Physician's Manual
Proximal Hypoglossal Nerve Stimulation Therapy for Obstructive Sleep Apnea

***aura6000™* Generator - Model 100.0100**
***aura6000™* Lead - Model 300.0100**
***aura6000™* Lead - Model 300.0200**
***aura6000™* Remote Control & Charger (RCC) - Model 500.0100**
***aura6000™* Charging Antenna (CA) - Model 500.0300**
***aura6000™* Clinical Manager (aCM) - Model 700.0100**

For Healthcare Professionals

March 2026

Rx Only

76-0000-6300/1

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1 Introduction to the aura6000™ System

Links to the following documents are found at www.livanova.com.

- aura6000™ System Symbols and Definitions
- aura6000™ System Glossary
- aura6000™ System Clinical Information
- Patient's Guide for Proximal Hypoglossal Nerve Stimulation Therapy

Detailed cybersecurity information is available upon request. For contact information, see Contacts and Resources.

1.1 Brief Device Description

The LivaNova USA, Inc. *aura6000™* system, used for proximal hypoglossal nerve stimulation (pHGNS), consists of the implantable *aura6000™* generator and lead (or cuff electrode) and an external programming system to change stimulation settings.

1.1.1 Generator

The generator is an implantable, multiprogrammable pulse generator that delivers electrical signals to the hypoglossal nerve. It is housed in a hermetically sealed titanium case and powered by a single rechargeable battery. Electrical signals are transmitted through the lead from the generator to the hypoglossal nerve. The lead and generator make up the implantable portion of the *aura6000™* system.

1.1.2 Lead

The lead, which delivers the electrical signal from the generator to the hypoglossal nerve, is insulated with silicone. It has a self-sizing cuff positioned around the hypoglossal nerve and a suture sleeve. The lead is available in 2 lengths to ensure optimal fit. The connector end of the lead is tunneled subcutaneously to the generator pocket.

1.1.3 Programming System

The external programming system includes the *aura6000™* Clinical Manager (aCM), the Remote Control & Charger (RCC), and the Charging Antenna (CA). The aCM is a software application that allows the interrogation and programming of the *aura6000™* generator. The aCM communicates with the generator via the RCC and a USB cable.

Patients are provided the RCC to start and stop a sleep session and a CA to charge the generator (Figure 1). The RCC also allows patients to adjust patient-specific therapy settings and determine implant status.

The RCC battery powers the RCC and CA.

Figure 1. Patient Generator Charging Configuration

1.2 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).

1.3 Contraindications, Warnings and Precautions

1.3.1 Contraindications

- 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 thepossibility 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, in turn, 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 RCC and CA are MR Unsafe devices. They are projectile hazards that 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

1.3.2 Warnings

Physicians should inform patients about all warnings, potential risks, and adverse events discussed in the *aura6000™* system physician's manuals and the patient's guide.

- **Do Not Modify** — Do not modify the RCC or CA unless directed by LivaNova. This includes the power cord supplied with the RCC.
- **Tamper-Evident Sticker** — Do not use the RCC if it has been tampered with. The RCC battery compartment is sealed with a tamper-evident sticker. If the sticker is missing or damaged, return the RCC to LivaNova as the functionality of the RCC cannot be guaranteed.
- **Device Components** — The use of non-approved or non-LivaNova components with this system may damage the system and increase the risk to the patient.The use of such components with this system may damage LivaNova components, result in loss of therapy, cause patient injury, and void the product warranty.
- **Device Malfunction** — Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage and other associated problems. Instruct patients to contact their doctor immediately if they experience painful stimulation so the physician can evaluate the device's performance. Prompt surgical intervention may be required if a malfunction occurs.
- **Device Manipulation / Twiddling** — Patients should never attempt to change the orientation, invert, or otherwise manipulate the generator. Doing so may damage the lead or flip the generator, making it impossible to charge or communicate with it, which may require surgery to correct.
- **Device Trauma** — Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted (e.g., firing shoulder firearms, contact sports, accidental impacts) could cause damage to the lead.
- **Strong Electromagnetic (EM) Disturbances** — The generator contains features that protect it from EM disturbances. Most electrical devices and magnets encountered in every day life are unlikely to affect the generator. However strong sources of EM disturbance can cause serious patient injury or death. The lead can act as an antenna that "picks up" strong sources of EM disturbance (e.g., MRI) and delivers excess current causing nerve or tissue damage.

- **Elevated Pressure Conditions** — Patients should be instructed not to 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 150kPa can damage the generator.
- **External / Internal Defibrillation or Cardioversion (Electrical)—** These procedures may damage the generator and can temporarily or permanently damage the nerve. Follow these recommendations to minimize current flowing through the generator and lead system:
  - Position defibrillation patches or paddles perpendicular to the generator and lead system and as far from the generator as possible.
  - Use the lowest clinically appropriate energy output (watt-seconds).
  - Confirm generator function after any internal or external defibrillation or cardioversion treatment.
- **Implant Damage** — Never implant a damaged generator or lead.
- **Submandibular Incision** — Incisions placed less than 2 cm below the inferior border of the mandible may increase the risk of injury to the marginal mandibular branch of the facial nerve, which controls muscles of facial expression. Careful attention to incision placement is critical to avoid postoperative facial asymmetry or nerve dysfunction.
- **Other Hospital or Medical Equipment and Procedures** — The following medical therapies or procedures may interfere with stimulation, cause permanent damage to the generator or lead (particularly if used in close proximity), 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 to assess the impact in generator performance has been done to date.The effect of these therapies on the device is not known.
- **Pediatric Use** — The safety and effectiveness of the *aura6000™* system have not been established for pediatric use.

1.3.3 Precautions

Physicians should inform patients about all precautions, potential risks, and adverse events discussed in the *aura6000™* system physician's manuals and the patient's guide.

1.3.3.1 Precautions — Patient Selection

Consider the following when determining whether proximal hypoglossal nerve stimulation (pHGNS) is right for a patient:

- Complete Concentric Collapse (CCC):
  - Drug-induced sleep endoscopy (DISE) is not required for patient selection for proximal hypoglossal nerve stimulation (pHGNS). Clinical studies did not exclude patients with CCC at the velum; however, CCC status was not systematically assessed as a separate subgroup. Because CCC was not characterized during enrollment, clinicians should exercise judgment when evaluating patients with suspected or confirmed CCC.

- Use of the *aura6000™* system should be carefully considered in patients who fall outside the studied population, including:
  - Patients below 22 or above 75 years of age
  - Patients with Body Mass Index (BMI) above 35 kg/m^2
  - Patients with Apnea-Hypopnea Index (AHI) below 15 or above 65 events/hour

1.3.3.2 Precautions — Related to Implantation

- Keep the computer and RCC out of the sterile field; they are non-sterile.
- Use the following considerations when you choose the generator implant location. Ensure the location is as follows:
  - Placed away from bony structures and areas of restriction/pressure to minimize the potential for discomfort and skin erosion
  - Accessible to the patient for proper operation of the RCC and CA
  - Close enough for the lead to reach the generator with a strain relief loop
  - Accounts for the patient's cosmetic needs.
- Charge the generator before opening the external package. For instructions on charging, see the *Technical Information - aura6000™ Programming System* chapter.
- Do not tie sutures directly on the lead.
- Always provide strain relief to minimize tension on the electrode cuff.
- Avoid handling the lead with sharp instruments.
- Use caution when using sharp instruments near the lead and generator.
- **Do not use a lead other than an *aura6000™* lead** — Use of other leads may damage the generator or injure the patient.

1.3.3.3 Precautions — Programming System

- Always perform the secure pairing between a generator and RCC in a controlled location.
- Avoid the use of the aCM computer adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, observe this equipment and the other equipment to verify that they operate normally.
- Do not connect other USB devices to the aCM computer while the aCM is running, except for the computer mouse and keyboard.
- Do not use the aCM computer for any purposes outside of its intended purpose (e.g., email access, web browsing).
- Only perform software or firmware updates on the aCM computer or RCC with explicit authorization from LivaNova.

1.3.3.4 Precautions — Programming System Security

- Do not bypass system controls on the aCM computer (e.g., altering user permissions or disabling the firewall).
- Do not use the application if there is a suspicion that the operating system or aCM software has been compromised. Report to your organization's IT security and LivaNova Technical Support immediately.
- Do not connect the aCM computer to insecure networks (e.g., open internet, hotel Wi-Fi, public hotspots).
- Report any lost or stolen aCM computers to Technical Support immediately.
- Do not share your aCM computer password with others. Technical Support will not request your device password.
- Do not connect any non-LivaNova provided devices or accessories to the RCC or aCM computer.

1.3.3.5 Precautions — Environmental and Medical Therapy Hazards

- **EM Disturbances—** EM disturbances that could affect the generator can be produced by various electrical devices in the home, work, or medical environment. There are three types of EM disturbance —conductive current, induced/coupled current, and radiated energy—which can occur alone or in combination and potentially cause enough interference to:
  - Turn the generator on or off
  - Cause a loss of or change in stimulation parameters, which results in the need for reprogramming or surgical replacement
  - Temporarily change the generator output
  - Cause a transient increase in or interruption of stimulation, which could be perceived as a tingle or shock sensation
  - Induce/conduct excessive current in the lead, causing tissue damage
  - Damage the generator or lead

  In addition, certain mechanical devices (e.g., ultrasound) may produce mechanical energy strong enough to cause interference.

  Whenever possible, deactivate the device first or monitor its functioning during the initial stages of, and after exposure to, any procedure that produces EM disturbances or mechanical energy. Table 1 provides EM interference types and how to minimize the effects.

Table 1. Interference Type and Minimization

Interference Type/Description	How to Minimize Effects
Electromagnetic Interference	
Conducted current—current introduced by something touching the body (e.g., electrocautery, defibrillation).	Turn the device off. Keep the generator / lead out of the conductive path. In surgery, once the electrodes are placed, they use only bipolar electrocautery. Do not place external defibrillator paddles over the generator.
Induced/coupled current—current generated by an electric or magnetic field and transmitted through the air without physical contact.	Lead wires will act as an antenna to electric fields, and lead loops will act to "pickup" magnetic fields. The electric/magnetic field strength decreases with distance, so move away from EMI sources to reduce EMI effects.
Radiation—high energy electromagnetic radiation traveling through the air (e.g., x-rays, radioactive materials)	High dose radiation can damage a generator. If possible, avoid placing the generator directly in the radiation beam. This type of damage to the device may not be immediately detectable.
Mechanical	
Mechanical interference—pressure waves generated by vibrating or ultrasonic transducers.	Avoid placing the generator/lead directly in the path of the pressure beam. The beam may damage the device, or the device may inadvertently concentrate therapeutic ultrasound and cause harm.

- **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-theftand security in retail stores and libraries and may not be readily visible.

1.3.3.6 Precautions — Hospital and medical environments

- **Always Check *aura6000™* System Operation —** Perform device diagnostics after any of the procedures mentioned in this manual. Additional precautions for these procedures are described below.
- **Electrosurgery** — Electrosurgery (electrocautery or radio frequency [RF] ablation devices) may damage the generator. During the implantation procedure, do not use electrosurgical equipment after the generator has been introduced to the sterile field. When performing other surgical procedures on a patient implanted with an *aura6000™* generator, attempt to minimize the current flowing through the generator and lead system by following these precautions:
  - Position the electrosurgery electrodes as far as possible from the generator and lead.
  - Avoid electrode placement that puts the generator or lead in the direct path of current flow or within the part of the body being treated.
  - Confirm that the generator functions as programmed after electrosurgery.

- **Electrostatic Discharge (ESD)** — ESD may damage the generator.
- **Extracorporeal Shockwave Lithotripsy** — This procedure may damage the generator. If therapeutic ultrasound is required, avoid positioning the area of the body where the generator is implanted in the water bath or in any other position that would expose it to ultrasound therapy. If these positions cannot be avoided, place the generator in Shelf Mode for treatment, and then after therapy, briefly charge the generator to take it out of Shelf Mode.
- **Mammography —** For clear imaging, patients may need to be specially positioned for mammography procedures because of the generator's location in the chest.
- **Therapeutic Radiation** — This procedure may damage the generator's circuitry. Sources of such radiation include therapeutic radiation, cobalt machines, and linear accelerators. The radiation effect is cumulative, with the total dosage determining the extent of damage. The effects of exposure to such radiation can range from a temporary disturbance to permanent damage and may not be detectable immediately.
- **Therapeutic Ultrasound —** Exposure to high ultrasonic frequencies may result in damage to the generator or lead. It is not recommended to use high-output ultrasonic devices, such as an electrohydraulic lithotripter or bone growth stimulator on patients with an implanted generator
- **Treatment That Involves Electrical Currents** — If the patient receives medical treatment for which electric current is passed through the body (such as from a TENS unit), the generator should be turned off and ensure the generator is functioning properly following treatment.
- **Routine Diagnostic Procedures** — Most routine diagnostic procedures, such as ultrasound and radiography, are not expected to affect system operation.

1.3.3.7 Precautions — Home occupational environments

- **Other Electromagnetic and Electromechanical Devices** — The aura6000™ system is tested to show it is immune to the reasonably foreseeable maximum electromagneticdisturbance 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 could be perceived 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.

1.3.3.8 Precautions — Generator and EMI effects on other devices

- **Interference During Programming or Interrogation** — Programming or interrogating the generator may momentarily interfere with other sensitive electronic equipment nearby. The generator is not expected to trigger airport metal detectors or theft-protection devices.
- **Items Affected by Strong Magnetic Fields** — The magnet in the CA may damage televisions, computer disks, credit cards, and other items affected by strong magnetic fields.

1.3.3.9 Precautions — Sterilization

The generator and lead have been sterilized using ethylene oxide (EO) gas and are supplied in a sterile pack to permit direct introduction into the operating field. A use-by date and method of sterilization are marked on each package. A sterilization process indicator is located on the inner sterile pack and is only used as an internal manufacturing process aid.

- **Do Not Re-sterilize** — Do not re-sterilize any *aura6000™* system product. Return any opened devices to LivaNova.

1.3.3.10 Precautions — Storage

- **Temperature and Humidity** — Store the *aura6000™* system generator and lead between - 10 °C (+14 °F) and + 55 °C (+ 131 °F). Temperatures outside this range can damage components.

  Note: Storage conditions for the *aura6000™* Programming System are found in the *Technical Information - aura6000™ Programming System* chapter.

- **Liquids and Moisture —** Do not store any *aura6000™* system products where they can be exposed to water or other liquids. Moisture can damage the seal integrity of the package materials.

1.3.3.11 Precautions — Handling

- **Do Not Implant —** Do not implant a device if any of the following has occurred:
  - The device has been dropped, which could result in damage to its internal components.
  - The outer or inner storage package has been pierced or altered, which could render it non-sterile
  - The expiration (use-before) date has expired, which could adversely affect the device's sterility.
- **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) from any part of the *aura6000™* system, including cables specified by LivaNova. Otherwise, degradation of the performance of this equipment could result.
- **Do Not Ultrasonically Clean** — Ultrasonically cleaning the generator may damage generator components.
- **Do Not Re-implant an Explanted Generator** — The generator and lead are single-use-only devices. **Do not re-implant an explanted generator or lead for any reason** as sterility, functionality, and reliability cannot be ensured, and infections may occur.
- **Do Not Incinerate** — The generator contains a sealed chemical battery, which could cause an explosion if exposed to the high temperatures of incineration or cremation.
- **Return Explanted Generators and Leads** — Explanted generators and leads are medical waste and should be handled as such according to local laws. Explanted generators and leads should be returned to LivaNova for examination and proper

disposal, along with a completed Returned Product Report form. If possible, use the aCM to place the generator into Shelf Mode before shipment. Before returning the generator or lead, disinfect the device components with Betadine®, Cidex® soak, or other similar disinfectant, and double-seal them in a pouch or other container properly labeled with a biohazard warning.

- **Device Handling** —The RCC and CA are sensitive medical devices and should be handled carefully. Dropping them on hard surfaces, in water, or otherwise rough handling can result in permanent damage.

  Note: It is recommended to store the RCC and CA in a carrying case when not in use.

- **Temperature** — If the RCC or CA has been exposed to temperatures outside of the operating range, wait 1 hour before starting therapy.

  Note: Operating conditions for the *aura6000™* Programming System can be found in the *TechnicalInformation - aura6000™ Programming System* chapter.

- **Exposure to Sunlight** — *Do not expose* your RCC or CA to direct sunlight. Doing so may degrade the plastic material on them.
- **Return RCC and CA** — Return the RCC and CA to LivaNova for examination and safe disposal.

1.3.3.12 Precautions — Other

- **Neck Brace** — If a patient requires a neck brace that cannot be removed, it is important that the brace selected does not obstruct access to the generator, because this could interfere with the patient's ability to charge the device or operate the system as intended.

LivaNova employs highly trained representatives and engineers worldwide to serve you and provide training to prescribers and implanters of the *aura6000™* system.

Physicians who prescribe the *aura6000™* system should have experience in the diagnosis and treatment of the condition for which the system is being prescribed and should be familiar with the use of neurostimulation systems.

Physicians who implant the *aura6000™* system should have experience with cranial nerve anatomy and surgical techniques and should review this manual before surgery.

Prior to use, all implanting physicians and clinical staff must complete LivaNova-provided training, which includes didactic instruction and hands-on experience. Training is tailored to each clinician's role and covers the implant procedure as well as post-implant management. Clinical staff involved in device titration will receive instructions on titration and hands-on operation of the LivaNova programmer system.

1.5 Essential Performance

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

1.6 System Shelf-Life, Sterility, and Service Life

Table 1A below provides a summary of sterility, shelf-life, and service life information for the aura6000 system components. Shelf-life refers to the period before a device is used, during which the packaging maintains a sterile barrier based on validation and aging studies. In contrast, service-life values are provided as general reference timeframes for the device's operational duration after implantation. These values do not represent absolute functional limits, nor do they imply that a component must be removed or replaced because a specific time period has passed. The decision for continued use of an implanted component should be based on the device's actual performance, its current battery status, and professional clinical judgment.

