to charge your generator.

To charge your generator:

1. Connect the antenna to your remote.
2. Clip the antenna amplifier to your shirt. Turn the antenna coil so the ImThera logo is visible,

and place it over your generator (Figure 7). The antenna coil and generator have magnets designed to align the antenna coil with the generator and hold it in place.

 **Caution:** DO NOT place the antenna amplifier over the antenna coil to charge your generator (Figure 8). Doing so may cause the antenna or generator to heat.


 **Caution:** Leaning forward or excessive movement may dislodge the antenna coil while charging. Choose an activity that limits motion while you charge your generator, but *do not fall asleep*.

Figure 7. Antenna Orientation

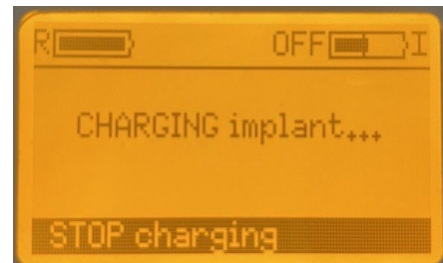


Figure 8. Unsafe Charging Configuration



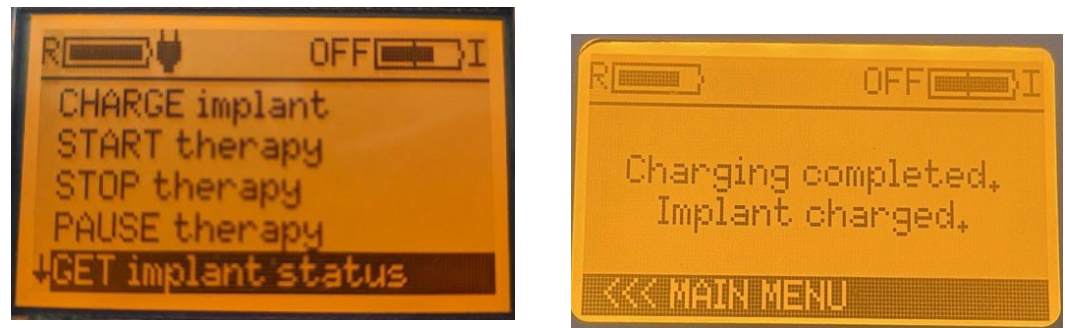
3. Press the **OK** button to turn on your remote.
4. Highlight **CHARGE implant**, and then press **OK** (Figure 9).

Figure 9. Charging Screen



5. Continue to charge the generator until it is fully charged. The generator battery icon on the remote will be completely black when charging is complete (Figure 10).

Figure 10. Generator Battery Fully Charged



TIPS:

- The ImThera logo on the antenna must face away from you, or the magnets will not hold it in place.
- To inhibit you from charging while sleeping, your remote will not permit you to charge your generator while therapy is on.
- Vertical bar on generator battery icon (Figure 10) indicates the minimum generator battery level to start therapy.
- If the antenna is not properly connected to your remote, the message “*Charging not possible. Connect charge antenna*” will display. If this occurs, double-check the connection and select **TRY AGAIN**.
- If your remote is not sufficiently charged before you try to charge the generator, 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.
- Avoid checking the generator battery, except when necessary. Checking your generator battery while charging uses your generator battery and extends the charging time.

8.5 Start a Sleep Session

When you plan to sleep, you will use your remote to tell your generator to start a sleep session.

To start a sleep session:

1. Press the **OK** button to turn on your remote.
2. When the Main Menu appears (Figure 11), highlight **START therapy**, then press the **OK** button. Keep the remote within 1.5m (3.3 feet) of the generator until the word “ON” or “PENDING” appears next to the generator battery icon.
3. After a set *Start delay* to give you time to fall asleep, your generator starts stimulation. You can adjust this *Start delay* to meet your needs.

Figure 11. Start Therapy



8.6 Pause or Stops Sleep Session

You will use the remote to pause or stop stimulation when you wake up.

