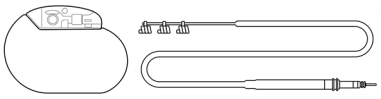
VNS Therapy™

PHYSICIAN'S MANUAL

VNS Therapy™ Generator and Lead Manual for Depression



Pulse™ Generator— Model 102

Pulse Duo™ Generator— Model 102R

Demipulse™ Generator— Model 103

Demipulse Duo™ Generator— Model 104

AspireHC™ Generator— Model 105

AspireSR™ Generator— Model 106

SenTiva™ Generator— Model 1000

SenTiva Duo™ Generator— Model 1000-D

Symmetry™ Generator — Model 8103

Lead — Model 302

PerenniaDURA™ Lead — Model 303

PerenniaFLEX™ Lead — Model 304

December 2023

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CE 0344

The year of authorization to affix the CE mark:

Model 102	2003
Model 102R	2003
Model 103	2005
Model 104	2005
Model 105	2011
Model 106	2014
Model 1000	2017
Model 1000-D	2020
Model 8103	2019
Model 302	2003
Model 303	2006
Model 304	2009

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CHAPTER 1

Introduction to the VNS Therapy System

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

- VNS Therapy System Glossary
- LivaNova Neuromodulation Symbols and Definitions

This topic includes the following concepts:

1.1. System—Brief Description

The LivaNova VNS Therapy system, used for vagus nerve stimulation, consists of an implantable generator, lead, and external programming system used to change stimulation settings. The generator and lead make up the implantable portion of the VNS Therapy system.

1.1.1. Generator

The generator is an implantable, multi-programmable pulse generator that delivers electrical signals to the vagus nerve via the lead. The generator is housed in a hermetically sealed titanium case and is powered by a single battery.

NOTE: For detailed technical information, see "Technical Information—Generators" on page 61.

1.1.2. Lead

The lead, which delivers the electrical signal from the generator to the vagus nerve, is insulated with silicone. It has two helical electrodes and an anchor tether, which are coiled around the left vagus nerve. The lead is available in multiple sizes to ensure optimal electrode fit on different size nerves. The connector end of the lead is tunneled subcutaneously to the generator pocket.

NOTE: For detailed technical information, see "Technical Information—Leads" on page 65.

1.1.3. Programming System

The external programming system includes a programming computer (Programmer) pre-installed with VNS Therapy programming software and a programming wand (Wand). The physician uses the programming system to read and change generator settings and obtain system integrity information. The software includes a System Diagnostics feature that is used to assess lead impedance.

1.2. System—Compatibility

The following table provides a list of features and compatibility for generators, surgical accessories, and programming systems. For detailed descriptions of programming modes and features, see " System Features and Modes" on page 71.

Table 1. System Compatibility

Generator Model	Compatible Lead (Header)	Surgical Accessories	Programming Features	Wand	Programmer
Depression Specific Devices					
Model 8103	Model 304 Model 303 Model 302	Model 502 Model 402	• Normal Mode • Guided Programming	Model 2000 v1.1+	Model 3000 v1.6+
Previously Implanted Generators					
Model 1000	Model 304 Model 303 Model 302	Model 502 Model 402	• Normal Mode • AutoStim Mode • Magnet Mode • Guided Programming • Scheduled Programming • Day-Night Programming • Low Heart Rate Detection • Prone Position Detection	Model 2000 all versions	Model 3000 all versions
Model 1000-D	Model 300	Model 502 Model 402	• Normal Mode • AutoStim Mode • Magnet Mode • Guided Programming • Scheduled Programming • Day-Night Programming • Low Heart Rate Detection • Prone Position Detection	Model 2000 v1.1+	Model 3000 v1.6 +
Model 106	Model 304 Model 303 Model 302	Model 502 Model 402	• Normal Mode • AutoStim Mode • Magnet Mode	Model 201 Model 2000 all versions	Model 250 v11.0 Model 3000 all versions
			• Guided Programming	Model 2000 all versions	Model 3000 all versions

Table 1. System Compatibility (continued)

Generator Model	Compatible Lead (Header)	Surgical Accessories	Programming Features	Wand	Programmer
Model 105 **Model 103** **Model 102**	Model 304 Model 303 Model 302	Model 502 Model 402	• Normal Mode • Magnet Mode	Model 201 Model 2000 all versions	Model 250 v11.0 Model 3000 all versions
			• Guided Programming	Model 2000 all versions	Model 3000 all versions
Model 104 **Model 102R**	Model 300	Model 502 Model 402	• Normal Mode • Magnet Mode	Model 201 Model 2000 all versions	Model 250 v11.0 Model 3000 all versions
			• Guided Programming	Model 2000 all versions	Model 3000 all versions

Table 2. Use of Features and Modes with Depression Patients

Features and Modes	Models
Available	
Normal Mode	All
Guided Programming*	Model 8103 Model 1000 Model 1000-D
Day-Night Programming	Model 1000 Model 1000-D
Scheduled Programming*	Model 1000 Model 1000-D
Not Recommended	
Magnet Mode	If available on model implanted
AutoStim Mode	If available on model implanted
Low Heart Rate / Prone Detection	If available on model implanted

Table 2. Use of Features and Modes with Depression Patients (continued)

Features and Modes	Models
Guided Programming	Model 106 Model 105 Model 104 Model 103 Model 102

*Guided and Scheduled Programming for depression devices are available on the Model 3000 Programmer only. If Guided Programming or Scheduled Programming are used for a depression patient implanted with a Model 1000 / Model 1000-D, a Custom Protocol should be entered and selected where both the Magnet Mode and AutoStim Mode Outputs are 0 mA for each desired step.

1.3. System—Package Contents

Table 3. System—Package Contents

Device	Package Contents
Generators	1 generator 1 hex screwdriver
Leads	1 lead 4 tie-downs
Tunneler	1 tunneler shaft 1 tunneler bullet tip 1 small-diameter sleeve (for single pin leads) 1 large-diameter sleeve (for dual pin leads)
Accessory Pack	1 hex screwdriver 1 single pin test resistor 1 dual pin test resistor 4 tie-downs
Wand Model 201	1 Wand with attached serial cable 1 9-Volt battery
Wand Model 2000	1 Wand with detached USB cable 2 AA batteries
Programmer (Model 250 and Model 3000)	VNS Therapy programming software installed on commercial tablet or handheld programming computer (includes commercial computer, power supply, and adapters)
Patient Kit	2 magnets (≥ 35 Gauss) 1 watch strap 1 clip

1.4. Education, Training, and Services

LivaNova employs highly trained representatives and engineers located throughout the world to serve you and provide training to prescribers and implanters of LivaNova products. Physicians must contact LivaNova before a VNS Therapy system is prescribed or implanted for the first time. In addition to the information provided herein, training material includes, but is not limited to, surgeon or prescriber physician training slide presentation, surgical video, training block and demo lead, etc. The required training (elements, duration, and frequency) to use LivaNova products depend on the product and physician. Needs can be discussed and arranged with your local LivaNova representative, or contact "Technical Support" on page 179.

CHAPTER 2

Indications, Warnings and Precautions

This topic includes the following concepts:

2.1. Intended Use and Indications

The VNS Therapy system is indicated for the treatment of chronic *or recurrent depression* for patients who are in a treatment-resisant or treatment-intollerant major depressive episode.

VNS Therapy may be approved for other indications in your market. All VNS Therapy labeling is located at www.livanova.com.

2.2. Contraindications

Unless otherwise specified, all indications, contraindications, and possible complications and adverse events are applicable to all implantable parts of the VNS Therapy system.

Vagotomy

The VNS Therapy system cannot be used in patients with a bilateral or left cervical vagotomy.

Diathermy

- Do not use shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (hereafter referred to as diathermy) on patients implanted with a VNS Therapy system. Energy delivered by diathermy may be concentrated into or reflected by implanted products such as the VNS Therapy system. This concentration or reflection of energy may cause the system to heat.
- Tests indicate that diathermy can cause the VNS Therapy system to heat well above temperatures required for tissue destruction. The heating that results from diathermy can cause temporary or permanent nerve, tissue, or vascular damage. This damage may result in pain or discomfort, loss of vocal cord function, or possible death if there is damage to blood vessels.
- Because diathermy can concentrate or reflect its energy off any size implanted object, the hazard of heating is possible when any portion of the VNS Therapy system remains implanted, including just a small portion of the lead or electrode. Injury or damage can occur during diathermy treatment whether the system is turned "ON" or "OFF".
- Diathermy is further prohibited because it may also damage the VNS Therapy system components and result in loss of therapy, which requires additional surgery for system explantation and replacement. All risks associated with surgery or loss of therapy would then be applicable.
- Advise your patients to inform all their healthcare professionals that they should not be exposed to diathermy treatment.

2.3. Warnings ⚠

Unless otherwise specified, all indications, contraindications, and possible complications and adverse events are applicable to all implantable parts of the VNS Therapy system.

2.3.1. Warnings—All Implants

Use

This device is a permanent implant. It is only to be used in patients with severe depression who are unresponsive to standard psychiatric management. It should only be prescribed and monitored by physicians who have specific training and expertise in the management of treatment-resistant depression and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device.

Not a Cure

Physicians should warn patients that VNS Therapy has not been determined to be a cure for depression. Patients should be counseled to understand that individual results will likely vary. Beneficial results might not become evident for months. Most patients will continue to require antidepressant medications and/or electroconvulsive therapy (ECT) in addition to VNS Therapy.

Worsening Depression/ Suicidality

Patients being treated with adjunctive VNS Therapy should be observed closely for clinical worsening and suicidality, especially at the time of VNS Therapy stimulation parameter changes or drug or drug dose changes, including either increases or decreases in the stimulation parameters or concomitant treatments. Consideration should be given to changing the therapeutic regimen of VNS Therapy or concomitant treatments, including possibly discontinuing VNS Therapy or the concomitant therapy, in patients whose depression is persistently worse or whose emergent suicidality is severe, abrupt in onset, or was not part of the patient's presenting symptoms.

Safety and Efficacy Not Established

The safety and efficacy of the VNS Therapy system have not been established for uses outside its approved indications for use. The safety and efficacy of VNS Therapy *have not been shown* for people with these conditions:

- Acute suicidal thinking or behavior
- Cardiac arrhythmias or other abnormalities
- History of dysautonomias
- History of previous therapeutic brain surgery or CNS injury
- History of schizophrenia, schizoaffective disorder or delusional disorders
- History of rapid cycling bipolar disorder
- History of respiratory diseases or disorders, including dyspnea and asthma
- History of ulcers (gastric, duodenal, or other)
- History of vasovagal syncope
- Only one vagus nerve
- Other concurrent forms of brain stimulation
- Pre-existing hoarseness
- Progressive neurological diseases other than depression

Dysfunctional Cardiac Conduction Systems

The safety and effectiveness of the VNS Therapy system in patients with predisposed dysfunction of cardiac conduction systems (re-entry pathway) have not been established. Evaluation by a cardiologist is recommended if the family history, patient history, or electrocardiogram suggests an abnormal cardiac conduction pathway. Serum electrolytes, magnesium, and calcium should be documented before implantation. Additionally, postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. Post-implant electrocardiograms and Holter monitoring are recommended if clinically indicated.

Bradycardia or Asystole During Implantation

It is important to follow recommended implantation procedures and intra-operative product tests described in the "Implantation Procedure Overview" on page 90. During the intra-operative System Diagnostics infrequent incidents of bradycardia and/or asystole have occurred. If asystole, severe bradycardia (heart rate < 40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics or during initiation of stimulation, physicians should be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS).

Additionally, postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. If a patient has experienced asystole, severe bradycardia (heart rate < 40 bpm), or a clinically significant change in heart rate during a System Diagnostics test at the time of initial device implantation, the patient should be placed on a cardiac monitor during initiation of stimulation.

The safety of this therapy has not been systematically established for patients that experience bradycardia or asystole during VNS Therapy system implantation.

External Defibrillation or Cardioversion (electrical)

External defibrillation or cardioversion (electrical) procedures may damage the generator and can temporarily or permanently damage the nerve. Follow these recommendations to minimize the flow of current through the generator and lead system:

- Position defibrillation patches or paddles perpendicular to the generator and lead system, and as far from the generator as possible.
- Use the lowest clinically appropriate energy output (watt-seconds).
- Confirm generator function after any internal or external defibrillation, or cardioversion treatment.

Magnetic Resonance Imaging (MRI)

Patients with the VNS Therapy system, or any part of the system, implanted should have MRI procedures performed **only as described in the MRI Guidance instructions for use**.

MR Unsafe Devices

The Wand, Programmer, and patient magnet are MR Unsafe devices. These devices are projectile hazards and must not be brought into the MR scanner room.

Excessive Stimulation

Excessive stimulation is the combination of an excess duty cycle (i.e., one that occurs when ON time is greater than OFF time) and high frequency stimulation (i.e., stimulation at ≥ 50 Hz). Excessive stimulation has resulted in degenerative nerve damage in laboratory animals. While LivaNova limits the maximum programmable frequency to 30 Hz, it is recommended that you do not stimulate with excess duty cycle.

Device Manipulation

Patients who manipulate the generator and lead through the skin (Twiddler's Syndrome) may damage or disconnect the lead from the generator and/or possibly cause damage to the vagus nerve. Patients, parents, and caregivers should be warned against manipulating the generator and lead.

Swallowing Difficulties

Dysphagia (difficulty swallowing) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with pre-existing swallowing difficulties and those with a history of drooling or hypersalivation are at greater risk for aspiration. Appropriate aspiration precautions should be taken for such patients. Use of the magnet to temporarily stop stimulation while eating may mitigate the risk of aspiration.

Dyspnea or Shortness of Breath

Dyspnea (shortness of breath) may occur with active VNS Therapy. Any patient with underlying pulmonary disease or insufficiency, such as chronic obstructive pulmonary disease or asthma, may be at increased risk for dyspnea and should have their respiratory status evaluated prior to implantation and monitored following initiation of stimulation.

Obstructive Sleep Apnea (OSA)

Patients with obstructive sleep apnea (OSA) may have an increase in apneic events during stimulation. Lowering stimulus frequency or prolonging "OFF" time may prevent exacerbation of OSA. Vagus nerve stimulation may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder. It is recommended that patients being considered for VNS Therapy who demonstrate signs or symptoms of OSA, or who are at increased risk for developing OSA, should undergo the appropriate evaluation prior to implantation.

Device Malfunction

Device malfunction could cause painful stimulation or direct current stimulation. Either event could cause nerve damage and other associated problems. Instruct patients, parents, and caregivers to use the magnet to stop stimulation if they suspect a malfunction, and then to contact their physician immediately for further evaluation. Prompt surgical intervention may be required if a malfunction occurs.