Table 1A. Summary of System Shelf-Life, Sterility, and Service Life Information

Device	Sterility	Shelf-Life	Service-Life
Implantable Pulse Generator	Sterile	1 year	At least 5 years
Lead	Sterile	2 years	At least 5 years
Charging Antenna (CA)	Non-sterile	Not Applicable	At least 1 year
Remote Control Charger (RCC)	Non-sterile	Not Applicable	At least 1 year
aura Clinical Manager (aCM)	Non-sterile	Not Applicable	Not Applicable

2 Benefits and Risks

Treating obstructive sleep apnea (OSA) offers well-documented benefits for physical health, mental wellbeing, 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.

For a complete explanation of benefits and risks, refer to the *aura6000™ System Clinical Information* document.

The OSPREY study showed that *aura6000™* therapy helped patients with moderate to severe obstructive sleep apnea (OSA) in several important ways, as early as 6 months of treatment, with durable results through 12 months:

- **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 during 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 (see Table 1B). With 12 months of treatment in the OSPREY study, this success rate in the treatment group improved to 65%.

Table 1B. Overall Responder Rate for the OSPREY Study (Primary Study Endpoint – Through Month 7)

	Treatment (N = 67)		Control (N = 37)	
Overall Responder Rate	39/67	(58.2%)	5/37	(13.5%)
Sex				
Female	10/18	(55.6%)	1/10	(10.0%)
Male	29/49	(59.2%)	4/27	(14.8%)
Age				
<65	31/54	(57.4%)	4/31	(12.9%)
>=65	8/13	(61.5%)	1/6	(16.7%)
Ethnicity				
Hispanic or Latino	8/10	(80.0%)	1/8	(12.5%)
Non-Hispanic or Latino	31/56	(55.4%)	4/29	(13.8%)
NOT REPORTED	0/1	(0%)	0/0	(0%)
Body Mass Index				
< 32	26/44	(59.1%)	4/21	(19.0%)
>= 32	13/23	(56.5%)	1/16	(6.3%)
Baseline OSA Severity				
Moderate	16/27	(59.3%)	4/14	(28.6%)
Severe	23/40	(57.5%)	1/23	(4.3%)

- **Improved Blood Oxygen Levels —** The OSPREY study also looked at how well oxygen levels were maintained during sleep, using the oxygen desaturation index (ODI).
  - Among treated patients, 56.7% had a greater than 50% 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 Sleepiness Scale (ESS) **–** Assesses the patient's level of daytime sleepiness, a key symptom that may interfere with daily activities and increase safety 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) **–** Evaluates how sleepiness affects the patient's ability to perform daily tasks, maintain productivity, and engage in social interactions. 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) **–** Captures the frequency of sleep interruptions, which may contribute to reduced sleep quality and cognitive performance. The

early benefit was maintained through 12 months of treatment.

- Sleep-Related Impairment (SRI) – Measures the extent to which sleep problems impact emotional well-being, energy levels, and social functioning. 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.

2.2 Adverse Events from the OSPREY Study

The tables in this section include adverse events (AEs) that occurred in more than 2% of subjects in the OSPREY study. The only device-related serious adverse events (SAEs) in the study were due to system revisions that required surgery (n=14). All other SAEs (n=6) reported in thestudy were not related to the *aura6000™* system, implantation, or stimulation, and were all reported as resolved or recovered. See Table 1C for a breakdown of serious and non-serious adverse events through month 13 of the study.

Table 1C. Summary of Serious and Non-Serious Adverse Events Through Month 13

Adverse Events	Non-device-related and Non-procedure-related Events e (n, %)	Device-related or Procedure-related Events e (n, %)
Non-serious	289 (88, 84.6%)	106 (47, 45.2%)
Serious	6 (5, 4.8%)	14* (11, 10.6%)

n: number of subjects with at least one event
% = (n/T X 100, where T is the total number of subjects in the ITT population)
e = number of events
Note: A subject can have more than one event
*: The 14 serious adverse device effects (SADEs) include 4 explants, 5 generator interventions, 4 lead replacement/generator interventions, and 1 lead repositioning/generator intervention that were not originally adjudicated by the Study Investigator or the Clinical Events Committee as serious adverse events (SAEs) or serious adverse device effects (SADEs). Excluding these events would result in 6 SAEs, none of which were device or procedure related.

For a complete list of adverse events observed in clinical studies, refer to the *Clinical Information Guide*.

2.2.1 System Revisions Requiring Surgery (Device-Related SAEs)

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 insufficientcharging 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.

2.2.2 Implant-Related Adverse Events

Table 2 summarizes implant-related adverse events reported in both active/stimulation and control subjects prior to the Month 13 visit. Only events occurring in more than 2% of subjects are included.

Table 2. Implant Procedure-Related Events Occurring in > 2% of Subjects in the First 13 Months in OSPREY

	Subjects with Events	
Adverse Events	**N**	**%**
Implant Site Pain	9	8.7
Oropharyngeal pain	8	7.7
Headache	7	6.7
Dysphagia	5	4.8
Neck pain	5	4.8
Hypoesthesia	4	3.8
Implant site swelling	4	3.8
Ear pain	3	2.9
Tongue movement disturbance	3	2.9

The following implant procedure-related events were reported twice each: odynophagia, implant site erythema, implant site extravasation, implant site hypoesthesia, medical device discomfort, swelling, stitch abscess, contusion, musculoskeletal discomfort, dysarthria, facial paresis and hypoesthesia oral.

The following implant procedure-related events were reported once each: speech disorder, vein rupture, temporomandibular joint syndrome, lip disorder, rash, arthralgia, eye pain,

glossodynia, ear discomfort, nausea, wound dehiscence, chest discomfort, salivary hypersecretion, hiccups, implant site irritation, oral contusion, swollen tongue, implant site infection, throat tightness, pain in jaw, tongue paralysis, paresthesia, vomiting, paresthesia oral, keloid scar, and procedural nausea.

2.2.3 Stimulation-Related Adverse Events

Table 3 summarizes stimulation-related adverse events reported in both active/stimulation and control subjects. Only events occurring in more than 2% of subjects are included. Subjects were randomized to active / stimulation, with therapy initiated 30 days post-implant.

Table 3. Stimulation-Related Adverse Events Occurring in > 2% of Subjects in the First 13 Months of the OSPREY study for subjects randomized to Active/ Stimulation

	Subjects with Events	
Adverse Event	**N**	**%**
Medical device discomfort	3	4.5
Glossodynia	3	4.5
Speech disorder	2	3.0
Neck pain	2	3.0
Dysphagia	2	3.0
Medical device pain	2	3.0

The following stimulation-related events were reported once each: toothache, tongue movement disturbance, ear pain, salivary hypersecretion, burning sensation, headache, tongue discomfort, dermatitis, tongue paralysis, oral pain, insomnia, and pain in jaw.

2.2.4 All Adverse Events in Subjects Randomized to the Active / Stimulation Group of the OSPREY Study

Table 4 summarizes all adverse events (AEs) within the first 30 days following implantation and Table 5 summarizes all AEs between day 31 and month 13. Only events occurring in more than 2% of subjects are included, regardless of their relationship to any aspect of the study.

Table 4. All Adverse Events (Day 0–30) Occurring in > 2% of Subjects Randomized to Active / Stimulation in OSPREY

	Subjects with Events	
Adverse Event	**N**	**%**
Headache	9	13.4
Implant site pain	6	9.0
Ear pain	4	6.0
Oropharyngeal pain	4	6.0
Dysphagia	4	6.0
Tongue movement disturbance	3	4.5
Implant site swelling	3	4.5
Hypoesthesia oral	2	3.0
Medical device discomfort	2	3.0
Tongue paralysis	2	3.0
Facial paresis	2	3.0
Procedural nausea	2	3.0
Restless leg syndrome	2	3.0
Implant site erythema	2	3.0
Neck pain	2	3.0
Speech disorder	2	3.0
Fall	2	3.0
Surgical intervention	2	3.0

The following adverse events reported in the first 30 days since implant were reported once each: medical device site discomfort, epigastric discomfort, lymphadenopathy, incision site dermatitis, ligament sprain, COVID-19, attention deficit hyperactivity disorder, bronchitis, urticaria, upper respiratory tract infection, migraine, swollen tongue, implant site hypoesthesia, swelling, sinusitis, blood pressure increased, dizziness, rash, osteoarthritis, implant site extravasation, cough, odynophagia, non-cardiac chest pain, dysarthria, implant site irritation, throat tightness, glossodynia, night sweats, arthralgia, atrial flutter, back pain, contusion, nausea, and musculoskeletal discomfort.

Table 5. All Adverse Events (Between Day 31 and Month 13) Occurring in > 2% of Subjects Randomized to Active/Stimulation in OSPREY

	Subjects with Events	
Adverse Event	**N**	**%**
COVID-19	9	13.4
Surgical intervention	6	9.0
Nasopharyngitis	6	9.0
Hypertension	6	9.0
Neck pain	5	7.5
Sinusitis	5	7.5
Dysphagia	4	6.0
Medical device discomfort	4	6.0
Glossodynia	4	6.0
Insomnia	4	6.0
Foot fracture	4	6.0
Pain in jaw	3	4.5
Cough	3	4.5
Glucose tolerance impaired	3	4.5
Upper respiratory tract infection	3	4.5
Headache	3	4.5
Influenza like illness	3	4.5
Ear pain	3	4.5
Hypoesthesia	3	4.5
Implant site pain	2	3.0
Tinnitus	2	3.0
Muscle strain	2	3.0
Fall	2	3.0
Dry mouth	2	3.0
Rhinorrhea	2	3.0
Diarrhea	2	3.0
Tongue discomfort	2	3.0
Obstructive sleep apnea syndrome	2	3.0
Urinary tract infection	2	3.0
Toothache	2	3.0
Nerve compression	2	3.0
Pyrexia	2	3.0
Tachycardia	2	3.0
Diverticulitis	2	3.0
Blood cholesterol increased	2	3.0
Medical device pain	2	3.0
Musculoskeletal discomfort	2	3.0

The following adverse events were reported once each: muscle twitching, muscle spasms, muscle contractions involuntary, memory impairment, fatigue, vulvovaginal mycotic infection, vomiting,

urinary incontinence, tonsillitis, tongue paralysis, face edema, tooth fracture, limb injury, vitamin D deficiency, concussion, wound infection staphylococcal, feeling hot, migraine, coronary artery disease, tongue disorder, inguinal hernia, gastroesophageal reflux disease, tendon injury, benign prostatic hyperplasia, cholelithiasis, synovial cyst, influenza, syncope, speech disorder, salivary hypersecretion, sacroiliitis, rosacea, implant site infection, rhinalgia, respiratory tract infection viral, hypoglossal nerve disorder, pharyngeal swelling, periarthritis, benign neoplasm of skin, butterfly rash, paresthesia oral, paresthesia, hypoesthesia oral, peripheral swelling, drooling, pollakiuria, acute sinusitis, anxiety, attention deficit hyperactivity disorder, back pain, blood testosterone decreased, burning sensation, clavicle fracture, cyst, dermatitis, dysarthria, head discomfort, head injury, hyperactive pharyngeal reflex, hypertonic bladder, hypoglycemia, implant site inflammation, implant site pruritus, injection site pain, large intestine perforation, medical device site discomfort, nasal dryness, nausea, nephrolithiasis, nightmare, non-cardiac chest pain, onychomycosis, oral mucosal erythema, oral pain, oropharyngeal pain, osteoarthritis, rotator cuff syndrome, and tongue movement disturbance.

3 Technical Information — aura6000 Generator

3.1 Physical Characteristics

The titanium case of the *aura6000™* generator is hermetically sealed and leak-rate tested. Specially designed feedthrus using platinum conductors form the electrical connection from the connector blocks to the circuitry through the hermetically sealed enclosure.

Table 6 provides the physical characteristics of the generator (all dimensions are nominal).

Table 6. Generator Physical Characteristics

Generator Model 100.0100	
Lead receptacle	1.5mm
Dimensions	47.5 x 33.3 x 9.4mm
Weight	16g
Connector Retention Strength	>10 N
Battery Life	Approximately 15 years (with nominal settings)
Torque Wrench	Nose: 6.37mm Handle: 22.6mm Hex shaft: 14mm
Suture Sleeve	3.7mm diameter, 12.7mm length
Package Contents	■ generator* ■ torque wrench ■ suture sleeves
* The *aura6000™* system generator is nonpyrogenic.	

3.1.1 Biological Compatibility

Materials exposed to the subcutaneous environment are biologically compatible. These materials have a long history in medical implants and have been found to be tissue-compatible. Table 7 provides a list of component materials.

Table 7. Generator and Lead Component Materials

Component	Material
Case	Titanium
Header	Epoxy
Lead connector blocks	MP-35N, Stainless steel
Setscrew plug	Silicone*
Torque wrench	Stainless steel, Teflon, Polyetherimide thermoplastic
Suture sleeve	Silicone*

* No component of the *aura6000™* system is made with natural rubber latex.

3.1.2 Power Source

The power source for the *aura6000™* generators is a rechargeable lithium-ion cell battery. Table 8 contains battery characteristics for the generator.

Table 8. Battery Characteristics

Model	Battery Chemistry	Maximum Capacity
Model 100.0100	Lithium ion	50 mA hr

3.1.3 Generator Battery Life & Replacement

Over time, the generator battery will lose its ability to hold a charge. As this happens, the generator will require more frequent charging by the patient.

The generator battery life is approximately 15 years after implant with nominal settings. Battery life can vary and may be shorter than this, depending on how the patient uses and charges the generator battery.

3.1.4 Identification

The generator can be identified on an x-ray by the x-ray tag codes provided in Table 9. The generator's serial number and model number are marked on its titanium case but do not appear on the X-ray.

Identify the serial and model numbers by interrogating the generator with the RCC or aCM.

Table 9. Generator X-Ray Tag Codes and Further Identification by Serial Number

Model	Possible X-Ray Tag Codes	Further Identification by Serial Number
Model 100.0100	iM A where: ■ iM = Manufacturer ■ A = represents the model (e.g., 100.0100)	N/A

Note: See the *Technical Information - aura6000™ Programming System* for details.

3.2 Stimulation Parameters

Generator stimulation parameters and available parameter settings are presented in Table 10.

Table 10. Stimulation Parameters & Available Parameter Settings

Waveform	Biphasic, charge-balanced waveform with anodic phase pulse amplitude equal to one-quarter of the cathodic phase pulse amplitude and anodic phase duration equal to four times the cathodic phase duration.
Output current	0 to 1992 µA
Pulse frequency	3 to 90 pps
Pulse width	50 to 400 µs

3.3 Communicating with the *aura6000* system

A compatible *aura6000™* programming system is required to communicate with and program the generator. A programming system consists of an RCC, a CA, and a compatible computer running the aCM software.

> **Note:** For more information on using the programming system, see the "Technical Information — *aura6000™*
> Programming System" chapter.

The generator and RCC communicate using a MedRadio Band at 401-406 MHz. The generator "listens" for a communication signal from the remote control charger. The synchronized nature of the communications and the underlying protocols used may cause a delay in responses to the user, giving the impression of a system that can be, at times, poorly responsive. This is inherent to the product's design.

The generator listens for and implements interrogations, parameter programming instructions, requests for diagnostics testing, and device history inquiries. In response, the generator transmits information on the stimulation parameter settings, changes its parameter settings, responds to requests for diagnostics testing, and provides device histories, respectively. Each time the generator transmits data, the aCM software saves it.

> **Note:** For details on viewing generator information on a programming computer, see the "Technical Information — *aura6000™* Programming System" chapter.

4 Technical Information — aura6000 Lead

4.1 Physical Characteristics

The *aura6000™* lead is made of medical-grade silicone tubing that encloses and insulates MP-35N multifilar conductors terminating on 6 platinum-iridium electrodes. The electrodes are held in a silicone, self-sizing cuff that holds them against the nerve. The lead is available in 2 lengths (25 cm (Model 300.0100) and 33 cm (Model 300.0200)).

Table 11 provides the physical characteristics of the lead (all dimensions are nominal).

Table 11. Lead Physical Characteristics

Lead Model 300.0100/300.0200	
Electrode Type	Self-sizing cuff
Electrode Pattern	6 contacts, ~50° radial spacing
Electrode cuff inner diameter	3.0mm
Connector	~1.5mm diameter, 2.3mm contact spacing
Overall Length	25cm (Model 300.0100) 33cm (Model 300.0200)
Torque Wrench	Nose: 6.4mm Handle: 22.6mm Hex shaft: 14mm
Suture Sleeve	3.7mm diameter, 12.7mm length
Package Contents	■ lead* ■ torque wrench ■ suture sleeves
* The *aura6000™* system lead is nonpyrogenic.	

4.1.1 Biological Compatibility

Materials exposed to the subcutaneous environment are biologically compatible. These materials have a long history in medical implants and have been found to be tissue-compatible. Table 12 provides a list of component materials.

Table 12. Lead Component Materials

Component	Material
Connector Pin	MP-35N, Platinum-iridium and Polyurethane
Lead Body Insulation	Silicone*
Electrode Conductor	Platinum-iridium
Electrode Cuff	Silicone*
Torque wrench	Stainless steel, Teflon, Polyetherimide thermoplastic
Suture sleeve	Silicone*

* No component of the *aura6000™* system is made with natural rubber latex.

4.1.2 Lead Life and Replacement

The lead lifespan is at least 5 years after implant. If a lead fracture were suspected through diagnostic tests, it would require replacement.

Events that can shorten the life expectancy of the lead are as follows:

- Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted
- The patient twists or picks at either the implanted lead or generator
- Improper surgical implantation of the aura6000™ generator or lead (e.g., inadequate strain relief loop, sutures placed directly on the lead body, suture sleeve not used, sutured to muscle).

