


















THN Sleep Therapy™ System

User's Manual

Explanation of symbols on product or package labeling

	Model number
	Serial number
	Manufacturing date
	Manufacturer
	Operating Instructions
	Storage temperature
	Conformite Europeene (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0344) and R&TTE Directive 1995/5/EC
	Type BF equipment
	Do not dispose in landfill
	Radio frequency transmitter
	Humidity range
	Atmospheric pressure range
	Federal Communications Commission
	Keep dry
	Caution – Consult instructions for use
IP02	Ingress protection case classification
IP20	Ingress protection enclosure classification

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CONTENTS

ABOUT THIS MANUAL	1
THERAPY OVERVIEW	1
AFTER YOUR SURGERY	2
The First Two Months	2
After Your Incisions Have Healed	2
WARNINGS	3
PRECAUTIONS	3
USING YOUR SYSTEM	5
Kit Contents	5
Device Overview	6
Getting Started	7
Recharging Your Remote	7
Turning Your Remote On and Off	8
Understanding the Remote Screen	8
Charging Your Implant	9
Starting a Sleep Session	10
Pausing or Stopping a Sleep Session	11
Adjusting Therapy	11
Setting Preferences	13
More Options	13
MAINTAINING YOUR REMOTE	14
Replacing Your Remote Control Battery	14
Handling & Cleaning	15
TROUBLESHOOTING	16
Error Messages	16
Resetting Your Remote	19
Elective Replacement Indicator (ERI)	19
Test Stimulation	20
Test Telemetry	20
CUSTOMER SERVICE INFORMATION	21
Technical Service	21
Product Registration Information	21
REMOTE CONTROL SPECIFICATIONS	21
LIMITED WARRANTY	25



IMTHERA

Manufacturer

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Authorized Representative in the European Community

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LIMITED WARRANTY

ImThera Medical, Inc., (referred to as ImThera) warrants to the patient who receives an aura6000 System (referred to as “aura6000”) that the aura6000 will be free from defects in workmanship and materials for a period of one year from the date of surgical implant. This warranty applies only to the patient who has the implanted device and no other person or entity. If the aura6000 fails to function within normal ranges within one year after the date it is implanted, ImThera will repair or replace the aura6000 component with a functionally equivalent device made by ImThera. No other relief whatsoever is available under this limited warranty. The limited warranty for a repaired or replacement aura6000 will last only for one year from the date of surgical implant of the original aura6000. Claims under this limited warranty are subject to the following additional conditions and limitations:

1. The product registration form must be completed and returned to ImThera within 30 days of surgery.
2. The device must be implanted before the “use before” date.
3. Failure of the device must be confirmed by ImThera.
4. The device must be returned to ImThera (or ImThera’s authorized agent) within 30 days after it fails to function within normal ranges. That device becomes ImThera’s property.
5. This limited warranty does not include failures to function within normal ranges caused by:
 - a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as “Acts of God”;
 - b) accident, misuse, abuse, negligence, or the customer’s failure to operate the aura6000 in accordance with manufacturer’s instructions;
 - c) unauthorized attempts to repair, maintain, or modify the aura6000 by the patient or any unauthorized third party; or
 - d) attaching equipment to the aura6000 that is not supplied or expressly authorized by ImThera.

This limited warranty is the only warranty that applies to the aura6000, and ImThera expressly disclaims any other warranty, express or implied, including any warranty of merchantability or fitness for a particular purpose. Under this limited warranty, ImThera will be responsible only for repair or replacement of the aura6000 with a functionally equivalent device made by ImThera and will not be liable for any damages (whether direct, indirect, consequential, or incidental) caused by the aura6000, whether the claim is based on warranty, contract, tort or any other theory.

Any translation of this Limited Warranty is done for local requirements and/or convenience only. In the event of a dispute between the English and any non-English versions, the English version of this Limited Warranty shall govern.

Declaration of Conformity

ImThera Medical declares that this product is in conformity with the essential requirements of Directive 1995/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices and that this device complies with Part 18 of the FCC Rules. This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation. For additional information, contact ImThera Technical Services.