- Pause stimulation- you need to get up briefly (e.g., to use the bathroom, speak on the phone) and plan to return to sleep; or
- Stop stimulation - you plan to stop sleeping

To pause or stop a sleep session:

1. Press the **OK** button to turn on your remote.
2. When the screen in Figure 12 appears, highlight **STOP therapy** or **PAUSE therapy**, and then press the **OK** button.

Figure 12. Stop or Pause Therapy



3. Keep the remote within 1.5m (3.3 feet) of the generator until the word “PAUSED” or “OFF” appears next to the generator battery icon.
4. For Pause only, if Auto-resume is enabled, stimulation will automatically resume after the Pause delay elapses.

If Auto-resume is not enabled, highlight **START therapy** and press the **OK** button when ready to go back to sleep. Your generator will start stimulation after the Pause delay elapses.

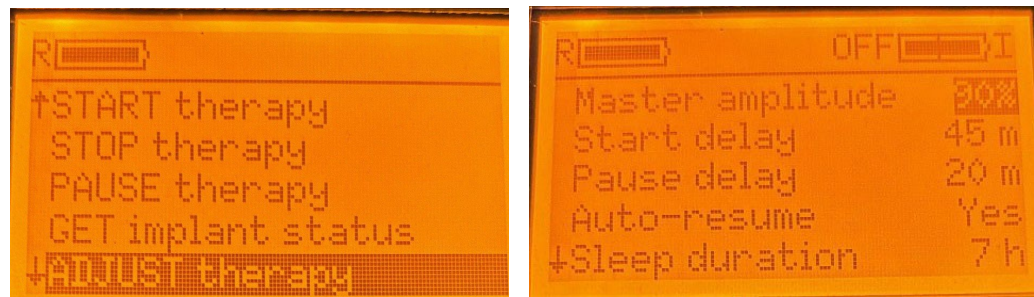
You can set the Pause delay to meet your needs.

8.7 Adjust Therapy

You can use this menu to adjust some of your therapy settings to make it more comfortable or convenient for you.

To access these settings, highlight **ADJUST therapy** and press the **OK** button. See Figure 13.

Figure 13. Adjust Therapy Menu



To change a setting, complete the steps below:

1. Highlight the setting you want to change and press **OK**.
2. Use the **UP/DOWN** buttons to change the setting value.
3. Press **OK** to change the setting.
 - **Master amplitude** — This setting allows you to adjust your therapy's amplitude (strength) within limits prescribed by your doctor.
 - **Start delay** — This setting allows you to adjust how long the generator will wait after you select **START therapy** before stimulation starts. For example, if falling asleep typically takes 45 minutes, you should set the Start delay to 45 minutes.
 - **Pause delay** — This setting allows you to adjust how long the generator will wait after you select **PAUSE therapy** before stimulation starts again. For example, if it typically takes 15 minutes to fall asleep after you get up to use the bathroom, then you should set the Pause delay to 20 minutes.
 - **Auto-resume** — This setting allows the Pause delay countdown to begin automatically after you select **PAUSE therapy**.
 - ⓘ **Note:** When you set Auto-resume to NO, you must select **START therapy** to resume therapy.
 - **Sleep duration** — This setting allows you to adjust how long therapy will stay on before it stops automatically. For example, if you typically sleep for 8 hours, set the Sleep duration to 8 hours.


8.8 Set Preferences

This menu allows you to adjust the backlight setting, brightness, and language displayed on your remote. To access these settings, highlight **SET preferences** and then press **OK**.

To change any of these settings below:

1. Highlight the line of the setting that you want to change and press **OK**.
2. Use the **UP/DOWN** buttons to change the setting value.
3. Press **OK** to change the setting
 - **Backlight** — The backlight has three settings that determine how long the backlight will stay on after each button press:

- ◆ Off - the backlight is not used.
- ◆ Eco - the backlight turns on for 30 seconds after each key press.