Device Trauma

Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted could possibly cause damage to the lead.

2.3.2. Warnings—Generators

2.3.2.1. Model 1000 (Serial Numbers <100,000 Only)

Potential Erroneous High Impedance Warning

Some Model 1000 generators (serial numbers < 100,000) report higher impedance values compared to prior models, due to a change in the timing of the impedance measurement during the diagnostic test pulse. This timing difference will not impact the battery longevity or the ability to safely deliver therapy. However, it may result in an erroneous high impedance warning:

- **Potential erroneous high impedance warning during implantation surgery**
  Erroneous high impedance is more likely for replacement generator surgeries compared to new implants due to fibrosis of the lead. Follow troubleshooting steps in the programming system physician's manual to resolve common sources of true high impedance (confirm lead pin insertion, setscrew tension, electrode placement on the nerve, irrigation of the nerve, and generator diagnostics indicative of normal function). If high lead impedance (≥ 5300 Ω) is still reported, consider lead or generator replacement.
- **Potential erroneous high Impedance Warning at follow-up or titration visit**
  If high lead impedance is observed (≥ 5300 Ω), perform a chest and neck x-ray (anteroposterior and lateral views) and contact "Technical Support" on page 179. Surgery is warranted if improper lead pin insertion or lead break is present in the x-ray. For implanted Model 1000 (serial numbers < 100,000), advise patients to report any change in perceived clinical symptoms related to stimulation (e.g., increase in depressive symptoms, painful stimulation, changes in perception of stimulation). In the absence of device-related complications (e.g., no changes in clinical symptoms), higher than expected lead impedance is not an indication of generator or lead malfunction. Continue to perform System Diagnostics at each visit to monitor for further increases in impedance.

2.4. Precautions ⚠

Physicians should inform patients about all potential risks and adverse events discussed in the VNS Therapy system directions for use.

2.4.1. Precautions—All Implants

General Precaution

Unless otherwise specified, all indications, contraindications, and possible complications and adverse events are applicable to all implantable parts of the VNS Therapy system.

Physician Training

Appropriate physician training is very important.
Physicians who prescribe should be experienced in the diagnosis and treatment of depression and should be familiar with the programming and use of the VNS Therapy system. See also "Education, Training, and Services" on page 15.
Physicians who implant the VNS Therapy system should be experienced with surgery within the carotid sheath and capable of performing the surgical technique used to implant the VNS Therapy system. See also "Surgeon Training" on page 86.

Use During Pregnancy
The safety and effectiveness of the VNS Therapy system have not been established for use during pregnancy. There are no adequate and well-controlled studies of VNS Therapy in pregnant women. Reproductive studies have been performed on female rabbits stimulated with a commercially available VNS Therapy system at stimulation dose settings similar to those used for humans. These animal studies have revealed no evidence of impaired fertility or harm to the fetus due to VNS Therapy. Because animal reproduction studies are not always predictive of human response and animal studies cannot address developmental abnormalities, VNS Therapy should be used during pregnancy only if clearly needed.

Effects on Other Medical Devices
The VNS Therapy system may affect the operation of other implanted devices (e.g., cardiac pacemakers, implanted defibrillators). Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker, defibrillator therapy, or other types of stimulators, careful programming of each system may be necessary to optimize the patient's benefit from each device. Furthermore, when the VNS Therapy system and another stimulator are implanted in the same patient, the two stimulators should be placed at least 10 centimeters (4 inches) apart to avoid communication interference. Users should refer to the product labeling for the concurrent device to determine if there are additional precautions that should be observed.

Device Reset	
Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	When the generator is reset, its stimulation output is disabled; however, all settings and device history are preserved. After a successful reset, the generator stimulation output may be re-enabled to resume operation at the previously programmed settings.
Model 102 Model 102R	A reset of the device will program the device OFF (output current = 0 mA).

Device History Loss	
Model 102 Model 102R	A reset of the device causes all device history information to be lost. The device history information (e.g., programmed patient initials, implant date, device serial number) should be documented before it is reset.

2.4.2. Precautions—Generator and Lead

2.4.2.1. Generators

Battery Depletion or Drain	
Model 102 Model 102R	**Do not use frequencies of 5 Hz or below for long-term stimulation.** These frequencies generate an electromagnetic trigger signal, which results in excessive battery depletion of the implanted generator. Therefore, use these low frequencies for short periods of time only.

2.4.2.2. Optional Generator Features

NOTE: For a full description of optional features, see " System Features and Modes" on page 71.

Day-Night Programming

Model 1000 Model 1000-D	Consider risk and benefits of altering a patient's known efficacious settings before this feature is used or when parameter adjustments are made. Assess patient tolerability of the alternate parameter set before the patient leaves the office visit. Inform your patients about when to expect a setting change (i.e., when Daytime settings transition into Nighttime settings).

Time-Based Features

Model 1000 Model 1000-D	Day-Night Programming does not automatically adjust for Day Light Savings or time zone changes. Tell the patient to follow-up with the physician for reprogramming, if needed.

2.4.2.3. Leads

Do Not Use a Lead Other Than a VNS Therapy Lead

Use a VNS Therapy single-pin lead with the single-receptacle generator or a VNS Therapy dual-pin lead with the dual-receptacle generator because use of other leads may damage the generator or injure the patient.

Lead Size

The lead is available in multiple sizes. Since it is not possible to predict in patients what size lead will be needed, **it is recommended that at least one alternate lead size be available in the operating room**. In addition, backups for leads should be available in the event of compromised sterility or damage induced during surgery. For lead size availability, see "Technical Information—Leads" on page 65.

Lead Related Adverse Events

Possible adverse events specifically related to the lead include migration, dislodgement, breakage, and corrosion.

Potential Effects of Lead Breaks

Lead fractures of the VNS Therapy system may prevent patients from receiving therapy. If a lead fracture is suspected, perform diagnostic testing to evaluate continuity within the system. If diagnostics suggest that a fracture is present, consider turning the generator to zero milliamps (0 mA) of output current. Continuing stimulation with a fractured lead may result in dissolution of the conductor material resulting in adverse events (e.g., pain, inflammation, and vocal cord dysfunction). The benefits and risks of leaving the generator ON (active stimulation) when a lead fracture is present should be evaluated and monitored by the medical professional treating the patient.
For details on diagnostic tests, see "Device Diagnostics" in the model specific programming system manual posted at www.livanova.com.

2.4.3. Precautions—Related to Implantation

2.4.3.1. Operative

Vagus Nerve Placement

The VNS Therapy system is indicated for use only in stimulating the left vagus nerve in the neck area inside the carotid sheath, **below where the superior and inferior cervical cardiac branches separate from the vagus nerve**. The safety and efficacy of the VNS Therapy system have not been established for stimulation of the right vagus nerve or of any other nerve, muscle, or tissue.

Reversal of Lead Polarity

Reversal of lead polarity has been associated with an increased chance of bradycardia in animal studies. It is important that the electrodes are attached to the left vagus nerve in the correct orientation. It is also important to make sure that leads with dual connector pins are correctly inserted (white marker band / serial number to + connection) into the generator receptacle.

Line-Powered Equipment

Exercise extreme caution if line-powered equipment is used to test the lead because leakage current can injure the patient.

Setscrew

Do not insert a lead in the generator receptacle until you visually **verify that the setscrew is sufficiently retracted** to allow insertion. Do not back the setscrew out further than needed for lead insertion.

Hex Screwdriver

Ensure that the hex screwdriver is fully inserted in the setscrew and then push in on the hex screwdriver and turn it clockwise until it clicks. To avoid a dislodged setscrew plug or damage to the setscrew, insert the hex screwdriver into the center of the setscrew plug and keep it perpendicular to the generator.

Infection Control

It is important to follow infection control procedures. Infections related to any implanted device are difficult to treat and may require that the device be explanted. The patient should be given antibiotics pre-operatively. The surgeon should ensure that all instruments are sterile prior to the operation. Frequent irrigation of both incision sites with generous amounts of bacitracin or equivalent solution should be performed prior to closure. To minimize scarring, these incisions should be closed with cosmetic closure techniques. Also, antibiotics should be administered postoperatively at the discretion of the physician.

2.4.3.2. Post-Operative

Lead Stabilization

The patient can use a neck brace for the first week to help ensure proper lead stabilization.

Programming After Surgery

Do not program the VNS Therapy system to an ON or periodic stimulation treatment for at least 14 days after the initial or replacement implantation. Failure to observe this precaution may result in patient discomfort or adverse events.

Vagus Nerve Damage

Some complications may be associated with damage to the vagus nerve:

- Hoarseness may be caused by device malfunction, nerve constriction, or nerve fatigue. Nerve constriction should be apparent within a few days after implantation and may require explantation of the lead. Nerve fatigue usually occurs after intense stimulation parameters have been used and might not be associated with any other adverse event. If fatigue is suspected, the generator should be turned off for several days until hoarseness subsides.
- Persistent hoarseness *not* associated with stimulation suggests possible nerve irritation and should be immediately investigated.
- Trauma to the vagus nerve at the implantation site could result in permanent vocal cord dysfunction.

Laryngeal Irritation

Laryngeal irritation may result from stimulation. Patients who smoke may have an increased risk of laryngeal irritation.

2.4.4. Precautions—Hospital and Medical Environments

Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field. If a generator ceases operation while in the presence of electromagnetic interference (EMI), moving away from the source may allow it to return to its normal mode of operation.

VNS Therapy System Operation

Always perform device diagnostics after any of the procedures mentioned herein. Additional precautions for these procedures are described below.

Routine Diagnostic Procedures

Most routine diagnostic procedures (e.g., fluoroscopy, radiography) are not expected to affect system operation.

Mammography

To obtain clear images, patients may need to be specially positioned for mammography procedures because of the location of the generator in the chest.

Therapeutic Radiation

Therapeutic radiation may damage the generator's circuitry. Sources of such radiation include therapeutic radiation, cobalt machines, and linear accelerators. The radiation effect is cumulative, with the extent of damage determined by the total dosage. The effects of exposure to such radiation can range from a temporary disturbance to permanent damage and may not be detectable immediately.

Electrosurgery

Use of electrosurgery [i.e., electrocautery or radio frequency (RF) ablation devices] may damage the generator. During the implantation procedure, do not use electrosurgical equipment after the generator is introduced to the sterile field. To minimize the current that flows through the generator and lead system when other surgical procedures are performed, follow these precautions:

- Position the electrosurgery electrodes as far as possible from the generator and lead.
- Avoid electrode placement that puts the generator or lead in the direct path of current flow or within the part of the body being treated.
- Confirm that the generator functions as programmed after electrosurgery.

Electrostatic Discharge (ESD)

ESD may damage the generator. Do not touch the metal shaft of the hex screwdriver when it is engaged with the generator setscrew. This shaft can serve as a path to conduct electrostatic discharges into the device circuitry.

Extracorporeal Shockwave Lithotripsy

Extracorporeal Shockwave Lithotripsy may damage the generator. If therapeutic ultrasound is required, do not position the area of the body where the generator is implanted in the water bath or in any other position that would expose it to ultrasound therapy. If that position cannot be avoided, program the generator output to 0 mA for the treatment, and then after therapy, reprogram the generator to the original parameters.

Treatment That Involves Electrical Currents

If the patient receives medical treatment for which electric current is passed through the body (e.g., from a TENS unit), either the generator output should be set to 0 mA or the function of the generator should be monitored during the initial stages of treatment.

Therapeutic Ultrasound

Routine therapeutic ultrasound could damage the generator and may be inadvertently concentrated by the device, causing harm to the patient.

NOTE: Diagnostic ultrasound has no known adverse effects on the generator or lead.

2.4.5. Precautions—Home Occupational Environments

Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field. If a generator ceases operation while in the presence of electromagnetic interference (EMI), moving away from the source may allow it to return to its normal mode of operation.

No Effect to Generator Expected

Microwave ovens, electrical ignition systems, power transmission lines, theft-prevention devices, and metal detectors that operate properly are not expected to affect the generator. However, because of their higher energy levels, sources such as transmitting antennas may interfere with the VNS Therapy system. It is suggested that the generator be moved away from equipment—typically at least 1.8 meters (6 feet)—that may cause interference.

⚠ CAUTION: The patient should seek medical advice before they enter environments that are protected by a warning notice that prevents entry by patients implanted with a cardiac pacemaker or defibrillator.

Cellular Phones

Based on current test data, RF emissions from cellular phones have no effect on generator operation. Cellular phones may contain magnets (see "Other Electro-Mechanical Devices" below.)

Electronic Article Surveillance (EAS) System Tag Deactivators

EAS System tag deactivators can interfere with VNS Therapy when they are operated in proximity of the generator. Potential effects include inhibited stimulation and accidental activations (Magnet or AutoStim). Patients should be cautioned to stay at least 60 centimeters (2 feet) away from EAS System tag deactivators to avoid potential interference.

Other Electro-Mechanical Devices

Strong magnets, tablet computers and their covers, hair clippers, vibrators, loudspeaker magnets, cellular phones, smart watches, wearable devices, and other similar electrical or electro-mechanical devices, which have a strong static or pulsing magnetic field, can cause accidental stimulation inhibition. Patients should be cautioned to keep such devices at least 20 centimeters (8 inches) away from the generator.

2.4.6. Precautions—Generator and EMI Effects on Other Devices

Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field. If a generator ceases operation while in the presence of electromagnetic interference (EMI), moving away from the source may allow it to return to its normal mode of operation.

Interference During Stimulation

During stimulation, the generator may interfere with devices that operate in the 30 kHz to 100 kHz range (e.g., pocket transistor radios and hearing aids). This interference is a theoretical possibility, and no effects on hearing aids have been reported, although the generator can interfere with a transistor radio. No specific tests have been done to date, and no definite information on effects is available. The patient should move—typically at least 1.8 meters (6 feet)—away from equipment with which it may interfere.

Interference During Programming or Interrogation

Programming or interrogation of the generator may momentarily interfere with other sensitive electronic equipment nearby. The generator is not expected to trigger airport metal detectors or theft-protection devices that are further than about 1.8 meters (6 feet).

Operation of Other Implanted Devices

The generator and the patient magnet may affect the operation of **other implanted devices**, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate generator responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system is necessary to optimize the patient's benefit from each device.

