

ImSIGHTS NEWSLETTER

Innovation in Implantable Therapy for the Treatment of Obstructive Sleep Apnea

CEO Corner



This is the second issue of our quarterly newsletter "ImSights" which was developed to bring you up to date information on our most recent developments and items of interest related to sleep apnea.

ImThera was recently chosen by MD+DI (Medical Device and Diagnostic Industry) periodical as one of the "50 companies to watch". We are honored to be amongst this select set of innovators and hope you enjoy reading the article [here](http://www.mddionline.com/article/50-companies-watch-0).
(www.mddionline.com/article/50-companies-watch-0)

On this issue we call attention to a special market need concerning commercial drivers with OSA in America. The Government, insurers, medical societies and driver's associations are collaborating on efforts to address the substantial OSA problem facing drivers on our roads. It is possible that many of the 14 million truck drivers on American roads have undiagnosed or untreated sleep apnea. An article below covers this pressing economic and health policy topic.

We also cover on this issue an introductory article by our scientific staff on the awake titration and calibration procedure of patients using the aura6000tm system.

We hope you enjoy the newsletter and look forward to staying in touch with you.

Marcelo G. Lima, President & CEO

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Send us your comments to
contact@imtheramedical.com

Curiosity: Did you know that people with OSA are SIX times more likely to have a driving accident and SEVEN times more likely to have multiple accidents?

- More than 800,000 drivers were involved in OSA-related car crashes in 2000, costing more than \$15.9 billion in damage claiming 1,400 lives;

- It's estimated that if all drivers with OSA were treated, \$11.1B in damages could be saved, along with 980 lives each year;

- MOST IMPORTANTLY, accident and health risks return to NORMAL when individuals are diagnosed and treated for OSA.

Read more [here](#), in the "Sleep Apnea and Trucking Conference" website.

Tech ImSights

An Overview of ImThera's Remote Control & Charger (RCC)

The aura6000 Implantable Stimulation System for the treatment of Obstructive Sleep Apnea is a highly advanced neurostimulator delivering state of the art treatment for this oppressive disease. Despite its complexity and sophistication, it is surprisingly easy for the patient to control and recharge his/her implanted stimulator (IPG) by using the Remote Control and Charger (RCC). This hand-held device allows the patient to initiate, pause, or terminate treatment every evening, to check the status of the implant, to recharge the IPG battery, and to test stimulator output and feel the response of the tongue muscles to the programmed stimulation.

The RCC, pictured below, rests on its Docking Station, which charges the RCC while it is not being used by the patient. The batteries of the RCC are rechargeable, and contain enough energy when fully charged to recharge the IPG for up to two hours at a time. When the rechargeable batteries of the RCC need replacing a door on the backside of the RCC easily accesses them. When traveling, the patients may use alkaline AA batteries and leave their Docking Station at home on their nightstand.

When the IPG needs to be recharged, a Charger Coil (CC) (pictured below) is attached to a connector at the top end of the RCC, the patient places the Charger Coil leather strap around his/her neck and places the attached coil and magnet over the IPG. The magnet in the coil seeks the magnet in the header of the IPG and maintains optimal alignment of the charger coil to the power-receiving coil of

the IPG. While the charging process is running the patient is free to take the RCC and move to any convenient location, it is not necessary to stay by the Docking Station.



The RCC has four pushbuttons and five LEDs. The four pushbuttons are used for 1) starting and stopping sleep therapy; 2) pausing and unpausing sleep therapy; 3) charging the implanted stimulator; and 4) testing the implanted stimulator.

Above each of the pushbuttons is an LED, the fifth LED is located below and to the right of the pushbuttons and provides information on the battery of the RCC. Each of the LEDs is able to display several colors to provide useful information to the patient. For instance, when the RCC is trying to find and communicate with the IPG the LED associated with the button blinks blue. When the IPG is being recharged, the LED associated with the Charge pushbutton blinks red for a low battery, amber for a medium battery, and green for a full battery.

The RCC communicates with the IPG using a radio frequency (RF) telemetry link on a special band just for medical devices called the Medical Implant Communication Services (MICS) band. The RCC and IPG are both linked to each other and will not communicate to other devices. Commands and responses are further protected using a special code that is computed for every message and checked by both RCC and IPG for integrity. Interference from RF signal sources might cause messages to be missed but will never cause a bad or unintended command to be activated. Like the IPG, the RCC also keeps track of all commands and actions of the RCC in an event log which can be acquired by the clinician when the patient visits the clinic. This event log is very useful in evaluating patient use and compliance with the therapy and for problem solving.

For more information on the use and care of the RCC, please contact us at:

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CAUTION: ImThera's device is not available for sale in the USA.

Introduction to the “Awake Titration” procedure

The ImThera Medical aura6000™ system is designed to reduce or eliminate Obstructive Sleep Apnea (OSA) by electrically stimulating the hypoglossal nerve during sleep, thus delivering muscle tone to key tongue muscles and effectively controlling upper airway flow.