⚠ **Caution: Lead replacement or removal due to lack of efficacy** is a medical judgment based on the patient's desires and health status, and must be carefully weighed against the known and unknown risks of surgery. At present, there are no known long-term hazards or risks associated with leaving the lead implanted beyond those already mentioned.

5 Technical Information — aura6000 Programming System

5.1 Cybersecurity Information

The *aura6000™* system qualifies as a cyber device under Section 524B of the Federal Food, Drug,and Cosmetic Act because it includes software, connects to networks, and may face cybersecurity threats.

Cybersecurity responsibilities for the *aura6000™* system are shared between LivaNova and the healthcare facility. The healthcare facility is responsible for the following actions:

- Create and disable user accounts in accordance with its IT policies
- Keep the aCM computer and RCC under secure physical control
- Apply network security measures and install Windows security updates
- Notify LivaNova Technical Support immediately if a device is lost or stolen

To access complete information about cybersecurity protections, facility responsibilities, and remaining risks, contact LivaNova Technical Support or the LivaNova Trust Center at **trustcenter@livanova.com** to request the Aura6000™ Product Security Statement.

5.2 Stimulation and Programming Principles

When applying electrical stimulation to a nerve bundle, three factors determine which fibers, if any, within the bundle will be excited.

- The first is the distance between the contact (electrode) and the fiber. The closer a fiber is to the contact, the higher the current gradient and the more likely that the fiber will be excited.
- The second is the diameter of the fiber. The larger the nerve diameter, the larger the voltage changes across the neural membrane, and the more likely the threshold for generating an action potential will be reached and the fiber will be excited.
- The third is the duration or pulse width of the stimulation. The longer the pulse width, the more likely the fiber will be excited.

The hypoglossal nerve is primarily a motor nerve (i.e., nerve fibers associated with muscle fibers). As the stimulation current or pulse width is increased, more nerve fibers get excited, more muscle fibers contract and more force is produced. The point at which this force is first generated is called the motor threshold. The point at which the optimal or best possible force or position of the tongue is obtained is called the therapeutic level. The sensory limit is the point at which sensation is no longer comfortable. It is important to determine the sensory limit and the level at which the desired therapeutic effect is obtained to balance the therapeutic effect with patient comfort.

In treating a sleeping patient suffering from obstructive sleep apnea, it is necessary to create airway patency without waking the patient. The stimulation of the tongue muscles only needs to be sufficient to move or stiffen the tongue or open the airway enough to prevent an apnea/ hypopnea from occurring.

In the *aura6000™* system, stimulation can be delivered through any of the six individual contacts or user-defined contact groups; although generally, it is provided by cycling between at least 2 contacts operating in sequence. A minimum of two contacts are typically

used to ensure the stimulation load is shared among muscles to reduce the likelihood of fatigue. While only a single contact will typically be on at any time during stimulation, it can be beneficial to activate several contacts simultaneously, and the system provides functionality to evaluate and configure stimulation using one or more contacts. Stimulation begins with the first contact, which ramps to a therapeutic level and dwells at the therapeutic level for a pre-determined period before stimulation begins at the next contact. This process repeats through the remainder of the selected and programmed contacts, and the cycle repeats for the duration of the sleep session.

⚠ **Caution:** If only one contact is useful, a gap time approximately equal to the contact's ON time may be used to reduce the likelihood of muscle fatigue.

The process of determining the appropriate stimulation parameters for a patient consists of the following distinct steps:

- **Sensory Limit Determination** — With the patient awake, the amplitude is slowly increased until the patient begins to feel the sensation is no longer comfortable or would cause them to awaken from sleep (the sensory limit).
- **Therapeutic Level Determination** — The therapeutic level is the level that strikes a balance between airway opening and comfort. Because the awake-level muscle responses and patient tolerance will be similar to, but not exactly equal to, the levels tolerated by the sleeping patient, it is then necessary to fine-tune the therapeutic level in a polysomnography (PSG) session.

In addition to stimulation amplitude and duration, the therapy can be adjusted according to the parameters below to either improve the therapeutic effect or reduce stimulation side effects:

- **Frequency Adjustment** — Higher frequencies are generally better tolerated by the patient and correspondingly decrease the likelihood of arousal due to stimulation during sleep. Frequencies that are too high may be uncomfortable for the patient. This discomfort level varies across patients. Try to use frequencies 50 pps or lower, as higher frequencies might cause muscle fatigue to occur more quickly.
- **Stimulation Ramping (Ramp Up Time)** — Stimulation is ramped up slowly to reduce the chance of startling the patient and causing arousal. Ramp Up Time parameters can be adjusted to the patient's needs.
- **Delayed Stimulation Onset (Start Delay)** — The onset of therapeutic stimulation is delayed until the patient has had time to fall asleep. This Start Delay time is adjustable. When the patient initiates a sleep session, the generator waits for the programmed start delay period to elapse before initiating stimulation. Stimulation will then be applied for the programmed sleep duration unless the patient uses their remote to pause or stop stimulation.

5.3 Detailed Device Description

The *aura6000™* Programming system includes the Model 500.0100 remote control and charger (RCC), the Model 500.0300 charging antenna (CA), and the Model 700.0100 aCM software installed on a computer to adjust the settings of the *aura6000™* system. The RCC contains a rechargeable battery that powers the RCC and CA, as well as a power cord.

The aCM is a software application installed on a computer that allows the interrogation and programming of the *aura6000™* generator. It can be used in conjunction with a polysomnography (PSG) system to optimize therapy settings in real-time by visualizing the active contact being used (1-6) and the stimulation amplitude applied on that contact. The aCM communicates with the generator via the RCC and a USB cable.

Patients are provided with an RCC and CA (Figure 2). Patients use the RCC (Figure 3) to start and stop a sleep session and the CA (Figure 4) to charge the generator (Figure 5). The RCC also allows patients to adjust therapy and determine their implant status.

⚠ **Caution:** Patients must bring their RCC to each office visit for therapy adjustments. RCC to generator pairing is specific to each patient.

⚠ **Warning:** Do not use the RCC if it has been tampered with. The RCC battery compartment is sealed with a tamper-evident sticker. If the sticker is missing or damaged, return the RCC to LivaNova as the functionality of the RCC may be compromised.

Figure 2. RCC and Power Cord & CA

1 - RCC

2 - CA

3 - RCC Power cord

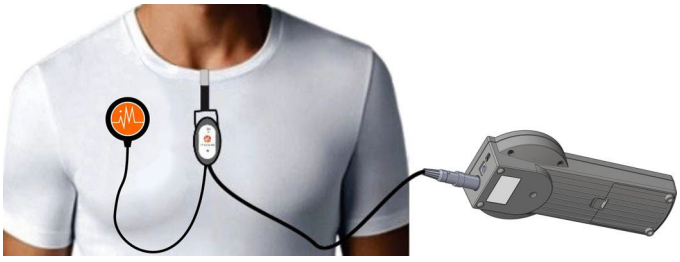
Figure 3. RCC Components

1 - CA port
2 - Power port
3 - Data port
4 - Battery compartment
5 - Up button
6 - Down button
7 - OK button

Figure 4. CA Components

1 - CA coil
2 - CA amplifier

Figure 5. Patient Generator Charging Configuration



5.4 RCC and CA Service Life

The RCC and CA have an expected service life of at least 1 year.

5.5 Prepare the System for First-Time Use

1. Charge the RCC (See “Charge the RCC” on page 27)
2. Connect the RCC to the aCM (See “Connect the RCC to the aCM” on page 28)
3. Pair the RCC with the generator (See “Pair the RCC with the Generator” on page 29)
4. Charge the generator fully (See “Charge the Generator Fully” on page 31)

5.6 Prepare the RCC for Use

5.6.1 Charge the RCC

Charge the RCC completely before the first use and before charging the generator. Fully charging the RCC may take longer than 60 minutes.

⚠ **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 RCC, complete the following steps:

1. Connect the power cord (Figure 6).
2. Plug the power cord into a wall outlet.

The battery and power cord icons will appear to indicate the battery is recharging. The battery icon will appear full when the RCC is fully charged (Figure 7).

Figure 6. Connect Power Cord to RCC

5.6.2 Turn the RCC On and Off

The RCC must be turned on and paired with a generator before it can control or charge the generator. To turn on the RCC, press the **OK** button on the RCC. When activated, the RCC will display the Main Menu.

ⓘ **Note:** For instructions on how to pair the RCC with a generator, see “Pair the RCC with the Generator” section.

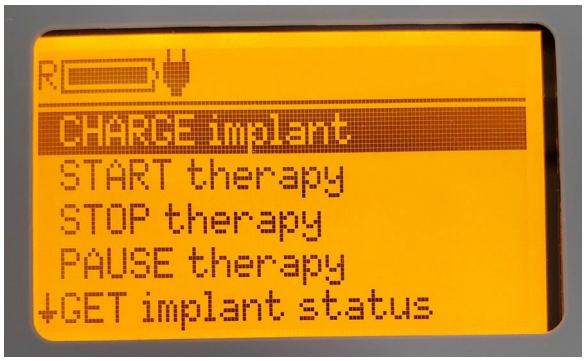
ⓘ **Note:** If you do not press any buttons the remote will dim after 30 seconds and power off within 5 minutes.

To turn the RCC off immediately, select **POWER OFF** and press the **OK** button.

5.6.3 RCC Screen

Once paired with a generator, use the RCC navigation buttons to control therapy and manage the system through the RCC screen (Figure 7). If the RCC is not paired with a generator, limited options will be available.

Figure 7. RCC Screen

Paired	Unpaired
	

Note: Remote Control Battery: The "R" beside the battery icon indicates the remote battery and shows its level. When charging your remote, a power cord icon will appear to the right of this battery.

Note: If your remote displays only the remote battery level (Figure 7) on the top left of the screen and no other information, the remote does not know your generator's current status. Select **GET implant status** on the Main Menu to refresh and display this information.

Note: Press and hold the **OK** button to cancel any action, even if there is no on-screen option to cancel.

5.7 Prepare the aCM for Use

5.7.1 Connect the RCC to the aCM

1. Connect a USB cable to the RCC and ensure that it is secure.

   Caution: When using the aCM in the operating room, the USB cable should be 3-5 m so that the aCM computer will be out of the sterile field.

   Caution: Do not connect other USB devices to the aCM computer while the aCM is running, except for the computer mouse and keyboard.

2. Turn on the RCC and place the RCC within 1.5m (5 feet) of the generator to ensure adequate range for connection.

   Note: If the generator is already paired with the RCC, it will automatically connect.

   Note: If the generator is not paired with the RCC, see the "Pair the RCC and Generator" section.

3. Identify a suitable work surface for the aCM computer. Place the aCM computer on this surface and attach the other end of the USB cable to it.
4. Start the aCM computer.

5. Verify the time and date on the aCM computer before starting the aCM application.

   Note: It is important to verify the time and date on the aCM and to set the time on both the RCC and generator. If you do not complete this correctly, there will be logging issues.

6. Double-click the **ImThera logo** to start the aCM application. When you start the aCM application, the Home screen (Figure 13) will appear, and the aCM will establish a connection with the attached RCC. If you have problems, see "Troubleshooting".
7. After the aCM application connects with the RCC, the system automatically connects to the generator already paired to the RCC. When you connect the RCC and generator to the system, the RCC Connection and IPG Connection lights on the left side of the Home screen will turn green, and the **Surgery** and **PSG** buttons will become active (Figure 13).

   Note: Use the generator serial number to confirm that you are connecting to the correct generator.

5.7.2 Pair the RCC with the Generator

1. To pair the generator with an RCC, navigate to the Administration screen (Figure 17) and proceed to step 3.
2. If the RCC is paired with an unintended generator, go to the Administration screen (Figure 17) and click **Forget Device**.
3. Place the CA with the ImThera logo facing up over the generator. You should feel the magnets in the CA and generator align.
4. Permanently or temporarily pair the RCC and generator:

   Note: The RCC and generator can take up to 4 minutes to pair.

   a. Permanently Pair — Click **Pair**. This is useful during surgery and when preparing the RCC to be sent home with a patient after the initial implant of the *aura6000™* generator and lead.

      Note: After you permanently pair an RCC to a generator, any other RCC previously paired will no longer communicate with that generator.

   b. Temporarily Pair — Click **Temporary**. This is useful if a patient has forgotten their permanently paired RCC for a scheduled office visit. Temporary pairing will end for any of the following conditions:

      - 15 hours elapse
      - The RCC is turned off, loses power, or resets
      - The generator enters Shelf Mode or resets
      - The generator communicates with its permanently paired RCC

5. After the RCC and generator are paired, the CA may be removed from the generator, and you can use the aCM to program therapy.

5.8 Prepare the Generator for Use

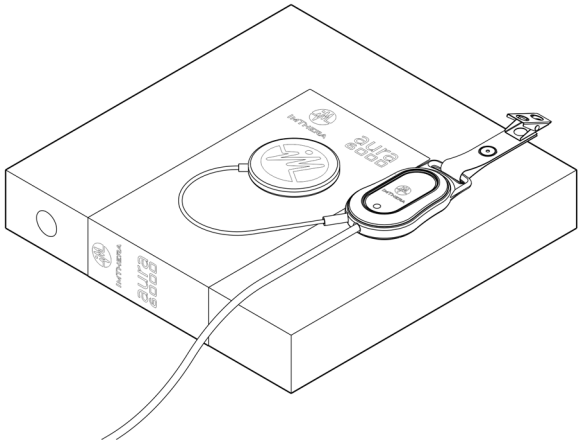
5.8.1 Take the Generator out of Shelf Mode

The generator is shipped in a special condition called Shelf Mode, which reduces power consumption to protect the generator battery from over-discharge. You must take the generator out of Shelf Mode before communicating with it.

To remove the generator from Shelf Mode, proceed as follows:

1. Connect the CA to the RCC.
2. Place the CA, with the ImThera logo facing up, over the generator product box (Figure 8). You should feel the magnets in the CA and generator align.

Figure 8. Align the CA with the Generator



Note: It is unnecessary to remove the generator from its double-layer sterile package to charge the generator

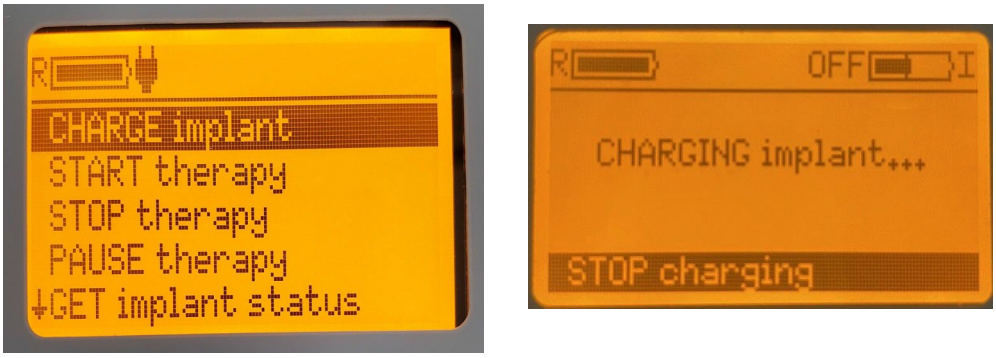
3. Check if the intended generator is paired with the RCC.

IF	THEN
The generator is not paired with the RCC.	▪ See “Pair the RCC with the Generator”. ▪ Once the generator is paired, the new generator will automatically come out of shelf mode and is ready to use. ▪ Disconnect the RCC from the aCM and proceed to “Charge the Generator Fully” on page 31

The generator is already paired and the generator is in shelf mode.	▪ Turn on the RCC and select **CHARGE implant** (Figure 9) ▪ Charge the generator for at least 30 seconds to take it out of Shelf Mode. ▪ To stop charging, select **STOP charging**.

Note: Refer to "Troubleshooting" if errors occur during charging.

Figure 9. Charge the Generator with the RCC and CA

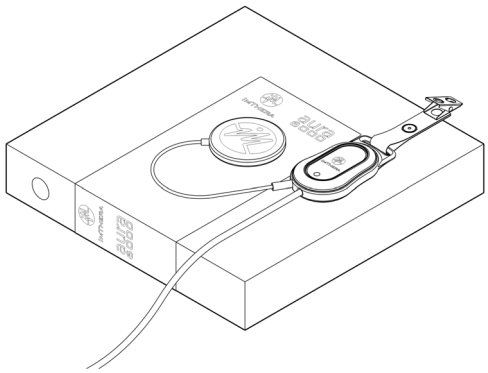


5.8.2 Charge the Generator Fully

Charge the generator fully before the implant surgery.

1. Connect the CA to the RCC.
2. Place the CA, with the ImThera logo facing up over the generator. You should feel the magnets in the CA and generator align. You can charge the generator before implantation while still in the product box or over the patient after it has been implanted (Figure 10).

Figure 10. Charge the Generator

In Product Box	After Implantation
	

Note: Removing the generator from its double-layer sterile package is unnecessary.

3. If the generator is not paired with the RCC, see "Pair the RCC with the Generator" section.
4. Turn on the RCC and select **CHARGE implant** (Figure 11).
5. Continue to charge the implant until the generator battery is fully charged (Figure 12).

