

Axonics SNM System®

Patient Therapy Guide



Axonics
Modulation
Technologies

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Caution: U.S. Federal law restricts this device for sale by or on the order of a physician

Label Symbols

Symbol	Description
	Manufacturer
	Product Model Number
	Manufacturing Date
	Non ionizing electromagnetic radiation
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (Notified Body reviewed) and RED 2014/53/EU (self-certified)
	Refer to instructions for use (Consult accompanying documents)
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Do not reuse
	Sterilized using Ethylene oxide
	Use by
	Do not use if package is damaged
	Do not re-sterilize
	Authorized representative in the European community
	Open here

Label Symbols

Symbol	Description
	For USA audiences only Caution: U.S. Federal law restricts this device for sale by or on the order of a physician
	Warning / Caution
	Product Literature
	Magnetic Resonance (MR) Conditional
IC	Industry Canada certification number
	This device complies with all applicable Australian Communications and Media Authority (ACMA) regulatory arrangements and electrical equipment safety requirements
FCC ID	US Federal Communications Commission device identification

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Who to Contact for Help

Please contact your doctors if you have questions about your health or the Axonics Sacral Neuromodulation therapy.

Axonics Patient Support

Axonics, located in Irvine, CA (USA) can help to answer questions about your Axonics SNM therapy. Please note that Axonics cannot talk about your medical condition.

Call: +1-877-929-6642

Hours: M-F, 8:00 am -5:00 pm (Pacific Time)

Indications for use

Axonics SNM therapy for bowel control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Contraindications

The Axonics SNM System is contraindicated for the following patients

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the Axonics SNM System.

What is Axonics SNM Therapy?

Who it Helps

Millions of people suffer from bowel control symptoms. These symptoms can be frustrating, embarrassing, and uncomfortable. Axonics Sacral Neuromodulation ("SNM") therapy may ease bowel control symptoms. This therapy is for people for whom other treatments did not work.

Axonics SNM therapy may help you if you have these symptoms:

Fecal or bowel incontinence – The inability to control bowel movements, causing unexpected stool (feces) leaks or frequent bowel movements

The Axonics SNM System delivers mild electrical pulses to the area of the sacral nerve located near the tailbone. These mild pulses may restore bladder control while not changing normal bowel function.

Stimulation may not cure your bowel control symptoms. However, it is expected to reduce your symptoms and improve your day to day life.

What is Axonics SNM Therapy?

Test Stimulation

If you and your doctor believe Axonics SNM Therapy is right for you, you will first undergo a test stimulation period. This will help determine if the therapy reduces your symptoms. For test stimulation, your doctor will choose to either use a temporary lead for up to 7 days or a long-term lead for up to 14 days. The implant procedure may be done in the doctor's office or in an operating room. The lead will be implanted and you will receive therapy from an external Trial Stimulator at home. A diary of your symptoms will be captured before and during your test stimulation period. This will help your doctor determine if you benefit from the therapy. Your doctor will use the results of your test stimulation period to determine if you should get the full implanted Axonics SNM System.

For more information on trialing the therapy, ask your doctor and refer to the Axonics Trial Guide (110-0062-001).

What is Axonics SNM Therapy?

The System

The Axonics SNM System consists of 4 key parts:

- A small implanted rechargeable Stimulator device that generates mild electrical pulses.
- A long insulated wire that is implanted near the sacral nerve. The wire delivers electrical pulses from the Stimulator to the area of the sacral nerve.
- A small handheld Remote Control device that allows the patient to monitor the Stimulator.
- A wireless Charger that charges the Stimulator battery.

The Axonics Stimulator has a battery that should last for 15 or more years under expected and worst-case stimulation settings.



Warnings

Diathermy

Shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) should not be used on patients implanted with the Axonics SNM System. Diathermy can transmit energy through the implanted system, potentially causing tissue damage at the location of the implanted electrodes, resulting in severe injury.

Magnetic Resonance Imaging (MRI)

The Axonics SNM System is a MRI conditional system. Refer to “MRI Guidelines for the Axonics Sacral Neuromodulation System” for more information.

Other Medical Procedures

Other medical procedures that may affect the Axonics SNM System and should be avoided include:

- Lithotripsy
- Monopolar electro surgery
- Microwave and Radio-frequency (RF) ablation
- Radiation therapy over the Neurostimulator
- Ultrasound or scanning equipment

Electromagnetic interference (EMI)

Electromagnetic interference is energy generated by

Warnings

equipment found at home, work, or in public that can interfere with the function of the Axonics SNM System. The Axonics SNM System includes features that provide protection from EMI so that most electrical devices encountered in a normal day are unlikely to affect the operation of the Neurostimulator. While everyday electrical devices are unlikely to affect the Neurostimulator, there are strong sources of EMI that may temporarily affect the operation of your stimulator, including anti-theft detectors found in stores used to detect stolen merchandise. If patients encounter any of these electrical devices, they should walk as far away from the sides of the anti-theft detector when passing through.

At the Airport, Courthouses, etc.

If patients encounter walkthrough metal detectors or security archways they should walk-through at a normal pace. These detectors should not affect the Stimulator. Hand-held security wands should be passed over the Stimulator quickly and should not affect the stimulator. Full-body security scanners (millimeter wave scanners) are used by the Transportation Security Administration (TSA) and are considered safe in patients that have a stimulator.

Additionally, patients should minimize their exposure by not lingering in the immediate area of the security systems. Some anti-theft detectors may not be visible. If patients feel poorly, they should walk away from the area and anti-theft detectors and security scanners.

Warnings

Case Damage

The Neurostimulator, Remote Control and Charger contain batteries with chemicals that can cause bodily harm, including severe burns, if exposed to your body. Do not rupture or pierce the devices or use the device that appears damaged or has visible internal components.

Use of Charger

If swelling or redness occurs near the Charger attachment site, discontinue to the use of Charger and consult your doctor before using the Charger again.

Precautions

Clinician training

Implanting clinicians should be trained on the implantation and use of the Axonics SNM System.

Prescribing clinicians should be experienced in the diagnosis and treatment of fecal incontinence and should be trained on the use of the Axonics SNM System.

