Appendix C – Company Materials

The aura6000™ system consists of an IPG with six independent current sources and a cuff electrode with six platinum-iridium disk contacts designed for the treatment of Obstructive Sleep Apnea (OSA). Stimulation is applied to the proximal trunk of the Hypoglossal Nerve to activate up to six regions of the tongue musculature. The goal of this treatment is to maintain muscle activity or tone during sleep so that the tongue does not have an opportunity to block the airway. Each contact is assigned to one or more functional groups. Functional groups may in turn be used to select regions of fibers within the nerve bundle that result in a desired tongue movement, position, or stiffness. The effort of moving the tongue to the desired position or state is thus shifted from one functional group to another functional group so that no single functional group is required to work all of the time.

The stimulation strategy employed by the THN system is depicted in Figure 1 below. After the patient has initiated a sleep session, a startup delay phase occurs during which no stimulation occurs, but which allows the patient to fall asleep without the sensation of stimulation. At the conclusion of this phase stimulation starts by turning on the first group, ramping that stimulation towards therapeutic levels to allow the patient to comfortably accept the stimulation. In the Treatment phase it can be seen that stimulation changes from group to group, each group having a ramp up in stimulation current. Stimulation may also have a ramp downwards but this is rarely used. Once all enabled groups have run their course the cycle repeats until the patient wakes up the next morning.

Therapy is programmed into the patient's IPG using the aura Clinical Manager (aCM) software application (Windows based). This program allows assignment of a remote control and charger (RCC) to a patient and the complete programming of stimulation parameters. Each RCC and IPG are uniquely identified by their serial numbers and use this information in their communications with each other to maintain secure data transfers.