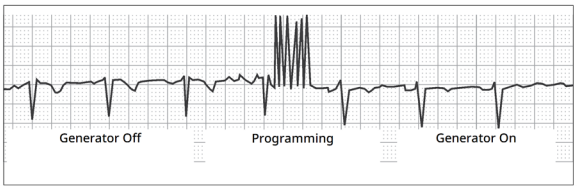
Items Affected by Strong Magnetic Fields

The magnet provided for inhibition of the generator may damage **televisions, computer disks, credit cards, and other items affected by strong magnetic fields**.

Effects on ECG monitors

Generator data communication produces an ECG artifact as shown below.

Figure 1. ECG Artifact Produced by Generator Communication



Interactions With Fetal Monitors

The ranges of operation for the VNS Therapy system and fetal monitors are dissimilar and no interaction would be expected. However, tests have not been performed and the potential may exist for interaction between the VNS Therapy system and fetal monitoring systems.

2.4.7. Precautions—Sterilization

The generator, lead, accessory pack, and tunneler have been sterilized with hydrogen peroxide (H_2O_2 or HP) gas plasma and are supplied in a sterile pack to permit direct introduction into the operating field.

NOTE: Either ethylene oxide (EO/EtO) gas or HP gas plasma may have been used on sterile devices previously distributed.

A use by date and method of sterilization is marked on each package. A sterilization process indicator is located on the inner sterile pack and is only used as an internal manufacturing process aid.

Do Not Re-Sterilize

Do not resterilize any VNS Therapy product. Return any opened devices to LivaNova.

2.4.8. Precautions—Storage

Liquids and Moisture

Do not store any components of the system where they may be exposed to water or other liquids. Moisture can damage the seal integrity of the package materials.

Nonpyrogenic

The implantable portions of the system are nonpyrogenic.

Temperature and Humidity

Store the devices in the system at the ranges indicated below. Conditions outside this range can damage components.

Table 4. Storage Temperature and Humidity Range

Device Type or Model	Temperature Range	Relative Humidity Range
Generators		
All Models	-20 °C (-4 °F) – +55 °C (+131 °F)	N/A
Leads		
All Models	-20 °C (-4 °F) – +55 °C (+131 °F)	N/A
Surgical Accessories		
Model 402 Model 502	-20 °C (-4 °F) – +55 °C (+131 °F)	N/A
Programming System		
Model 201	-20 °C (-4 °F) – +55 °C (+131 °F)	5% – 95%
Model 2000	-20 °C (-4 °F) – +55 °C (+131 °F)	Up to 95% includes condensation
Model 250	-20 °C (-4 °F) – +55 °C (+131 °F)	10% – 90%
Model 3000	-20 °C (-4 °F) – +55 °C (+131 °F)	10% – 90% non-condensing
Magnet		
Model 220	-20 °C (-4 °F) – +55 °C (+131 °F)	N/A

2.4.9. Precautions—Handling

2.4.9.1. Before Use / Implant

Dropped Device

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

Use By Date

Do not implant or use a sterile device if the use by date has expired. This can adversely affect the device's longevity and sterility.

Sterile Device Integrity

Do not implant or use a sterile device if the integrity of the outer or inner sterile barrier has been pierced or altered.

Do Not Ultrasonically Clean

Do not ultrasonically clean any VNS Therapy system components. Ultrasonically cleaning the generator may cause damage.

Do Not Re-implant an Explanted Device

Components of the VNS Therapy system provided sterile are single-use only devices. **Do not re-implant an explanted generator or lead for any reason**, because sterility, functionality, and reliability cannot be ensured, and infections may occur.

2.4.9.2. After Explant

Do Not Incinerate the Generator

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

Return Explanted Generators and Leads

Explanted generators and leads are medical waste and should be handled in accordance with local laws. They should be returned to LivaNova for examination and proper disposal, along with a completed Return Product Form. Before device components are returned, disinfect them with Betadine®, Cidex® soak, or other similar disinfectant, and double seal them in a pouch or other container properly labeled with a biohazard warning. For directions, see "Contacts and Resources" on page 179.

CHAPTER 3

Depression Information—Clinical Studies

This topic includes the following concepts:

3.1. Pivotal and Pilot Clinical Studies

3.1.1. Pivotal and Pilot Studies—Safety

Except where noted otherwise, the safety information presented in this section derives from the pivotal (D-02) study. The D-02 study of VNS Therapy consisted of both an acute and a long-term phase to collect data regarding the safety and efficacy of VNS Therapy as an adjunctive treatment for persons with chronic or recurrent treatment-resistant depression.

NOTE: See also "Intended Use and Indications" on page 17.

3.1.1.1. Device Performance

The VNS Therapy system performed according to its specifications. Most device issues were communication difficulties resolved by repositioning the programming Wand or replacing the programming Wand batteries. One high lead impedance occurred requiring replacement; a lead break due to fatigue at the electrode bifurcation was noted. Most device complaints were resolved on the day of the initial complaint.

3.1.1.2. Adverse Events

3.1.1.2.1. Events Reported

The number (and percentage) of subjects reporting an adverse event during the 0-3 month period and during the 9-12 month period of the pivotal (D-02) study is depicted in the table below for the most commonly reported adverse events. Adverse events were coded using the COSTART 5 dictionary. Note that some subjects may have reported multiple events.

Table 5. Adverse Events Reported During VNS Therapy at 0-3 Months and 9-12 Months (D-02)

Adverse Event	0–3 Months (N=232)	9–12 Months (N=209)
Voice Alteration	135 (58.2%)	113 (54.1%)
Increased Cough	55 (23.7%)	13 (6.2%)
Neck Pain	38 (16.4%)	27 (12.9%)
Dyspnea	33 (14.2%)	34 (16.3%)
Dysphagia	31 (13.4%)	9 (4.3%)
Paresthesia	26 (11.2%)	9 (4.3%)
Laryngismus	23 (9.9%)	10 (4.8%)
Pharyngitis	14 (6.0%)	11 (5.3%)
Nausea	13 (5.6%)	4 (1.9%)
Pain	13 (5.6%)	13 (6.2%)

Table 5. Adverse Events Reported During VNS Therapy at 0-3 Months and 9-12 Months (D-02) (continued)

Adverse Event	0–3 Months (N=232)	9–12 Months (N=209)
Headache	12 (5.2%)	8 (3.8%)
Insomnia	10 (4.3%)	2 (1.0%)
Palpitation	9 (3.9%)	6 (2.9%)
Chest Pain	9 (3.9%)	4 (1.9%)
Dyspepsia	8 (3.4%)	4 (1.9%)
Hypertonia	6 (2.6%)	10 (4.8%)
Hypoesthesia	6 (2.6%)	2 (1.0%)
Anxiety	5 (2.2%)	6 (2.9%)
Ear Pain	5 (2.2%)	6 (2.9%)
Eructation	4 (1.7%)	0
Diarrhea	4 (1.7%)	2 (1.0%)
Dizziness	4 (1.7%)	3 (1.4%)
Incision Site Reaction	4 (1.7%)	2 (1.0%)
Asthma	4 (1.7%)	3 (1.4%)
Device Site Reaction	4 (1.7%)	0
Device Site Pain	4 (1.7%)	2 (1.0%)
Migraine Headache	4 (1.7%)	2 (1.0%)

It is important to note that subjects often had comorbid illnesses and almost all study subjects were also receiving antidepressant and other drugs that could have contributed to these events.

3.1.1.2.2. Discontinuation Due to Adverse Events

In the feasibility (D-01) study, no discontinuations were related to adverse events attributed to VNS Therapy or the implant procedure. By the time all continuing subjects in the pivotal (D-02) study had at least 1 year of VNS Therapy, 3% (8/235) of the subjects had discontinued VNS Therapy for an adverse event-related reason. The reasons for these 8 discontinuations included 1 case each of suicide, implant-related infection necessitating device removal, hoarseness, lightheadedness, post-operative pain, chest and arm pain, sudden death (of unknown cause), and worsening depression (reported by the investigator as an adverse event rather than as lack of efficacy).

3.1.1.3. Serious Adverse Events (SAEs)

3.1.1.3.1. SAEs

The SAEs described in this section are based on investigator reports from the pivotal (D-02) study from study initiation through the data cutoff date for submission; the data cutoff date included the entire period of

evaluation for subjects who did not complete 12 months of VNS Therapy and included a minimum of 12 months of evaluation during VNS Therapy for all subjects who continued the study for 12 months or longer.

During the pivotal (D-02) study, 12 SAEs were considered related to the implant procedure (wound infection, asystole, bradycardia, syncope, abnormal thinking, vocal cord paralysis, aspiration pneumonia, voice alteration, device site reaction [2 reports], acute renal failure, and urinary retention). During the acute phase of the D-02 study, investigators did not report any SAE to be related to stimulation. During the long-term phase of the D-02 study, 8 SAEs were considered at least possibly related to stimulation (sudden death of unknown cause, syncope (2 reports), dizziness, a manic depressive reaction in a subject with bipolar disorder, hemorrhage GI, paresthesia, and an incident of worsening depression. The table below displays all the SAEs reported during the D-02 study prior to the data cutoff date, regardless of relationship to implantation or stimulation.

Table 6. Serious Adverse Events Reported in D-02 Study – Regardless of Relationship to Implantation or Stimulation

Event	Acute (N=235)		Long Term (N=233)	
	Number of Events Treatment (N=119) /Sham (N=116)	Number of Subjects	Number of Events	Number of Subjects
Worsening Depression	5/7	11	62	31
Suicide Attempt	0	0	7	6
Syncope	0	0	4	3
Dehydration	1/1	2	1	1
Wound Infection	1/0	1	1	1
Cholecystitis	0/1	1	1	1
Gastrointestinal Disorder	0	0	2	2
Abnormal Thinking	1/0	1	1	1
Convulsion	0	0	2	2
Device Site Reaction	2/0	2	0	0
Pneumonia	0/1	1	0	0
Abdominal Pain	0	0	1	1
Accidental Injury	0	0	1	1
Chest Pain	0	0	1	1
Overdose	0	0	1	1
Peritonitis	0	0	1	1
Sudden Unexplained Death	0	0	1	1
Suicide	1/0	1	0	0
Surgical Procedure	0	0	1	1

Table 6. Serious Adverse Events Reported in D-02 Study – Regardless of Relationship to Implantation or Stimulation (continued)

Event	Acute (N=235)		Long Term (N=233)	
	Number of Events Treatment (N=119) /Sham (N=116)	Number of Subjects	Number of Events	Number of Subjects
Asystole	1/0	1	0	0
Bradycardia	1/0	1	0	0
Cholelithiasis	0	0	1	1
Constipation	0	0	1	1
Myasthenia	0/1	1	0	0
Confusion	1/0	1	0	0
Dizziness	0	0	1	1
Drug Dependence	0	0	1	1
Manic Depression	0	0	1	1
Somnolence	0	0	1	1
Vocal Cord Paralysis	0/1	1	0	0
Breast Cancer	0	0	1	1
Aspiration Pneumonia	1/0	1	0	0
Voice Alteration	0/1	1	0	0
Acute Renal Failure	0/1	1	0	0
Enlarged Uterine Fibroid	0	0	1	1
Urinary Retention	1/0	1	0	0

3.1.1.3.2. Deaths

Four deaths occurred during the pivotal (D-02) study: one after the subject had given consent, but before the subject was implanted; the second, a suicide; the third, a death of unknown cause; and the fourth, a subject who developed multi-organ failure.

3.1.1.3.3. Unanticipated Adverse Device Effects

Two events in the pivotal (D-02) study met criteria for an unanticipated adverse device effect (UADE). Both these events were non-specific complications of surgery related to the implant procedure and occurred before stimulation began. One UADE was an episode of acute renal failure thought to be secondary to antibiotic administration, and the other was an episode of altered mental status thought to be due to perioperative narcotic administration.

3.1.1.4. Safety Considerations Specific to Depressed Patients

Two specific safety concerns in the use of all antidepressant therapies are the precipitation of manic or hypomanic episodes and the possible effect of antidepressant therapy on suicidal ideation and behavior.

3.1.1.4.1. Antidepressant Treatments and Manic or Hypomanic Reaction

Although patients with bipolar disorder experience manic episodes as the cardinal feature of their disorder, effective antidepressant therapies themselves can occasionally precipitate a manic or hypomanic episode. Antidepressant therapies can also occasionally precipitate a manic or hypomanic episode in patients without a prior history of mania who are being treated for a major depressive episode.

In the pivotal (D-02) study, 6 hypomanic or manic reactions were identified according to DSM-IV criteria or the Young Mania Rating Scale (YMRS). Five were observed in subjects with a known history of prior hypomanic or manic episodes. One of the events was considered serious and the subject was hospitalized.

3.1.1.4.2. Suicidal Ideation, Suicide Attempts, Suicide, and Worsened Depression

Suicidal ideation was analyzed by examining the $HRSD_{24}$ Item 3 scores. At 12 months of VNS Therapy, 90% of the subjects in the pivotal (D-02) study showed either improvement (56%) or no change (34%) in their Item 3 scores. During the acute D-02 study, 2.6% of the sham subjects and 1.7% of the stimulation subjects increased their Item 3 score by 2 or more points, indicative of an increase in suicidal ideation. During the long-term D-02 phase, 2.8% of the subjects had an increase in their Item 3 score by at least 2 points at 12 months compared to baseline. In a non-randomized control group of subjects treated with standard antidepressant therapies without VNS Therapy (the D-04 study population), 1.9% of the subjects had an increase of at least 2 points. Based on the occurrence of any increase in Item 3 score from baseline to 12 months, 10% of the D-02 subjects had an increase compared to 11% of the D-04 population. Conversely, 27% of the D-02 subjects decreased their score by at least 2 points at 12 months compared to baseline, whereas only 9% of the D-04 subjects did.

Suicide attempts and completed suicides in the D-02 and D-04 studies are shown in the table below. As noted above, 1 subject committed suicide in the acute phase and 6 attempted suicide during the long-term phase of the D-02 study (N = 235). One of the 6 subjects noted in the long-term phase attempted suicide twice. Although safety data were not prospectively collected for the D-04 study, the healthcare utilization form documented suicide attempts. Three suicide attempts were reported for the D-04 study through the first year of the study (N=124)

Table 7. Suicide Attempt and Suicide Rates

	Number of Patients	Patient Years	Suicide Attempts/ Patient Years	Suicide/ Patient Years
D-02	235	502	2.4%	0.2%
D-04	124	118	2.5%	0.0%

In the acute phase of the D-02 study, there were 12 reports of worsening depression, 5 in the stimulation group (5 of 119 subjects) and 7 in the sham group (7 of 116 subjects). One of the treatment-group reports occurred prior to stimulation initiation. Following acute phase exit and during the long-term phase of stimulation, 62 events were reported in 31 subjects. The number of episodes of worsening depression per subject ranged from 1 to 6. Although specific rates of worsening depression (and other safety endpoints) were not collected during the D-04 study, "hospitalizations for psychiatric illness," which might be a reasonable surrogate for worsening depression, were recorded. The rate of this event was 0.237 events per patient-year in the D-04 group compared to 0.293 events of worsening depression per patient-year in the D-02 group.