Use in specific populations

The safety and effectiveness of this therapy has not been established for:

- Pregnant women
- Pediatric use (patients under the age of 18)
- Patients with progressive, systemic neurological diseases
- Bilateral stimulation

Potential Adverse Events

Implantation and use of the Axonics SNM System incurs risk beyond those normally associated with surgery, some of which may necessitate surgical intervention. These risks include, but are not limited to the following:

- Adverse change in voiding function (bowel and/or bladder)
- Allergic or immune system response to the implanted materials that could result in device rejections
- Change in sensation or magnitude of stimulation which has been described as uncomfortable (jolting or shocking) by some patients
- Device fracture/failure
- Device migration
- Electrical shock
- Heating or burn at Neurostimulator site
- Infection
- Lack of efficacy
- Pain or irritation at Neurostimulator and/or lead site
- Reoperation/Revision
- Seroma, hemorrhage, and/or hematoma
- Suspected lead or Neurostimulator migration or erosion
- Suspected nerve injury (including numbness)
- Suspected technical device malfunction
- Transient electric shock or tingling
- Unintended nerve activation
- Undesirable change in pelvic function

Clinical Summary of Expected Results

The safety and effectiveness of SNM therapy and the Axonics System is based on published studies from medical journals. Additionally, safety data for the Axonics SNM System was reviewed from the ARTISAN-SNM study, which was an investigational device exemption (IDE) pivotal study in which 129 patients with urinary urgency incontinence (UUI) were treated with the Axonics SNM System.

Evaluation of Safety

The safety of the Axonics SNM System was evaluated based on two sources of data,

- the published articles on the use of the InterStim System for fecal incontinence and
- a review of any adverse events (AE) from the ARTISAN-SNM study (the IDE study for the Axonics SNM System for urinary control). The ARTISAN-SNM study was conducted in 15 US clinical sites under G170100 and evaluated 129 implanted patients.

Literature Source Evaluation of Safety

The literature provided strong evidence to support a low serious AE (SAE) rate for the use of the InterStim System in 330 patients treated with the device to treat fecal incontinence.

All AEs and SAEs reported per article are provided in **Table 1**.

Table 1: Adverse Events Reported in the Literature for the InterStim System.

Article Reference	Follow up duration	Adverse Events	SAE
Hull, 2013 (120 subjects)	5 years	<ul style="list-style-type: none"> • Pain at implant site (32.5%) • Paresthesia (19.2%) • Change in sensation of stimulation (11.7%) • Infection, implant site (10%) • Urinary incontinence (8.3%) • Battery depletion (6.7%) • Diarrhea (6.7%) • Pain, extremity (5.8%) • Change in stimulation, undesirable (5.8%) • Pain, buttock (5.0%) • Migration, Implant (2.5%) • Other (58.3%) 	<ul style="list-style-type: none"> • Pain at implant site (9%) • Infection, implant site (3.3%) • Battery depletion (0.8%) § • Other (9.2%)
Patton, 2016	2.7 years	<ul style="list-style-type: none"> • Lead migration (13%) 	<ul style="list-style-type: none"> • NR †

Clinical Summary

Article Reference	Follow up duration	Adverse Events	SAE
(127 subjects)		<ul style="list-style-type: none"> • Explantations (11%) • Infection, wound (6%) • Infection, implant (4%) • Reoperation (4%) • Neurostimulator revision (4%) • Pain, Neurostimulator site (3%) • Hematoma (2%) 	
Tjandra, 2008 (53 subjects)	12 months	<ul style="list-style-type: none"> • Uncomfortable sensation (9%) • Pain at implant site (6%) • Seroma (2%) 	• NR ‡
Rydningen, 2017 (30 subjects)	6 months	<ul style="list-style-type: none"> • Pain at Neurostimulator (NR ‡) • Neurostimulator revision (NR ‡) 	• NR ‡

§ One event of battery depletion occurred which was considered serious because of the patient being admitted to hospital for > 24 hrs; however, no complications occurred during or after the battery replacement.

‡ NR: Rates are not reported by author or not relevant since the sample size is too small (N<30) to have a meaningful rate associated with it.

Clinical Summary

Axonics Clinical Data Evaluation of Safety

The ARTISAN-SNM Study was a single arm, prospective, multicenter, unblinded, pivotal study with the primary objective of evaluating the safety and effectiveness of the Axonics SNM System for the treatment of Urinary Urgency Incontinence (UUI), a subtype of overactive bladder (OAB). The study was conducted in 15 US Centers (97 patients implanted) and 5 Centers in Western Europe (32 patients implanted).

A total of 181 AEs were reported among 80 subjects across the entire study experience at 6-months. Out of 181 AEs, 180 AEs occurred in implanted subjects, and one (1) AE occurred in a subject that was enrolled in the study but not implanted. Of the 180 AEs, 7 were SAEs and no SAEs were procedure-related or device-related. Out of the 173 non-serious AEs, 13 were related to device, and 15 were related to procedure (as shown in the tables below). One (1) death occurred from complications following multiple perforated diverticulum of the large intestine. The death was not related to device or procedure. None of the reported AEs were unanticipated. The total number and percentage of AEs by event category, seriousness, and relatedness to device or procedure is presented in **Table 2** and **Table 3**.

Table 2: Device Related AEs and SAEs Reported in the ARTISAN-SNM Study.

AE Type	Device Related		Serious Device Related	
	Events (n)	Subjects (n/N) (%)	Events (n)	Subjects (n/N) (%)
Proctalgia	1	1 (0.8)	0	0 (0.0)
Pain	1	1 (0.8)	0	0 (0.0)
Medical device discomfort	1	1 (0.8)	0	0 (0.0)
Implant site pain	2	2 (1.6)	0	0 (0.0)
Incision site infection	1	1 (0.8)	0	0 (0.0)
Pain at extremity	2	2 (1.6)	0	0 (0.0)
Groin Pain	1	1 (0.8)	0	0 (0.0)
Dysasthesia	1	1 (0.8)	0	0 (0.0)
Lead dislodgement	1	1 (0.8)	0	0 (0.0)
Vulvovaginal pain	1	1 (0.8)	0	0 (0.0)
Vulvovaginal discomfort	1	1 (0.8)	0	0 (0.0)
Total	13	13 (10.1)	0	0 (0.0)