ABOUT THIS MANUAL

This manual provides instructions for the proper use of your aura6000® THN Sleep Therapy System. This manual will show you how to:

- recharge your remote control
- charge your implant
- start a sleep session
- pause or stop a sleep session
- maintain your remote control

THERAPY OVERVIEW

Your aura6000 THN Sleep Therapy System is designed to keep your upper airway open while you sleep so that you can breathe better. This is done by stimulating one of your hypoglossal nerves.

Your aura6000 system consists of both implanted and external components that are designed to work together. The implanted components are: a neurostimulator (also called an implant); and a lead (a small wire with an electrode cuff around your hypoglossal nerve). The external components are the remote control (remote) and the charging antenna (antenna).

Your doctor has adjusted your implant to customize your therapy to your needs. Call your doctor if you feel that your therapy settings need to be adjusted.

When you plan to go to sleep, you will use your remote to start a *sleep session*. Since you may feel the stimulation pulses when you are awake, your aura6000 system has been designed to delay the start of stimulation to give you time to fall asleep. You can adjust the duration of this *start delay* to meet your needs.

Your aura6000 system will deliver therapy until the programmed *sleep duration* elapses unless you pause or stop stimulation. Pausing therapy is intended to be used when you wake up but plan to go back to sleep soon, for example if you go to the bathroom or need to answer the phone. Stopping therapy turns stimulation off, and keeps it off until you start it with your remote.

AFTER YOUR SURGERY

It is important to keep all your doctors' appointments and follow your doctor's instructions to minimize the chance of post-surgical problems and give yourself the best chance for a full recovery.

The First Two Months

During your surgery you were implanted with a lead in your neck and an implant in your chest. It is normal for you to feel some discomfort at your surgical sites for several days. This feels like a bruise. However, call your doctor if you notice any swelling, pain, or redness near your incisions.

Immediately after surgery, your doctor may:

- prescribe medication for post-surgical pain
- prescribe antibiotics to prevent infection

Caution: Do not place the antenna on an unhealed wound. The remote and antenna are not sterile.

You may experience discomfort at your incision sites for up to two months. This is a normal part of the healing process. Over time your body will form scar tissue around your implant and lead, which will help to keep them in place. During this time, you should:

- avoid disturbing the implant and lead, lifting heavy objects, and making extreme head or neck movements that could change the position of the electrode cuff on the nerve; and
- avoid activities that could damage the implant or lead by mechanical force or direct impact.

After Your Incisions Have Healed

After your incisions have healed, they will require no special care. However, there are still several things that you must do, and several things that you must avoid, to prevent problems and to maximize the benefit that you get from your aura6000 system. See the Warnings and Precautions sections for specific things that you must and must NOT do.

Electromagnetic Immunity

The Remote Control and Charger, Model 500.0100 (including the charging antenna and power cord), hereafter the 'system', is intended for use in the professional healthcare and home healthcare environments. Electromagnetic Immunity tests in accordance with requirements of ETSI EN 301 489-3 V1.5.1 and ETSI EN 301 489-27 V1.1.1 and IEC/EN 60601-1-2.

Immunity Test	Compliance Level	IEC 60601 Test Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV contact ±15 kV air Class C	±2, 4, 8 kV contact ±2, 4, 8, 15 kV air	The relative humidity should be at least 5%. Electrostatic discharge may result in temporary loss of function, requiring the user to restart or reset the system. Mains power quality should be that of the typical public low voltage power supply. The RCC contains a battery that must be charged for use without mains power.
Electrical fast transient/burst EN 61000-4-4	±2 kV for power supply lines (no input/output lines) Class B	±2 kV for power supply lines ±1 kV for input/output lines	
Surge EN 61000-4-5	±1 kV differential mode ±2 kV common mode Class A	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions and variation on power supply lines EN 61000-4-11	<5% U _T for 0.5 cycle 40% U _T for 5 cycles 70% U _T for 25 cycles, Criterion B & C	<5% U _T for 0.5 cycle 40% U _T for 5 cycles 70% U _T for 25 cycles	
Magnetic Fields	3 A/m	30 A/m	See the following table, <i>Recommended Separation Distance between RF Transmitters and the Remote Control and Charger Model 500.0100.</i>
Radio Frequency Common Mode EN 61000-4-6	6 Vrms 150 kHz-80 MHz	6 Vrms 150 kHz-80 MHz	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz-2.5 GHz	28 V/m 80 MHz-2.5 GHz	

Note: U_T is the mains voltage prior to application of the test level.