Figure 11. Charging the Generator with the RCC & CA

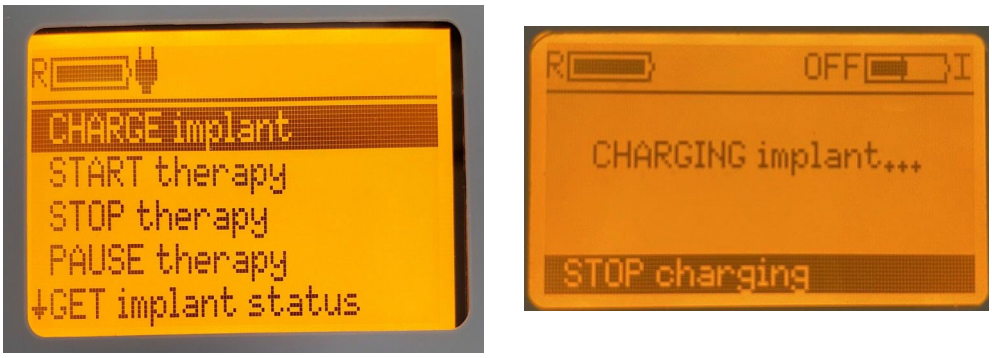


Figure 12. Generator Battery Fully Charged

6. The generator may not be able to communicate with the RCC if it is too far away during charging, or if the generator battery is too low. If this happens, the RCC will display "Unable to connect to the implant" and then continue charging. The generator will continue to charge, but the generator may not automatically communicate to the RCC when it completes charging, so charging may appear to take longer.

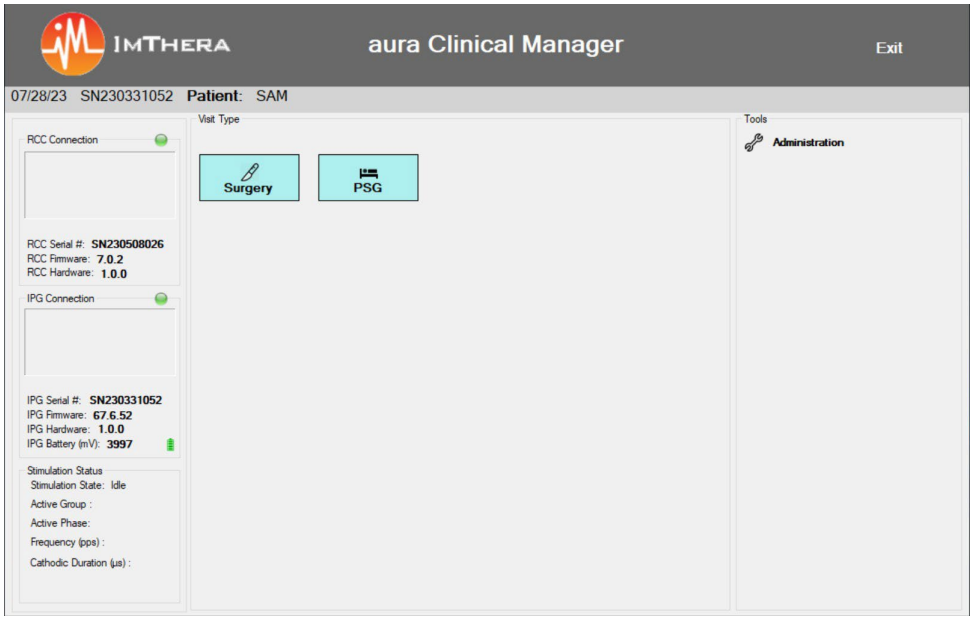
Note: See the "Troubleshooting" section for more information.

5.9 aCM Screen Description

5.9.1 Home Screen

When the aCM is started, the application attempts to connect to an RCC through one of the USB ports. The first screen that appears when the aCM is successfully started is the Home screen (Figure 13).

Figure 13. Home Screen



The Home screen is the launch point for the 2 visit-type screens: Surgery and PSG. Each visit-type screen has functions related to that activity, plus some common functionality accessible from all screens.

The Home screen also allows you to access the Administration screen (Figure 17), where pairing options are found.

5.9.2 Common Functions Accessible from Visit Screens

All visit screens (Surgery and PSG) have the following common functionalities:

1. **Home / Exit** — **Home** takes you back to the Home screen, and **Exit** takes you out of the application.
2. **Title Bar** — The title bar contains the following information about the visit: date, generator serial number, and Patient ID.
3. **Checklist** — The "Surgery Screen" includes a list of recommended steps to complete for the visit.
4. **System Status** — The system status area on the left side of the screen provides the following:

   a. RCC Connection

   b. Generator Connection

   c. Stimulation Status

   You should monitor the system status indicators when using the aCM application. The system status area is located on the left side of all screens.

   - Green = good connection
   - Yellow = connection in progress
   - Orange = connection is being re-established (for the RCC, check the USB connection)

- Gray = disconnected (for the RCC, check the USB connection)
- Blue = generator is stimulating

5. **Actions** — The actions area on the right side of the screen provides the actions available for each specific visit screen.
6. **Generate Report** — Lets you to create a visit report, including changed parameters. The report can be printed or saved in PDF format.
7. **Advanced Settings** — Provides access to Global Parameter, Master Amplitude, Smooth Start, and Impedance Parameter settings. (Figure 18).

5.9.3 Surgery Screen

The Surgery screen (Figure 14) is used during the implant surgery. This screen enables you to:

- Verify proper operation of the system
- Determine the motor levels
- Verify the viability of the electrode-hypoglossal nerve interface
- Enter the lead serial number

Test Contact Impedances: At the top of the Surgery screen is the Test Contact Impedances section. Click **Test Impedance** to test the impedance between the generator and each of the 6 electrode contacts. This enables the surgeon to confirm the electrical integrity and functionality of the generator and the lead with a single button press.

Note: Acceptable impedance ranges are found in the *Implant Procedure* chapter of this manual.

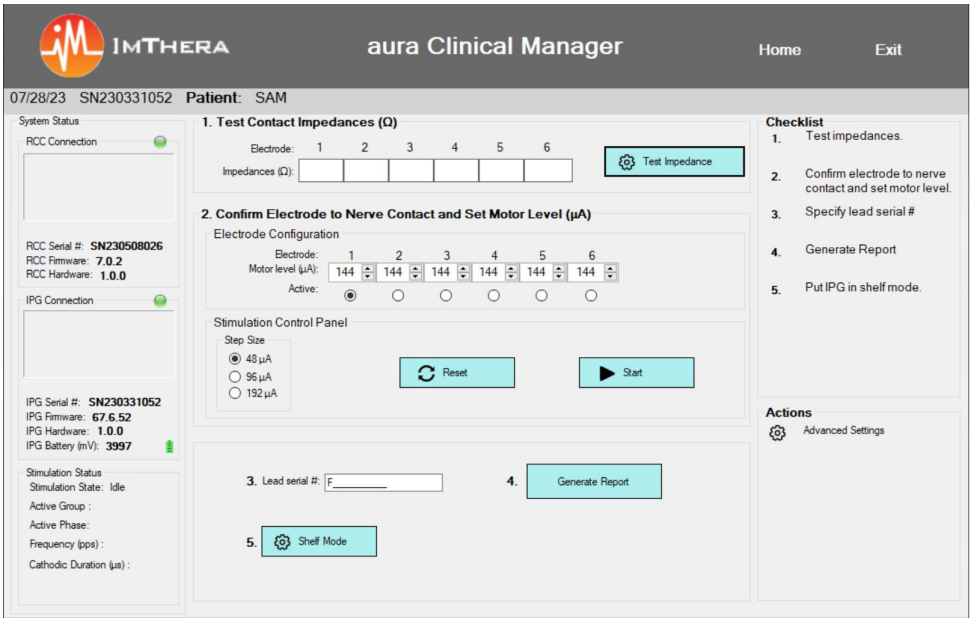
Determine the Motor Levels: The motor levels are determined by testing each electrode contact individually.

1. Click **Start** under the Stimulation Control Panel section. Stimulation will start at the first contact at the default amplitude (144 µA).
2. Click the **up / down arrows** next to each contact to adjust the stimulation amplitude. The amplitude (in µA) is displayed in the box below the corresponding contact (Figure 14).

   Note: The **up / down arrows** on the aCM computer keyboard are used to adjust values for each contact, and the **left / right arrows** switch between electrodes.

3. Increase the stimulation amplitude until muscle twitches are observed at the stimulation frequency (default 3pps in the Surgery screen). When muscle twitches are observed, the viability of the electrode-hypoglossal nerve interface is verified.
4. Select the radio button below next contact you want to activate. Repeat steps 1-3 for each contact. The motor level for each contact is saved automatically.

Figure 14. Surgery Screen



At the end of the surgery, complete the following steps:

1. Enter the lead serial number.
2. Click **Generate Report** to generate a report.
3. Click **Shelf Mode** to place the generator into Shelf Mode.
4. Click **Home** or **Exit** to leave the surgery screen.

Note: If the generator is inactive for 72 hours, it will automatically go into Shelf Mode.

5.9.4 PSG Screen

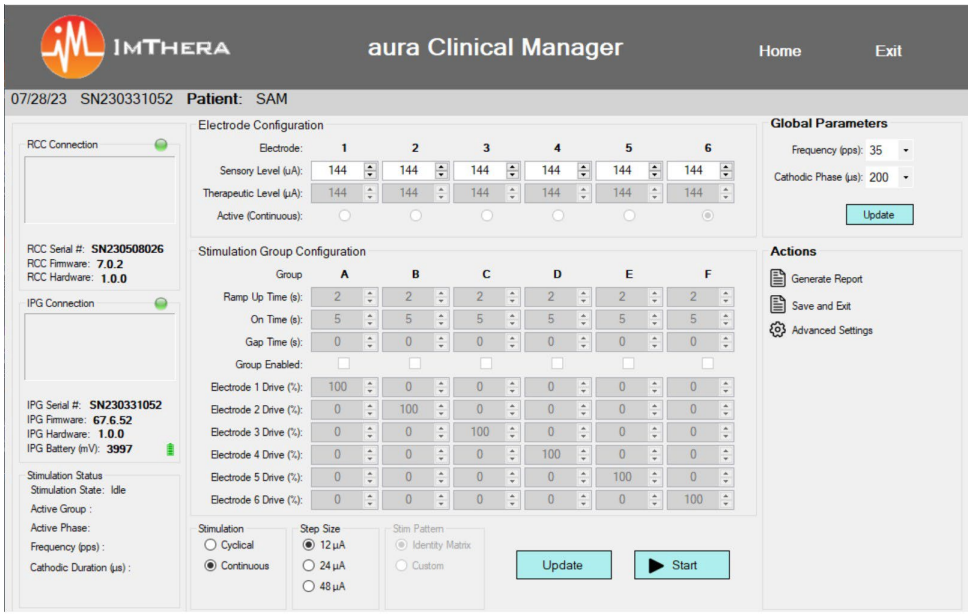
The PSG Screen is used to determine the therapeutic stimulation parameters for the patient and to configure the generator otherwise. The PSG screen can be operated in Continuous Mode (Figure 15) and Cyclical Mode (Figure 16). The difference between Continuous and Cyclical stimulation modes is that in Continuous Mode stimulation is delivered continuously on a single contact until the operator clicks **Stop** to stop stimulation. Contrastingly, in Cyclical mode, stimulation is cycled between enabled contacts at the **Ramp Up Time**, **On Time**, **and Gap Time** shown on the screen. Since the **Ramp Up Time**, **On Time**, **and Gap Time** are only used in Cyclical Mode, these parameters are visible, but grayed out as nonfunctional while Continuous Mode is selected.

The left part of the PSG screen is the same in both Continuous and Cyclical mode. System status information is on the lower left area of the screen. The Global Parameters section is on the right side of the screen.

5.9.4.1 PSG Screen — Continuous Mode

The Continuous Mode (Figure 15) is used with an awake patient to determine the Sensory Limit for each contact. These values are used later to identify the amplitude expected to cause a patient to wake from stimulation. The final therapeutic programing amplitude should be set at or below the patient's sensory limit.

Figure 15. PSG Screen, Continuous Stimulation



To set the Sensory Limit for each contact, complete the following steps:

1. **Select a Contact**
   Click the radio button next to the contact you want to evaluate.
2. **Adjust Amplitude**
   Click the **up or down arrow** to increase or decrease the amplitude for the selected contact. To change the step size from the default 12 µA value to 24 or 48 µA, choose the appropriate value in the **Step Size** box.
3. **Start Stimulation**
   Click **Start** to activate stimulation. While stimulation remains active, continue adjusting the amplitude as needed.
4. **Save Changes**
   The system automatically saves your changes. You can also click **Update** at the bottom of the screen to save manually. Stimulation continues until you click **Stop**, even if you select a different contact.

Note: Use the **up / down arrows** on the aCM computer keyboard to adjust values for each contact, and the **left / right arrows** switch between electrodes.

Once the amplitude for that contact is defined, you can move between contacts by selecting the radio button below the contact you would like to activate. The stimulation amplitude for the contacts will be displayed (in µA) in the box corresponding to the therapy mode (Sensory or Therapeutic) for each contact. Any changes made in the Sensory Limit or Therapeutic levels are automatically saved.

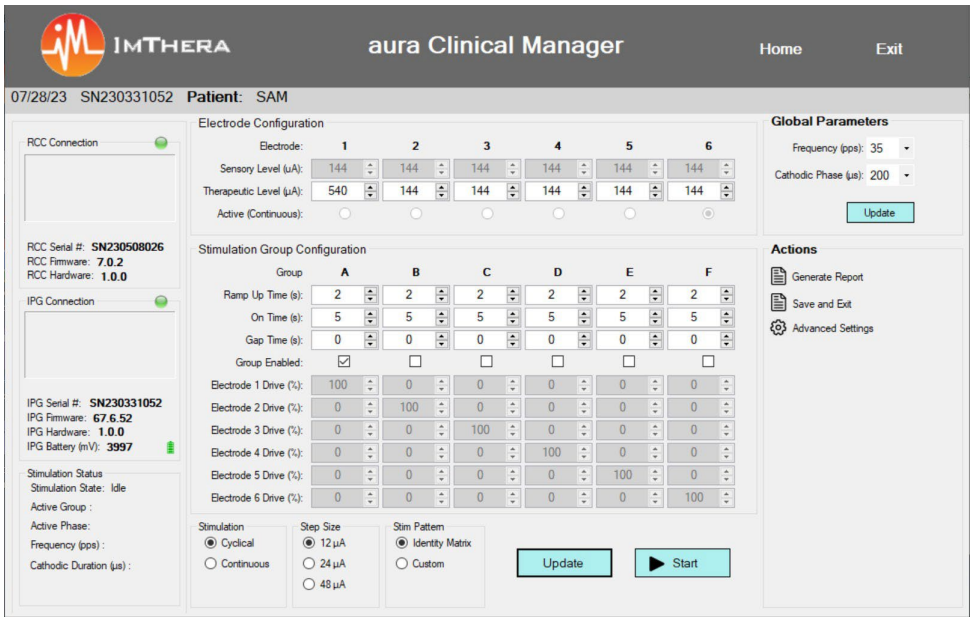
Note: When in continuous mode, you cannot change the Therapeutic level. Only the Sensory level can be changed.

5.9.4.2 PSG Screen — Cyclical Mode

Cyclical Mode (Figure 16) is used during polysomnography (PSG) to titrate the stimulation parameters of the Therapeutic stimulation. Perform individual contact titration or evaluation to determine each contact's therapeutic level and efficiency in a sleeping patient. This screen is also used as part of titration to perform the therapeutic program titration and contact combinations to determine the combination and sequencing of contacts that provide the best therapeutic benefit in a sleeping patient.

The check boxes labeled **Group Enabled** allow you to choose the contacts to be used in the therapeutic program (and PSG). The **On Time** (includes ramp up) boxes enable you to adjust how long each contact will be on, while the **Gap** sets the length of "idle" time between two contacts.

Figure 16. PSG Screen, Cyclical Stimulation



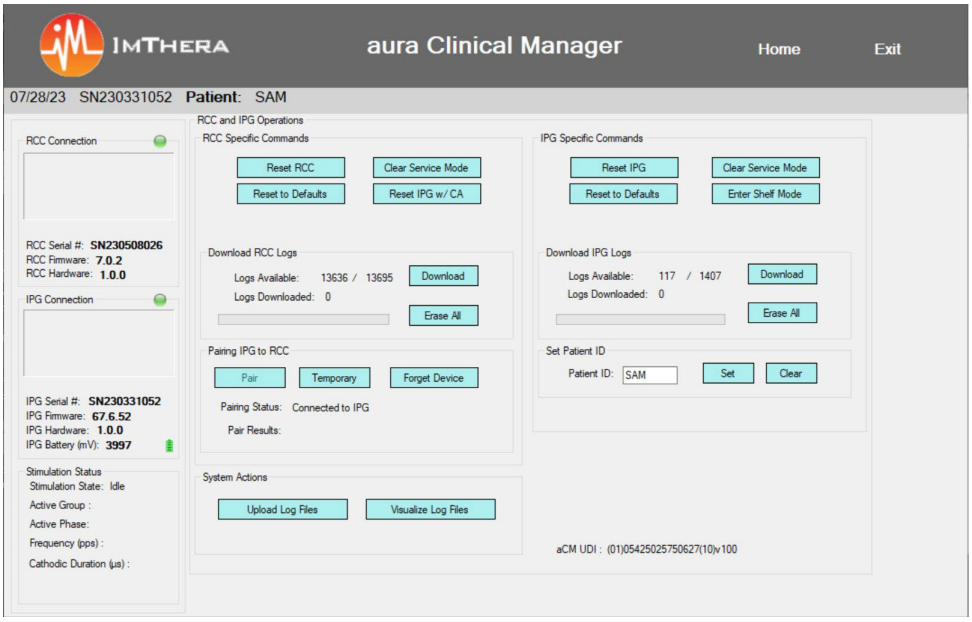
The amplitude settings for each contact are shown on the Therapeutic level row. If these settings require modification during the PSG, click the **up/down arrows** next to each contact to increase or decrease the values. It is adjusted in microamps (µA) as described in "PSG Screen — Continuous Mode". You can adjust the amplitude and all other parameters when stimulation is on.

> **Note:** The **up/down arrows** on the aCM computer keyboard adjust values for each contact and the l**eft/ right arrows** switch between electrodes.