Table 3: Procedure Related AEs and SAEs Reported in the ARTISAN-SNM Study

AE Type	Procedure Related		Serious Procedure Related	
	Events (n)	Subjects (n/N) (%)	Events (n)	Subjects (n/N) (%)
Vomiting	1	1 (0.8)	0	0 (0.0)
Implant site pain	1	1 (0.8)	0	0 (0.0)
Hypersensitivity	1	1 (0.8)	0	0 (0.0)
Allergy to chemicals	1	1 (0.8)	0	0 (0.0)
Incision site infection	1	1 (0.8)	0	0 (0.0)
Fungal infection	1	1 (0.8)	0	0 (0.0)
Procedural pain	4	4 (3.1)	0	0 (0.0)
Incision site pain	1	1 (0.8)	0	0 (0.0)
Paraesthesia	1	1 (0.8)	0	0 (0.0)
Keloid scar	1	1 (0.8)	0	0 (0.0)
Dermatitis papillaris capillitii	1	1 (0.8)	0	0 (0.0)
Suture insertion	1	1 (0.8)	0	0 (0.0)
Total	15	13 (10.1)	0	0 (0.0)

Note: A total of 15 events occurred in 13 subjects.

The time course and resolution status of device-related and procedure-related adverse events (AEs) from the Artisan-SNM study are provided in Tables below. All AEs and their resolution status are reported as of the data lock date of 18 January 2019. Tables 4 and 5 provide summarized information.

Clinical Summary

Device-related adverse events

Table 1: Summary and time-course device-related adverse events

Number of implanted subjects = 129							
AE Type	Implant to 2 Weeks	2 weeks to 1 Month	1 Month to 3 Months	3 Months to 6 Months	6 Months to 12 Months	Beyond 12 Months	Status Resolved*/ Ongoing
Total events	1	4	2	3	3	0	13/0
Proctalgia	0	0	0	1	0	0	1/0
Pain	0	1	0	0	0	0	1/0
Medical device discomfort	0	0	0	0	1	0	1/0
Implant site pain	1	0	1	0	0	0	1*/0
Incision site infection	0	1	0	0	0	0	1/0
Pain in extremity	0	1	0	1	0	0	1/0
Groin pain	0	0	1	0	0	0	1/0
Dysaesthesia	0	0	0	0	1	0	1/0
Lead dislodgement	0	1	0	0	0	0	1/0
Vulvovaginal pain	0	0	0	0	1	0	1/0
Vulvovaginal discomfort	0	0	0	1	0	0	1/0

* Includes events that were resolved with sequelae

Clinical Summary

Procedure-related adverse events

Table 5: Summary and time-course of procedure-related adverse events

Number of implanted subjects = 129							
AE Type	Implant to 2 Weeks	2 weeks to 1 Month	1 Month to 3 Months	3 Months to 6 Months	6 Months to 12 Months	Beyond 12 Months	Status Resolved*/ Ongoing
Total events	10	3	1	1	0	0	13/2
Vomiting	1	0	0	0	0	0	1/0
Implant site pain	1	0	0	0	0	0	1*/0
Hypersensitivity	0	1	0	0	0	0	1/0
Allergy to chemicals	1	0	0	0	0	0	1/0
Incision site infection	0	1	0	0	0	0	1/0
Fungal infection	0	1	0	0	0	0	1/0
Procedural pain	4	0	0	0	0	0	3/1
Incision site pain	1	0	0	0	0	0	1/0
Paraesthesia	0	0	1	0	0	0	0/1
Keloid scar	0	0	0	1	0	0	1*/0
Dermatitis papillaris capillitii	1	0	0	0	0	0	1*/0
Suture insertion	1	0	0	0	0	0	1/0

* Includes events that were resolved with sequelae

Evaluation of Effectiveness

The analysis of effectiveness for the treatment of fecal incontinence was based on a review of the same four (4) articles discussed above for safety, but with the addition of a study by Melenhorst et al. The five (5) studies encompassed 430 subjects. The ARTISAN study was not used in the assessment of effectiveness because its primary objective was to treat urinary urgency incontinence, not fecal incontinence. Key effectiveness outcomes are presented in **Table 6**.

Table 6: Effectiveness Outcomes Reported in the Literature for the InterStim System.

Article Reference	# Subjects Receiving Test Stimulation	# Subjects Receiving Permanent Implant (% of subjects receiving test stimulation)	Follow up Duration with Permanent Implant <i># subjects at follow up (% of subjects receiving permanent implant)</i>	Effectiveness Endpoint (Responder ₅₀ Rate, St. Mark's score, FI episodes or other)
Hull, 2013	133	120 (90%)	5 years 72 subjects (60%)	Responder ₅₀ Rate: 89% (64/72 subjects), Mean number of FI episodes per week: Baseline: 9.1 5 years: 1.7 36% (26/72) were totally continent
Patton, 2016		127; 112 after test stimulation (68%); 15 implants without trial	2.7 years 91 subjects (72%)	St. Mark's score: baseline: 14.4 (95% CI: 13.44, 15.33) follow-up: 10.3 (95% CI: 9.2, 11.44)

Article Reference	# Subjects Receiving Test Stimulation	# Subjects Receiving Permanent implant (% of subjects receiving test stimulation)	Follow up Duration with Permanent Implant <i># subjects at follow up (% of subjects receiving permanent implant)</i>	Effectiveness Endpoint (Responder ₅₀ Rate, St. Mark's score, FI episodes or other)
Melenhorst, 2007	134	100 (75%)	25.5 months <i>33 subjects (33%)</i>	Mean number of FI episodes per 3 weeks: baseline: 31.3 3 years: 4.5 Mean number incontinent days per 3 weeks: baseline: 12.7 3 years: 3.3
Tjandra, 2008	60	53 (88%)	12 months <i>53 subjects (100%)</i>	Mean number of FI episodes per week: baseline: 9.5 ± 12.8 (SD) 12 months: 3.1 ± 10.1 (SD) Mean number incontinent days per week: baseline: 3.3 ± 2.4 (SD) 12 months: 1 ± 1.7 (SD) Wexner Score: baseline: 16. ±1.3 12 months: 1.2 ± 1.8 47% (25/53) were totally continent
Rydningen, 2017	N/A	30 (N/A)	6 months <i>30 subjects (100%)</i>	St. Mark's score: Baseline: 19.0 ± 2.5 (SD) 6 months: 7.7 ± 5.5 (SD)

In the Hull, et al study, a total of 133 patients met all the inclusion and exclusion criteria and underwent test stimulation for a period of 10 to 14 days to determine the effectiveness of the therapy. There were 120 patients who achieved a ≥50% improvement in incontinent bowel episodes (met Responder₅₀ Rate) and subsequently underwent implantation with the approved SNM device. Patients had a

Clinical Summary

follow-up of up to 5 years. The results are reported as the proportion of patients that had a minimum of a 50% reduction of fecal incontinence episodes (Responder₅₀ Rate). The change from baseline in the Fecal Incontinence Quality of Life (FIQL) questionnaire and the Fecal Incontinence Severity Index (FISI) were also evaluated.