Electromagnetic Compatibility Declarations

Electromagnetic Emissions

The Remote Control and Charger, Model 500.0100 (including the charging antenna and power cord), hereafter the 'system', is intended for use in the professional healthcare and home healthcare environments. RF Emissions Limits and Methods of Measurement per: FCC Part 15B; ETSI EN 301 489-3 V1.5.1 and ETSI EN 301 489-27 V1.1.1, CISPR 11 and IEC60601-1-2.		
Emission Test	Class/Group	Electromagnetic Environment Guidelines
Radio frequency emissions CISPR 11	Group 1	The system uses RF energy for its internal functions, to communicate with the implant (MedRadio band 401-405 MHz), and to charge the implant (13.56 MHz).
RF emissions CISPR 11	Class A	The system is suitable for use in the professional healthcare and home healthcare environments, and may be directly connected to the public low-voltage power supply network, provided the following caution is heeded: Caution: This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to reorient or relocate the system, or shield the location.
Power Line Harmonic emissions EN 61000-3-2	Class A	
Conducted Emissions EN 55022	Class B	
Power Line Flicker EN 61000-3-3	Criterion A	The system is suitable for use in the professional healthcare and home healthcare environments, and may be directly connected to the public low-voltage power supply network.

WARNINGS

Diathermy—Tell your healthcare professionals (doctors, dentists, physical therapists, etc.) that you must **NEVER** be exposed to diathermy treatment. You may be injured or your system may be damaged during diathermy treatment: i) whether the system is on or off; ii) wherever diathermy is used on your body; and iii) whether diathermy delivers heat or not.

Magnetic Resonance Imaging (MRI)—You should not undergo MRI. MRI exposure may result in: i) dislodgement of implanted components; ii) heating of the implant and/or lead electrodes which may in turn damage tissue or the implant electronics; and/or iii) voltage induction through the lead and implant.

Cardiac Devices—If you have a cardiac device, it may interact with your implant in various ways, including but not limited to:

- Defibrillation therapy from an implanted defibrillator (ICD) may damage your implant.
- The cardiac device may sense the pulses from your implant and respond inappropriately.

Other Hospital or Medical Equipment—Always tell your health care personnel that you have an implanted medical device before undergoing any medical procedure or exam. The following medical therapies or procedures may interfere with stimulation, cause permanent damage to your implant or lead, (particularly if used in close proximity to your implant or lead), or inadvertently concentrate energy and cause harm: electrocautery; internal or external defibrillation; radiation therapy; lithotripsy; high-output ultrasound; magnetic stimulation, TENS, FES, or any other form of electrical stimulation. Your health care personnel should contact ImThera for more information as appropriate.

PRECAUTIONS

Patient Identification Card—Carry your patient identification card with you at all times. This card lists your doctor's name and telephone number and provides basic information about your system. The information is important for others to know, should you need to bypass a security system, or in case of a medical emergency.

Charging—Your implant battery must be charged on a

regular basis to keep it from becoming too low and becoming permanently damaged. While charging, your remote, antenna, and/or implant may become warm. If this becomes uncomfortable, stop charging until the heat dissipates or try charging more frequently for a shorter duration. If heating persists, tell your doctor. Do not charge while sleeping.

Device Manipulation—Never attempt to change the orientation of, invert or otherwise manipulate your implant. Doing this may damage your lead or flip your implant and make it impossible to charge or communicate with your implant. If this happens, you may need surgery to correct it.

Device Failure—If your system stops working, turn off the implant and contact your doctor so that your system can be evaluated.

Handling—Your remote and antenna are sensitive medical devices and should be handled with care. Dropping them on hard surfaces or in water, or other rough handling, may permanently damage them.

Other Components—Your remote and antenna are intended to be used solely with components supplied by ImThera. The use of non-ImThera components with this system may result in damage to ImThera components, loss of therapy, or patient injury and will void the product warranty.

Home or Work Environment—Your implant and remote should not be affected by normal operation of equipment such as household appliances, machine shop tools, microwave ovens, cell phones, or AM/FM radios. Strong electromagnetic fields such as those produced by retail theft detectors, airport screening devices, welding equipment, induction furnaces, power generators or power transmission lines may cause unintended stimulation. If you suspect interference with any electrical device, avoid using your system near that electrical device. Avoid prolonged exposure to RFID sources. RFID sources may not necessarily be located near the door of a building.