5.9.5 Administration Screen

Use the Administration screen (Figure 17) primarily for advanced system troubleshooting and to set the Patient ID. You can also use this screen to permanently pair the generator with the patient's RCC or temporarily pair it with any RCC in the physician's office. The Patient ID can be any three letters (e.g., the patient's initials or first three letters of their last name). The Patient ID is simpler to remember than the generator serial number, which makes it easier to confirm that the aCM connects to the intended generator. Contact Technical Support if you have questions or need assistance using this screen.

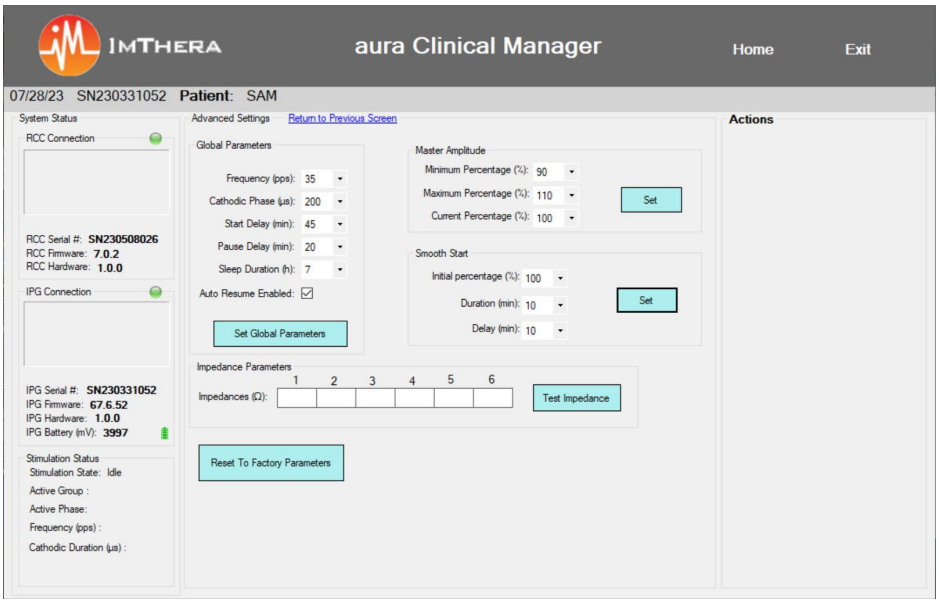
Figure 17. Administration Screen



5.9.6 Advanced Settings Screen

The Advanced Settings screen (Figure 18) has 4 major sections: Global Parameters, Master Amplitude, Smooth Start, and Impedance Parameters. This screen allows you to set how long stimulation onset will be delayed after starting (Start Delay) or resuming (Pause Delay) a sleep session. It also allows you to set the maximum duration of a sleep session (Sleep Duration) which can be helpful if a patient forgets to turn off their generator when they wake up.

Figure 18. Advanced Settings Screen



5.9.6.1 Global Parameters

From the Global Parameters box you can adjust the following parameters:

- **Frequency** — This sets the stimulation pulse frequency in pulses per second (pps). All contacts use the same frequency.
- **Cathodic Phase (Duration)** — This sets the stimulation pulse width. All contacts use the same pulse width.
- **Start Delay** — This parameter determines how long the therapy will wait after the Start Therapy command is sent before the generator starts to deliver stimulation. This can be set in 15-minute increments from 0 to 60 (i.e., 0, 15, 30, 45, 60) to give the patient time to fall asleep.
- **Pause Delay** — This is similar to the Start delay, except that it is used when a patient resumes a sleep session after pausing. Typically, this delay will be shorter than the Start delay since patients often take less time to resume sleep. This can be set from 5 to 30 minutes (i.e., 5, 10, 20, 30).
- **Sleep Duration** — This sets how long the sleep session, which includes Start Delay, will run unless the patient stops it sooner. It can be set to a minimum of 4 hours and a maximum of 10 hours.

5.9.6.2 Master Amplitude

Master Amplitude enables the physician to give patients some control over their therapy amplitude (strength). Some patients, particularly shortly after initiating therapy, find that the most effective airway opening parameters are initially uncomfortable. Clinical experience shows that over time patients will tolerate higher stimulation amplitudes. This feature enables physicians to retain the optimal efficacy parameters (100%) while allowing patients to adjust within a predefined range (set by the physician) until they can get used to the higher stimulation amplitudes. Set the Master Amplitude Minimum Percentage at a comfortable level for the patient.

> **Note:** Physicians should encourage patients to increase their Master Amplitude setting as soon as practicable, to obtain maximum therapeutic benefit.

Note: The levels of therapeutic stimulation are limited for safety reasons. If the therapeutic output current is programmed near the maximum allowable current for any contact, the aCM system will limit the programmability of the Master Amplitude Maximum Percentage to remain within an acceptable range.

5.9.6.3 Smooth Start

Smooth Start allows a slow ramp of stimulation at the start of a sleep therapy session. The physician sets the percentage that scales the therapeutic levels, the duration of the start ramp from the scaled levels to the therapeutic levels, and a delay or hold time during which no ramp occurs, but stimulation remains at the scaled level. Typically the delay would be set to 0 (0, 10, 20-minute options), the duration set to 10 or 20 minutes (0, 10, 20-minute options), and the percentage set to 80% (60%, 70%, 80%, 90%, 100% options).

5.9.6.4 Impedance Test

Click **Test Impedance** to test the impedance between the generator and each of the 6 electrode contacts.

5.9.6.5 Reset to Factory Parameters

To reset all the stimulation parameters of the *aura6000™* generator to the original factory settings, click **Reset to Factory Parameters**, which can be helpful in troubleshooting.

5.10 Operating the aCM

5.10.1 Surgery - Motor Threshold Level Testing

Motor levels are determined during surgery by increasing amplitude until the muscle twitches with each pulse (the motor threshold). A low stimulation frequency of 3pps makes this easy to see. This confirms proper system operation and proper electrode cuff position.

To determine and record Motor Threshold Levels, proceed as follows:

1. Start the aCM computer, verify the correct time and date, and start the aCM application. Click **Surgery**.

   Note: Confirm all impedances are within the acceptable range (200 to 3000 Ohms) before starting Motor Threshold Level Testing.

   Note: Follow the steps listed in the surgery screen's checklist section.

2. Inform the observer before you start stimulation, and instruct them to watch for twitches at the submandibular incision site.

   Note: Twitches will occur at the stimulation frequency. The surgery screen's default frequency is 3 pulses per second.

3. Click **Start** in the "Confirm Electrode to Nerve Contact and Set Motor Level (µA)" panel to start testing the first contact. Stimulation starts immediately at 144 µA.

   Note: Stimulation will continue until you click **Stop** to turn it off.

   Note: To move between contacts, select the radio button below the contact you want to activate.

4. Watch for twitches at the submandibular incision site. If the observer does not see any twitches, click the **up arrow** to increase the amplitude until the observer sees twitches. This amplitude is the Motor Threshold Level for this contact.

   Note: Twitches will occur at the stimulation frequency. The frequency on the surgery screen is 3 pulses per second.

   Note: See the *Implant* chapter for more information on Motor Threshold Level.

5. Evaluate the next contact. Select the radio button below the contact you want to activate.
6. Repeat steps 4 and 5 until all six contacts are evaluated.

> **Note:** All values are automatically saved.

7. If motor levels and impedance data are acceptable, the wounds may be closed, and the surgery will be complete.
8. Add the lead serial number in the **Lead serial #** box.
9. Click **Generate Report** to create a session report. Print and attach the report to the patient's records.
10. Place the generator into Shelf Mode.
    a. Click **Shelf Mode**.
    b. Wait 45 seconds.
    c. If a battery voltage value is displayed, the generator is not in Shelf Mode. Retry steps a and b.
11. Click **Exit**.

5.10.2 PSG — Titration of Stimulation Parameters

1. Ensure that the generator is fully charged.
2. Connect a USB cable between the RCC and the aCM. Place the RCC at a distance that allows telemetry to occur between the generator and the RCC.

> **Note:** USB cables longer than 5 m are unreliable (per USB standards). For distances greater than 5 m, use a USB extender approved by LivaNova.

3. At the aCM computer, verify that the date and time are correct, and start the aCM application.
4. Ensure you connect to the correct generator, then click **PSG**.
5. Select **Advanced Settings** on the right side of the PSG screen. Then, click **Test Impedance** to confirm that the impedances are within an acceptable range.

> **Note:** See the *Implant* chapter for an acceptable impedance range.

6. To return to the PSG screen, click **Return to Previous Screen.**

5.10.2.1 Sensory Limits

Determining the sensory limits informs the titration process about the initial stimulation amplitude, and gives you an idea of stimulation parameters that may wake the patient during PSG. Routinely measuring the sensory limits will provide information on how the sensory limits have changed over time.

Evaluate Sensory Limits when the patient is awake.

1. Advise the patient to relax their tongue. Tell the patient that they may feel something when the stimulation turns on, and ask them to signal when it is no longer comfortable.
2. Click **Continuous** in the stimulation section.

3. Select the contact you wish to evaluate by clicking the radio button associated with that contact. Click the **up or down arrow** associated with the selected contact to increase or decrease the amplitude.

   Note: You can change the amplitude step size 12 µA default value to 24 or 48 µA.

4. Click **Start** to turn on stimulation immediately. With stimulation on, click the **up or down arrow** to increase or decrease the amplitude of desired contact.
5. Changes will be saved automatically.

   Note: You can also click **Update** to save changes.

   Note: Stimulation will continue until you click **Stop** or select another contact to be activated.

5.10.2.2 Therapeutic Levels

The therapeutic level is the level that strikes a balance between effective treatment and comfort. Determining the therapeutic levels provides the levels tolerated by the sleeping patient and when it is necessary to titrate the therapeutic level during a PSG session.

1. To begin evaluation for therapeutic level switch to **Cyclical** mode.

   Note: Changing the mode to **Cyclical** will automatically move you from the sensory level to the therapeutic level row of the electrode configuration.

2. Select the contact you wish to evaluate by checking the **Group Enabled** box under Stimulation Group Configuration.

   Note: Be sure to deselect any contact that should not be included in the evaluation.

3. Select the **Therapeutic** row and then click the **up or down arrow** to adjust the therapeutic level of the first contact to evaluate. Click **Start** to immediately start stimulation at the highlighted amplitude.

   Note: Stimulation will stay on until you click **Stop** or click an **up/down arrow** to move to the next contact.

4. To assess the efficacy of an individual contact at various amplitudes, check one contact at a time to activate and make sure all other contacts are disabled.
5. ings for individual contact assessment during therapeutic level evaluation are as follows:
   a. **Ramp Up Time:** 0 – 2 seconds (default is 1 second)
   b. **On Time:** 5 – 7 seconds nominal

      Note: The range is 3 – 16 seconds, but values greater than 12 are not recommended unless there is a clear benefit.

   c. **Gap Time:** 0 –16 seconds

      Caution: Do not perform individual contact assessment with 0 gap.

      Caution: For one active contact, set the gap time approximately equal to the contact's ON time to reduce the likelihood of muscle fatigue.

6. Click the **up arrow** to increase stimulation amplitude (the step size by default is 12 µA and can be changed under **Step Size**) and click **UPDATE** to send the new value to the generator. Observe each change in amplitude for a minimum of 3 – 4 breaths, and a maximum of 5 minutes.
7. Evaluate the contact efficacy at various amplitudes and continue to increase the amplitude until the optimal therapeutic range is identified or the patient's arousal threshold is reached.

   Note: If stimulation causes arousal, decrease by 12 µA or 24 µA. Discontinue if stimulation is poorly tolerated or impairs airflow.

   To move to the next contact for evaluation, select the box for the next contact and uncheck the current contact box.

   b. Changes are saved automatically.

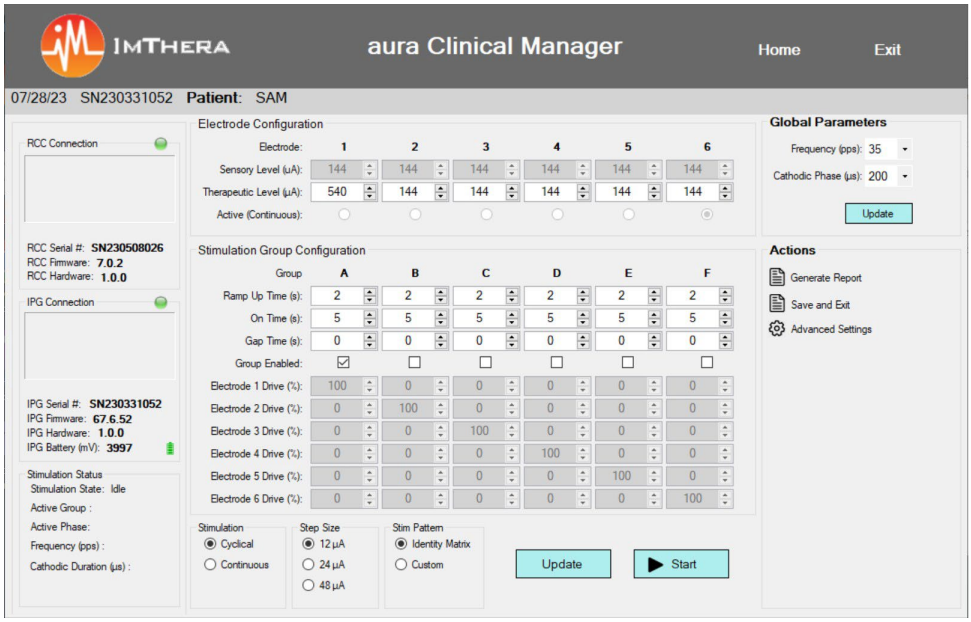
8. Determine contact efficacy. An effective contact consistently demonstrates the following, in order of importance:
   a. Improvement in airflow as assessed by nasal pressure (PTAF) signal
      - Reduced frequency of apnea/hypopnea
      - Increase in waveform amplitude
      - Rounding flow curve indicative of reduced flow limitation
   b. Improvement in peripheral capillary oxygen saturation (SpO_2)
      - Clinically significant increase of the desaturation level
      - Stabilized to the extent that excursions are limited to no more than 3%
   c. Reduced rate of arousal noted in EEG
9. Repeat steps listed above for each of the 6 contacts

   Note: This portion of titration aims to define the therapeutic window for exploration during paired titration, characterized by improvement relative to the baseline of flow inferred from nasal pressure and interpreted improvement in SpO_2.

5.10.3 PSG — Titration of Stimulation Parameters

Use **Cyclical** mode (Figure 19) to deliver stimulation that matches a patient initiated sleep session. The aCM provides information about which contact is being stimulated to assist you in interpreting the PSG data, so you can adjust the stimulation parameters while the patient sleeps.

Figure 19. PSG Screen



Keep the following points in mind when planning to adjust stimulation parameters in a PSG:

1. The generator will consume more battery during a PSG, so it is very important that it be fully charged before the PSG session begins. The generator cannot be charged while the therapy is on.
2. Place the RCC near the patient. Connect the RCC to the aCM using a USB cable, typically many meters from the patient's sleeping location. This cable should be long enough so you do not have to enter the patient's room to adjust the aCM.
3. Download the generator's Event Log and generate a report after each PSG. Place a copy of the report in the patient's record.

To operate the aCM during a PSG proceed as follows:

1. Ensure that the generator is fully charged.
2. Connect a USB cable between the RCC and the aCM. Place the RCC at a distance that allows telemetry to occur between the generator and the RCC.
3. Start the aCM computer, verify the correct time and date, and start the aCM application.
4. Press **OK** button to power On the RCC.
5. Wait for the patient to fall asleep.

Note: To avoid waking the patient, turn off RCC beeping and LCD backlight.

6. After the patient has fallen asleep, click **PSG**.
7. Click the **Cyclical** radio button, and then click **Start**. Stimulation will start in a few seconds.

Note: The stimulation will stay on until you click **Stop Stimulation** to turn it off or until an amount of time equal to the Sleep Duration passes.

8. **Ramp Up**, **On Time**, and **Gap** will turn green to tell you which contact is currently on. By monitoring these lines when apneas, hypopneas or arousals occur, you will know which contact to adjust.
9. If you decide that you would like to adjust the stimulation parameters, then proceed as follows:
    a. To adjust amplitude, use the direction arrows to highlight the appropriate contact, and then click the **up/down arrow**.
    b. On times and gaps can also be adjusted when stimulation is on; however, you must click **Update** to save changes.
10. After determining the therapeutic amplitudes and contact arrangements under which the patient's sleep therapy will be delivered, consider the following:
    a. Stimulation is provided by cycling between at least 2 contacts operating in sequence. Use at least 2 contacts to ensure the stimulation load is shared among muscles to reduce the likelihood of fatigue.

    ⚠ **Caution:** If only one contact is useful, use a gap time approximately equal to the contact's ON time.

    b. Global Parameters, Master Amplitude, and Smooth Start can be adjusted through the "Advanced Settings Screen" before the visit is complete.
11. To use the desired contact arrangement when activated by the patient via the RCC for a standard night of therapy, ensure **Cyclical** mode is selected.
12. When you have finished the PSG, click **Generate Report** to generate a report of the PSG visit. Click **Exit** to leave the session.

5.11 Maintenance, Handling and Disposal

Follow the guidelines below for proper handling and storage of the programming system.

- To clean the external surfaces of the RCC and CA, wipe with a pre-moistened or damp cloth using one of the following cleaners: isopropyl alcohol (70-90%), ethanol, or CaviCide®.
- The RCC and CA are rated as IP22. They are protected from touch by fingers or similar objects and moderate amounts of dripping water. Keep the RCC and CA dry because additional exposure to water or other liquids could cause performance loss.
- Do not sterilize any parts of the programming system.
- Regularly inspect the programming system parts for damage. Return any damaged parts to LivaNova.
- Do not operate the programming system near water or other fluids nor immerse any components in liquids. Doing so may cause permanent damage.
- Do not drop. Dropping on hard surfaces may cause permanent damage.
- Never expose the RCC, its power cord or the CA to storage temperatures below -10 °C or above 55 °C (Table 15).