Of the 120 subjects receiving permanent implants in the Hull study, 5 year responder rates were available for 72 subjects (60%). Among these subjects, 89% (64/72) had at least a 50% improvement from baseline in weekly incontinent episodes and 36% (26/72) of patients at 5 years post-implantation had achieved total continence. The average number of weekly incontinent episodes decreased from 9.1 at baseline to 1.7 at 5 years. In addition, improvements in all four (4) scales of the FIQL from baseline to 5 years post-implantation were statistically significant. With the use of the patient weighting for scores, the mean FISI decreased from 37.95 at baseline to 28.33 at the 5-year follow-up.

In the Patton, et al study, the investigators evaluated the improvement in the St. Mark's score, which is a patient scoring of fecal incontinence from 0 (completely continent) to 16 (completely incontinent). An initial enrollment of 166 subjects underwent trial testing of which 112 progressed to a permanent SNM implant. An additional 15 subjects received an implant without the testing phase, giving a total of 127 subjects of which 109 subjects were available for follow-up and 91 were included in the analysis (18 did not respond to a survey). The mean follow-up was 2.7 years. Continence improved from a baseline St. Mark's mean score of 14.4 (95% CI: 13.44, 15.33) to a follow-up mean score of 10.3 (95% CI:

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9.2, 11.44).

In the Mellenhorst, et al. study, of 134 subjects with at least one (1) episode of FI per week, there were 100 subjects that received a permanent implant. The mean number of FI episodes per 3 weeks decreased from 31.3 episodes at baseline to 4.5 episodes at 3 years. The mean number of FI days per 3 weeks decreased from 12.7 at baseline to 3.3 at 3 years. There were 21 subjects that were considered to be late failures based on the relapse of symptoms to < 50% improvement from baseline symptoms, implementation of another therapy for FI and patient dissatisfaction.

In the Tjandra, et.al study, the absolute decrease in the number of FI episodes was evaluated in 120 subjects (minimum Wexner incontinence score of > 12, mean of 16) that were randomized to SNM or control group having optimal medical therapy (pelvic floor exercises, bulking agents, and dietary control). During the test period for the SNM cohort, incontinence episodes improved by more than 50% in 54 of 60 patients (90%). Full systems were implanted in 53 of these 54 patients, who were then followed for 12 months. Subjects that received SNM had a decrease of the mean incontinence episodes per week from 9.5 to 3.1 and a mean decrease in incontinent days per week from 3.3 to 1 at 12 months. Complete continence was accomplished in 25 SNM patients (47.2%). The mean Wexner score at baseline was 16 at baseline, and 1.2 at 12 months. There was also improvement in FIQL index in all 4 domains (lifestyle, coping/behavior, depression/self-perception and embarrassment) as compared to the control subject cohort. There was no improvement in the FIQL in the 60 control

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subjects.

In the Rydningen, et al study, the effectiveness of InterStim was evaluated in comparison to submucosal injection of collagen (Permacol) among 58 female patients (30 SNM and 28 Permacol) with FI. Both patient groups had a baseline St. Mark's score > 8 and $\geq 50\%$ improvement with a test period evaluation. The reduction in the St. Mark's score between baseline and 6 months was 11.2 (SD 5.3) in the SNM group versus 2.3 (SD 5.0) in the Permacol group, resulting in a treatment difference of 8.9 (95% CI: 6.1–11.7), in favor of SNM. SNM was also superior to Permacol regarding the four (4) domains of the FIQL.

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6. McCrery R, Lane F, Benson K, et al. Treatment of Urinary Urgency Incontinence Using a Rechargeable SNM System: 6-month Results of the ARTISAN-SNM Study. *J Urol*. 2019 Jul 26 [Epub ahead of print]

Getting the Axonics SNM System

The Procedure

The Axonics SNM System will be implanted in an operating room. You may be given general anesthesia or a mild anesthetic along with local sedation.

The doctor will insert a needle just above the tailbone to locate the sacral nerve. Test stimulation will be used to test the needle location and the nerve response. Your doctor will look for muscle responses in your buttocks and big toe. The muscle responses confirm that the needle is stimulating the correct nerve. If you are under local anesthesia, the doctor may ask you how the stimulation feels. You may feel a “pulling” or “tingling” in the pelvic muscles or big toe. Women may feel the stimulation in the vaginal area. Men may feel the stimulation in the scrotum. Some patients feel no sensation at all. Then the lead will be implanted where the needle was placed. Medical imaging (x-ray for example) may be used to confirm the location of the lead.

Next the Stimulator will be implanted, usually in the upper buttock area and always under the skin. Before the procedure, you should talk with your doctor about where the Stimulator will be implanted. The Stimulator will be connected to the implanted lead.

Patients usually go home on the same day as the procedure.

Getting the Axonics SNM System

You may feel some pain or discomfort in the first couple of weeks after surgery in the area of the implant as your skin heals. Your doctor may also give you drugs to help with pain. Your doctor or their staff will give you detailed instructions on what to do following your surgery.

In the first few weeks after your procedure, limit your activities. Limiting activities will help you avoid the moving of your implanted lead. This helps ensure that therapy will be effective. When cleared by your doctor, you can go back to regular day to day activities. You will need to continue to avoid some extreme activities (see the section of this guide on “Physical Activity Precautions”).