3.1.1.5. Adverse Events Relationship to VNS Therapy and Duration of Events

The pivotal (D-02) study investigators determined whether an adverse event (AE) was possibly, probably, or definitely related to implantation of, or stimulation by, the VNS Therapy generator and lead.

3.1.1.5.1. Adverse Events Related to Implantation

Because all eligible study subjects in the pivotal (D-02) study were implanted with the VNS Therapy system device, no control was available to assess whether an adverse event was related to the surgery. Investigators, therefore, determined which adverse events were related to implantation. The events reported as related to implantation and occurring in at least 10% of the subjects who received VNS Therapy system implants in the pivotal (D-02) study were device site pain, device site reaction, incision pain, dysphagia, hypoesthesia, pharyngitis, voice alteration, and incision site reaction. The complete list of implantation-related adverse events is shown in the tables below.

NOTE: Although not seen as part of the pivotal (D-02) study, seroma formation is a potential implantation related adverse event.

Table 8. Implantation-Related Adverse Events that Occurred in ≥ 5% of Subjects in the Acute Phase of the Pivotal (D-02) Study

D-02 Acute Phase Incidence of Surgery-Related AEs (n=235)	
Body as a Whole	
Incision Pain	36%
Device Site Pain	23%
Device Site Reaction	14%
Headache	8%
Neck Pain	7%
Pain	7%
Digestive System	
Dysphagia	11%

Table 8. Implantation-Related Adverse Events that Occurred in ≥ 5% of Subjects in the Acute Phase of the Pivotal (D-02) Study (continued)

D-02 Acute Phase Incidence of Surgery-Related AEs (n=235)	
Nausea	9%
Nervous System	
Hypoesthesia	11%
Paresthesia	6%
Respiratory System	
Voice Alteration	33%
Pharyngitis	13%
Dyspnea	9%
Cough Increased	6%
Skin and Appendages	
Incision Site Reaction	29%

Table 9. Implantation-Related Adverse Events that Occurred in < 5% of Subjects in Acute Phase-Pivotal (D-02) Study

System	Implantation Related Adverse Events
Body as a Whole	Abdominal Pain, Allergic Reaction, Anaphylactic Reaction, Asthenia, Back Pain, Chest Pain, Chills, Fever, Infection, Injection Site Pain, Neck Rigidity, Photosensitivity Reaction, Surgical Injury, Viral Infection, Wound Infection
Cardiovascular System	Arrhythmia, Asystole, Bradycardia, Hemorrhage, Migraine, Palpitation, Syncope, Tachycardia
Digestive System	Anorexia, Constipation, Diarrhea, Dyspepsia, Flatulence, Gastrointestinal Disorder, Vomiting
Endocrine System	Thyroid Disorder
Hemic and Lymphatic System	Ecchymosis, Lymphadenopathy
Metabolic and Nutritional Disorders	Edema, Hyperglycemia, Peripheral Edema
Musculoskeletal System	Arthralgia, Joint Disorder, Myalgia, Myasthenia
Nervous System	Abnormal Dreams, Agitation, Ataxia, Dizziness, Hypertonia, Insomnia, Nervousness, Neuralgia, Neuropathy, Thinking Abnormal, Tremor, Vasodilatation, Vocal Cord Paralysis
Respiratory System	Aspiration Pneumonia, Asthma, Atelectasis, Bronchitis, Hiccup, Hypoxia, Laryngismus, Laryngitis, Lung Disorder, Respiratory Disorder, Rhinitis, Sinusitis, Sputum Increased
Skin and Appendages	Application Site Reaction, Maculopapular Rash, Pruritus, Rash, Sweating

Table 9. Implantation-Related Adverse Events that Occurred in < 5% of Subjects in Acute Phase-Pivotal (D-02) Study (continued)

System	Implantation Related Adverse Events
Special Senses	Ear Disorder, Ear Pain, Tinnitus
Urogenital System	Acute Kidney Failure, Dysuria, Metrorrhagia, Urinary Retention

3.1.1.5.2. Duration of Implant-Related Adverse Events

As can be seen in the table below, many of the individual incidences of the most common implantation-related AEs resolved within 30 days. Hypoesthesia (generally described as a localized numbness) and voice alteration, however, tended to be more persistent in some individuals. For example, in 17 of 24 reports of implantation-related hypoesthesia, the event continued beyond 3 months. Hypoesthesia would be an expected side effect of nerve injury during surgery. The persistence of voice alteration in some subjects is difficult to assess because it could represent surgical injury to the innervation of the larynx, but vagus nerve stimulation itself can cause voice alteration.

Table 10. D-02 Acute Phase Duration of Treatment-Emergent Adverse Events Related to Implantation – Reported by > 10% of Subjects

	Duration to Resolution of Event in Days by all Implanted Subjects					
	1–7 Days	8–14 Days	15–30 Days	31–60 Days	61-90 Days	>90 Days
	Total N = 235 through 30 days, 234 for 31 to 90, 233 for >90 days Number within each box indicates number of subjects whose event resolved within the days shown (i.e., 27 subjects had the event of device site pain resolve within 7 days)					
Body as a Whole						
Device Site Pain	27	4	9	9	3	4
Device Site Reaction	5	5	8	9	2	8
Incision Pain	28	18	21	10	3	6
Digestive System						
Dysphagia	2	5	9	5	2	5
Nervous System						
Hypoesthesia	0	0	3	2	2	17
Respiratory System						
Pharyngitis	10	8	10	2	0	1
Voice Alteration	11	7	22	17	3	21
Skin and Appendages						
Incision Site Reaction	19	16	24	16	2	14

3.1.1.5.3. Stimulation-Related Adverse Events

Among AEs judged by investigators to be stimulation-related in the D-02 study acute phase treatment group, 7 events occurred at a frequency of 10% or greater: voice alteration (55%), cough increased (24%), dyspnea (19%), neck pain (16%), dysphagia (13%), laryngismus (11%), and paresthesia (10%).

Table 11. Stimulation-Related Adverse Events that Occurred in ≥ 5% of Subjects in Treatment Versus Control – Acute Phase Pivotal (D-02)

	D-02 Treatment (n=119)	D-02 Sham-control* (n=116)
Body as a Whole		
Incision Pain	6 (5%)	3 (3%)
Neck Pain	19 (16%)	1 (<1%)
Digestive System		
Dysphagia	15 (13%)	0 (0%)
Nausea	8 (7%)	1 (<1%)
Nervous System		
Paresthesia	12 (10%)	3 (3%)
Respiratory System		
Cough Increased	28 (24%)	2 (2%)
Dyspnea	23 (19%)	2 (2%)
Laryngismus	13 (11%)	0 (0%)
Pharyngitis	9 (8%)	1 (<1%)
Voice Alteration	65 (55%)	3 (3%)

*These subjects were not receiving stimulation during this phase.

Table 12. Stimulation-Related Adverse Events that Occurred in < 5% of Subjects in the Treatment Group, Acute Phase– Pivotal (D-02) Study

System	Stimulation-Related Adverse Events
Body as a Whole	Asthenia, Chest Pain, Device Site Pain, Device Site Reaction, Headache, Neck Rigidity, Pain
Cardiovascular System	Migraine, Palpitation, Postural Hypotension, Syncope, Tachycardia
Digestive System	Anorexia, Constipation, Diarrhea, Dyspepsia, Eructation, Flatulence, Increased Appetite, Vomiting
Metabolic and Nutritional Disorders	Weight Gain
Musculoskeletal System	Myalgia, Myasthenia

Table 12. Stimulation-Related Adverse Events that Occurred in < 5% of Subjects in the Treatment Group, Acute Phase– Pivotal (D-02) Study (continued)

System	Stimulation-Related Adverse Events
Nervous System	Abnormal Dreams, Agitation, Depression, Dizziness, Emotional Lability, Hypertonia, Hypoesthesia, Insomnia, Manic Reaction, Nervousness, Sleep Disorder, Somnolence, Twitching, Vasodilatation
Respiratory System	Asthma, Hiccup, Respiratory Disorder, Rhinitis
Skin and Appendages	Incision Site Reaction
Special Senses	Ear Pain, Tinnitus
Urogenital System	Amenorrhea

3.1.1.5.4. Stimulation-Related Events, Long-Term Phase

The table below lists stimulation-related adverse events that occurred at an incidence of ≥ 5% during the pivotal (D-02) study. These adverse events were observed over quarters of stimulation. Note that this table also includes observations after 24 months of treatment. Subjects are counted only once within each preferred descriptive term, e.g., neck pain, nausea, pharyngitis, and time interval.

Table 13. Stimulation-Related Adverse Events that Occurred in ≥ 5% of Subjects by Time Intervals After Initiation of Stimulation – Pivotal (D-02) Study

	0–3 Mos n=232	> 3–6 Mos n=225	> 6–9 Mos n=217	> 9–12 Mos n=209	> 12–24 Mos n=184
Body as a Whole					
Neck Pain	16%	11%	14%	13%	15%
Pain	6%	7%	5%	6%	5%
Headache	5%	4%	4%	3%	3%
Digestive System					
Dysphagia	13%	8%	7%	5%	5%
Nausea	6%	2%	2%	1%	1%
Nervous System					
Paresthesia	11%	7%	3%	4%	4%
Respiratory System					
Voice Alteration	59%	60%	58%	54%	52%
Cough Increased	24%	10%	8%	7%	4%
Dyspnea	14%	16%	15%	16%	14%
Laryngismus	10%	8%	8%	6%	5%
Pharyngitis	6%	4%	4%	5%	4%

Table 14. Stimulation-Related Adverse Events that Occurred in < 5% of Subjects – Long-Term Phase - Pivotal (D-02) Study

Body as a Whole	
	Abdominal Pain, Asthenia, Chest Pain, Device Site Pain, Device Site Reaction, Flu Syndrome, Incision Pain, Neck Rigidity, Sudden Unexplained Death, Viral Infection
Cardiovascular System	
	Bradycardia, Hypotension, Migraine, Palpitation, Postural Hypotension, Syncope, Tachycardia
Digestive System	
	Anorexia, Colitis, Constipation, Diarrhea, Dyspepsia, Eructation, Flatulence, Gastritis, Gastrointestinal Disorder, Increased Appetite, Vomiting
Metabolic and Nutritional Disorders	
	Weight Gain, Weight Loss
Musculoskeletal System	
	Athralgia, Joint Disorder, Myalgia
Nervous System	
	Abnormal Dreams, Agitation, Amnesia, Anxiety, Confusion, Depression, Dizziness, Dry Mouth, Emotional Lability, Hypertension, Hypertonia, Hypoesthesia, Insomnia, Manic Reaction, Manic Depressive Reaction, Nervousness, Sleep Disorder, Somnolence, Speech Disorder, Thinking Abnormal, Tremor, Twitching, Vasodilatation, Vocal Cord Paralysis
Respiratory System	
	Asthma, Hiccup, Respiratory Disorder, Rhinitis, Stridor
Skin and Appendages	
	Incision Site Reaction, Sweating
Special Senses	
	Amblyopia, Deafness, Ear Pain, Eye Pain, Tinnitus
Urogenital System	
	Amenorrhea, Menstrual Disorder

3.1.1.5.5. Late-Emerging Adverse Events

After the first 3 months of stimulation, the incidence of first-reported (new event types) stimulation-related adverse events did not exceed 1.3% of total study subjects for any event.

Table 15. Incidence of First Reported Stimulation-Related Adverse Events Experienced After 3 Months of VNS Therapy

Body System	COSTART Term	Treatment Group (N=117) N (%)	Delayed Treatment Group (N=116) N (%)	Total (N=233) N (%)
Body as a Whole	Back Pain	1 (<1%)	0	1 (<1%)
	Flu Syndrome	1 (<1%)	0	1 (<1%)
	Sudden Unexpected Death	1 (<1%)	0	1 (<1%)
	Viral Infection	1 (<1%)	0	1 (<1%)
Cardiovascular System	Hypotension	1 (<1%)	0	1 (<1%)
	Syncope	3 (3%)	0	3 (1%)
Digestive System	Colitis	2 (2%)	0	2 (<1%)
	Gastritis	2 (2%)	1 (<1%)	3 (1%)
Metabolic and Nutritional Disorders	Weight Gain	1 (<1%)	2 (2%)	3 (1%)
	Weight Loss	1 (<1%)	0	1 (<1%)
Musculoskeletal System	Arthralgia	0	1 (<1%)	1 (<1%)
	Joint Disorder	0	1 (<1%)	1 (<1%)
	Myalgia	0	1 (<1%)	1 (<1%)
Nervous System	Speech Disorder	0	1 (<1%)	1 (<1%)
	Vocal Cord Paralysis	0	1 (<1%)	1 (<1%)
Respiratory System	Stridor	1 (<1%)	0	1 (<1%)
Special Senses	Amblyopia	1 (<1%)	0	1 (<1%)
	Deafness	2 (2%)	0	2 (<1%)

NOTE: First reported stimulation-related AEs are defined as stimulation-related AEs that were reported after the first 3 months of VNS Therapy and for which no subject reported an AE that coded to that term during the first 3 months.

NOTE: AEs were coded using the COSTART 5 dictionary.

NOTE: Subjects were reported only once within each preferred term.

NOTE: Includes all AEs where relationship to stimulation was recorded as possible, probable, or definite.

3.1.1.5.6. Duration of Stimulation-Related Events

Subjects who reported adverse events during the first 3 months of stimulation and continued to be observed during the next 9 months were evaluated by 3-month intervals for continuation or resolution of their events. The largest decreases were noted between the first and second quarters of stimulation. The most notable exception was voice alteration. During the first quarter, 135 of 209 subjects (65%) reported voice alteration. Of those 135 subjects, 90 continued to report it during the fourth quarter of stimulation.