Driving and Operating Equipment—Do not attempt to use your system while driving or operating equipment.

CUSTOMER SERVICE INFORMATION

Technical Service

ImThera Medical Technical Service may be reached at +1-858-259-2980 between 9:00-5:00 Pacific Time, or via email at support@ImTheraMedical.com.

Product Registration Information

A temporary Patient Identification Card was given to you after surgery by your doctor. Carry this card with you at all times. This card may help you get through airport security and provides information that doctors will need in the event of a medical emergency, or if you receive any form of medical care.

Following registration, a permanent card will be sent to you. If you don't receive a permanent card within 60 days, send an email to support@ImTheraMedical.com to request one. If you move, or change your phone number or email, send an email to support@ImTheraMedical.com to update your information, so that ImThera Medical can reach you if there is a problem with your system.

You may also reach ImThera by writing to:

Customer Service Department
ImThera Medical, Inc.
12555 High Bluff Drive, Suite 310
San Diego, CA 92130 USA

REMOTE CONTROL SPECIFICATIONS

Dimensions:	203 x 95 x 38 mm
Weight:	225 g
Storage Conditions:	-25 to +55°C, +5°C to 35°C at up to 90% Relative Humidity, >35°C to 70°C at a water vapor pressure up to 50hPa
Remote Control and Charger Operating Conditions:	+5°C to 40°C; 15% to 90% Relative Humidity (non-condensing); 700hPa to 1060hPa atmospheric pressure
Charging Antenna Operating Conditions:	+5°C to 30°C; 15% to 90% Relative Humidity (non-condensing); 700hPa to 1060hPa atmospheric pressure
Radio type:	MICS telemetry
Power input:	15W (7.5V @ 2A)

Test Stimulation

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

To test stimulation:

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

Test Telemetry

Your remote and implant use radio signals to communicate with each other. The *TEST telemetry* feature allows you to test the strength and quality of these signals.

To test telemetry:

1. Scroll to *MORE options* then press the OK button.
2. Press the down button to highlight *TEST telemetry* then press the OK button.
3. The signal strength (SS) and signal quality (SQ) will be displayed on your remote screen, and your remote will beep to indicate the remote signal strength. The faster the beeping the stronger the signal.
4. When finished, highlight << *Main Menu* and press OK.

TIPS:

- The SS and SQ values will be between 0 and 10. Higher numbers indicate better signal strength and signal quality.
- If SS is low, then move the remote closer to the implant and/or change its orientation.
- If SS is high and SQ is low, then this could indicate that you are close to a source of interference. Move to a different room and try again.

USING YOUR SYSTEM

Kit Contents



Figure 1

A: Remote control (remote)

B: Charging antenna (antenna)

C: Remote Control Power cord

Device Overview

Your aura6000 remote is used to control and charge your aura6000 implant.

Both your remote and your implant contain rechargeable batteries. Your remote is recharged by connecting it to a wall power outlet. Your implant is charged transcutaneously—through the skin—by connecting the antenna to your remote and placing the antenna over your implant.

Your remote has three navigation buttons (UP, DOWN, OK) and a LCD display that are used to control your therapy and indicate the status of your implant and remote, as shown in Figure 2.



Figure 2

- | | |
|--------------------------|----------------|
| 1. Charging antenna port | 5. UP button |
| 2. Power port | 6. DOWN button |
| 3. Data port | 7. OK button |
| 4. Battery compartment | |



Resetting Your Remote

Very rarely, it may be necessary to reset your remote. To do so, press the UP button for 10 seconds and then release the button. The Main Menu should appear.

Elective Replacement Indicator (ERI)