5.12 Troubleshooting

5.12.1 Service Mode

If a major hardware or firmware issue is detected, the RCC or generator will enter Service Mode. If this occurs, follow the troubleshooting in Table 13.

5.12.1.1 RCC in Service Mode

When the RCC is in Service Mode, you can use the RCC and aCM for the following:

The RCC

- Display the RCC serial number, firmware version, and hardware version
- Turn the RCC on and off
- Charge the RCC

The aCM

- Download RCC logs
- Clear the Service Mode

5.12.1.2 Generator in Service Mode

When the generator is in Service Mode, you can use the RCC for the following:

The RCC

- Read generator serial number, battery voltage, firmware version, and hardware version
- Charge the generator

The aCM

- Clear the Service Mode on the generator
- Put generator into Shelf Mode
- Reset the generator by command or with the CA
- Download generator logs

5.12.2 RCC Error Messages

For information to help you understand and resolve RCC error conditions, see Table 13.

Table 13. RCC Troubleshooting

Problem/Message	Reason	User Action
The RCC display is blank.	The **OK** button press was not detected.	■ Press the **OK** button.
	No power.	■ Charge the RCC. ■ If the issue persists, contact LivaNova for replacement.
	The RCC needs to be reset.	■ Press and hold the **OK** button for at least 6 seconds and release. This turns the RCC power OFF. ■ Press and release the **OK** button to power ON the RCC.
	The display is broken.	■ Contact LivaNova for replacement.
When plugged in, the remote does not display the battery icon.	The power cord is not plugged into a wall outlet.	■ Plug the power cord into a wall outlet. ■ Try a different wall outlet.
	The power cord is not connected to the RCC.	■ Disconnect and reconnect the power cord from the RCC.
"Unable to connect to the implant"	The RCC is too far away from the generator.	■ Move the RCC closer to the generator and try again.
	The generator battery is low.	■ Charge the generator and try again. ■ **Note**: It may take up to 1.5 hours to completely charge the generator. ■ **Note:** The generator can be charged for a short period of time when the RCC cannot connect to the generator.
	The RCC is not paired with the generator.	■ Move the RCC closer to the generator, move away from other electronic devices, and try again. ■ Select GET implant status on the RCC Main Menu to refresh. ■ Turn the RCC OFF and ON. ■ Pair the generator with the RCC. ■ If you have tried the other solutions and the issue persists, contact LivaNova.
	There is interference from other electronic devices in the area.	■ Move away from other electronic devices.
	RCC failure.	■ Contact LivaNova.
"Therapy is ON Charging not possible"	You cannot charge the generator when therapy is ON.	■ Finish the therapy session then charge the generator.

Problem/Message	Reason	User Action
"Charging not possible. Connect charge antenna"	Your CA is not connected to the RCC.	■ Disconnect and reconnect the RCC and the CA and retry the charging process. ■ If the issue persists, contact LivaNova.
	The CA may not be aligned with the generator.	■ Properly align the CA with the generator and minimize misalignment or disruption during charging. ■ If the issue persists, contact LivaNova.
	The CA may not be plugged in correctly.	■ Remove the CA and verify the orientation of the connector. ■ Ensure the CA is fully plugged in.
	CA failure.	■ Contact LivaNova.
"Charging not possible. Insufficient power in remote control"	The RCC battery is too low to charge the generator.	■ Plug the RCC power cord into a wall outlet. The generator can be charged while the RCC is charging.
"Charging not possible. High charging current"	A metal object is too close to the CA coil.	■ Ensure no metal objects are near the CA and try to charge again. ■ If the issue persists, contact LivaNova.
	Charging system failure.	■ Contact LivaNova for a replacement.
"Maximum temperature exceeded. Please wait..."	The CA has reached the temperature limit.	■ The RCC monitors the temperature of the CA. You can begin to charge after the CA cools down. ■ Consider moving to a cooler location. ■ Ensure the CA is not covered with material such as a blanket.
The LED light on the CA is flashing and the generator is charging slowly.	The CA has reached the temperature limit.	■ The RCC monitors the temperature of the CA. You can begin to charge after the CA cools down. ■ Consider moving to a cooler location. ■ Ensure the CA is not covered with material such as a blanket.
"Low efficiency See manual"	The generator charging session is unsuccessful due to CA misalignment with the generator or other interference.	■ Reposition the CA over the generator. ■ The patient 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:** Patients should not wear jewelry near the charging system. ■ If the issue persists, contact LivaNova.
The generator charges slowly.	Charging system failure.	■ Reposition the CA over the generator and ensure proper alignment. ■ Remove unnecessary metal from between the charging coil and the generator. ■ Charge the generator in a cooler environment. ■ If the issue persists, contact LivaNova.
"Telemetry error. Retry or see manual"	There is no communication between the RCC and the generator.	■ Properly align the CA over the generator. ■ Move away from other electronic devices. ■ Remove obstructions from between the RCC and the generator. For example, ensure there are no books, laptops, pets, or parts of the patient's body between the RCC and the implant site. ■ Ensure a clear line of sight from the RCC to the generator implant site. ■ If the issue persists, contact LivaNova.

Problem/Message	Reason	User Action
You cannot charge the generator, even with the RCC plugged into a wall outlet.	The CA and/or RCC may not be plugged in properly.	■ Check the connections between the CA and the RCC. ■ Align the CA on the generator. ■ Plug the RCC completely into the wall outlet. ■ Charge the generator and check if the issue still occurs.
"Charging not possible. Maximum time exceeded"	The maximum time allowed for a charge session has been reached.	■ Allow the CA to cool then restart charging. ■ Continue to charge until the desired charge is reached.
"Battery Low. Charge implant, then try again"	The generator battery is low.	■ Charge the generator. ■ Instruct the patient to charge their generator at least every other day.
It takes longer than usual to charge the RCC.	The RCC may need to be replaced.	■ Contact LivaNova.
The RCC screen is not readable.	The RCC screen brightness is too low.	■ Go to settings and set the brightness to high. ■ If the issue persists, contact LivaNova.
Stimulation cannot be felt.	Therapy is ON and the amplitude is too low to be felt.	■ Select **GET implant status** on the Main Menu to confirm that the generator is ON and the patient feels nothing. ■ If you and your patient are satisfied, no further action is needed. ■ If you and your patient are unsatisfied with therapy, adjust the therapy parameters or advise your patient to use **Master Amplitude** to increase therapy for their sleep session. Check the master amplitude or consider an adjustment to therapeutic levels.
	Therapy is OFF - Your patient's sleep duration is shorter than actual sleep time.	■ Advise your patient to increase sleep duration.
	Therapy is OFF - The generator battery depleted during the sleep session.	■ Use **GET implant info** to check the generator battery. If *Implant Batt* is less than 3.44 V, advise your patient to charge their generator more completely and more often.
	Therapy is OFF - System failure.	■ Contact LivaNova.
"Master Amplitude Control adjustment not possible."	Master Amplitude Control settings are not programmed.	■ See "Master Amplitude" for how to set Master Amplitude Control settings.
"Testing not possible"	Therapy is ON.	■ Turn OFF therapy and try testing again. ■ If the issue persists, contact LivaNova.
"Remote Disabled. Service Required. See Manual."	Hardware or firmware issue.	■ Continue the previous action and use the device as usual. ■ If the error persists, reset the RCC. To do this, press and hold the **OK** button for at least 6 seconds and release it to power OFF the RCC, then press and release the **OK** button again to power ON the RCC. ■ If this issue persists, contact LivaNova.
"Implant Disabled. Service Required. See Manual."		
"External control enabled"	The RCC is connected to the aCM.	■ Unplug the RCC from the aCM.

Problem/Message	Reason	User Action
The RCC header shows the following icon (flashing or solid) 	The RCC battery is not present or may have an issue.	■ Disconnect the RCC 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 LivaNova.

5.12.3 aCM Error Conditions

For information to help you understand and resolve RCC error conditions, see Table 14.

Table 14. aCM Troubleshooting

Problem/Message	Reason	User Action
You are unable to start the computer.	No power.	■ Charge your computer. ■ Plug in your computer.
You are unable to log in to the aCM computer	Screen says "Unlock the PC".	■ Select "Switch User" and enter your login credentials assigned to this device.
	Forgot password.	■ Contact LivaNova to reset your password.
Window Security detected a threat or suspicious file	Malware or viruses found on the computer.	■ Stop using the aCM computer immediately and contact your facility's IT department ■ If this issue cannot be resolved, contact LivaNova for device replacement
The aCM is unable to find the generator that I want to link to.	The generator is in Shelf Mode.	■ See "Pair the RCC with the Generator".
	The generator battery is low.	■ Charge the generator for at least 10 minutes, then try again. **Note:** The generator can communicate with the RCC during its charging process.
	The CA is not placed on the generator.	■ Place the CA on the generator you want to pair with and attempt to pair with the generator again.

Problem/Message	Reason	User Action
The aCM cannot pair with the generator.	The RCC is too far from the generator.	■ Move the RCC closer to the generator, then try again.
	The generator battery is low.	■ Charge the generator for at least 10 minutes, then try again. **Note:** The generator can communicate with the RCC during its charging process.
	The RCC is unresponsive.	■ Reset the RCC - Disconnect the USB cable, press the **OK** button for at least 6 seconds, release it, then reconnect the USB cable.
	The aCM software is unresponsive.	■ Exit the aCM application, disconnect the RCC from the aCM, reconnect it, then restart the aCM.
	The user has not accepted remote access on the RCC.	■ Accept the message on the RCC screen to allow remote access.
	The CA is not placed on the generator.	■ Place the CA on the generator you want to pair with and attempt to pair with the generator again.
	There are too many generators in the area.	■ If more than 3 generators are present within the communication range of the generator, once pairing fails, use the serial number entry prompt to perform targeted pairing.
The RCC connection indicator is orange in System Status.	The RCC is not connected, or the USB is not recognized.	■ Disconnect the RCC USB cable from aCM and reconnect. ■ If the RCC connection indicator does not turn green, unplug all USB devices connected to the aCM and reconnect the RCC. ■ If the issue persists, contact LivaNova.

5.13 Programming System Specification and Guidance

5.13.1 Programming System Specifications

Table 15 provides a list of Programming System hardware specifications.

Table 15. Programming System Specification

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

5.13.2 Electromagnetic Emissions and Immunity Guidance for RCC

The RCC is intended to be used in the electromagnetic conditions specified in Table 16, Table 17 and Table 18.

Table 16. Electromagnetic Emissions

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

Table 17. 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 - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 18. Electromagnetic Immunity to Proximity Fields from RF Wireless Communications Equipment

Test Frequency	Services for which the recommended separation distance is 30 cm (12 in.)	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		

5.13.3 FCC Requirements

The *aura6000™* generator and RCC 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™ RCC 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.

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.

6 Implantation

6.1 Surgeon Training

Physicians who implant the *aura6000™* generator and lead should be thoroughly familiar with this manual and have completed all associated training materials.

All programming should be performed by or under the supervision of a physician familiar with the use and operation of the programming software.

Note: Contact Technical Support to request other training materials and support.

6.2 Surgical Components and Materials

6.2.1 Surgical Components (Required)

- 2 generators (1 primary and 1 backup)
- 2 leads (1 primary and 1 backup)

  Note: For lead size availability, see the *Technical Information - aura6000™ Lead* section.

  Note: The 33 cm lead length will satisfy all surgical cases. However, based on surgeon and patient preference, the 25 cm lead may be considered. When selecting among available lead lengths to implant, consider the patient's anatomy and ensure the lead length can support adequate strain relief per instructions found in the Implantation Procedure section.
- 1 programming system (non-sterile)

  Note: Remember to use proper technique when you introduce non-sterile items into a sterile field.

6.2.2 Surgical Materials

The following is a list of materials typically used during the implantation procedure. LivaNova does not provide these materials due to availability of commercial off-the-shelf options and their use depends on surgeon preference or optional use. Follow the manufacturer's instructions when using any of these materials:

- 1 tunneler / shunt passer to route the lead from the nerve incision site to the generator pocket

  Note: The LivaNova Model 402 Tunneler is compatible with the *aura6000™* system. If you choose this tunneler, use the provided small-diameter (3.4 mm inside diameter) sheath.
- Sterile sleeve bag to bring the RCC and cable into the sterile field
- Vessel loops and/or silicone sheet to aid in the manipulation of the nerve (optional but recommended)
- Nerve locator to locate the hypoglossal nerve (optional but recommended)
- Skin flap gauge ~7 mm to assist in the measurement of generator pocket depth (optional)

6.3 How to Open the Sterile Pack

Before you open the sterile pack, examine it carefully for evidence of damage or compromised sterility. Do not use it if the outer or inner sterile barrier is open or has damage. An opened or damaged product should be returned to LivaNova.

⚠ **Caution**: Do not open the sales pack if it has been exposed to extreme temperatures or if there is any evidence of external damage or damage to the package seal. Instead, return it unopened to LivaNova.

⚠ **Caution**: Do not implant or use a sterile device if the device has been dropped. Dropped devices may have damaged internal components.

⚠ **Caution**: Open the sterile lead pack only after exposing the hypoglossal nerve and selecting the appropriate lead size.

To open the sterile pack, do the following:

1. Grasp the tab and peel back the outer cover.
2. Use sterile technique to remove the sterile inner tray.
3. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.

6.4 Recommendations for Implantation

In general, implantation of the *aura6000™* system is similar to accepted practice for implantation of a cardiac pacemaker, except for the placement of the cuff electrode and the subcutaneous routing of the lead body. The surgical approach and techniques will vary with the surgeon's preference. To ensure correct lead placement, review the following recommendations for implantation, lead and suture sleeve placement, and other essential steps.

⚠ **Caution:** To maximize system performance and minimize possible mechanical damage to the nerve or lead, **pay careful attention to cuff electrode placement and lead routing.**

- Critical to the implant's long-term success are proper techniques for the position of the cuff electrode on the hypoglossal nerve and the provision of adequate strain relief.
- LivaNova recommends that any extra lead body be coiled and placed in the chest pocket to the side of the generator.
- Adequate exposure of the hypoglossal nerve ($>$ 3 cm) facilitates the placement of the cuff electrode on the nerve. Stretching the nerve or allowing it to dry during implantation may result in temporary swelling of the nerve. If extensive manipulation of the nerve is performed, administer an IV shot of cortisone at the end of the procedure to reduce risk of tongue paresis.
- LivaNova recommends testing the generator's output and the implanted system's performance (motor threshold level and impedance) at implantation as described in *Technical Information - aura6000™ Programming System*.
- Peri-operative monitoring should be performed for wound and cardiorespiratory issues, per surgeon's and anesthesiologist's discretion, as appropriate for OSA patients.
- Antibiotic prophylaxis should be administered prior to device implantation in accordance with institutional surgical protocols. Postoperative antibiotics may be

prescribed at the discretion of the implanting physician. For subsequent surgical or

dental procedures, standard clinical judgment should be used to determine the need for prophylaxis based on the nature of the procedure and patient-specific risk factors.

⚠ **Caution**: **Infections related to any implanted device are difficult to treat**, and explantation of the *aura6000™* generator and/or lead may be required.

- Incisions should be closed with a layered closure technique to minimize scarring. Avoid the use of metal surgical staples during closure as they may interfere with postoperative charging and device communication.

6.5 Pre-Surgical Steps

6.5.1 Before Surgery and Outside of the Sterile Field

Before the surgery you need to prepare the programming system and the generator for use. The following sections found in the *Technical Information - aura6000™ Programming System* section, provides detailed instructions.

1. Use the aCM to pair the RCC to the generator. See "Pair the RCC with the Generator".
2. Remove the generator from Shelf Mode. See "Take the Generator out of Shelf Mode".
3. Ensure the generator is fully charged (see "Charge the Generator Fully").

6.5.2 Interrogate the device

Before opening the generator sterile package, verify that the generator is operable. Use the aCM to interrogate the generator and read the generator battery charge level. See the aCM Operator's Manual for instructions on how to operate the aCM.

Confirm that the RCC-to-generator RF range will be sufficient to communicate with the generator without placing the RCC into the sterile field. Place the RCC and USB cable in a sterile sleeve bag if the RCC needs to enter the sterile field to communicate with the generator.

6.6 Patient Preparation

1. Determine the appropriate ipsilateral side for generator and lead placement, and prepare that side of the neck and infraclavicular region for surgery.

   ⚠ **Caution:** If possible, place the generator contralateral to any other active implanted device to minimize the potential of interaction between them.

2. Mark the incision sites as follows:
   a. With the patient seated before sedation, mark the lead incision with a 5-6 cm transverse cervical line over the anticipated course of the hypoglossal nerve. Ensure the incision is placed at least 2 cm below the inferior border of the mandible.
   b. Mark a 5 cm incision for generator placement about two finger widths (~3.5 – 4 cm) below the clavicle, at the mid-clavicular line or more medially, depending on patient anatomy.
   c. ~5 mm below the generator incision line (Step 2b.), draw a rectangular box (5 cm wide, 4 cm high) on the skin to represent the outline of the generator.

6.7 Lead Placement

1. Make a 5–6 cm incision at least 2 cm below the inferior border of the mandible and centered over the lesser cornu of the hyoid bone along the previously marked neck incision, “Section 6.6 Patient Preparation”.
2. Retract the submandibular gland.
3. Use blunt dissection to expose a 2–3 cm length of hypoglossal nerve distal to the *ansa cervicalis.* The hypoglossal nerve forms the superior border of the Pirogoff triangle, which is further delineated by the intermediate tendon of the digastric muscle as its inferior border and the posterior border of the mylohyoid muscle as its anterior boundary. These anatomical landmarks should be used to guide nerve identification. Follow appropriate technique to avoid injury to the marginal mandibular nerve, similar to precautions taken in submandibular gland surgery.