Table 16. Duration of Early Stimulation-Related Events Through 1 Year (D-02 Study)

Preferred Term	N Reporting Event During First 3 Mos.[1] (N=209)	N (%) Continuing to Report Event During Succeeding Quarters[2] (N=209)		
	0–3 Mos.	3–6 Mos.	6–9 Mos.	9–12 Mos.
Voice Alteration	135	115 (85%)	101 (75%)	90 (67%)
Cough Increased	55	18 (33%)	15 (27%)	11 (20%)
Neck Pain	38	17 (45%)	19 (50%)	16 (42%)
Dyspnea	35	22 (63%)	18 (51%)	16 (46%)
Dysphagia	31	16 (52%)	10 (32%)	6 (19%)
Paresthesia	26	12 (46%)	6 (23%)	4 (15%)
Laryngismus	23	13 (57%)	9 (39%)	5 (22%)
Pharyngitis	14	3 (21%)	2 (14%)	2 (14%)
Nausea	13	3 (23%)	1 (8%)	2 (15%)

[1]Entries are the number of subjects who experienced the AEs between implantation and 3 months.

[2]Number of subjects who continued to experience the same adverse event between months 3 and 6, months 6 and 9, and months 9 and 12.

NOTE: Subjects were counted only once within each preferred term and time interval.

3.1.1.6. Severity of Adverse Events

Investigators rated adverse events as mild, moderate, or severe according to the protocol definitions: mild events were transient and easily tolerated by the subject; moderate events caused discomfort and interrupted usual activities; severe events caused considerable interference with the subject's usual activities.

Most adverse events for the feasibility (D-01) study and pivotal (D-02) study were mild or moderate. Because the pivotal (D-02) study included a sham-control group, further analysis of severity rating was performed. After 3 months of treatment, there were 280 (43%) adverse events that were categorized as mild, 293 (45%) as moderate, and 73 (11%) as severe in the sham-control group. The active VNS Therapy group had 360 (47%) adverse events categorized as mild, 349 (45%) as moderate, and 61 (8%) as severe.

3.1.1.7. VNS Therapy Continuation Rates

Of the 295 subjects implanted during both the feasibility (D-01) and pivotal studies (D-02), 270 subjects (92%) were still receiving VNS Therapy at 12 months and 242 subjects (82%) were still receiving VNS Therapy at 24 months. This compares to 12- and 24-month continuation rates of 95% and 83%, respectively, for the subjects implanted in the epilepsy pre-approval trials.

3.1.2. Pivotal and Pilot Studies—Effectiveness

3.1.2.1. Feasibility (D-01) Study

The primary efficacy measure in the open-label feasibility (D-01) study was the percent of subjects responding (response was defined as a 50% or greater improvement in the $HRSD_{28}$ score). Of the 59 subjects with evaluable data, 18 (31%) responded at acute study exit, which was 12 weeks after implantation. Observation of subjects continued. After 1 year of adjunctive VNS Therapy, 25 of 55 subjects (45%) responded, and after 2 years, 18 of 42 (43%) responded. After 1 and 2 years of treatment, 27% and 21% of the subjects, respectively, were in remission (defined as $HRSD_{28}$ scores less than or equal to 10. Other measures of depressive symptoms (CGI, MADRS, BDI, IDS-SR) and quality of life (MOS-36) supported the $HRSD_{28}$ scores.

3.1.2.2. Pivotal (D-02) Study

The pivotal (D-02) study of VNS Therapy consisted of both an acute and a long-term phase to collect data regarding the safety and efficacy of VNS Therapy as an adjunctive treatment for persons with chronic or recurrent treatment-resistant depression.

3.1.2.2.1. Pivotal D-02 Study, Acute Phase

The acute phase was a 12-week (after implantation), double-blind, randomized, parallel-group sham treatment-controlled, multi-center study. Subjects were assigned randomly to either the treatment (stimulation) group or control (sham) group and results of these 2 groups were compared. All subjects in both groups meeting the eligibility criteria for participation in the study were implanted with the VNS Therapy generator and VNS Therapy lead. The VNS Therapy system remained OFF for 2 weeks after implantation to allow for recovery from surgery. Most subjects in the pivotal (D-02) study were being treated with 1 or more antidepressant medications at the time of enrollment. Medications were to remain constant at the pre-implant baseline dosages throughout the acute phase for both the treatment and sham-control groups.

Sham Control: Sham-control group subjects were treated the same as the treatment group, except that the output current of the device remained at 0.0 mA so that it did not deliver stimulation during the acute phase.

Treatment Group: Two weeks after implant, stimulation was initiated for the treatment group. Over the next 2 weeks, parameters were adjusted to subject tolerance, then remained constant for the rest of the acute phase (8 weeks). Decreases in stimulation parameters were permitted to accommodate subject tolerance.

3.1.2.2.2. Pivotal D-02 Study, Long-Term Phase

All pivotal (D-02) study subjects who completed the acute phase were eligible to continue into the long-term extension phase, during which all subjects received active VNS Therapy. During the first 10 weeks of the extension phase, sham-control subjects (also referred to as the delayed treatment group for the long-term phase), received stimulation parameter adjustments. Weekly or every other week clinic visits and assessments were identical to those experienced by the treatment group during the acute phase. Otherwise, the protocol specified monthly clinic visits for both groups through 12 months of active VNS Therapy. Various

assessments, including depression ratings, were performed throughout this period. During the long-term extension phase, investigational site programmers were allowed to adjust stimulation parameters as clinically indicated. Additionally, concomitant antidepressant treatments could be added, removed, or adjusted as clinically indicated.

3.1.2.3. Comparative Assessments

Outcomes from a non-randomized comparative study (D-04) were compared with the long-term outcomes in study D-02. D-04 was a long-term, prospective, observational study to collect data regarding usual standard-of-care for treatment-resistant chronic or recurrent depression in persons who were experiencing a major depressive episode at the time of admission. Clinical (depression assessments) and quality of life outcomes were assessed at baseline, 3, 6, 9, and 12 months.

3.1.2.3.1. Concomitant Therapies

Subjects enrolled in the comparative (D-04) study met the same enrollment criteria regarding chronicity or recurrence of depression, previous treatment failures, and severity of depression as subjects in the pivotal (D-02) study. Because the study was observational in nature, the protocol did not specify therapies for the treatment of depression; rather the physician managing the study subject's depression selected therapy according to clinical judgment. Thus antidepressant therapy in the comparative (D-04) study comprised "standard of care" treatment (also known as "treatment as usual"). The entire range of treatment options available for the comparative (D-04) study subjects was also available to the pivotal (D-02) study subjects as concomitant treatment to their VNS Therapy. Thus subjects in both the long-term pivotal (D-02) extension and the comparative (D-04) study received standard-of-care treatment; however, only the pivotal (D-02) study subjects received VNS Therapy.

3.1.2.3.2. Comparison of D-02 and D-04 Study Populations

The comparative (D-04) study was conducted at 13 investigational sites, 12 of which were also pivotal (D-02) study sites. The similarities in the key inclusion criteria and study sites provide a basis to expect that the demographic and disease characteristics of both groups would be comparable, which was confirmed by the results of the analyses conducted to examine the comparability. The D-04 subjects provided a comparison group for the pivotal (D-02) study subjects at 12 months. See the table below.

Table 17. Description of Subjects in Pivotal (D-02) and Comparative (D-04) Studies

Parameter	Statistic	D-02 (N=205)	D-04 (N=124)
Age (years)	Mean	46.3	45.5
Male	N (%)	74 (36)	39(31)
Female	N (%)	131 (64)	85(69)
Caucasian	N (%)	198 (97)	111(90)*
African-American	N (%)	3 (1)	5 (4)
Hispanic	N (%)	3 (1)	2 (2)

Table 17. Description of Subjects in Pivotal (D-02) and Comparative (D-04) Studies (continued)

Parameter	Statistic	D-02 (N=205)	D-04 (N=124)
Unipolar	N (%)	185 (90)	109 (88)
Bipolar	N (%)	20 (10)	15 (12)
Recurrent	N (%)	161 (87)	93 (85)
Single Episode	N (%)	24 (13)	16 (15)
Length of Current MDE (mos)	Mean (S.D.)	49.9 (52.1)	68.6 (91.5)
# Failed Trials in Current MDE	Mean (S.D.)	3.5 (1.3)	3.5 (1.3)
Received ECT Lifetime	N(%)	108 (53%)	32 (26%)*
Received ECT, Current MDE	N(%)	72 (35%)	15 (12%)*
Duration of Illness (yrs)	Mean (S.D.)	25.5 (11.9)	25.8 (13.2)
Lifetime Episodes of Depression*			
0-2	N(%)	50 (24)	31 (25)
3-5	N(%)	69 (34)	36 (29)
6-10	N(%)	56 (27)	18 (15)
>10	N(%)	19 (9)	32 (26)
No Suicide Attempts in Lifetime	N(%)	140 (68)	80 (65)
Treatment Induced (hypo) Mania	N(%)	16 (8)	6 (5)
Hospitalizations for Depression	Mean (S.D)	2.7 (5.4)	2.1 (2.9)
ECT Treatment Within Past 2 Yrs	N(%)	54 (26)	19 (15)

*$P < .05$

This comparison analyzed evaluable populations of 205 adjunctive VNS Therapy subjects (D-02) and 124 usual standard-of-care subjects (D-04). Groups were well matched, with similar demographic, psychiatric, and mood disorder treatment histories. The only relevant significant differences between groups were previous ECT history (with higher usage of ECT found in the D-02 group) and number of lifetime episodes of depression (with a higher percentage of the D-04 group reporting >10 lifetime episodes). These differences were handled within the efficacy analysis by use of a propensity adjustment.

3.1.2.4. Data Analysis: D-02 and D-04 Studies

3.1.2.4.1. Pivotal (D-02) Study

The primary efficacy variable for both the acute and the long-term phases of the pivotal (D-02) study was the Hamilton Rating Scale for Depression-24 item ($HRSD_{24}$). For the acute-phase analysis, the $HRSD_{24}$ response rate (percentage of subjects with a ≥ 50% improvement from baseline to 3 months, acute phase exit) was compared between the treatment and the sham-control groups. For the long-term phase, a linear regression model was used to assess the changes in $HRSD_{24}$ raw scores. Secondary efficacy analyses included within

and between-group comparisons of 1) the Inventory of Depressive Symptomatology-Self Report (IDS-SR), 2) the Clinical Global Impressions (CGI), 3) the Montgomery-Åsberg Depression Rating Scale (MADRS), and 4) the Medical Outcome Survey 36-Item Short Form Health Survey (MOS SF-36).

3.1.2.4.2. Comparative (D-04) Study

The primary efficacy variable for the D-02 and D-04 comparative analysis was the IDS-SR (raw scores). Multiple assessments with the IDS-SR allowed use of a linear regression model for the analysis. The $HRSD_{24}$ was used as a secondary assessment variable to analyze differences in response rates and raw score changes between subjects in the pivotal (D-02) and comparative (D-04) studies. Subjects in the comparative (D-04) study were assessed with the $HRSD_{24}$ only at baseline and 12 months.

Secondary analyses included IDS-SR average change, IDS-SR response, IDS-SR remission, IDS-SR sustained response, and $HRSD_{24}$ remission. Other secondary analyses included the CGI response.

3.1.2.4.3. Propensity Scores

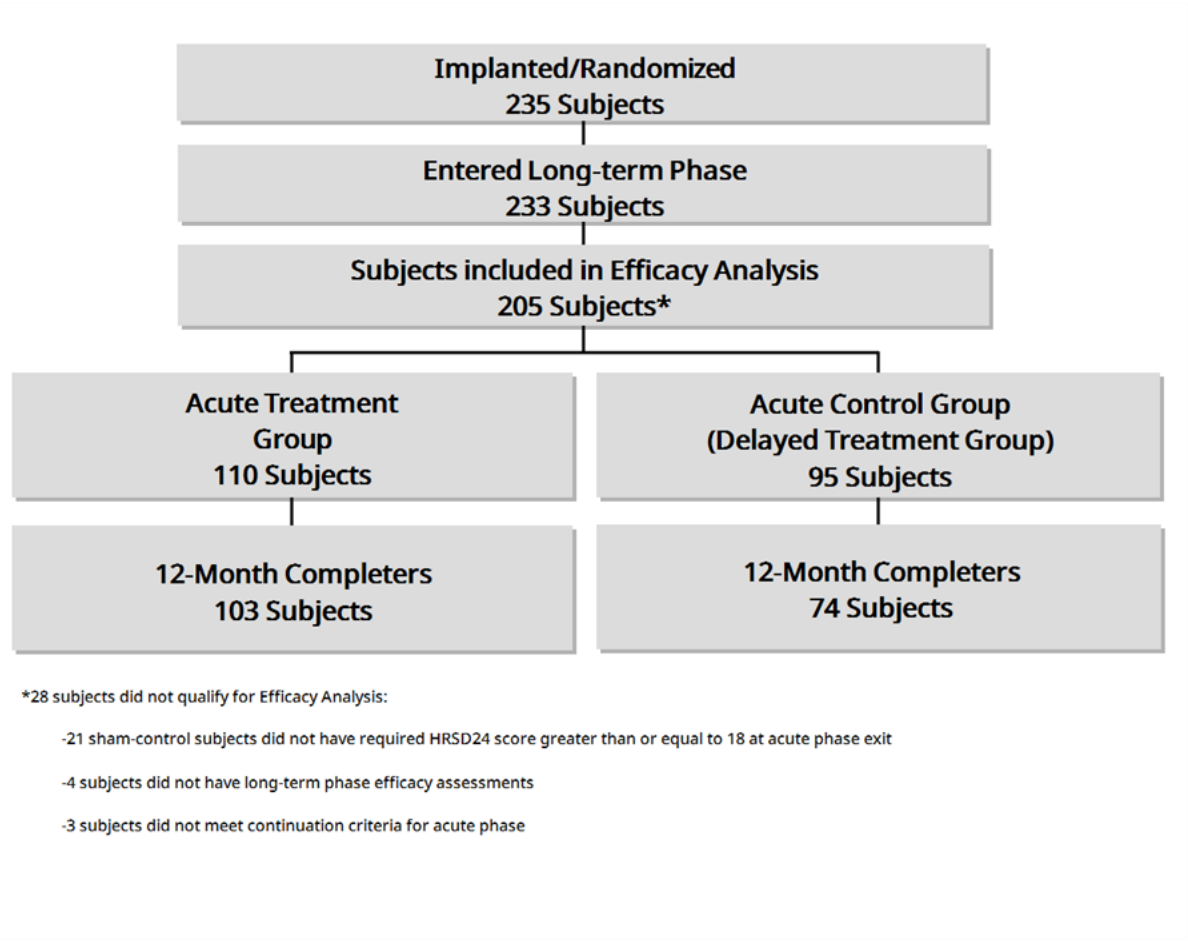
Propensity scores were calculated for the pivotal (D-02) study and comparative (D-04) study groups and used in the linear regression analysis to address the potential impact of baseline differences on differences in outcome between the 2 groups. Propensity scores provide a scalar summary of the covariate information (e.g., age, number of prior depressive episodes, etc.). They are not limited by the constraints of traditional methods of adjustment, which can only use a limited number of covariates for adjustment.