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



Problem /Message	Reason	What you need to do
"No therapy program."	Your doctor has not programmed your implant.	<ul style="list-style-type: none"> • Contact your doctor and ask the doctor to program your implant.
Stimulation cannot be felt.	Therapy is ON and your amplitude is too low to be felt.	<ul style="list-style-type: none"> • Use <i>Get implant status</i> to confirm that the implant is ON and you feel nothing. • If you are satisfied with your therapy, then do nothing. • If you are not satisfied with your therapy use Master Amplitude to increase the amplitude of your therapy, and/or contact your doctor to have your therapy adjusted.
	Therapy is OFF— <i>Sleep duration</i> is shorter than the time you slept.	<ul style="list-style-type: none"> • If you would like to feel therapy when you wake up, then increase the <i>Sleep duration</i> (see <i>Adjust Therapy</i>).
	Therapy is OFF—Your implant ran out of battery during the night.	<ul style="list-style-type: none"> • Use <i>GET implant info</i> to check the implant battery. If <i>BATT</i> is less than 3.44V then charge your IPG more fully or more often.
	Therapy is OFF—System failure	<ul style="list-style-type: none"> • Contact your doctor for assistance.
R 	The remote's battery either overheated or is damaged.	<ul style="list-style-type: none"> • Unplug the remote from the wall outlet to let the battery cool. If this fails, then disconnect the battery from the remote (see <i>Replacing Your Remote Control Battery</i>), wait 10 seconds, then reconnect the battery. • If this problem persists, call your doctor or ImThera.
	The ERI has been activated.	<ul style="list-style-type: none"> • See the <i>Elective Replacement Indicator</i> section of this document.

Getting Started

The battery inside your remote control is shipped disconnected from your remote. You must first install and recharge the battery in your remote before you can use it. See the *Replacing Your Remote Control Battery* and the *Recharging Your Remote* sections for information on how to install and recharge the battery in your remote.

Recharging Your Remote

Your remote is powered by a rechargeable battery. Use the power cord provided to fully recharge your remote before using it for the first time. Fully recharging your remote can take up to 90 minutes.

To recharge your remote:

1. Connect the power cord as shown in Figure 3.
2. Plug the power cord into a wall outlet.

Your remote will beep and a battery icon and a power cord icon will appear to indicate that your remote control's battery is recharging. When your remote is fully recharged, the battery icon on your remote will be completely black, and the power cord icon will disappear.

Note: ImThera recommends keeping your remote plugged in to its power cord whenever it is not in use, so that it will always be fully recharged.



Figure 3

Turning Your Remote On and Off

Unlike your TV remote control, your aura6000 remote must be turned on before it can control, or charge, your implant.

To turn on your remote, press any button once. Once activated, the remote will display the Main Menu (or the charging screen, if the implant is being charged).

Your remote will automatically turn off after 30 seconds if no buttons are pressed. To turn your remote off immediately, scroll down to **POWER OFF remote**, and press the OK button.

Understanding the Remote Screen

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

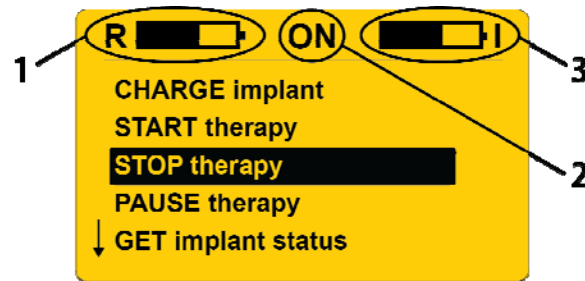


Figure 4

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

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

Problem /Message	Reason	What you need to do
"Charging not possible. Connect charge antenna"	Charging antenna is not properly connected to the remote	<ul style="list-style-type: none"> • Disconnect and reconnect the antenna to the remote.
	Charging antenna failure	<ul style="list-style-type: none"> • Contact your doctor or ImThera to order a replacement device.
"Charging not possible. Insufficient power in remote control"	Remote battery is too low to charge the implant	<ul style="list-style-type: none"> • Plug the remote into a wall outlet. You can charge your implant while the remote recharges.
"Charging not possible. High charging current"	Implant too close to charging antenna	<ul style="list-style-type: none"> • Put a piece of adhesive bandage on the charging antenna to increase the distance between the implant and charging antenna.
	Charging system failure	<ul style="list-style-type: none"> • Contact your doctor or ImThera to order a replacement device.
"CHARGING implant... Low efficiency"	Implant charging slowly	<ul style="list-style-type: none"> • Place the antenna directly on your skin. • Reposition the antenna over the implant. • Use a tension bandage to push the antenna closer to the implant. • Contact your doctor.
Implant charges slowly	Charging through clothing	<ul style="list-style-type: none"> • Try the steps described under <i>Charging implant... low efficiency</i>.
	Implant too deep	
	Charging system failure	
	Checking implant battery too often	<ul style="list-style-type: none"> • Avoid checking implant status until charging has finished.
"Telemetry error"	The implant and remote are unable to communicate with each other.	<ul style="list-style-type: none"> • Move the remote closer to the implant and/or move away from other electronic devices, and try again. • Use <i>TEST telemetry</i> to diagnose the problem. • Tell your doctor if this problem persists.
"Usage info incomplete."	Missing some usage information	<ul style="list-style-type: none"> • Nothing. Your doctor will reset this at your next visit.
"Adjusting not possible"	Feature not enabled	<ul style="list-style-type: none"> • Contact your doctor.