   Note: Make sure to leave perineural tissues intact.

   Note: Take care not to disrupt the blood vessels or lymphatics surrounding the hypoglossal nerve.

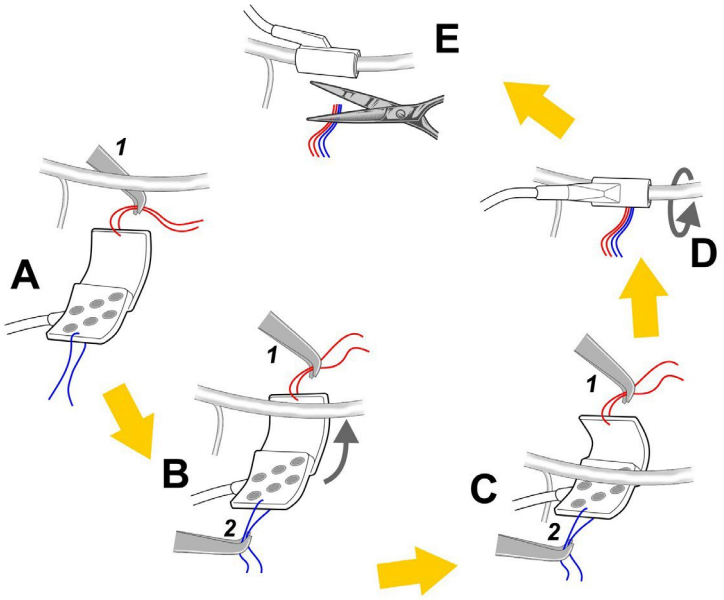
   Note: If a nerve locator is used, ensure the device is set to the “twitch” setting or delivers pulses at 4 pulses per second or less.

4. Place the electrode cuff ventrolateral to the exposed nerve so the lead cable exits superiorly.
5. Position the electrode cuff around the nerve as follows:

   Note: [Optional] Instruct an assistant to use a vein retractor to gently lift the hypoglossal nerve.

   a. Figure 20A — Position forceps #1 (red thread) ventromedial to the nerve, then advance its angled tip laterally beneath the nerve to grasp the red thread on the medial edge of the electrode cuff.
   b. Figure 20B — Use forceps #2 to grasp the blue thread on the lateral edge of the electrode cuff and spread the electrode cuff open.
   c. Figure 20C — Use forceps #1 (red thread) to pull the cuff under the nerve to the medial side and release forceps #2 (blue thread) when the lateral edge of the cuff reaches the nerve.
   d. Figure 20D — Allow the electrode cuff to furl around the nerve completely. Release the blue thread first to ensure that the cuff flap with the red thread is on the outside of the cuff and not against the hypoglossal nerve, which would preclude some electrodes from contacting the nerve.
   e. Figure 20E — Cut and remove the red and blue threads from the cuff then rotate the cuff so the lead cable exit is on the superficial side of the nerve.

Figure 20. Lead Placement – Right-Sided Anatomical View



6.7.1 Reposition the Lead

If the lead must be repositioned or removed, proceed cautiously to avoid damage to the surrounding tissue. Avoid cutting or otherwise damaging the repositioned lead.

6.8 Generator Placement

1. Select the site for the generator pocket. See the "Precautions" section of this manual for important information on selecting the generator pocket site.

   Note: The generator and lead should be implanted on the same (ipsilateral) side.

   Caution: Before pocket dissection, if using monopolar electrocautery, switch to bipolar electrocautery.

2. Make a ~5 cm mediolateral incision (equal to the width of the generator) along the line drawn.
3. Using blunt dissection or sharp surgical dissection (with bipolar electrocautery), create a subcutaneous pocket for generator placement deep to the subcutaneous fat at a uniform depth, at least 5 mm deep but no deeper than 10 mm from the skin surface. Make the pocket just large enough to contain the generator, while ensuring that the incision is not positioned directly over the generator.

   Caution: Ensure the implant depth is uniform and no deeper than 10 mm below the skin. Otherwise, post-operative charging may be inefficient or unsuccessful and the patient may not receive therapy.

   Note: See *Introduction to the aura 6000* system for precautions on the use of electrosurgery.

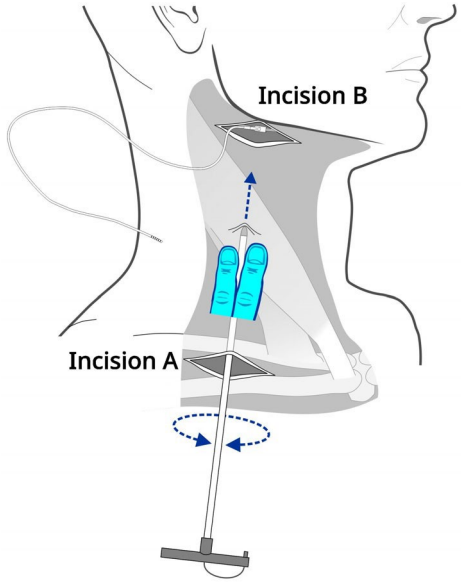
4. Use a tunneler, shunt passer, or other suitable method to tunnel the proximal end of the lead to the generator pocket.

a. [Optional] Bend the shaft ~10-15 degrees at ~10 cm from the tip to make it easier to steer the tunneler.

b. Tunnel subcutaneously from incision A (infraclavicular) to incision B (submandibular) (Figure 21)

c. Direct the tip by trapping it between the fingers of one hand while advancing the tunneler forward. The tunneler may be bent to ensure that the tip stays near the skin.

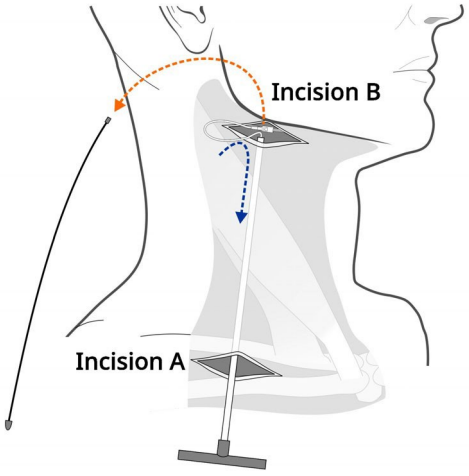
Figure 21. Tunnel from Chest Incision to Neck Incision



d. Remove the tip and withdraw the tunneler, leaving behind the sleeve connecting incisions A (infraclavicular) and B (submandibular).

e. Insert enough lead into the sleeve to reach from incision B to incision A (~15cm). (Figure 22)

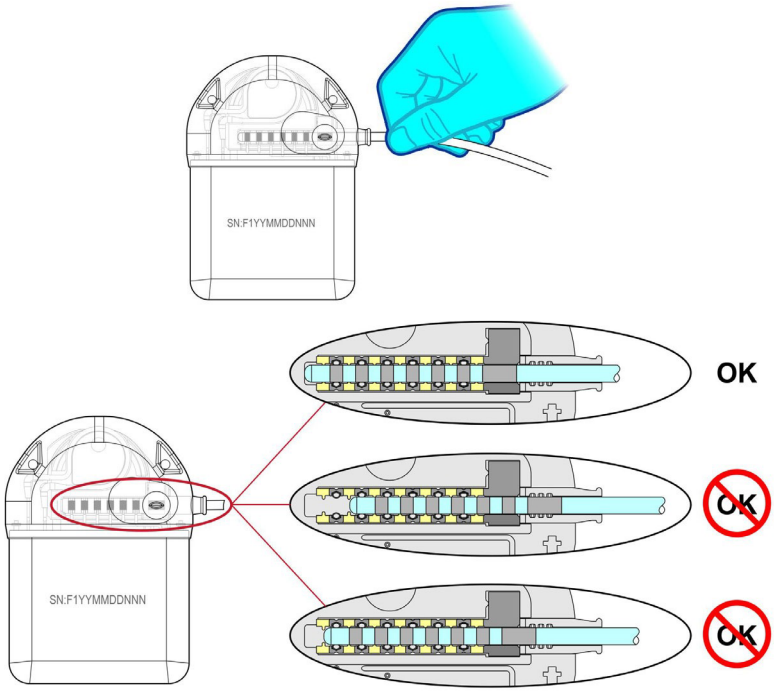
Figure 22. Route the Lead



f. Withdraw the tunneler to leave behind the lead exiting at incision A.

5. Use sterile gauze to wipe any visible blood or tissue from the metal contact bands on the proximal end of the lead.
6. Hold the lead 5 mm from the proximal end while you insert the lead into the generator header. Continue to insert in 5 mm increments until the lead is fully inserted. You will feel the lead bottom out in the header and see that the proximal end of the most distal band on the lead is within the setscrew block (Figure 23).

Figure 23. Connect the Lead to the Generator



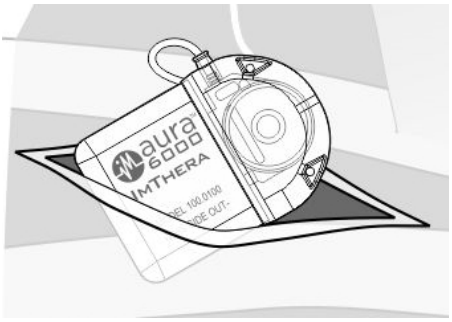
Note: The setscrew may move during transit, and it may be necessary to retract it slightly to permit the lead to enter the header.

Caution: Do not tighten the setscrew yet.

7. Place the generator into the generator pocket (metal portion first) with the ImThera logo facing outward (Figure 24). Ensure that the lead is not sharply bent.

Note: Do not suture until after impedance and motor threshold testing.

Figure 24. Place Generator in Pocket



6.9 Test the System

1. Flush the neck incision with saline solution and ensure the generator is in tissue contact.
2. Use the aCM to verify that acceptable impedances exist for a minimum of 4 electrode contacts (out of the 6 available contacts). Table 19 provides acceptable impedance values.

Note: See *Technical Information - aura6000™ Programming System* for aCM operating instructions.

Table 19. Impedance Values

Impedance (Ohms)	Interpretation/Action
<200	Low. Troubleshoot; see below.
200-3000	OK
>3000	High. Troubleshoot; see below.

a. For low impedance — Inspect the lead body for tears or cuts. If cuts and tears are present, replace the lead and retest impedance. If issue persists, replace the generator and retest.

b. To address high impedance, perform the following steps:

- Ensure that the generator is properly placed in the generator pocket or making tissue contact
- Confirm the electrode cuff with the contacts securely contacts the nerve. If necessary, adjust the cuff's position around the nerve.
- Flush the incision with saline to verify there is no air gap or bubble between the electrode contact and the nerve.
- Verify the lead is inserted correctly into the generator (Figure 23).
- Disconnect the lead from the generator to confirm there is no visible blood or tissue on the lead terminal bands. Reinsert the lead (Figure 23).
- If the issue persists, first explant and replace the lead. If that does not resolve the problem, then explant and replace the generator.

3. Use the aCM to verify that noticeable and acceptable muscle movements (contractions at the neck level) occur when stimulated. Muscle twitches originating from the electrode incision site and under the jaw are clearly visible to the unaided eye at a stimulation frequency of 3 pulses per second. Since the 6-contact cuff with its selectivity accesses the hypoglossal nerve at various locations, twitches of different tongue muscle groups from the base of the tongue to the chin are expected as different electrodes are selected for their respective motor threshold evaluation. These twitch responses are caused by the programmed stimulation parameters and serve as a reliable indicator that the hypoglossal nerve has been adequately activated by the electrode contact under evaluation. Table 20 provides acceptable motor

threshold levels. Optimal or acceptable motor thresholds are needed for a minimum of 4 electrode contacts (See Step 2 above).

Table 20. Motor Threshold Levels

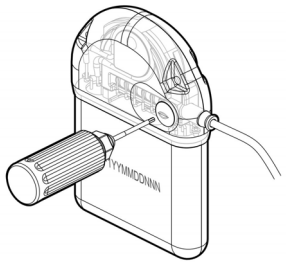
Stimulation Level (microamps)	Interpretation/Action
<500	Optimal
500-1500	Acceptable. Confirm that the electrode cuff is around the nerve (not a tendon or other nearby structure)
>1500	Recheck impedance and reposition the electrode cuff as necessary until movements can be seen at lower stimulation levels

6.10 Complete the Procedure

1. Remove the generator from the pocket and use the torque wrench provided to tighten the setscrew until it "clicks" (Figure 25).

Caution: To avoid damaging (stripping) the setscrews and/or dislodging the setscrew plugs, insert the torque wrench into the center of the setscrew plug, keeping it perpendicular to the generator.

Figure 25. Tighten the setscrew



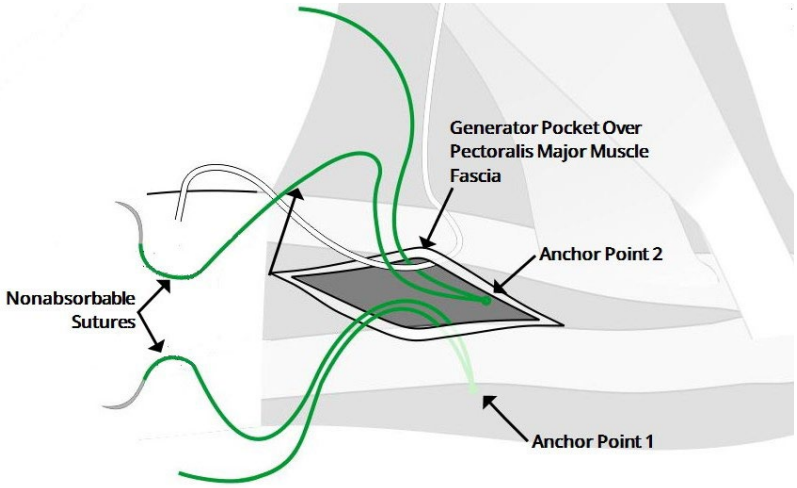
2. Prepare to secure the generator in the pocket as follows:
   a. Determine where the generator anchor holes will lay within the generator pocket.
   b. Place and tie a 2-0 nonabsorbable braided suture in the deep fascia at the inferior generator anchor point location (Anchor Point 1), leaving long suture tails (Figure 26). Do not tie the suture so tight as to constrict the tissue.

Note: To aid in Step 2d, leave the thread attached to the suture needle.

   c. Repeat Step 2b at the superior generator anchor hole.

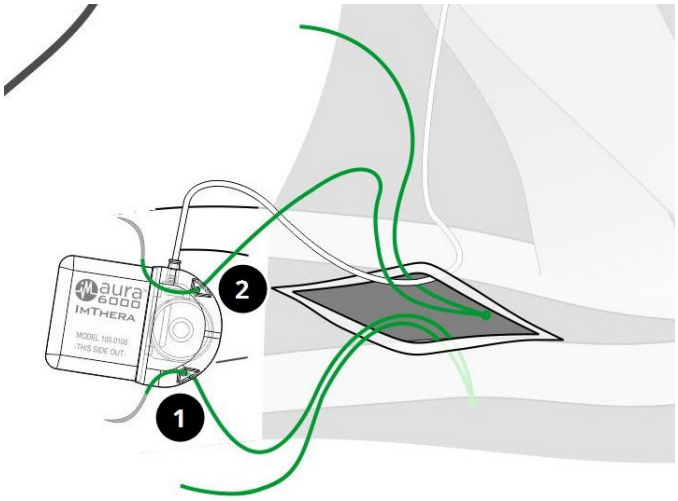
Note: Do not tie the suture to the generator until the impedance and motor thresholds have been tested according to Steps 2 and 3 in "Test the System" on page 62.

Figure 26. Generator Pocket Anchor Points



d. Thread the inferior and superior sutures through the inferior and superior generator anchor holes, respectively (Figure 27).

Figure 27. Thread Sutures Through Anchor Holes

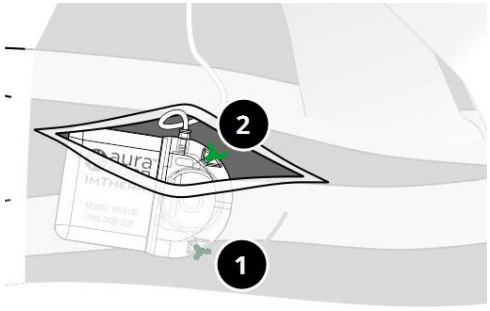


1 Inferior sutures and generator suture hole

2 Superior sutures and generator suture hole

3. Tie the generator sutures to stabilize the generator within the generator pocket (at anchor points 1 and 2 (Figure 28).
4. Cut the needle from the sutures.

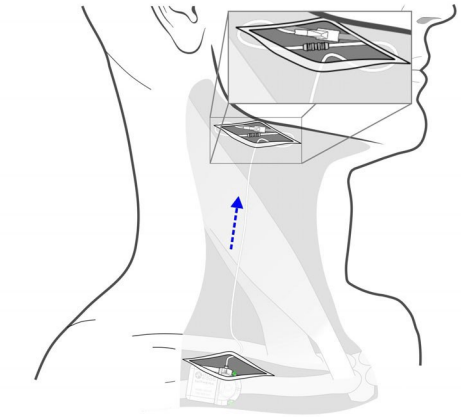
Figure 28. Stabilize the Generator Within Pocket



5. Gently pull the lead back toward the electrode cuff and create an s-shaped lead section near the neck incision (Figure 29).

⚠ **Caution:** To avoid abrasion, keep excess lead away from the generator.

Figure 29. Strain-Relief



6. Secure the lead as follows:
   a. Place the suture sleeve around the lead approximately 4-5 cm from the electrode cuff.
   b. Tie a 2-0 nonabsorbable braided suture to the tissue (anchoring the sleeve to the nearby fascia or the digastric tendon) approximately 1-2 cm ventral to the electrode cuff (Figure 30A). Ensure the suture is snug but not so tight as to apply undue constriction to the lead.
   c. Tie the suture's tails around the suture sleeve's center groove (Figure 30B).