Note: *Similar to any surgical procedure, there are risks with this procedure. Risks include bleeding, bruising, swelling, and infection. Please discuss the procedure and any concerns with your doctor.*

Getting the Axonics SNM System

Tracking Your Symptoms

A diary is used to track your symptoms. You will need to fill out a diary for several days before and after your System is implanted. The diary provides important information to your doctor that helps your doctor decide if you could benefit from Axonics SNM therapy. It is important to fill out the diary when symptoms occur.

You should carry your diary with you when you are tracking your symptoms and use the diary to record symptom data. Please always bring your diary with you to your doctor visits.

Your doctor, or their staff, will show you how to complete your diary. You should contact them if you have questions.

What to Expect

Your Stimulator may be turned on when you leave the hospital or very soon thereafter. You may feel a similar sensation as what you felt during test stimulation. It should not be uncomfortable or painful. You should feel a small amount of sensation at all times, and you should increase your stimulation amplitude if you are not feeling sensation. Stimulation should be on for 24 hours per day, 7 days per week.

If your therapy feels uncomfortable or painful, your doctor can change the stimulation. It may take more than one try by your doctor to find a stimulation setting that gives you both comfort and good symptom relief.

The following items are important for managing your Axonics SNM System:

- Follow-up appointments
- Your patient ID card
- Precautions about physical activity
- Precautions about medical procedures
- Precautions about electromagnetic interference
- Your Remote Control
- Recharging your Stimulator

Note: *The feeling of your stimulation can change over time. Contact your doctor if your stimulation becomes uncomfortable or if your symptoms worsen.*

Support Resources

There are resources to help you live with your Axonics SNM System.

Training

You will be trained on how to use your Remote Control and how to charge your Stimulator by your doctor's staff. You will also be told about the precautions and warnings to be aware of. If you have questions or problems using your system, ask your doctor and his or her staff for more training.

Patient Identification (ID) Card

You will be given a patient ID card that contains basic information about you and your System. Your patient ID card shows that you have an implanted Stimulator if you have an emergency.

If you lose your patient ID card, please contact Axonics for a new card.

Follow-up Visits

You will have regular doctor visits to check on your health and the Axonics SNM System. Your doctor will help with problems and may change your stimulation settings. If you want to stop therapy you should discuss this with your doctor. Your doctor may or may not advise removal of the Axonics SNM system.

Please bring your Remote Control to your follow-up visits.

Physical Activity Precautions

Patients should avoid activities that put the implanted system under extreme stress.

- Avoid rubbing the Stimulator through the skin and activities that require excessive or repetitive twisting, bending, bouncing or stretching. These activities can damage the implanted system resulting in loss of symptom relief and additional surgery. Examples of activities to avoid are gymnastics, mountain biking, and sky diving, skiing and other sports. Less extreme activities should not impact your system, like running, jogging, road biking, swimming, and sexual activity.
- Scuba diving below 10 meters (33 feet) of water or entering hyperbaric chambers above 200kPa should be avoided.
- A perceived increase in stimulation may be caused by electromagnetic interference, postural changes, and other activities. You may find this uncomfortable (a jolting or shocking feeling). Before engaging in activities that receiving a jolt would be unsafe for you or those around you, lower the stimulation amplitude to the lowest setting and turn off the Neurostimulator.

Consult your doctor if you have any questions or concerns about physical activities.

Living with the Axonics SNM System

Medical Procedure Precautions

Some medical procedures could damage your Axonics SNM System.

Talk to your doctor about your Axonics SNM System before having any medical procedure.

Magnetic Resonance Imaging (MRI)

The Axonics SNM System is a MRI conditional system. Refer to “MRI Patient Guidelines for the Axonics Sacral Neuromodulation System” for more information.

Diathermy

Shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) should not be used on patients implanted with the Axonics SNM System. Diathermy can transmit energy through the implanted system, potentially causing tissue damage at the location of the implanted electrodes, resulting in severe injury.

Other Medical Procedures

Additional medical procedures that may affect your Axonics SNM System and should be avoided include:

- Lithotripsy
- Monopolar electro-surgery
- Microwave and Radio-frequency (RF) ablation
- Radiation therapy over the Neurostimulator
- Ultrasound or scanning equipment

Effects on Other Implanted Devices

The effect of the Axonics SNM System on the operation of other implanted devices, such as cardiac devices, other Neurostimulators, and implantable drug pumps, is not known. In particular, if the Axonics device is implanted close to one of these devices, they may have sensing problems and/or inappropriate device responses. Potential interference issues should be investigated before surgery by clinicians involved with both devices. The programming of the devices may need to be optimized to provide maximum benefit from both devices.

Neurostimulator Interaction with Implanted Cardiac Devices

When a patient needs both an Axonics SNM System and an implanted cardiac device (for example, a pacemaker or defibrillator), interactions between the two devices should be discussed by the patients' physicians involved with both devices (such as the cardiologist, electrophysiologist, urologist, and urogynecologist) before surgery. To reduce potential interference, the devices should be implanted on opposite sides of the body and as far away from each other as practical.

The stimulation pulses produced by the Axonics SNM System may interact with cardiac devices that sense cardiac activity, leading to inappropriate behavior of the cardiac device.

Living with the Axonics SNM System

EMI Precautions

Energy from equipment found at home, work, or in public can potentially interfere with the Axonics SNM System. This is called electromagnetic interference (EMI). The Axonics SNM System has features that protect from EMI. Most electrical devices will not affect the Stimulator. Keep your distance from powerful electrical items to reduce the risk of potential problems.

Everyday electrical devices are not likely to affect your Stimulator. There are strong sources of EMI that have a higher risk. These include, anti-theft detectors found in stores to detect stolen merchandise. If you encounter any such devices, walk far away from the sides of the device when passing through. Some anti-theft detectors may not be visible. If you feel poorly, walk away from that area.

Airport security systems should not cause any interference problems with your Stimulator. Airport authorities advise patients to carry their Patient ID Card with them when traveling. They advise you to walk through metal detectors or security archways normally. Handheld security wands should move over stimulator quickly. Full-Body Scanners (millimeter wave scanners) are considered safe with implants by Transportation Security Administration (TSA). However, you should not linger within the detection zone.

You may encounter additional equipment that generates EMI. This equipment is unlikely to affect the Axonics SNM System if you follow these guidelines:

Living with the Axonics SNM System

Bone growth stimulators – The external coils of bone growth stimulators should be kept at least 45 cm (18 in) away from the Axonics SNM System. Do not use a bone growth stimulator if it is not working as intended.