TROUBLESHOOTING

Error Messages

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

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

Charging Your Implant

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

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

To charge your implant:

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

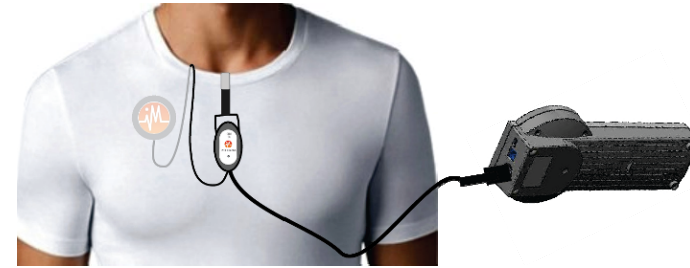


Figure 5

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



Figure 6

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

TIPS:

- The ImThera logo on the antenna must be facing away from you, or the magnets will not hold the antenna in place.

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

Starting a Sleep Session

When you plan to go to sleep, you will use your remote to instruct your implant to start a sleep session. To start a sleep session:

1. Press any button once to turn on your remote.
2. When the Main Menu appears (see Figure 7 below) highlight *START therapy*, then press the OK button.
3. The remote will then try to send a signal to the implant. Keep the remote within range of the implant until the word “ON” appears in the top middle of the screen.

After a delay that allows enough time for you to fall asleep, your implant will start to deliver stimulation. You can adjust this *Start delay* to meet your needs.

6. Discard the old battery in accordance with local regulations.

Handling & Cleaning

Your remote and accessories are sensitive medical equipment. Use care when handling your remote and accessories. Careless handling such as dropping on hard surfaces or submerging in water may cause permanent damage and will void its warranty. Never expose your remote and accessories to temperatures above 55 °C.

Your remote and antenna may be cleaned using a damp cloth and mild detergents. Do not submerge or use abrasive cleaners.

MAINTAINING YOUR REMOTE

Replacing Your Remote Control Battery

Your remote is equipped with a rechargeable battery that can be replaced if it no longer holds a sufficient charge.

Note: If your battery does not look like the one in Figure 9, then contact ImThera technical support for assistance.

To replace the remote battery:

1. Open the battery compartment door and remove the old battery from the compartment.
2. Grasp the three wires near the connector (see illustration), and pull gently to disconnect the old battery.

Note: There is no latch to disconnect. Just pull gently.

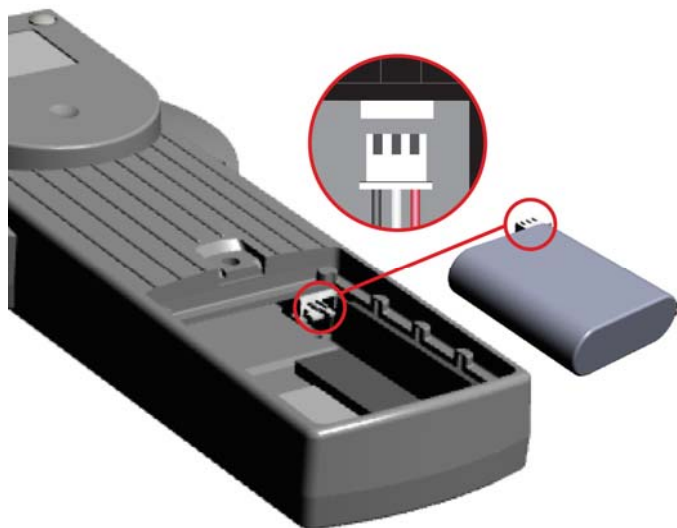


Figure 9

3. Orient the battery pack connector so that the three metal strips are on top, then slide the connector into position.

Note: If the battery has any power in it, then you will hear the remote beep when the battery is connected.