Awake Titration is one of the key steps (4 weeks after the implantation surgery) of the Targeted hypoglossal Nerve (THN) Sleep Therapy. Titration is the process that determines the stimulation parameters that will be used during sleep to treat the patient. The goal of the treatment is to keep the tongue continuously stimulated by using multiple groups of electrode contacts to take turns in providing muscle tone and tongue position.

In a short visit (30 minutes) to the physician’s office the patient is asked to sit upright and a small fibroscope is passed through the anterior nasal cavity to the posterior aspect of the nasopharynx (Figure A).

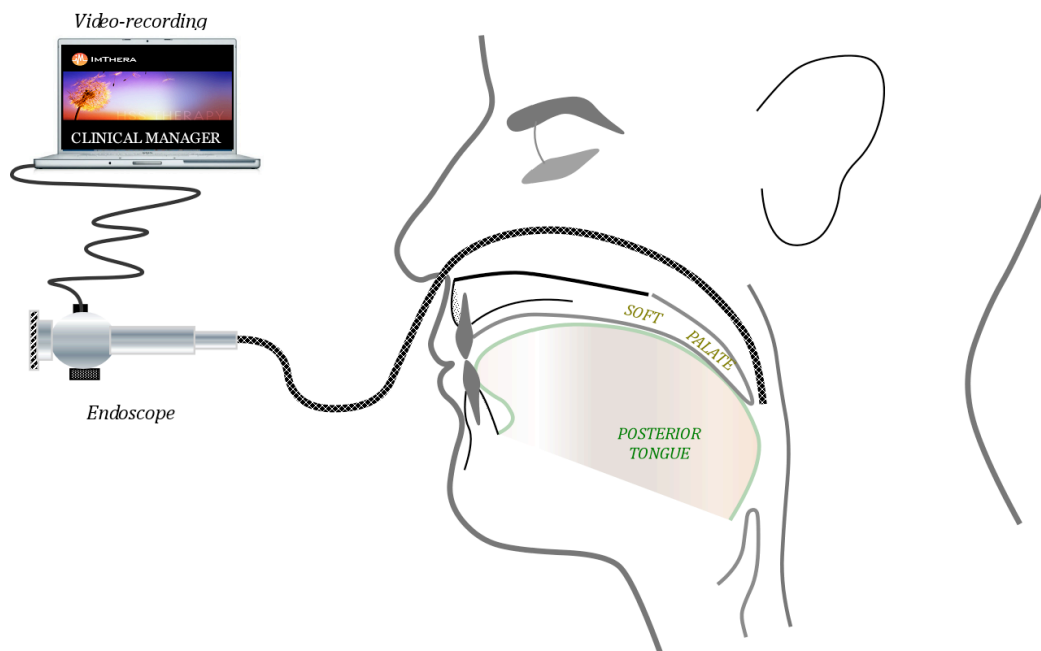


Figure A: Diagram showing the Endoscopic process during the titration session

The physician observes the airway (*via* live endoscopic videography) and evaluates the movements of the posterior tongue. All 6 electrode contacts are tested for their sensory and motor thresholds (the current amplitude at which the patient first perceives the stimulation pulses and the current amplitude at which the clinician first observes tongue motion) and treatment or target levels (the current amplitude at which the tongue is stimulated enough to achieve a clinically useful outcome with significant clearance of the tongue from the rear of the throat). The physician uses the aura Clinical Manager (aCM) program for controlling and manipulating the levels of these sleep

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The patient is also able to fine-tune the stimulation levels by using the rotary wheel of the “Patient’s Stimulator Adjuster” (Figure B) to ensure comfortable stimulation that still provides functional levels for the therapy.