Dental drills and ultrasonic probes –The drill or probe should be kept 15 cm (6 in) away from the Neurostimulator. The Neurostimulator should be turned off.

Electrolysis – The electrolysis wand should be kept at least 15 cm (6 in) away from the Neurostimulator. The Neurostimulator should be turned off.

Electromagnetic field devices – The following equipment or environments should be avoided or you should exercise caution around:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters such as those used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (generally safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (generally safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (generally safe if outside the fenced area)

Living with the Axonics SNM System

Laser procedures – The laser should not be directed at the Neurostimulator. The Neurostimulator should be turned off.

Psychotherapeutic procedures – Equipment used for psychotherapeutic procedures may induce electrical currents which may cause heating at the lead electrodes and could result in tissue damage. Equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) during psychotherapeutic procedures have not been established as safe to operate in a patient with a Neurostimulator. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Radiation therapy – Neurostimulator operation may be affected by high-radiation exposure. Sources of high-radiation should not be directed at the Neurostimulator. Neurostimulator damage due to high-radiation exposure may not be immediately evident, and exposure should be limited using appropriate measures, including shielding and adjusting the beam angle to avoid exposure to the Neurostimulator.

Transcutaneous electrical nerve stimulation (TENS) – TENS electrodes should not be placed in locations where the TENS current passes over any component of the Axonics SNM System. Discontinue using TENS if it starts affecting the performance of the Axonics SNM System.

If you think that an EMI generating equipment or environment is affecting the function of their Axonics SNM

Living with the Axonics SNM System

System, you should:

1. Move away from the equipment or object.
2. Turn off the equipment or object. (if possible)
3. Use the patient Remote Control to adjust stimulation if necessary and to confirm the system is functioning appropriately.

If you are unable to eliminate the interference or believe the interference has altered the effectiveness of your therapy, you should contact your clinician.

Sources of strong EMI can result in the following:

- **Serious patient injury**, resulting from heating of the Neurostimulator and/or leads that causes damage to surrounding tissue.
- **System damage**, which may require surgical replacement due to change in symptom control.
- **Operational changes to the Neurostimulator**, causing it to turn on or off or to reset the settings, resulting in loss of stimulation or return of symptoms, causing a need for reprogramming by the clinician.
- **Unexpected changes in stimulation**, leading to a sudden increase or change in stimulation, which may be experienced as a jolting or shocking sensation. While the sensation may be uncomfortable, the device would not be damaged nor would it cause direct injury to the patient. In rare cases, the change in stimulation may cause the patient to fall and be injured.

Using Your Remote Control

Introduction



The Axonics SNM System includes a Remote Control that you should carry with you at all times. You can monitor your Stimulator using the Remote Control.

You should not need the Remote Control to change your stimulation. Your doctor should set your stimulation settings.

Your doctor will train you to use your Remote Control. A summary of how to use the Remote Control is on the following pages.

Note: *Bring your Remote Control to all your doctor visits.*

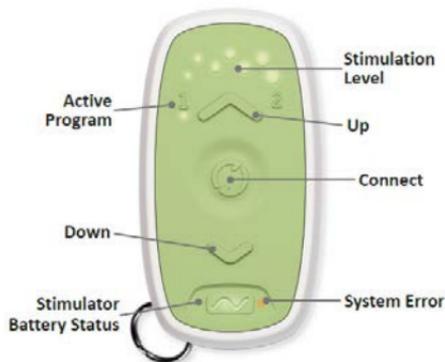
Using Your Remote Control

Recommended Use and Care

- Carry your Remote Control with you at all times in case you need to adjust stimulation or check the battery status of your Stimulator.
- To avoid damaging the Remote Control, do not drop it in liquid or clean it with harsh cleaners. You can clean the Remote Control with damp, soft cloth as needed.
- Avoid placing the Remote Control over or near other active implanted medical devices (for example pacemaker, defibrillator and other neurostimulators)
- Do not use the Remote Control near flammable or explosive gases.

Using Your Remote Control

Buttons and Lights



Stimulation Level – Shows the strength of stimulation

Up – Turn up stimulation level or Turn on stimulation to default level

Connect – Connect or disconnect the Patient Remote to the Stimulator

Down – Turn down stimulation level or Turn off stimulation

System Error – Shows there is an error in the Remote Control or Stimulator

Stimulator Battery Status – Shows if the battery needs charging

Active Program – Not applicable

Using Your Remote Control

Connecting to the Stimulator

To use your Remote Control, follow these steps to connect to the Stimulator:

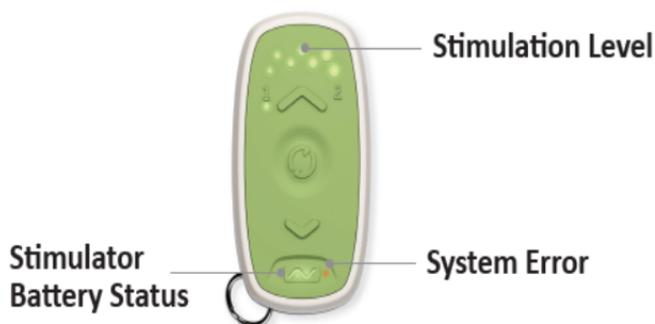
1. Hold the Remote Control comfortably in front of you on the same side of your body as your Stimulator.
2. Press the “Connect” button on the center of the Remote Control.
3. The stimulation level lights will flash. Flashing means the Remote Control is trying to connect to the Stimulator. It may take up to 12 seconds for the Remote Control to start communicating with the Stimulator.
4. Watch for the stimulation level lights to stop flashing and the Stimulator battery light to turn on. This means the Remote Control is communicating with the Stimulator. If no lights are on, the connection failed. Move the Remote Control closer to where the Stimulator is implanted and try again.