 **Note:** If you do not press any buttons, the screen will dim after 30 seconds. The remote will power off within 5 minutes of inactivity.

- ◆ On - the backlight turns on whenever the screen is on.
- **Brightness** — This setting allows you to choose the screen brightness (Low, Medium, or High) of the backlight on the remote screen.
- **Language**—This setting allows you to choose the language displayed on the remote screen.

8.9 More Options

For device information or to test stimulation, highlight **MORE options** and then press **OK**.

- **TEST stimulation** — See “Test Stimulation” on page 35. for information on this feature
- **GET remote info** — Select this option to check your remote battery level, serial number, hardware version, and software version.
- **GET implant info** — Select this option to check your generator battery level, serial number, hardware version, and software version.

8.10 Maintain Your Remote

The remote has a rechargeable battery. If the battery stops charging, contact Technical Support to return your remote to LivaNova for examination and safe disposal or to request a replacement.

8.11 Handling and Cleaning

Your remote and antenna are sensitive medical equipment. Use care when handling your remote and antenna. Careless handling (e.g., dropping on hard surfaces, submerging in water) may cause permanent damage and will void the product warranty.



Caution: Keep the remote and antenna in the carrying case when not in use.



Note: Storage and operating conditions for the remote and antenna can be found in the “Remote Control and Charging Antenna Specifications” on page 38.

You may clean your remote and antenna using a damp cloth and mild detergent. Do not submerge or use abrasive cleaners.



Note: The remote and antenna are rated as IP22. They are protected from touch by fingers or similar objects and moderate amounts of dripping water. Keep your remote and antenna dry because additional exposure to water or other liquids could cause performance loss.

9 Troubleshooting

9.1 Error Messages

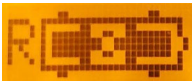
Your remote displays messages to inform you of minor issues and warnings to you. Contact your doctor if you cannot solve any problems with your system.

Table 7. Error Messages

Problem /Message	Reason	What you need to do
The remote display is blank.	The OK button press was not detected.	<ul style="list-style-type: none"> Press the OK button.
	No power.	<ul style="list-style-type: none"> Charge your remote. If the issue continues, contact your doctor.
	Your remote needs to be reset.	<ul style="list-style-type: none"> Press and hold the OK button for at least 6 seconds and release. This action turns the remote power OFF. Press and release the OK button to power ON the remote.
	The display is broken.	<ul style="list-style-type: none"> Contact your doctor.
When plugged in, the remote does not display the battery icon.	The power cord is not plugged into a wall outlet.	<ul style="list-style-type: none"> Plug the power cord into a wall outlet. Try a different wall outlet.
	The power cord is not connected to your remote.	<ul style="list-style-type: none"> Disconnect and reconnect the power cord to your remote. See “Charge Your Remote” on page 25.
<i>“Unable to connect to the implant”</i>	Your remote is too far from your generator.	<ul style="list-style-type: none"> Move your remote closer to your generator and try again.
	Your generator battery is low.	<ul style="list-style-type: none"> Charge your generator and try again. Note: It may take up to 1.5 hours to charge your generator completely. Note: You can charge your generator even when your remote cannot connect to your generator.
	Your remote is not paired with your generator.	<ul style="list-style-type: none"> Move your remote closer to your generator, move away from other electronic devices, and try again. Select GET implant status on your remote Main Menu to refresh. Turn your remote OFF and ON. If you tried these solutions but cannot connect to your generator, contact your doctor.
	There is interference from other electronic devices in the area.	<ul style="list-style-type: none"> Move away from other electronic devices.
	Remote failure.	<ul style="list-style-type: none"> If you have tried the other solutions and the issue continues, contact your doctor.
<i>“Therapy is ON Charging not possible”</i>	You cannot charge your generator when therapy is ON.	<ul style="list-style-type: none"> Finish your therapy session, and then charge your generator.