⚠ **Caution:** Never suture directly to the lead.

   d. Route the lead in a smooth s-shaped path (Figure 30B). Do not allow the lead to bend or kink and keep the cuff and lead body parallel to the nerve to avoid torque or tension on the nerve.

Figure 30. Place the suture sleeve

30A **30B**

7. In the unlikely event of excess lead being present in the pocket and while the safety loop has been created according to above instructions, coil the remaining lead to the side of the generator.

   Note: Do not place the lead under tension. Ensure enough excess lead length in both the generator pocket and at the cuff end of the lead so body movements do not stretch the lead or dislodge the cuff.

8. Close and dress all incisions.

   a. Close the subcutaneous tissue and the superficialis fascia along the generator's upper border to stabilize the pocket's vertical dimension.

   b. Close the skin separately from the subcutaneous layer, about 5 mm above the previous suture line, to prevent implant extrusion (deep and superficial closure lines should not face each other).

      Caution: Do not use metal surgical staples to close the generator pocket. The staples may heat when the generator is charged.

   c. Place a skin closure on the incision for 2 weeks while it heals.

   d. Place the generator into Shelf Mode to preserve the battery and avoid use by the patient. Click **Shelf Mode** on the aCM Surgery Screen. If the generator is inactive for 72 hours, it will automatically go into Shelf Mode.

      Note: See *Technical Information - aura6000™ Programming System* for Shelf Mode instructions.

6.11 Post-Implant Guidance and Patient Materials

6.11.1 Physician Instructions to Patient

Provide the following guidance to patients after the implant procedure:

- **Review the Patient's Guide thoroughly.** Encourage patients to read all sections and ask questions about any warnings, precautions, hazards, or instructions they do not understand.
- **Restrict physical activity for 3-4 weeks.** Advise patients to avoid strenuous exercise, sports, and heavy lifting. They should 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 the implant.** Patients should notify their personal physician, consulting specialists, dentist, or any other healthcare provider about their implanted device before undergoing any medical procedure or diagnostic exam.

- **Report any unusual stimulation immediately.** If patients experience painful or irregular stimulation, they should contact their physician right away so the device can be evaluated.
- **Always carry the implant card with you.** Remind patients to keep their implant identification card with them at all times, in case of an emergency or when receiving medical care.
- **Ensure no metal objects are near the charging antenna while charging.** Remind patients to remove metal objects such as jewelry, body piercings, and other metal materials while charging the device.

6.11.2 Patient Materials

6.11.2.1 Patient's Guide

Make sure the patient has access to the Patient's Guide and ask them to read it and ask questions if needed.

6.11.2.2 Implant Warranty and Registration Form

The generator includes an Implant Warranty and Registration Form that a healthcare provider or representative *must* complete. Space is provided to record generator and lead information. If the surgery is for replacement, include explanted device information. Follow the instructions on the form to return a copy to LivaNova.

All local privacy laws should be followed when this form is completed. This information is required to be collected and maintained by LivaNova 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.

6.11.2.3 Patient Implant Card

The implant card contains information about the patient's generator and lead. After the implant, give the cards to the patient or caregiver and tell them to complete them with their device information (if not already included), the patient's name, other identifying information (e.g., patient number), and their treating physician's name and phone number. Tell them to carry their implant card with them at all times.

7 Replacement and Removal Procedure

7.1 Introduction

Replacement or removal of the *aura6000™* generator or lead may be needed for several reasons:

- Replacement of the generator may be required because the generator battery is no longer able to charge and cannot communicate or provide therapy.
- Replacement of the lead may be necessary if a broken or damaged lead is suspected, based on diagnostic tests or x-ray evaluation.
- System removal may be required in cases of infections or certain medical procedures.

Note: For precautions related to the implantation procedure, see "Precautions-Related to Implantation."

Note: Return explanted or opened and unused components of the *aura6000™* system to LivaNova.

These instructions are intended to be general guidelines. If you have questions about the procedures contact Technical Support.

7.2 Surgical Components and Materials

7.2.1 Surgical Components (Required)

- 1 replacement generator and/or lead
- At least 1 back-up generator and/or lead
- 1 programming system (non-sterile)

Note: Remember to use the proper technique when introducing non-sterile items into a sterile field.

Note: The 33 cm lead length will satisfy all surgical cases. However, based on surgeon and patient preference, the 25 cm lead may be considered. When selecting among available lead lengths to implant, consider the patient's anatomy and ensure the lead length can support adequate strain relief per instructions found in the Implantation Procedure section.

7.2.2 Surgical Materials

The following is a list of materials typically used during the implantation procedure. LivaNova does not provide these materials due to availability of commercial off-the-shelf options and their use depends on surgeon preference or optional use. Follow the manufacturer's instructions when using any of these materials:

- 1 tunneler/shunt passer to route the lead from the nerve incision site to the generator pocket

Note: The LivaNova Model 402 Tunneler is compatible with the *aura6000™* system. If you choose this tunneler, use the provided small-diameter (3.4 mm inside diameter) sheath.

- Sterile sleeve bag to bring the RCC and cable into the sterile field

- Vessel loops and / or silicone sheet to aid in the manipulation of the nerve (optional but recommended)
- Nerve locator to locate the hypoglossal nerve (optional but recommended)
- Skin flap gauge ~7 mm to assist in the measurement of generator pocket depth (optional)

7.3 How to Open the Sterile Pack

Before you open the sterile pack, examine it carefully for evidence of damage or compromised sterility. Do not use it if the outer or inner sterile barrier is open or has damage. An opened or damaged product should be returned to LivaNova.

⚠ **Caution**: Do not open the sales pack if it has been exposed to extreme temperatures or if there is any evidence of external damage or damage to the package seal. Instead, return it unopened to LivaNova.

⚠ **Caution**: Do not implant or use a sterile device if the device has been dropped. Dropped devices may have damaged internal components.

⚠ **Caution**: Open the sterile lead pack only after exposing the hypoglossal nerve and selecting the appropriate lead size.

To open the sterile pack, do the following:

1. Grasp the tab, and peel back the outer cover.
2. Use sterile technique to remove the sterile inner tray.
3. Grasp the inner tray's tab, and carefully peel off the cover to expose the contents without dropping them.

7.4 Replacement - Pre-Operative Steps

For all replacement surgeries, the patient should consent pre-operatively to receiving a new generator and new lead in case either is damaged during replacement surgery.

For a list of components and surgical materials, see "Surgical Components and Materials".

7.4.1 Before Surgery

7.4.1.1 Generator

1. Use the aCM to test the impedance before the patient enters the OR.
2. Place the generator into Shelf Mode before surgery.

   ⓘ **Note:** See *Technical Information - aura6000™ Programming System* for impedance testing and Shelf Mode instructions.

3. Review an x-ray of the generator to determine the route of the lead to avoid inadvertent damage to the lead during generator removal.
4. Consult the physician (prescriber) before surgery to determine parameter settings following the placement of a new generator.

7.4.1.2 Lead

1. If possible, review an x-ray of the lead to confirm the existence of a lead discontinuity (i.e., lead break or pin disconnected).
2. Consult the physician (prescriber) before surgery to determine the parameter settings in case the generator is also replaced.

7.5 Generator Replacement - Intra-Operative Steps

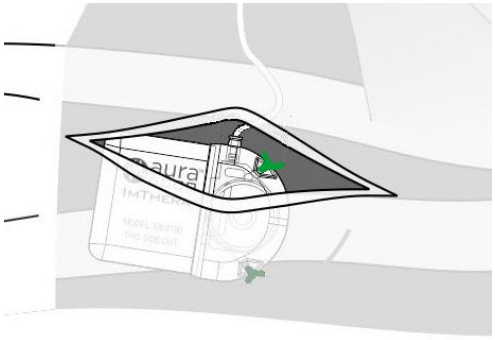
1. Open the generator pocket (Figure 31):
   a. Locate the generator pocket implant scar and confirm the generator location by palpation.

      Note: Scar should be two finger widths below the clavicle (~3.5-4 cm) and ~5 cm long.

   b. Surgically open the generator pocket by making a ~5 cm incision using blunt dissection above or below the existing implant scar and withdraw the generator. Use care during generator removal and avoid force that may damage the lead.

      Caution: Only use bipolar electrocautery with an implanted patient. See *Introduction to the aura 6000* system for precautions on the use of electrosurgery.

Figure 31. Open Generator Pocket



2. Cut the nonabsorbable silk sutures attached to the generator header from the underlying fascia to allow the removal of the generator.
3. Use the torque wrench provided with the replacement generator to loosen the setscrew in the old generator.
4. Grasp the lead close to the header's silicone lead strain relief during removal from the generator.
5. Use gentle traction to remove the lead from the old generator header.
6. If the patient is under general anesthesia, to complete the surgical procedure, follow steps 5 through 7 of the "Generator Placement" section in the *Implantation* chapter.
7. Confirm proper impedance measurements on all therapeutically enabled contacts to verify the lead viability by completing Step 2 of the "Test the System" section in the Implantation chapter.

   Note: Surgeons should use clinical judgment if unused contacts return out-of-range impedances.

   Note: Inform the awake patient that the impedance measurement may be transiently painful.

8. Perform the motor threshold testing for patients under local anesthesia during an awake titration.

   Note: Neck incision may not be accessible, or traditionally observed fasciculations may not be easily observed.

7.6 Lead Replacement - Intra-Operative Steps

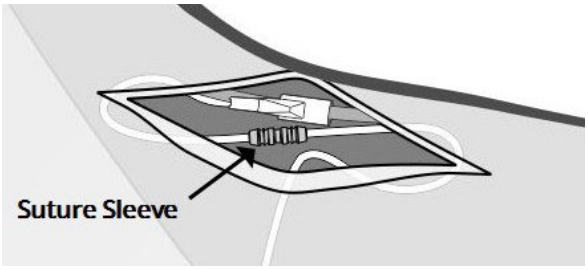
1. Identify the suture sleeve (Figure 32):
   a. Identify the scar from the submandibular incision.
   b. Make a 5-6 cm incision around the scar.
   c. During revision procedures, elevate skin and subplatysmal flaps as performed during the initial implantation. Retract the submandibular gland to expose the surgical field. Follow the original lateral tissue planes where possible. Midline dissection through the mylohyoid and geniohyoid muscles is not recommended for pHGNS revision procedures, as this approach is intended for therapies targeting terminal branches of the hypoglossal nerve.
   d. Open the generator pocket.
   e. Use the torque wrench to unscrew the setscrew in the generator header and gently pull the lead out of the generator header.
   f. Mildly tug at the base of the lead (in the generator pocket) to identify the suture sleeve location.

      Note: Look for mild tugging in the submandibular opening.

   g. Utilize blunt dissection to better access the lead cuff location (remove scar tissue as appropriate). Follow appropriate technique to avoid injury to the marginal mandibular nerve, similar to precautions taken in submandibular gland surgery.

      Caution: Only use bipolar electrocautery with an implanted patient. See Introduction to the aura 6000 system for precautions on the use of electrosurgery.

Figure 32. Identify Suture Sleeve

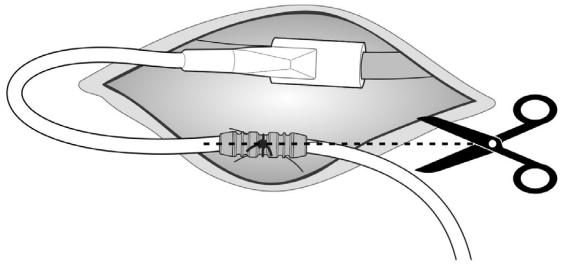


2. Follow the steps below for lead removal. The surgeon may choose not to complete a full lead removal if, in their judgment, dissecting fibrotic scar tissue results in excessive risk to the nerve or surrounding structures.
   a. Remove the suture from the suture sleeve to disconnect it from the fascia (Figure 33), and progressively dissect the connective tissue as you expose the lead cable.
   b. Pull the lead carefully to find the cuff and nerve.

c. Dissect around connective tissue (fibrosis) to fully expose and free the cuff from any connective tissue.

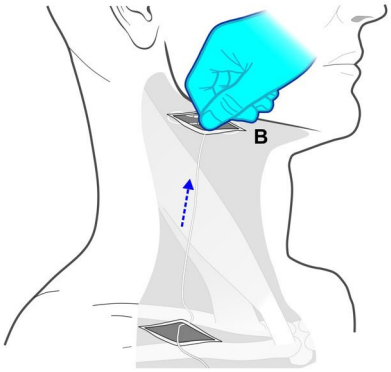
d. Carefully and gently pull the cuff off the nerve.

Figure 33. Removal of Suture Sleeve from Fascia



3. Once removed from the nerve, grasp by the cuff to pull the entire lead from the submandibular incision point (Figure 34).

Figure 34. Removal of Lead from Neck Incision Area



4. To replace the lead and complete the surgical procedure follow steps 3 through 5 of the "Lead Placement" section in the *Implantation* chapter.
5. To verify impedance and motor threshold levels, follow steps 2 and 3 of the "Test the System" section in the *Implantation* chapter.
6. Close and suture all open incision points.

7.7 Removal of Generator and Lead

⚠ **Caution**: Explanted generators and leads are medical waste and should be handled as such according to local laws. They should be returned to LivaNova for examination and proper disposal, along with a completed Returned Product Report form. If possible, use the aCM to place the generator into Shelf Mode before shipment. Before returning the generator or lead, disinfect the device components with Betadine®, Cidex® soak, or other similar disinfectant, and double-seal them in a pouch or other container properly labeled with a biohazard warning.

⚠ **Caution**: The generator contains a sealed chemical battery, and an explosion could result if subjected to incineration or cremation temperatures.

If removal is medically necessary, LivaNova recommends removing as much of the generator and lead as can be safely accomplished. The surgeon may choose not to complete a full lead removal if, in their judgment, dissecting fibrotic scar tissue results in excessive risk to the nerve or surrounding structures.

- Assess the degree of fibrotic in-growth in and around the lead cuff.
- Remove the entire system, if possible.
- If fibrotic encapsulation hinders the safe removal of the entire system, transect as much of the lead wire as possible.
- If there are any portions of the implanted system remaining in the body, diathermy and MRI procedures are contraindicated.

> **Note:** For detailed information regarding the use of diathermy or MRI with the *aura6000™* system, see contraindications, warnings, and precautions in the *Introduction to the aura6000™ system* section.

Contact LivaNova for the return of any *aura6000™* system component.

8 Limited Replacement Warranty

LivaNova USA, Inc., warrants the *aura6000™* system against any defects due to faulty material orworkmanship for a period of two (2) years from the date of implantation. This warranty appliesonly to the original purchaser of the *aura6000™* system generator and lead and the patient implanted with it. This Limited Replacement Warranty also applies only when the product is used in accordance with the product's physician's manual and excludes damage due to improper handling, defacing, accident (including dropping), misuse, or normal wear and tear. This product is not warranted when used or implanted by a person(s) not trained in or familiarwith the *aura6000™* system physician's manual. This Limited Replacement Warranty is not a representation that any one *aura6000™* system generator or lead will last the entire time of theLimited Replacement Warranty.

In no event shall LivaNova USA or its affiliates, Inc. be liable for any special, incidental, indirect, or consequential damages based on the failure of the device to function within normal tolerances, or resulting from damage to the device by external forces, whether the claim is based on warranty, contract, tort, or otherwise, or in connection with the purchase, use, or surgical implantation of this device or associated components or costs over and above the original purchase price from LivaNova USA, Inc. or its affiliates.

To qualify for the Limited Replacement Warranty, the following conditions must be met:

1. A properly completed Implant and Warranty Registration form for both the *aura6000™* system generator and the *aura6000™* system lead must be returned to LivaNova USA, Inc.within sixty (60) days of device implantation;
2. The battery in the *aura6000™* system generator cannot have been depleted as a result of programming to unusually high output currents or pulse widths, which will cause a high energy/current drain;
3. The *aura6000™* system lead cannot have been cut or damaged due to excessive handling or abuse during surgical implantation;
4. The product must have been used and prescribed in accordance with the *aura6000™* system physician's manual;
5. The *aura6000™* system generator or lead must have been implanted prior to its"Expiration Date;"
6. The defective *aura6000™* system generator or lead that is the subject of the warranty claim must be returned to LivaNova USA, Inc. with an accompanying Authorization number. To obtain an authorization number contact Technical Support at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).
7. The *aura6000™* system generator or lead that is the subject of the warranty claim mustbe confirmed by LivaNova USA, Inc.s' Quality Assurance Department as meeting the terms of this Limited Replacement Warranty.
8. All returned *aura6000™* system generators and leads shall become the property ofLivaNova USA, Inc.

⚠ **Caution: Return explanted generators and leads** to LivaNova USA, Inc. for examination and proper disposal, along with a completed Returned Product Report form. Before returning the lead, disinfect the device components with Betadine®, Cidex® soak, or another similar disinfectant, and double-seal them in a pouch or other container properly labeled with a biohazard warning.

If the *aura6000™* system generator or lead that is the subject of the warranty claim is determinedto meet the terms of this Limited Replacement Warranty, LivaNova USA, Inc. or its affiliates willprovide the original purchaser or its designee with a no-cost replacement. LivaNova USA, Inc. or its affiliates reserve the right to replace a product that meets the terms of this Limited Replacement Warranty with the most comparable product currently available. Returned biohazardous product should be clearly identified as such on the outside surface of the package.

This Limited Replacement Warranty excludes any and all other warranties, whether express, implied, or statutory, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. This Limited Replacement Warranty shall be the exclusive warranties and remedies available to any person. No person has any authority to bind LivaNova USA, Inc. to any representation, condition, or warranty except this Limited Replacement Warranty.

While this warranty gives you specific legal rights, you may also have other rights that vary from state to state or that encroach upon the above.

9 Contacts and Resources

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

CONTACTS

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

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Toll free: +1 800 332 1375 (US/Canada)

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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_en
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.