4. Close the battery compartment door.
5. Recharge the remote.

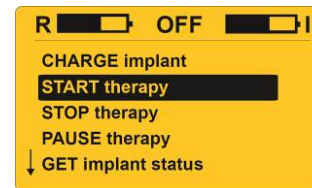


Figure 7

Pausing or Stopping a Sleep Session

When you wake up, you will use your remote to either: i) pause stimulation if you need to get up briefly to use the bathroom or speak on the phone and plan to return to sleep; or ii) stop stimulation if you plan to stop sleeping. To pause or stop a sleep session:

1. Press any button once to turn on your remote.
2. When the screen shown below appears, highlight your choice – *STOP therapy* or *PAUSE therapy* as appropriate, and then press the OK button.

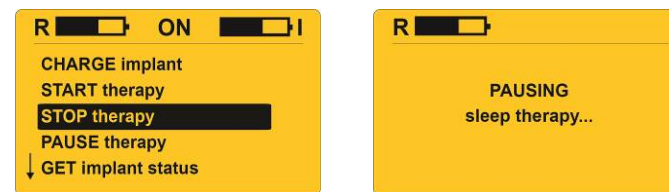


Figure 8

3. The remote will then try to send a signal to the implant. Keep the remote within range of the implant until the word “PAUSED” or “OFF” appears in the top middle of the screen.
4. (For Pause only) If *Auto-resume* is enabled, stimulation will automatically resume after the *Pause delay* elapses.

If *Auto-resume* is not enabled, then highlight *START therapy* and press the OK button when you are ready to go back to sleep and your implant will start to deliver stimulation after the *Pause delay* elapses.

You can adjust the *Pause delay* to meet your needs.

Adjusting Therapy

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

these settings, highlight *Adjust therapy* and then press OK.

To change any of these settings: i) highlight the line of the setting that you want to change; ii) press OK; iii) use UP/DOWN to change the value of the setting; and then iv) press OK to change the setting.

- *Master amplitude:* This setting enables you to adjust the amplitude (strength) of your therapy within limits prescribed by your doctor. You should always use the highest setting that doesn't wake you up.
- *Start delay:* This setting enables you to adjust how long the implant will wait after pressing *START therapy* before beginning to deliver stimulation. For example, if it typically takes you 45 minutes to fall asleep, then you should set this to 45 minutes.
- *Pause delay:* This setting enables you to adjust how long the implant will wait after pausing therapy before resuming stimulation. For example, if it typically takes you 15 minutes to fall asleep after getting up to use the bathroom, then you should set this to 15 minutes.
- *Auto-resume:* This setting enables you to choose whether, after pressing *Pause therapy*, you would like the *Pause delay* countdown to begin: i) automatically and immediately after pressing *Pause therapy*; or (ii) only after you press *START therapy*. When *Auto-resume* is set to *No*, you must press *START therapy* to resume therapy.
- *Sleep duration:* This setting enables you to adjust how long therapy will stay on before automatically stopping. For example, if you typically sleep for 8 hours, then set this to 8 hours.

Setting Preferences

You can use this menu to adjust the beeper tone, backlight setting, backlight brightness and language displayed on your remote.

To change any of these settings: i) highlight the line of the setting that you want to change; ii) press OK; iii) use UP/DOWN to change the value of the setting; and then iv) press OK to change the setting.

- *Beeper:* The beeper has four settings: Off, Low, Medium and High.
- *Backlight:* The backlight has three settings that determine how long the backlight will stay on after each button press. The settings are: Off (backlight not used), Eco (backlight on for 15 seconds after each key press), and On (backlight on whenever the screen is on).
- *Brightness:* This setting enables you to choose the brightness of the backlight on the screen of your remote. There are three settings: Low, Medium and High.
- *Language:* This setting enables you to choose the language displayed on the screen of your remote.

More Options

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

- *TEST stimulation:* See the *Troubleshooting* section for information on this feature.
- *GET remote info:* Select this option to check your remote's battery level, serial number, hardware version and software version.
- *GET implant info:* Select this option to check your implant's battery level, serial number, hardware version and software version.
- *GET usage info:* Select this option to get information about how often you have used your system.
- *TEST telemetry:* See the *Troubleshooting* section for information on this feature.