Problem /Message	Reason	What you need to do
<i>“Charging not possible. Connect charge antenna”</i>	The charging antenna is not connected to your remote.	<ul style="list-style-type: none"> • Disconnect and reconnect the charging antenna to your remote and retry the charging process. • If the issue continues, contact your doctor.
	The charging antenna may not be aligned with the generator.	<ul style="list-style-type: none"> • Properly align the charging antenna with your generator and minimize misalignment or disruption during charging. • If the issue continues, contact your doctor.
	The charging antenna may not be plugged in correctly.	<ul style="list-style-type: none"> • Remove the charging antenna and verify the orientation of the connector. • Ensure the charging antenna is fully plugged in.
	Charging antenna failure.	<ul style="list-style-type: none"> • Contact your doctor.
<i>“Charging not possible. Insufficient power in remote control”</i>	Your remote battery is too low to charge your generator.	<ul style="list-style-type: none"> • Plug your remote into a wall outlet. • Note: You can charge your generator while your remote is charging.
<i>“Charging not possible. High charging current”</i>	A metal object is too close to the charging antenna.	<ul style="list-style-type: none"> • Ensure no metal objects are near the charging antenna and try to charge again. • If the issue continues, contact your doctor.
	Charging system failure.	<ul style="list-style-type: none"> • Contact your doctor for a replacement.
<i>“Maximum temperature exceeded. Please wait...”</i>	The charging antenna has reached the temperature limit.	<ul style="list-style-type: none"> • Your remote monitors the temperature. You can begin to charge after the antenna cools down. • Consider moving to a cooler location. • Ensure the charging antenna is not covered with material such as a blanket.
The charging antenna’s LED light is flashing and the generator is charging slowly.	The charging antenna has reached the temperature limit.	<ul style="list-style-type: none"> • Allow the charging antenna to cool down. • Consider moving to a cooler location. • Ensure the charging antenna is not covered with material such as a blanket.
<i>“Low efficiency. See manual”</i>	The generator charging session was unsuccessful due to misalignment of the charging antenna with the generator or other interference.	<ul style="list-style-type: none"> • Reposition the charging antenna over your generator. • You may be wearing something metal (such as jewelry) or thick clothing that interferes with charging. Remove jewelry and thick clothing and try to charge again. • Note: Do not wear jewelry near the charging system • If the issue continues, contact your doctor.
The generator charges slowly	Charging system failure.	<ul style="list-style-type: none"> • Reposition the charging antenna over the generator and ensure proper alignment. • Remove unnecessary material from between the charging antenna and the generator. • Charge your generator in a cooler environment. • If the issue continues, contact your doctor.
<i>“Telemetry error. Retry or see manual”</i>	There is no communication between your remote and your generator.	<ul style="list-style-type: none"> • Properly align the charging antenna over the generator. • Move away from other electronic devices. • Remove obstructions from between your remote and the generator. • Ensure a clear line of sight from your remote to your generator implant site. For example, ensure there are no books, laptops, pets, or parts of your body between your remote and implant site. • If the issue continues, contact your doctor.