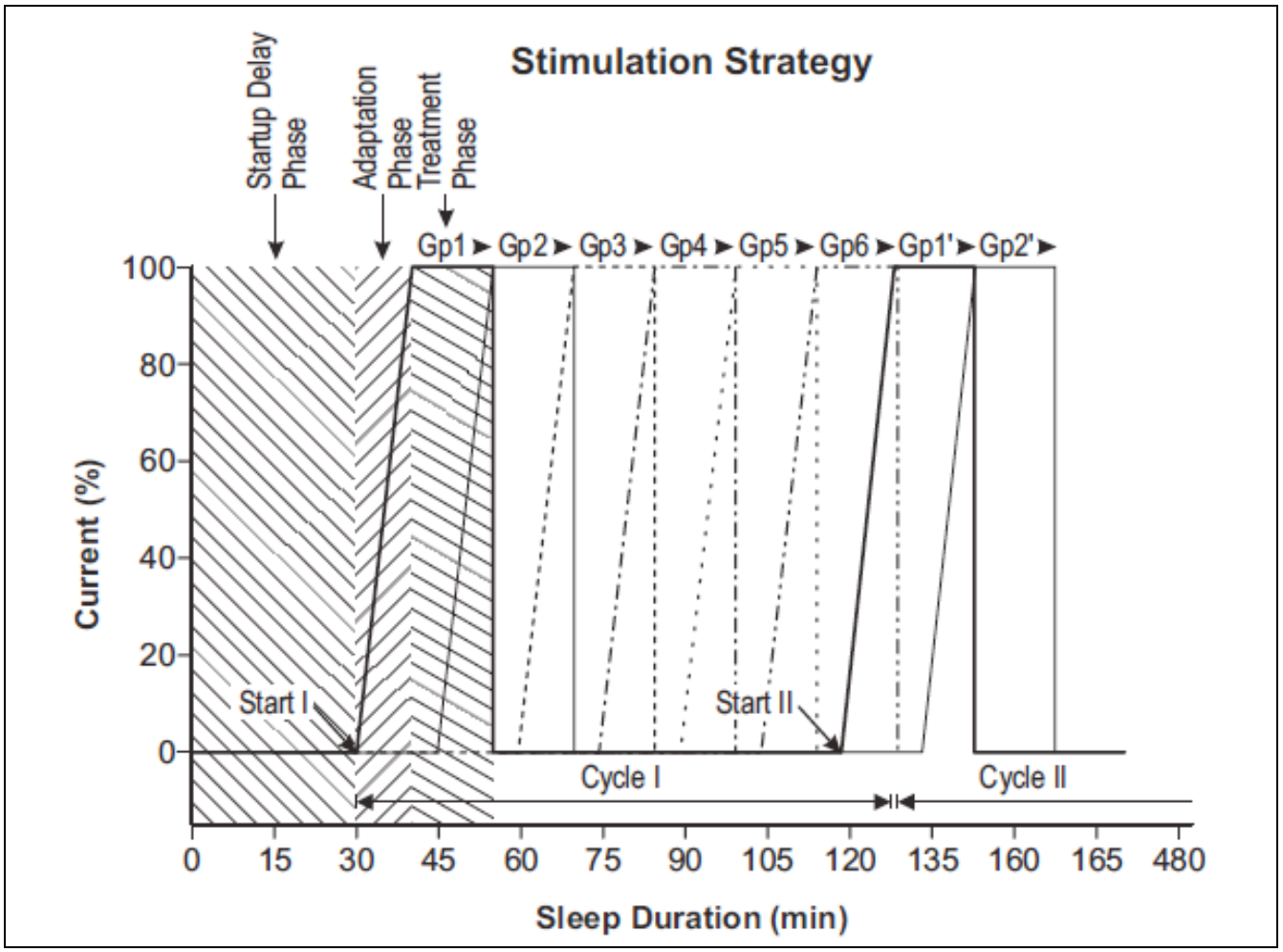

Figure 1 - Stimulation Strategy

ImThera aura6000® System Technical Data	
STIMULATION PARAMETERS	
Output current	0-3 mA in 256 linear steps, asymmetrical biphasic, 4:1 Cathodic:Anodic with 50µs interphase delay, 6 independent biphasic current sources, monopolar with respect to case
Pulse frequency	1 to 100 Hz
Pulse width	50 to 1000 µsec
Stimulus ON time	0 to 30 min
Stimulus Gap time	0 to 30 min
Cathodic Phase Duration	10µs to 1000µs (30µC/phase/cm^2 Limit)
Anodic Phase Duration	40µs to 4000µs

Startup Delay	0 to 60 minutes
Pause Delay	0 to 60 minutes
Stimulation Groups	6
Contacts per Group	Up to 6, percentage for each group 0-100%
Load Capacity	200 to 2000Ω
Impedance Measurement Range	200 to 4000Ω
Recharge Depth and Rate	3mm to 10mm, 31mA
TELEMETRY	
Type	MedRadio
Device diagnostic and history report	Battery level and charging status, device testing results, impedance history and battery history, system event log
Device parameter programming	View and upload stimulation parameters (amplitude, frequency, pulse width, ON/OFF time, etc.)
POWER SOURCE	
Battery	Secondary cell - Lithium-Ion
Capacity	50 mAh
Charging	Inductive coupling
Rated Number of Cycles	>3000
Lifetime	≥ 14 years
PHYSICAL CHARACTERISTICS	
IPG:	
MATERIALS	
Case	Titanium, hermetically sealed
Header	Poured Epoxy
MEASUREMENTS	
Dimensions	45 mm x 32 mm x 8 mm, 11.5cc
Weight	20 g
LEAD CONNECTOR	
Type	Ring, 6 Contacts + Retention Sleeve
External Diameter	1.5 mm
Material	Platinum-Iridium 90:10 contacts, MP35N Retention Sleeve, Silicone
Retention Strength	>10N
Locking/unlocking	One Setscrew
LEAD:	
Diameter	1.5 mm
Insulation	Silicone
Conductor coil construction	6 cables

Wire material	1x19 MP35N DFT Ag Core, ETFE Insulation
Overall length	27 cm
Lead resistance	< 100 Ohms
ELECTRODE:	
Type	Self-sizing cuff
Material	Silicone, Platinum-Iridium 90:10
Contact pattern	6 contacts organized in two sets of three contacts, 50º spacing, 2mm diameter
Inner diameter	3.5 to 4.5 mm
REMOTE CONTROL AND CHARGER (RCC):	
Case	ABS
Dimensions	20cm x 6cm x 3cm
Display	Graphic LCD with Backlight
Keyboard	3 button (up, enter, down)
Power	NiMH, rechargeable
CHARGE ANTENNA (CA):	
Case	ABS
Dimensions	5cm x 3.5cm x 1cm
Technology	Class E amplifier, 13.56MHz

Appendix D – Company Support

The COMPANY will provide support to the awardee in the form of training, use manuals, surgical instructional materials and guidance in the use of the system.

Should minor changes in system performance be required custom firmware (FW) or software (SW) may be provided. If extensive functional changes are required then the COMPANY can provide under contract changes to FW and SW to implement the unique functionality required.

Should special leads or tools be required then the COMPANY can provide under contract design and manufacturing services to implement the unique requirements of the AWARDEE.