3.1.2.4.4. Responder Rate

Response was prospectively defined as a $\geq 50\%$ improvement from baseline for the IDS-SR, $HRSD_{24,}$ and MADRS ratings and as a score of much or very much improved for the CGI improvement rating. Remission (complete response) was prospectively defined as an $HRSD_{24}$ score of ≤ 9, a MADRS score of ≤ 10, or an IDS-SR score ≤ 14.

All statistical analyses were performed using the updated SAS version 8.2. All statistical tests were 2-sided and performed at the 0.050 level of significance. No adjustments were made for multiple outcome measures.

Figure 2. Pivotal Study, Long-term Phase



3.1.2.5. Results: Pivotal Study (D-02)

To view a flowchart that depicts subjects from the acute phase through the long-term phase of the pivotal (D-02) study, see "Pivotal D-02 Study, Long-Term Phase" on page 46.

For information that describes subjects in the pivotal (D-02) and comparative (D-04) studies, see "Pivotal (D-02) Study" on page 46.

3.1.2.5.1. Acute Phase, Pivotal Study (D-02)

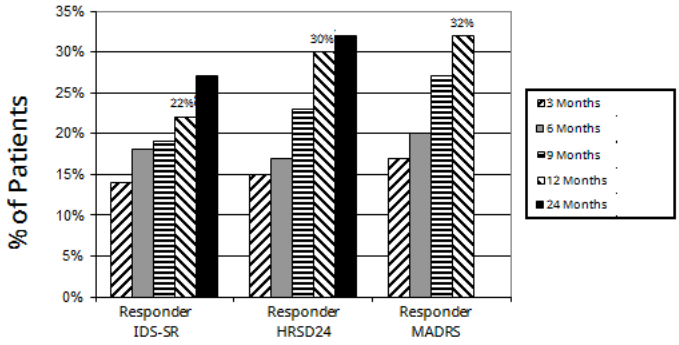
In the primary efficacy measure, $HRSD_{24}$ response rate, (the percentage of subjects achieving a ≥ 50% improvement in $HRSD_{24}$ total score from baseline to acute phase exit), 15% of the treatment group and 10% of the sham-control group were responders (*P* = .238). Analyses using a secondary efficacy parameter, the IDS-SR, did show a statistically significant advantage for VNS Therapy over sham treatment: 17% response versus 7% response (*P* = .032) using the last observation carried forward (LOCF) method.

3.1.2.5.2. Long-Term Phase, Pivotal Study (D-02)

During long-term adjunctive VNS Therapy, the D-02 subjects exhibited statistically significant and clinically meaningful improvement. The primary analysis found statistically significant improvement from baseline in

$HRSD_{24}$ scores averaged over 12 months ($P < .001$). Additionally, clinical significance was shown, using the $HRSD_{24}$, IDS-SR, MADRS, and CGI.

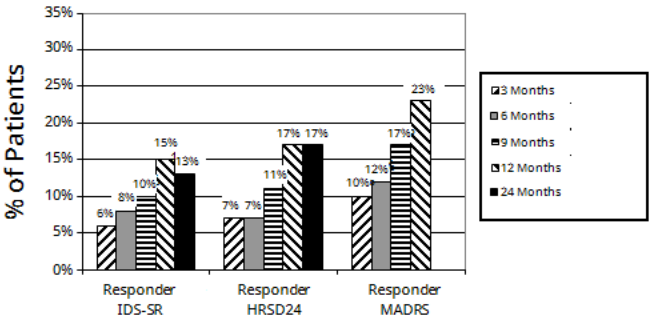
Figure 3. Responder Quarterly Results for D-02 Evaluable Subjects



This graph reports the evaluable population for each assessment at each visit.

Number of D-02 Evaluable Subjects—Responder Quarterly Results			
Months	IDS-SR	HRSD	MADRS
3	203	205	205
6	192	197	197
9	185	186	196
12	180	181	181
24	157	157	N/A

Figure 4. Remitter quarterly results for D-02 evaluable subjects



This graph reports the evaluable population for each assessment at each visit.

Number of D-02 Evaluable Subjects—Remitter Quarterly Results			
Months	IDS-SR	HRSD	MADRS
3	203	205	205
6	192	197	197
9	185	186	196
12	180	181	181
24	157	157	N/A

Table 18. Responders, Remitters, and Percent Change Pivotal (D-02) Study, 12-Month Completer Population

	$HRSD_{24}$*	IDS-SR†	MADRS‡
	12-Month Visit	12-Month Visit	12-Month Visit
Responders – N (%)			
Treatment	34/103 (33%)[2]	25/102 (25%)	34/103 (33%)[2]
Delayed treatment	18/71 (25%)	13/71 (18%)	22/71 (31%)[1]
All 12-Month Completers	52/174[a] (30%)[3]	38/173 (22%)[1]	56/174 (32%)[3]
Remitters – N (%)			
Treatment	19/103 (18%)[2]	16/102 (16%)[1]	25/103 (24%)[2]
Delayed treatment	10/71 (14%)	10/71 (14%)	16/71 (23%)[1]
All 12-Month Completers	29/174 (17%)[2]	26/173 (15%)[2]	41/174 (24%)[3]
Mean Percent Change from Baseline			
Treatment	31.9% [3]	27.8% [3]	32.9% [3]
Delayed treatment	26.5% [3]	17.3%[3]	26.3% [3]

Table 18. Responders, Remitters, and Percent Change Pivotal (D-02) Study, 12-Month Completer Population (continued)

	$HRSD_{24}$*	IDS-SR†	MADRS‡
	12-Month Visit	12-Month Visit	12-Month Visit
All 12-Month Completers	29.7% [3]	23.5% [3]	30.2% [3]

1 $P < .05$; 2 $P < .01$; 3 $P < .001$; Response and Remitter used the Exact McNemar's test compared with 3 months; Percent change used the paired t-test (change from pre-stimulation baseline).

* Three subjects did not have 12-month $HRSD_{24}$ assessments. (These 3 subjects did have 11-month assessments.)

† One subject did not have a baseline IDS-SR assessment and several others did not have 12-month assessments, which accounts for the varying Ns in the comparison of $HRSD_{24}$ with IDS-SR data.

‡ Two delayed-treatment subjects did not have 12-month MADRS assessments.

3.1.2.5.3. Quality of Life Assessment

The observed improvement in depression among subjects in the pivotal (D-02) study long-term phase was supported by improved quality of life as measured by the MOS SF-36. Significant improvement was observed in several of the MOS SF-36 subscales: Vitality, Social Functioning, Role Functioning – Emotional, Mental Health ($P < .01$).

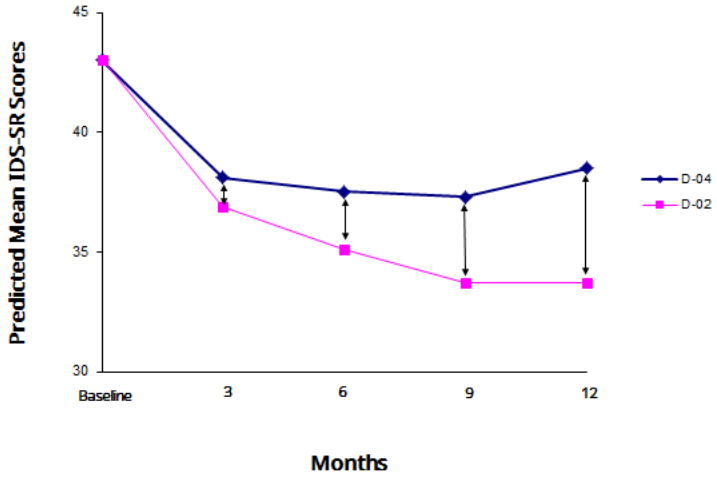
3.1.2.6. Results: Comparison of D-02 and D-04 Studies

The D-04 study provided a control group of similarly ill subjects who received usual standard-of-care therapies for 12 months but were not implanted with the VNS Therapy device.

3.1.2.6.1. Primary Effectiveness Outcome

The primary and secondary analyses comparing subjects treated with VNS Therapy plus usual standard-of-care (pivotal, D-02) with subjects treated with usual standard-of-care alone (comparative, D-04) showed that adjunctive VNS Therapy produced statistically significantly greater improvement in depressive symptoms over 1 year of treatment. The primary efficacy analysis, a repeated measures linear regression analysis of the IDS-SR over 1 year, showed a statistically significant ($P < .001$ evaluable; $P < .001$ intent to treat) difference favoring adjunctive VNS Therapy.

Figure 5. Comparison of IDS-SR Scores of Pivotal (D-02) Versus Comparative (D-04) Study Subjects by Quarter (Repeated Measures Linear Regression Analysis), Evaluable Population



	Months				
	B/L	3	6	9	12
Mean D-04 Scores	43.0 (N=124)	38.1 (N=120)	37.5 (N=119)	37.3 (N=116)	38.5 (N=112)
Mean D-02 Scores	43.0 (N=201)	36.9 (N=200)	35.1 (N=195)	33.7 (N=183)	33.7 (N=177)
Predicted Mean Difference	0	-1.2	-2.4	-3.6	-4.8
Actual Mean Difference	-0.9	-4.6	-4.1	-5.0	-6.6

3.1.2.6.2. Secondary Analyses

Additionally, the following secondary analyses were statistically significant and showed adjunctive VNS Therapy improved depressive symptoms more than usual standard-of-care alone after 12 months of therapy.

Figure 6. Secondary Analyses: IDS-SR_{30} and $HRSD_{24}$ Categorical Outcomes at 12 Months (Evaluable Observed Analysis)

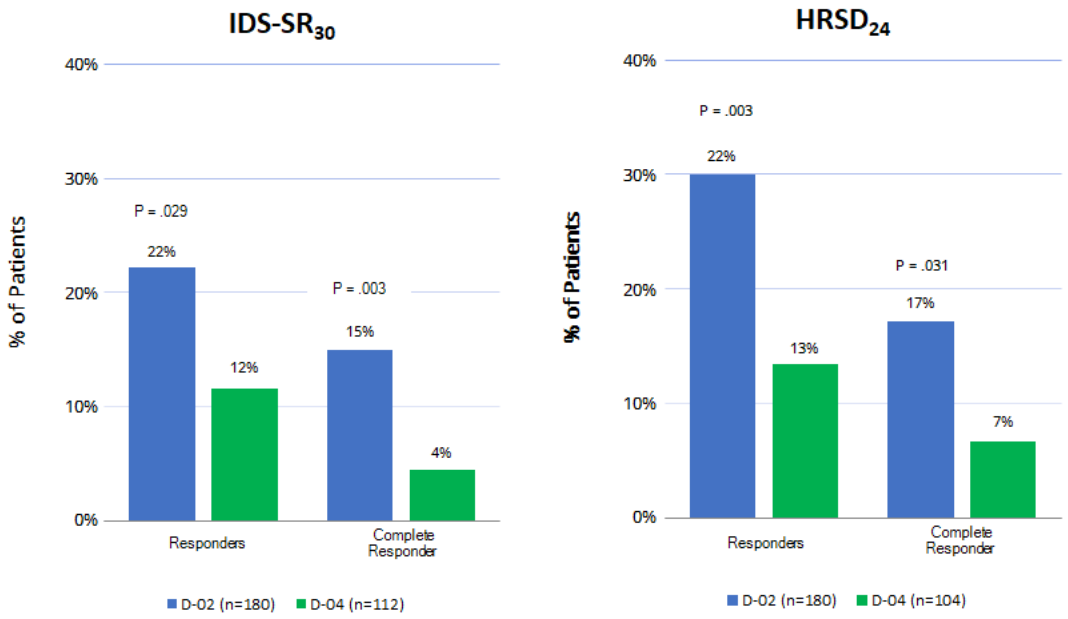
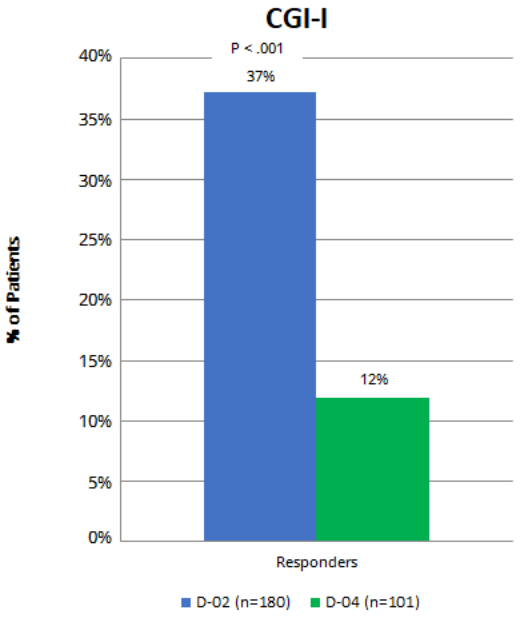


Figure 7. Secondary Analyses: CGI-I Categorical Outcome at 12 Months (Evaluable Observed Analysis)



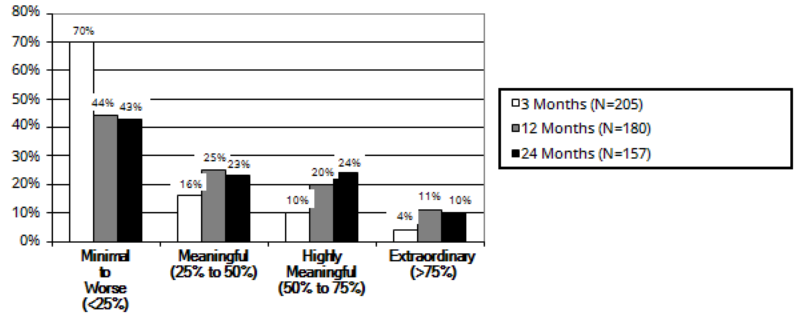
3.1.2.7. Clinical Benefit Over Time

To explore whether these subjects were receiving benefit that was not fully reflected in the response rates, they were assigned to categories according to "clinical benefit." Clinical benefit was prospectively defined as extraordinary (≥ 75% improvement in $HRSD_{24}$), highly meaningful (50% to <75%), meaningful (25% to <50%), minimal (0% to <25%), and worsened (less than 0%). This scale is consistent with studies in many chronic

illnesses that define less than a 50% improvement as a clinically meaningful response (e.g., schizophrenia, obsessive compulsive disorder).