Problem /Message	Reason	What you need to do
You cannot charge the generator, even with the remote plugged into a wall outlet.	The charging antenna and/or remote may not be plugged in properly.	<ul style="list-style-type: none"> • Check the connections between the charging antenna and your remote. • Align the charging antenna on your generator. • Plug your remote completely into the wall outlet. • Charge your generator and check what issue occurs.
<i>“Charging not possible. Maximum time exceeded”</i>	The maximum time allowed for a charge session has been reached.	<ul style="list-style-type: none"> • Allow the charging antenna to cool, then restart charging. • Continue to charge until the desired charge is reached.
<i>“Battery Low. Charge implant, then try again”</i>	Your generator battery is low.	<ul style="list-style-type: none"> • Charge your generator. • Ensure you charge your generator at least every other day.
It takes longer than usual to charge the remote.	Your remote may need to be replaced.	<ul style="list-style-type: none"> • Contact your doctor.
The remote screen is not readable.	Your remote screen brightness is too low.	<ul style="list-style-type: none"> • Go to settings and set the brightness to high. • If the issue continues, contact your doctor.
Stimulation cannot be felt.	Therapy is ON, but the amplitude is too low to be felt.	<ul style="list-style-type: none"> • Use Get implant status on the MAIN MENU to confirm that the generator is ON, but you feel nothing. • If you are satisfied with your therapy, then do nothing. • If you are unsatisfied with your therapy, use Master Amplitude to increase the amplitude of your therapy, or contact your doctor to adjust your therapy.
	Therapy is OFF—Your sleep duration setting is shorter than the time you slept.	<ul style="list-style-type: none"> • If you want to feel therapy when you wake up, increase the Sleep duration. See <i>“Adjust Therapy” on page 29</i>).
	Therapy is OFF—Your generator ran out of battery during the sleep session.	<ul style="list-style-type: none"> • You can use GET implant info to check the generator battery. If Implant Batt is less than 3.44 V, charge your generator more fully and more often.
	Therapy is OFF—There is a system failure.	<ul style="list-style-type: none"> • Contact your doctor.
<i>“Master Amplitude Control adjustment not possible.”</i>	Your doctor did not program Master Amplitude Control settings.	<ul style="list-style-type: none"> • Contact your doctor.
<i>“Testing not possible”</i>	Therapy is ON.	<ul style="list-style-type: none"> • Turn OFF therapy and try testing again. • If the issue continues, contact your doctor.
<i>“Remote Disabled. Service Required. See Manual.”</i>	There might be a hardware or firmware issue.	<ul style="list-style-type: none"> • Continue your previous action and use the device as usual.
<i>“Implant Disabled. Service Required. See Manual.”</i>		<ul style="list-style-type: none"> • If the error continues, then reset your remote. To do this, press and hold the OK button for at least 6 seconds and release it to power OFF the remote, then press and release the OK button again to power ON the remote. • If the issue continues, contact your doctor.

Problem /Message	Reason	What you need to do
<p>The remote header shows the following icon (flashing or solid)</p> 	<p>The remote's battery is not present or may have an issue.</p>	<ul style="list-style-type: none"> • Disconnect the remote power cord from the wall outlet and reconnect it, then allow it to charge for a few minutes. • If the icon does not go away, contact your doctor.

9.2 Reset Your Remote

Very rarely, it may be necessary to reset your remote. To do so, press the **OK** button for at least 6 seconds and then release the button. The Main Menu should appear.

9.3 Test Stimulation

The test stimulation function allows you to test the stimulation settings your generator is programmed to by delivering 1 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.

10 Device Complications

Complications linked to the *aura6000™* system can result from:


- Surgery
- System malfunction (not working)
- Battery depletion (running out)
- Touching or moving the device through the skin

10.1 Surgery

All types of surgery carry some risks. Some risks are related to the surgery itself, such as being exposed to effects of anesthesia. Other risks are related to the implanted device. There are potential mechanical complications related to the surgical implantation or revision of the device. The generator and/or lead can, but rarely do, move or come through the skin. Also, the lead can break or become disconnected from the generator. Ask your doctor if you have any concerns about surgical risks.


10.2 Generator Malfunction (Device Not Working Right)

Though rare, a generator can malfunction. The stimulation from a generator that is not working right can cause **pain at the generator site, intense neck pain, choking, or trouble breathing.**

 **Caution:** Stimulation from a generator that is not working right could damage the **hypoglossal nerve** and lead to tongue weakness (paresis) or other complications. A generator malfunction could cause the battery to run out sooner than expected. **Call your doctor immediately if you have any of these symptoms** or if stimulation becomes painful, irregular, or nonstop.

10.3 Manipulation of the Generator and Lead

The generator is secured into place during surgery, but the device can move slightly. After surgery, it may be possible to feel the lead under your skin. This feeling is normal and should become less obvious over several weeks. You should never manipulate the lead.