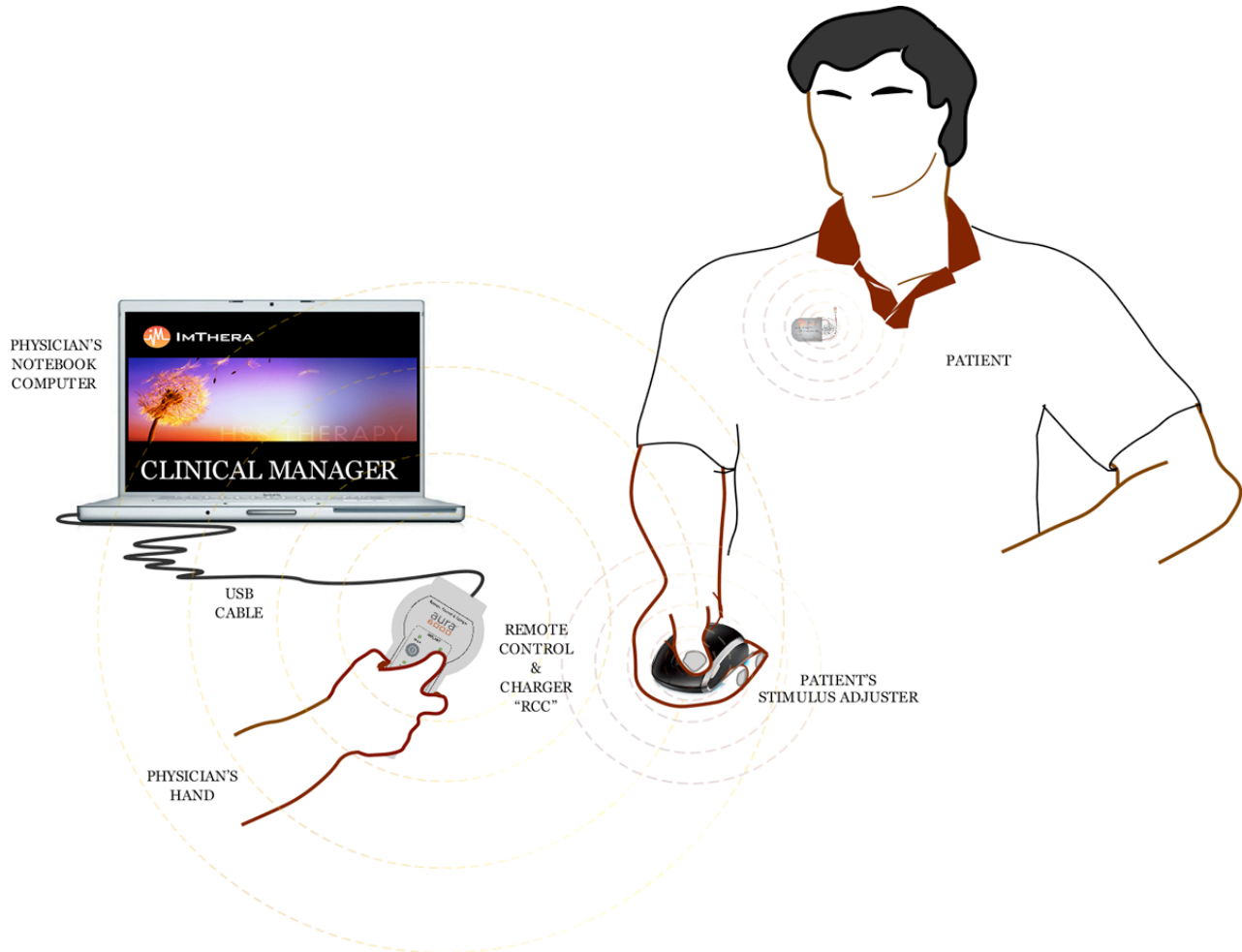


Figure B: Diagram showing a Patient fine-tuning stimulation parameters using “Patients Stimulus Adjuster” during the titration session



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Sleep Apnea and Trucking Conference 2010

Russ Craig, ImThera's Vice President of Business Development, attended the first Sleep Apnea & Trucking Conference held May 11 & 12 in Baltimore. The Conference was sponsored by the American Sleep Apnea Association, the American Trucking Associations, and the Federal Motor Carrier Safety Administration (FMCSA).

The commercial trucking industry is highly regulated, with a focus on safety. The FMCSA requires biannual physical examinations of licensed commercial drivers that include screening for sleep apnea. Over 8.4 million such exams are given every year. Failure of this examination results in license revocation.

Good statistics are hard to come by, but fatigue (from all causes, including OSA) is estimated to play a role in 31-41% of major commercial vehicle crashes, although it is cited as a cause in almost 100% of accident related law suits. Limited studies suggest that moderate to severe obstructive sleep apnea (OSA) is present in 10.5% of commercial drivers, while compliance with CPAP is highly variable, ranging from 60% in Quebec to 5% in California. Commercial drivers with OSA are estimated to be at a 2-7 times increased risk of collision compared to unimpaired drivers.

Anti-discrimination regulation makes it difficult to avoid hiring commercial drivers with sleep apnea, yet trucking companies, if sued, bear the burden of proof to demonstrate that they have taken all possible steps to ensure drivers are not driving in a fatigued state. Meanwhile, a Tri-Society Task Force (American College of Occupational and Environmental Medicine, American College of Chest Physicians, and the National Sleep Foundation) has recommended:

- 1- tightening monitoring for OSA substantially
- 2- denying medical certification if it is detected, until
- 3- CPAP utility and compliance is demonstrated

It also recommends continual monitoring for ongoing compliance.

In this kind of environment, where drivers face a loss of livelihood and trucking companies are under continual threat of suit, requiring detailed record keeping to demonstrate due care in employing "safe drivers", an OSA implant could be highly attractive. Drivers receive care for their OSA, and can demonstrate compliance through downloads of the implant event log, while trucking companies can show due care through making the therapy available and recording compliance evidence on a regular basis.

ImThera will be working with trucking companies, industry associations, and liability insurers once the aura6000 is approved in the US, to ensure that the benefits of that therapy are widely recognized and available.



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