Note: Moving the Patient Remote while it is connected to the Stimulator may result in disconnection

Using Your Remote Control

Reading the Lights



Stimulator Battery Status Indicator



Solid Green: Stimulator battery will last for 4 or more days

Flashing Green: Stimulator battery is charging



Solid Orange: Stimulator battery will last for 2 to 4 days

Flashing Orange: Stimulator battery will last for 2 days or less

Stimulation Level Indicators



No stimulation



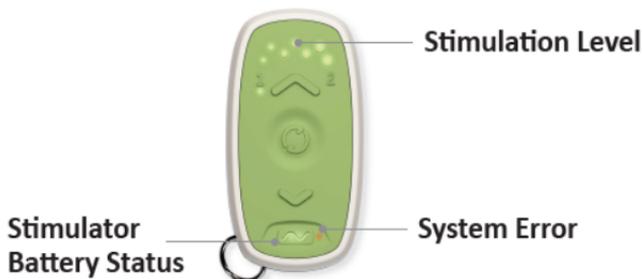
Default level set by your doctor



Maximum level

Using Your Remote Control

Monitoring Stimulation Status



System Error light

When you try to connect to your Stimulator, the Remote Control will check for errors. Call your doctor when the red error light is on.

Red light flashes – Ask for a new Remote Control.

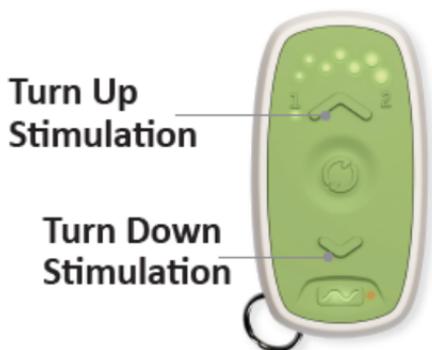
Red light is on at all times – The doctor needs to test your Stimulator. Make an appointment to see your doctor.

Note: The Remote Control is not serviceable. It must be returned to Axonics for replacement.

Using Your Remote Control

Changing Stimulation

You should feel stimulation at all times, and if you do not feel the stimulation you should increase the stimulation strength. If you need to change your stimulation, you can use your Remote Control to turn up or down the stimulation or completely turn off the stimulation.



Turn Up Stimulation

Press + Release: Turn up stimulation strength by one level

Press + Hold for 5 seconds: Turn stimulation on
(if stimulation is off)

Turn Down Stimulation

Press + Release: Turn down stimulation strength by one level

Press + Hold for 5 seconds: Turn stimulation off

Note: *The Remote Control will vibrate when a command has been successfully received by the Stimulator. A change in the stimulation level lights will also occur.*

Charging Your Stimulator

Introduction



The Axonics SNM System includes a small rechargeable Stimulator that will typically need to be recharged every one (1) or two (2) weeks.

How often you need to charge will depend on the stimulation level settings of the Stimulator. When your doctor programs your Stimulator, they will tell you how often you should charge. You can check your battery status using your Remote Control so you know when to charge.

To charge, you place the Charger on your skin over the Stimulator implant site. The Charger passes energy through the skin to charge the Stimulator battery. The amount of time it will take to charge the battery will depend on how low the Stimulator battery is. This usually should not take more than two hours.

Charging Your Stimulator

The Axonics Charging-System allows you to customize how you charge:

- Determine how often you want to charge - charge more often for shorter charge times
- Select from 2 options for holding your Charger in place during charging – you can use the carrier or the charge belt
- Pick your preferred activity for while you charge – you can perform basic activities while charging

The Axonics SNM System provides sound, vibration, and visual feedback to help you charge your Stimulator.

Detailed instructions on using your Charger will be given by your doctor and his or her staff. A summary is on the following pages.

Note: The rechargeable Neurostimulator battery should provide 15 or more years of service. With repeated charging the battery may lose capacity and require recharging more often. Notify your doctor if you experience a change in the life of your rechargeable Neurostimulator battery that requires charging more than twice as often as when initially programmed. For example, notify your doctor if your fully charged Stimulator battery initially lasted 2 weeks and after several years only lasts for 1 week.

Note: *Do not lie on your charger or wear heavy clothing or a blanket over the charger as this could cause heat to build up around the charger.*

Charging Your Stimulator

Charging-System Components



Charger

Charges the Stimulator



Carrier

Holds the Charger in place during charging



Charge Belt

Holds the Charger in place during charging



Dock

Stores and charges the Charger



Power Supply

Connects the Dock to a power source

Charging Your Stimulator

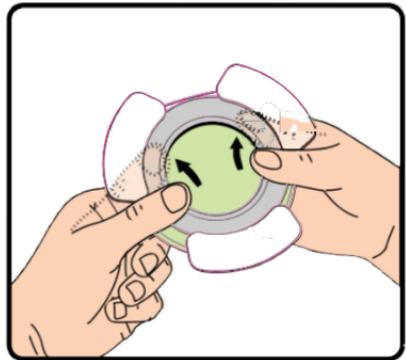
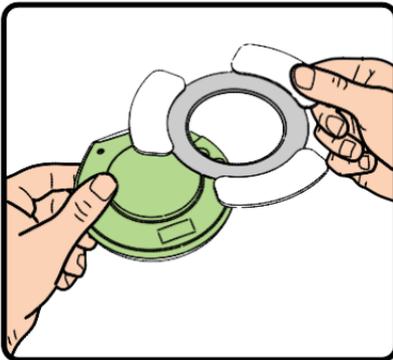
Get the Charger Ready

1. Remove the Charger from the Dock

Note: A green light on the Charger means it has enough power to fully charge the Stimulator



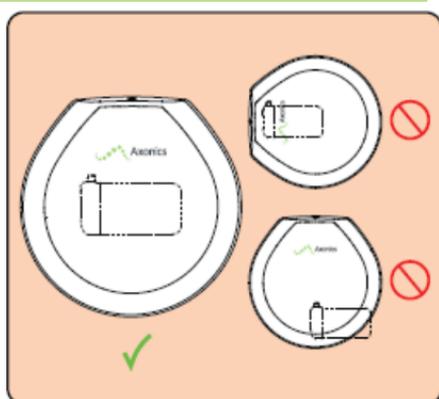
2. Snap the Charger on the Carrier (shown below) or the Charge Belt. If you use the Carrier, remove the plastic liner to expose the adhesive patches



Charging Your Stimulator

Align the Charger with the Stimulator

For best charging, place the Charger over your implanted Stimulator. You should place your Charger with the button facing up if your Stimulator is placed horizontally (as shown to the right). Your doctor will inform you if your Stimulator is placed in a different way.