 **Caution:** Never move or twist the generator or manipulate the lead. Doing so could damage the lead or your hypoglossal nerve and require the replacement of the generator and lead.

11 Patient Registration and Safety Listing

Government agencies require implantable device makers to contact people in case of emergencies related to the device. LivaNova has a list of people who have had the generator and lead implanted. The information is kept in confidential files and is a permanent record of the implantation surgery. LivaNova will release a file only if required by law.



Caution: If you move, send LivaNova **a change of address notice** (see “CONTACTS AND RESOURCES” on page 43).

12 Remote Control and Charging Antenna Specifications and Guidance

12.1 Remote Control and Charging Antenna Specifications

Table 8 provides a list of Remote Control and Charging Antenna specifications.

Table 8. Remote Control and Charging Antenna Specifications

	Remote Control	Charging Antenna
Storage Conditions		
Temperature	-10°C to +55°C (+14°F to +131°F)	-10°C to +55°C (+14°F to +131°F)
Relative Humidity	0 to 95% (non-condensing)	0 to 95% (non-condensing)
Operating Conditions		
Temperature	+5 °C to +30 °C (+41°F to +86°F)	+5 °C to +30 °C (+41°F to +86°F)
Relative Humidity	15% to 80% (non-condensing)	15% to 80% (non-condensing)
Power Source	Internally powered: 1 Lithium Ion Battery	Powered by remote
Radio Type Frequency	MedRadio Band, 401-406MHz	n/a
Power Input	15W (7.5V @ 2A)	n/a
Communication Distance	1.5m from remote to generator	n/a
Charging Frequency	n/a	13.56 MHz
Charging Distance	n/a	5-10mm from charging antenna coil to generator
RF Receiver Bandwidth	300MHz to 464MHz	n/a
RF Transmitter ERP	20 uW Max	n/a
Modulation	GFSK	n/a
Applied Part	Entire device is Type BF	Entire device is Type BF

12.2 Electromagnetic Emissions Guidance for Remote Control

The Remote Control is intended to be used in the electromagnetic conditions specified in Table 9, Table 10 and Table 11.

Table 9. Electromagnetic Emissions

Emissions Test	Compliance Level
RF Emissions CISPR 11	Group 1, Class B

Table 10. Electromagnetic Immunity

Immunity Test	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact discharge +/-15 kV air discharge.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 & 60 Hz.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz.
Conducted RF - SIP/SOP IEC 61000-4-6	3 V, 0.15 MHz - 80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 11. Electromagnetic Immunity to Proximity Fields from RF Wireless Communications Equipment

Test Frequency	Services for which the recommended separation distance is 30 cm (12 inches)	Compliance Level
385	TETRA 400	27 V/m
450	GMRS 460, FRS 460	28 V/m
710	LTE Band 13, 17	9 V/m
745		
780		
810	GSM 800/900 TETRA 800, IDEN 820, CDMA 850, LTE Band 5	28 V/m
870		
930		
1720	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	28 V/m
1845		
1970		
2450	Bluetooth® 2.1, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28 V/m
5240	WLAN 802.11 a/n	9 V/m
5500		
5785		

12.3 FCC Requirements

The *aura6000™* generator and remote have been tested for compliance with FCC regulations. Changes or modifications not expressly approved by LivaNova could void the user's authority to operate the monitor.

aura6000™ generator FCC ID: 2AGS5-IPG

aura6000™ remote FCC ID: 2AGS5-RCC

These devices comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

These transmitters are authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and may not interfere with stations operating in the 400.15-406 MHz band in the meteorological aids, meteorological satellite, and earth exploration satellite services (i.e., transmitter and receivers used to communicate weather data) and must accept any interference received, including interference that may cause undesired operation. This transmitter shall be used only in accordance with FCC Rules governing the Medical Device Radiocommunication Service.

i **Note:** "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU (International Telecommunication Union)] Radio Regulations.

These terms are used in this manual.