As shown below, clinical benefit increased over time. The percent of subjects realizing at least a meaningful clinical benefit at 12 months was significant when compared to those experiencing a similar benefit after 3 months (Stuart-Maxwell test, $P < .001$).

Figure 8. Clinical Benefit After 3, 12, and 24 Months (D-02 Evaluable Population; $HRSD_{24}$)



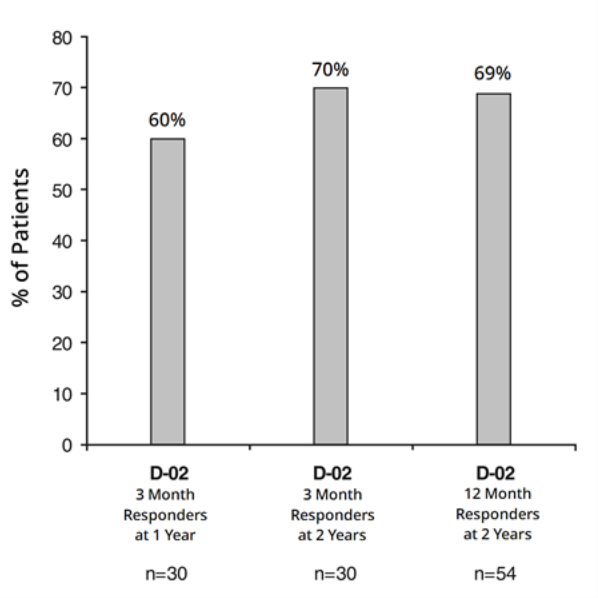
The subjects realizing at least a meaningful clinical benefit after 12 months of adjunctive VNS Therapy included subjects who sustained their 3-month meaningful or greater benefit and those who had minimal to no 3-month benefit and accrued at least a meaningful benefit after 12 months. Of the 56 subjects who had at least a meaningful benefit at 3 months, 41 (73%) continued to have at least a meaningful benefit at 12 months and 34 (61%) of these same 56 subjects had at least the *same* level of clinical benefit after 12 months of adjunctive VNS Therapy as they did after 3 months. Of the 118 subjects who realized minimal–to-worse clinical benefit after 3 months of adjunctive VNS Therapy, 56 (47%) had at least a meaningful benefit after 12 months of adjunctive VNS Therapy.

A majority (56%) of evaluable subjects treated with adjunctive VNS Therapy realized at least a meaningful clinical benefit after 12 months of treatment. After 24 months of VNS Therapy, 57% of evaluable subjects realized at least a meaningful clinical benefit.

3.1.2.8. Maintaining Response (2-year Data)

An analysis of subjects having an initial ≥ 50% reduction in HRSD score at the designated "early" visit (3 months or 12 months) and then maintaining at least a ≥ 40% reduction at the later visit (1 or 2 years), was performed for the D-02 Study. Data are presented below in a bar graph (see below), with each bar showing the percent of subjects that maintained their early response at the later observation.

Figure 9. Maintenance of Adjunctive VNS Therapy Response (% of $HRSD_{24}$ Responders who Maintained Response at 1 and 2 Years



When IDS data were used instead of HRSD data, similar results were observed (61% of 3-month responders were also responders at 12 months, 57% of 3-month responders were also responders at 24 months, and 85% of 12-month responders were also responders at 24 months). By contrast, no D-04 3-month responder maintained that response at the 12-month observation.

3.1.2.9. Standard-of-Care Antidepressant Treatments During the Long-Term Phase of Study D-02 and During Study D-04

3.1.2.9.1. Electroconvulsive Therapy

Electroconvulsive therapy (ECT) use was similar among the pivotal (D-02) and comparative (D-04) study subjects (7% and 6%, respectively) during the first year of observation.

3.1.2.9.2. Antidepressant Drugs and Response

Antidepressant drug use was significantly greater among pivotal (D-02) study subjects who were non-responders and comparative (D-04) study subjects overall than among the pivotal (D-02) study subjects who achieved a response ($P < .001$). During the 12 months, 77% of the pivotal (D-02) study non-responders and 81% of all comparative (D-04) study subjects either added a new antidepressant treatment or increased an existing antidepressant dose by an antidepressant resistance rating (ARR) level of 1 or more. By contrast, only 56% of the pivotal (D-02) study subjects who were responders to VNS Therapy either added a new antidepressant treatment or increased an existing antidepressant dose by an antidepressant resistance rating (ARR) level of 1 or more.

For the evaluable group at 12-months, 61 subjects were responders while 144 subjects were non-responders (N=205). On a percentage basis twice as many pivotal (D-02) study responders had no ARR changes or

removed or decreased medications by at least 1 ARR level or were not taking medications as compared to the non-responders (44% versus 23%, respectively).

3.1.2.9.3. Medication Censoring Analyses

Additional medication censoring analyses were performed using the D-02 and the D-02 versus D-04 repeated measures linear regression methods to evaluate further the potential effect of medication changes. This censoring approach used a missing data paradigm to calculate the D-02 results that would have been observed under conditions where no intercurrent changes in medications would have occurred in the D-02 group. The approach censors the D-02 IDS-SR scores after the point at which a subject had a significant medication increase (ARR increase) or ECT treatment, and the last pre-censored score is carried forward and used for subsequent assessment periods. The censoring had the effect of truncating the VNS treatment benefit from 12 months to an average of 7 months. In the D-02 censored analysis, the average $HRSD_{24}$ change from baseline was –0.25 points per month in the repeated measures linear regression ($P < .001$).

The D-02 censored versus D-04 IDS-SR repeated measures linear regression comparison was an asymmetric comparison of the VNS group treated for 7 months with VNS plus no changes from baseline treatments versus the D-04 group treated for a full 12 months with unlimited standard-of-care treatments (no censoring was performed on the D-04 data). The results of the censoring analysis approached but did not reach statistical significance in the comparison of the D-02 group with the D-04 group ($P = .052$; 95% CI -0.37, 0.00) for the evaluable population.

3.2. Clinical Study Bibliography

A bibliography of animal, clinical, and mechanism of action studies is available from LivaNova on request.

CHAPTER 4

Technical Information

This topic includes the following concepts:

4.1. Technical Information—Generators

4.1.1. Physical Characteristics

The titanium case of the VNS Therapy generator is hermetically sealed and leak-rate tested. Specially designed feedthrus that use platinum conductors make the electrical connection from the connector blocks to the circuitry through the hermetically sealed enclosure. The table below provides physical characteristics for all generator models.

Table 19. Generator Physical Characteristics

Model	Lead Receptacle	Dimensions*	Weight	Connector Retention Strength with Lead
Model 1000 Model 103 Model 8103	3.2 mm (0.126 in.) (single-pin lead)	45 mm x 32 mm x 6.9 mm (1.8 in. x 1.3 in. x 0.27 in.)	16 g (0.56 oz)	> 10 N
Model 106 Model 105 Model 102	3.2 mm (0.126 in.) (single-pin lead)	52 mm x 52 mm x 6.9 mm (2.0 in. x 2.0 in. x 0.27 in.)	25 g (0.88 oz)	> 10 N
Model 104 Model 1000-D	5 mm (0.2 in.) (dual-pin lead)	45 mm x 39 mm x 6.9 mm (1.8 in. x 1.6 in. x 0.27 in.)	17 g (0.63 oz)	> 10 N
Model 102R	5 mm (0.2 in.) (dual-pin lead)	52 mm x 58.4 mm x 6.9 mm (2.0 in. x 2.3 in. x 0.27 in.)	27 g (0.95 oz)	> 10 N

*Measurements (typical) – all dimensions nominal

4.1.2. Biological Compatibility

Materials exposed to the subcutaneous environment are biologically compatible. All of these materials have a long history in medical implants and have been found to be tissue compatible. The table below provides a list of component materials for all generator models.

Table 20. Generator Biological Compatibility

Component	Material
Case	Titanium, hermetically sealed
Header	Polyurethane—Tecothane™ TT-1075D-M Thermoplastic
Lead Connector Block	Stainless steel
Setscrew Plug	Silicone*

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

4.1.3. Power Source

The table below contains battery characteristics for the generator.

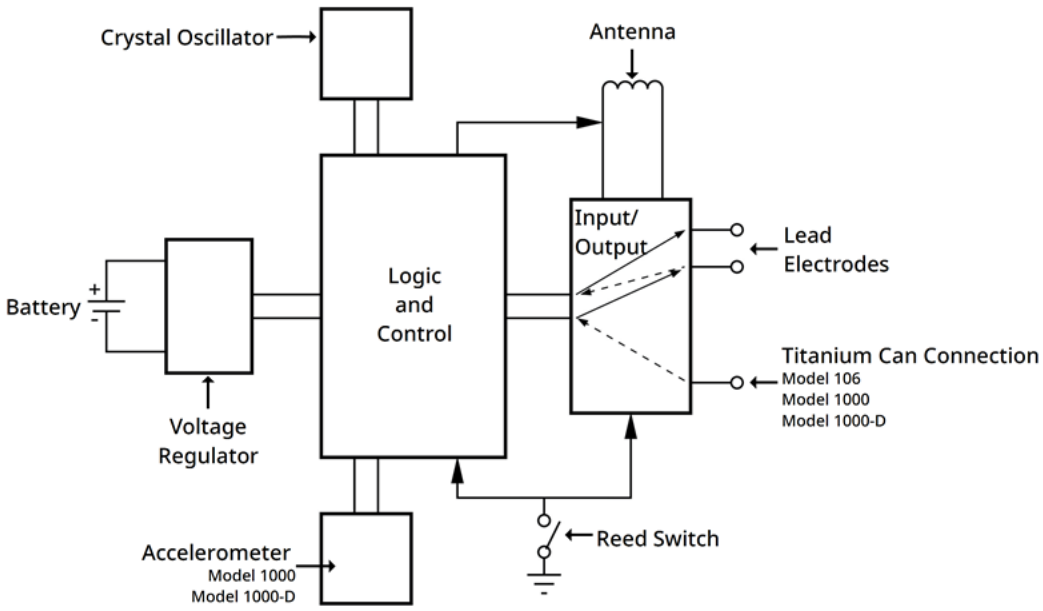
Table 21. Battery Characteristics

Model	Battery Manufacturer & Model	Battery Chemistry	Open Circuit Voltage	Maximum Capacity	Self Discharge	Battery Voltage Drop at End of Service (EOS)
Model 1000 Model 1000-D Model 104 Model 103 Model 8103	Wilson Greatbatch Ltd. Model 2183	lithium carbon monofluoride	3.3	1 Amp-hour	reduces capacity by < 1% per year	gradual drop in voltage at EOS
Model 106 Model 105 Model 102 Model 102R	Wilson Greatbatch Ltd. Model 2075	lithium carbon monofluoride	3.3	1.7 Amp-hours	reduces capacity by < 1% per year	gradual drop in voltage at EOS

4.1.4. Circuitry

The generator uses complementary metal oxide semiconductor (CMOS) integrated circuits, including a microprocessor. The circuitry is schematically represented below.

Figure 10. Generator Circuitry



For descriptive purposes, the generator circuitry is divided into functional sections as shown in the table below.

Table 22. Generator Circuitry Functionality

	Model 1000 Model 1000-D	Model 106	Model 105 Model 104 Model 103 Model 102 Model 102R Model 8103
Voltage Regulator	Regulates the system power supply.	Regulates the system power supply.	Regulates the system power supply.
Crystal Oscillator	Provides a timing reference.	Provides a timing reference.	Provides a timing reference.
Logic and Control	Controls overall generator function.	Controls overall generator function.	Controls overall generator function.
	Receives and implements programming commands	Receives and implements programming commands	Receives and implements programming commands
	Collects and stores telemetry information, processes sensory input, and controls scheduled and sensory-based therapy outputs	Collects and stores telemetry information, processes sensory input, and controls scheduled and sensory-based therapy outputs	Collects and stores telemetry information, processes sensory input, and controls scheduled and sensory-based therapy outputs
Antenna	Receives programming signals.	Receives programming signals.	Receives programming signals
	Transmits telemetry information to the programming Wand	Transmits telemetry information to the programming Wand	Transmits telemetry information to the programming Wand
Reed Switch	Provides a mechanism to inhibit the generator's output	Provides a mechanism to inhibit the generator's output	Provides a mechanism to inhibit the generator's output
	Provides amplification of cardiac signals	Provides amplification of cardiac signals	
Input / Output	Develops and modulates signals delivered to the lead	Develops and modulates signals delivered to the lead	Develops and modulates signals delivered to the lead
	Allows the traditional VNS Therapy electrodes to serve as therapy outputs	Allows the traditional VNS Therapy electrodes to serve as therapy outputs	Allows the traditional VNS Therapy electrodes to serve as therapy outputs
Accelerometer	Provides information related to patient posture	N/A	N/A

4.1.5. Identification

The generator can be identified on an x-ray by the tag codes provided below. The serial number and model number of the generator are marked on its titanium case, but do not appear on the x-ray.

The serial number and model number are identified when the generator is interrogated with the programming system.

NOTE: For details on generator interrogation see the model specific programming system manual posted at www.livanova.com .