To place the Charger, hold the Charger over your Stimulator. Slowly move the Charger in that area until you hear one long tone. This indicates the Charger is properly aligned and is charging the Stimulator. When you hear the long tone, press the carrier adhesives onto your skin or strap the belt tightly in place.

Charging Your Stimulator

Monitor Your Charging

During charging you can monitor charging by observing the following indicators:

Recharge Status	Feedback
The Stimulator is charging	Flashing green lights on Charger and Remote Control
Charging has been interrupted	Three beeps and vibration (repeats every 5 seconds)
Charging has been completed	Rising tone (repeats 3 times). + Charger and Remote Control lights stop flashing

If your charging is interrupted realign the Charger with the Stimulator to resume charging.

Charging Your Stimulator

Completing Charging

When you have completed charging the Stimulator:

1. Remove the Charger and the carrier or charge belt
 - a) Dispose of the carrier in the trash
 - b) Store the charge belt until the next charging
2. Place the Charger on the Dock to ensure it has enough power next time you charge your Stimulator



Note: *The Charging System is not serviceable. If you experience an issue, the Charging System must be returned to Axonics for replacement.*

Device Disposal

To dispose of any component of your system, it is recommended to return the component back to your doctor.

Do not throw the components in the regular trash. Follow your local government rules to dispose of any component, particularly components with batteries.

Do not throw any components with batteries (or the batteries themselves) in fire as the battery may explode.

Introduction

This section will help you solve issues with your Axonics SNM System. If you experience issues with your therapy, using your Remote Control, or using the Charging System, please see if the following troubleshooting steps might resolve your issue.

Contact your doctor or Axonics Customer Support if you need help resolving your issue, including for issues not included in this section.

Remote Control Troubleshooting

Issue	Presentation	Resolution
Remote Control will not connect to Stimulator	Remote Control lights scroll then go off. Battery Status indicator is not lit.	Move Remote Control closer to Stimulator and retry connection. Next try charging the Stimulator. If issue persists, contact your doctor
Remote Control will not connect to Stimulator	Remote Control does not respond when "Connect" button is pressed	Contact your doctor for a new Remote Control
Error indicator is visible on the Remote Control	Red error light flashes for 12 seconds then is off	Disconnect Remote Control from Stimulator; Press "Up" and "Down" buttons to check if they are stuck; Reconnect to Stimulator. If issue persists, contact your doctor
Error indicator is visible on the Remote Control	Red error indicator is on	Contact your doctor
Unable to adjust stimulation	Remote Control connects to Stimulator but stimulation cannot be turned up or turned down	Contact your doctor
Unable to adjust stimulation	Remote Control lights are scrolling or Remote Control lights are not illuminated	Reconnect and retry adjustment. Contact your doctor
Damage to Remote Control	Remote Control appears physically damaged	Stop use of the Remote Control. Contact your doctor to discuss replacement
Discomfort or pain due to stimulation	Constant pain or discomfort in the groin or buttocks	Turn down stimulation level. If issue persists, turn off stimulation and contact your doctor
Remote Control will not turn off	Light(s) will not turn off	Retry turning the Remote Control off (press "Connect" button). Contact your doctor for replacement.

Charging Troubleshooting

Issue	Presentation	Resolution
Charger is not charging the Stimulator	The power light on the Charger is green. Nothing happens when you place the Charger over the Stimulator.	Retry placing the Charger, making sure the Charger is placed the correct way over your Stimulator (see “Where to Place the Charger”). If you still cannot charge, contact your doctor.
Charger is not charging the Stimulator	The power light on the Charger is blank and does not turn on when you press the power button.	Place the Charger on the Dock to charge the Charger. Retry charging when the Charger light is solid green.
Charger is not charging the Stimulator	Charging stopped. Three beeps are heard and the Charger vibrated.	Check the Charger power level. If “green”, place the Charger over the Stimulator again. If charging does not start, contact your doctor.
Dock will not charge the Charger	Charger is placed in Dock and the power light does not come on.	Check to make sure the Dock is plugged in to an outlet using the power supply. Next, pick up and put the Charger back in the Dock. Make sure it is lined up with the Dock correctly. If you still cannot charge the Charger, contact your doctor.
Dock will not charge the Charger	Charger is placed in Dock and red error light comes on.	There is an error in charging the Charger. Turn the Charger off then back on. If the red light is still on, contact your doctor.
Damage to the Charger	Charger has visible damage.	Do not use your charger. Contact your doctor to discuss replacement.
Stimulator has to be charged more often	Over time, the Stimulator battery provides 50% less stimulation time between charges than it did after initial programming.	If stimulation settings were changed recently, the change in charging frequency is expected. If stimulation settings were not changed, contact your doctor to discuss the change in your Stimulator battery life.
Error light is on	The Charger shows a red light when it is turned on.	There is an error in the Charger. Turn the Charger off then back on. If the red light is still on, contact your doctor.

System Specifications

Stimulation Output

Parameter	Range
Frequency	2 – 130 Hz
Pulse Width	60 – 450 us
Amplitude	0 – 12.5 mA

Additional technical information is available. Please contact Axonics if you want to request additional information.

Wireless Communication

This device complies 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

This transmitter is authorized by rule under the Medical Device Radio communication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the

System Specifications

Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation.

This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radio communication Service. Analog and digital voice communications are prohibited.

Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Note: Changes and modifications to the system are not authorized by Axonics could void FCC and IC certification and negate the user's authority to use the product.

Quality of Wireless Service: This device operates in the 401-406 MHz frequency and the maximum effective radiated power of the Neurostimulator communication is below the limit of 25 μ W ERP/EIRP as specified in EU: EN ETSI 301-839 and USA: FCC 47 CFR Part 95; Subpart I. The Remote Control, Clinician Programmer, or Charger have to be within 1 meter from the Neurostimulator or Trial Stimulator for

System Specifications

successful communication.

Wireless Security: The Neurostimulator or Trial Stimulator can only communicate with a single Remote Control that is paired to it using the Clinician Programmer. Any Axonics Clinician Programmer or Charger can communicate with a Neurostimulator. Additional mechanisms exist to ensure the integrity of radio data.



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