***aura6000™* system**

The *aura6000™* system provides proximal hypoglossal nerve stimulation and includes a generator, lead, remote, and antenna.

central sleep apnea (CSA)

A disorder in which your breathing repeatedly stops and starts during sleep. It occurs because the brain does not send the proper signals to the muscles that control your breathing.

diathermy

Diathermy is a treatment to promote healing or relieve pain.

EAS system

Electronic Article Surveillance system is a technological method for preventing shoplifting from retail stores, stealing books from libraries, or removing properties from office buildings. Special tags are fixed to merchandise or books and are removed or deactivated when the item is properly bought or checked out. At the exits of the store or entrances to restrooms, a detection system sounds an alarm or otherwise alerts the staff when it senses active tags. Note that some systems might not be readily visible.

EM disturbance

A coupling or interference caused or generated by an electrical circuit that can potentially degrade the performance of the system.

electrode

Part of the *aura6000™* lead that connects to the hypoglossal nerve.

generator(implant)

aura6000™ generator; device implanted in the patient's chest. The generator contains the battery and delivers stimulation to the hypoglossal nerve through the *aura6000™* lead.

hypoglossal nerve

A nerve that originates in the brain stem and extends through the neck to the mandible and muscles of the tongue.

hypoglossal nerve stimulation

Periodic electrical signals sent from the generator to the hypoglossal nerve.

ImThera

The company that owns the *aura6000™* system trademark. The ImThera logo may appear on your charging antenna and remote control.

LCD display

An LCD (liquid-crystal display) is a flat screen that shows images by using liquid crystals and special filters to control light.

lead

aura6000™ lead; small wire that is implanted and connects the *aura6000™* generator to the hypoglossal nerve.

MR

Magnetic resonance.

MR Unsafe

An item that poses hazards in all MRI environments

MRI

Magnetic resonance imaging.

obstructive sleep apnea (OSA)

A sleep-related breathing disorder that involves a decrease or complete halt in airflow during sleep despite an ongoing effort to breathe. It occurs when the muscles relax during sleep, causing soft tissue in the back of the throat to collapse and block the upper airway.

pHGNS

Proximal hypoglossal nerve stimulation

RFID

Radio Frequency Identification (RFID) is a technology for tracking and identification. Each RFID label or tag has an electronic chip that works with radio frequency to provide wireless tracking capability. Some libraries use RFID to prevent book theft. Note that some systems might not be readily visible.

stimulate

Send electrical signal; with THN Sleep Therapy, the generator sends an electrical signal through the lead to a hypoglossal nerve, which carries the signal to the tongue muscles.

stimulation

The electrical signal sent from the generator to the tongue.

CONTACTS AND RESOURCES

For information and support in use of the *aura6000™* system or any of its accessories, contact LivaNova.

CONTACTS



LivaNova USA, Inc.
100 Cyberonics Boulevard
Houston, Texas 77058
USA

Tel: +1 281 228 7200 (Worldwide)
Toll free: +1 800 332 1375 (US/Canada)
Fax: +1 281 218 9332
Website: www.livanova.com



Cormedics Medizintechnik GmbH
Bahnhofstrasse 32
82041 Deisenhofen Germany

+49 89 66658790

+49 89 54999030

TECHNICAL SUPPORT

Available 8:00 am - 5:00 pm CT

Toll free: +1 866 882 8804 (US/Canada)
Tel: +1 281 228 7330 (Worldwide)
Email: SleepApnea.Support@LivaNova.com

REGULATORY AUTHORITY WEBSITES

Report all adverse events related to the device to LivaNova and to your local regulatory authority.

Australia <https://www.tga.gov.au/>

Canada <https://www.canada.ca/en/health-canada.html>

EU <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

UK <https://ec.europa.eu/growth/sectors/medical-devices/contacts>

US <https://www.fda.gov>

Other Resources

Summary of Safety and Clinical Performance (SSCP)

<https://ec.europa.eu/tools/eudamed> (when available). If not available, contact Technical Support to request a copy.