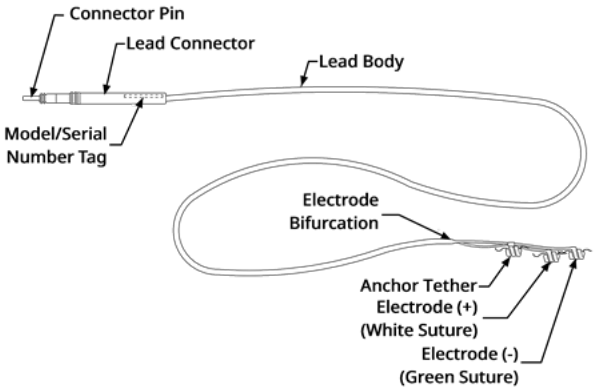
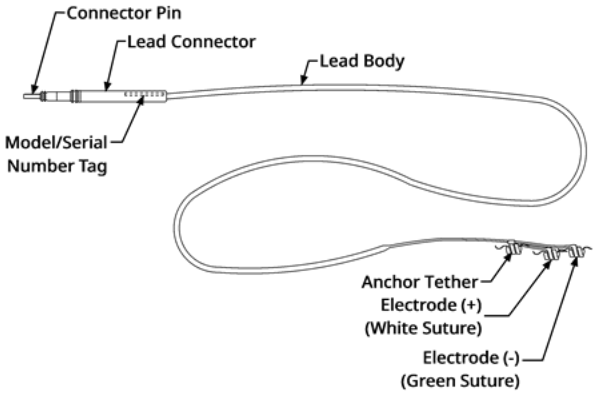
Table 23. Generator Identification

Model	Possible X-ray Tag Codes	Further Identification by Serial Number
Model 1000 Model 1000-D	LIVN VNS	N/A
Model 106 Model 105	CYBX	N/A
Model 104 Model 103 Model 8103	CYB A VNS A	N/A
Model 102	CYBX CYBX-J-XX (XX = year, e.g. 10 for 2010)	Serial numbers <1000000
Model 102R	CYBX CYBX-J-XX (XX = year, e.g. 10 for 2010)	Serial numbers ≥1000000

4.2. Technical Information—Leads

Applicable Models:	PerenniaFLEX™ Model 304 (where available)	PerenniaDURA™ Model 303	Model 302

Figure 11. Leads

Model 304 Model 302	Model 303
	

4.2.1. Physical Characteristics

Table 24. Lead Physical Characteristics

Components	Dimensions*	Connector Assembly	Retention Strength With Generator
Lead Connector	3.2 mm (0.127 in.) D	One (1)	> 10 N
Connector Pin	1.27 mm (0.05 in.) D	N/A	N/A
Connector Ring	2.67 mm (0.105 in.) D	N/A	N/A
Lead Body	2 mm (0.08 in.) D 43 cm (17 in.) L	N/A	N/A
Electrodes and Anchor Tether	**Helical**: 2 mm (0.08 in.) ID **Helical:** 3 mm (0.12 in.) ID **Separation**: 8 mm (0.31 in.) center to center	N/A	N/A
Tie-Down	5.7 mm x 7.7 mm (0.22 in x 0.30 in.)	N/A	N/A

* All dimensions nominal; diameter (D); inner diameter (ID); Length (L)

Table 25. Lead Body Physical Characteristics

Model	Conductor Coil Construction	Resistance (pin / ring to electrode)
Model 302 Model 304	Helical, quadfilar	120 to 180 Ω
Model 303	Helical, trifilar	180 to 250 Ω

4.2.2. Biological Compatibility

Materials exposed to the subcutaneous environment are biologically compatible. All of these materials have a long history in medical implants and have been found to be tissue compatible.

Table 26. Lead Biological Compatibility

Components	Material
Lead Connector	Silicone*
Connector Pin	300 series Stainless Steel
Connector Ring	300 series Stainless Steel
Lead Body	**Conductor**: MP-35N alloy **Insulation**: Silicone*
Electrodes and Anchor Tether	**Helical**: Silicone* elastomer **Conductor**: Platinum/Iridium alloy **Suture**: Polyester
Tie-Down	**Material**: Radio-opaque silicone*

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

4.2.3. Lead Lifespan and Replacement

The lead's lifespan is undetermined at this time. A lead would require replacement if a lead fracture were suspected through diagnostic tests.

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

- Blunt trauma to the neck and/or any area of the body beneath which the lead is implanted
- Patient twists or picks at either the implanted lead or generator
- Improper surgical implantation of the VNS Therapy system (e.g., inadequate strain relief loop, sutures placed directly on the lead body, tie-downs not used, sutured to muscle)

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

CHAPTER 5

Generator Directions for Use

This topic includes the following concepts:

5.1. Stimulation Parameters and Available Parameter Settings

Stimulation Parameters and Available Parameter Settings		
Stimulation Parameters	Model 1000 Model 1000-D	Model 106
Output Current	0–2.0 mA in 0.125-mA steps (± 0.1 mA or ± 10%; whichever is greater); 2–3.5 mA in 0.25-mA steps (± 0.1 mA or ± 10%; whichever is greater)	0–2.0 mA in 0.125-mA steps (± 0.1 mA or ± 10%; whichever is greater); 2–3.5 mA in 0.25-mA steps (± 0.1 mA or ± 10%; whichever is greater)
Signal Frequency	1, 2, 5, 10, 15, 20, 25, 30 Hz ± 6%	1, 2, 5, 10, 15, 20, 25, 30 Hz ± 6%
Pulse Width	130, 250, 500, 750, 1000 µsec ± 10%	130, 250, 500, 750, 1000 µsec ± 10%
Signal ON Time	Normal Mode—7, 14, 21, 30, 60 sec	Normal Mode—7, 14, 21, 30, 60 sec (+ 7 sec/ - 15%)
Signal OFF Time	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps) ± 4.4 sec or ± 1%, whichever is greater	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps) ± 4.4 sec or ± 1%, whichever is greater
Reset Parameters	Settings are unchanged, but output is disabled (0 mA)	Settings are unchanged, but output is disabled (0 mA)
Day-Night Programming		
Day-Night Programming	Enabled or Disabled; When enabled, allows user to program the generator to deliver 2 independent sets of stimulation parameters at different times during a 24-hour period.	N/A
Nighttime Period	Time period for which Nighttime values are active; 1-23 hours in 30-minute increments	N/A
Nighttime Values	Programmable parameters for Nighttime stimulation include the following: • Normal Mode output current • Normal Mode frequency • Normal Mode pulse width • Normal Mode ON time • Normal Mode OFF time	N/A

Stimulation Parameters and Available Parameter Settings		
Stimulation Parameters	Model 1000 Model 1000-D	Model 106
Scheduled Programming Parameters		
Scheduled Programming	Enabled or Disabled — When enabled, allows user to schedule automated increases in output current using a protocol of up to 7 steps	N/A
Interval Between Steps	Default value: 14 days; range is from 7 days to 28 days	N/A
Step Values	Programmable parameters for each step of a protocol: • First step: All stimulation parameters • Subsequent steps: output currents only	N/A

5.1.1. Generators Without AutoStim

Stimulation Parameters and Available Parameter Settings			
Stimulation Parameter	Model 105	Model 104 Model 103	Model 102 Model 102R
Output Current	0-3.5 mA in 0.25-mA steps (± 0.1 mA or ± 10%; whichever is greater)	0–3.5 mA in 0.25-mA steps* ± 0.25 ≤ 1 mA, ± 10% > 1 mA	0–3.5 mA in 0.25-mA steps* ± 0.25 ≤ 1 mA, ± 10% > 1 mA
Signal Frequency	1, 2, 5, 10, 15, 20, 25, 30 Hz ± 6%	1, 2, 5, 10, 15, 20, 25, 30 Hz ± 6%	1, 2, 5, 10, 15, 20, 25, 30 Hz ± 6%
Pulse Width	130, 250, 500, 750, 1000 µsec ± 10%	130, 250, 500, 750, 1000 µsec ± 10%	130, 250, 500, 750, 1000 µsec ± 10%
Signal ON Time	Normal Mode—7, 14, 21, 30, 60 sec (+ 7 sec/ - 15%)	7, 14, 21, 30, 60 sec† ± 15% or + 7 sec, whichever is greater	7, 14, 21, 30, 60 sec† ± 15% or + 7 sec, whichever is greater
Signal OFF Time	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps), + 4.4/- 8.4 sec or ± 1% whichever is greater	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps), + 4.4/- 8.4 sec or ± 1% whichever is greater	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps), + 4.4/- 8.4 sec or ± 1% whichever is greater
Reset Parameters	Settings are unchanged, but output is disabled (0 mA)	Settings are unchanged, but output is disabled (0 mA)	0 mA, 10 Hz; 500 µsec; ON time, 30 sec; OFF time, 60 min

*For output currents ≤ 1 mA, the tolerance is ± 0.25 mA. Maximum output is 12.5 ± 2.5 V with the exception of 10 Hz, 7 seconds On Time, in which case the maximum output is 4.4 V and 0.25 mA tolerance. This 0.25 mA tolerance also applies to 15 Hz, 7 seconds On Time, 0.5 mA output current.

†For signal ON time > 7 sec, there is no ramp-down at 15 Hz with 0.5 mA and at 10 Hz with 0.5-1.75 or 2.75 mA. For signal ON time at 30 sec, actual ON time is 40 sec for 10 Hz with 0.25 mA and 38 sec for 15 Hz with 0.25 mA.

Stimulation Parameters and Available Parameter Settings	
Stimulation Parameter	Model 8103
Output Current	0–3.5 mA in 0.25-mA steps* ± 0.25 ≤1 mA, ± 10% > 1 mA
Signal Frequency	1, 2, 5, 10, 15, 20, 25, 30 Hz ± 6%
Pulse Width	130, 250, 500, 750, 1000 µsec ± 10%
Signal ON Time	7, 14, 21, 30, 60 sec† ± 15% or + 7 sec, whichever is greater
Signal OFF Time	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, 3 min, and 5 to 180 min (5 to 60 in 5-min steps; 60 to 180 in 30-min steps), + 4.4/- 8.4 sec or ± 1% whichever is greater
Reset Parameters	Settings are unchanged, but output is disabled (0 mA)

*For output currents ≤ 1 mA, the tolerance is ± 0.25 mA. Maximum output is 12.5 ± 2.5 V with the exception of 10 Hz, 7 seconds On Time, in which case the maximum output is 4.4 V and 0.25 mA tolerance. This 0.25 mA tolerance also applies to 15 Hz, 7 seconds On Time, 0.5 mA output current.

†For signal ON time > 7 sec, there is no ramp-down at 15 Hz with 0.5 mA and at 10 Hz with 0.5-1.75 or 2.75 mA. For signal ON time at 30 sec, actual ON time is 40 sec for 10 Hz with 0.25 mA and 38 sec for 15 Hz with 0.25 mA.

5.2. System Communication

5.2.1. Programming System

A compatible VNS Therapy programming system is required to communicate with and program the generator. The external programming system includes a programming computer (Programmer), pre-installed with VNS Therapy programming software and a programming wand (Wand). See "System—Compatibility" on page 11

NOTE: For more information such as the proper placement of the Wand, connection of the Wand to the computer, and use of the programming system, see the model specific programming system manual posted at www.livanova.com

5.2.2. Communication

The generator “listens” for a communication signal from the Wand. Communication usually initiates between 1 and 4 seconds (between 3 and 10 seconds for Model 102 and Model 102R) but may be prolonged or interrupted in the presence of electromagnetic interference (EMI). Complete communication, which may take up to one minute, depends on the type and amount of information to be transferred between the generator and the Wand. The download of additional information may take more time.

The generator listens for and implements interrogations, parameter programming instructions, requests for diagnostics testing, and device history inquiries. In response, the generator transmits information on the stimulation parameter settings, changes its parameter settings, responds to requests for diagnostics testing, and provides device histories, respectively. Each time these data are transmitted by the generator, they are saved by the programming software to a database.

NOTE: For details on how to view database information, see the model specific programming system manual posted at www.livanova.com

In addition to the programming system, a magnet that activates a reed switch in the electronic circuitry can be used for one-way communication to the generator. The magnet can be used to temporarily inhibit stimulation and reset the generator.

5.3. System Features and Modes

NOTE: For a compatibility table for generator models, modes and features, see "System—Compatibility" on page 11.

5.3.1. Modes

5.3.1.1. Normal Mode

After the generator has been programmed, the stimulation will repeat in accordance with the programmed ON and OFF cycle (Normal Mode) until the generator receives communication from the programming system or is inhibited with a magnet. Immediately after successful programming, the generator delivers a programmed stimulation that enables the Programmer to evaluate patient response. If programming is performed during stimulation, stimulation will be terminated. After programming, stimulation starts again with the revised settings.

5.3.2. Features

5.3.2.1. Day-Night Programming Introduction

Applicable Models:	Model 1000	Model 1000-D

CAUTION: Time-based features do not automatically adjust for daylight saving time or time zone changes. Tell the patient to follow up with their physician for reprogramming if needed.

NOTE: For a compatibility table for generator models, modes, and features, see "System—Compatibility" on page 11.

Day-Night Programming is an optional feature that allows the generator to deliver two independent sets of therapy parameters at different times during a 24-hour period. This feature allows you to do the following:

- Choose unique daytime and nighttime settings
- Define the time each parameter set is active

The physician specifies what parameters will change, and a time period during the 24-hours when the alternate parameter set should be active. After the Day-Night program has been defined, the generator will alternate between the 2 independent parameter sets on a daily basis. This feature provides the physician the ability to further customize the delivery of VNS Therapy to accommodate to each individual patient's needs after a target level has been established for the patient.

As with any therapy setting change, the risk and benefits of altering a patient's known efficacious settings should be considered when adjustments are made. Inform your patients about when to expect a setting change (i.e. when Daytime settings transition into Nighttime settings). In addition, patient tolerability of the alternate parameter set should be assessed prior to the patient leaving the office visit.

NOTE: Day-Night Programming is not available in Guided Mode.

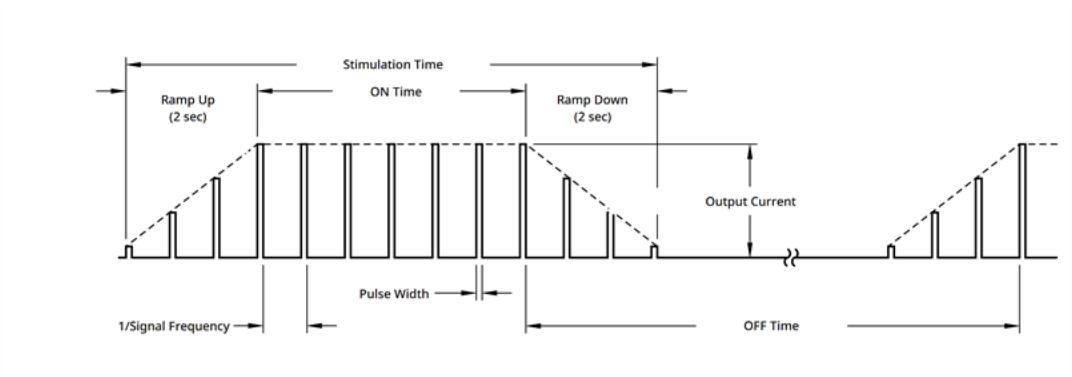
NOTE: For details on how to use Day-Night Programming, see Day-Night Programming in the model specific programming system manual posted at www.livanova.com.

5.4. Stimulation Parameters and Duty Cycle

5.4.1. Programmable Parameters

The graphic representation of stimulation shown below depicts the relationship of the programmable parameters.

Figure 12. Stimulation



NOTE: Frequencies < 10 Hz do not ramp.

Each parameter can be independently programmed, thereby offering multiple setting combinations from which the physician may select optimal stimulation for the patient.

The stimulation graphic shows that the output pulse can be varied both by amplitude (output current) and duration (pulse width). The number of output pulses delivered per second determines the frequency.

5.4.2. Duty Cycle

The percentage of time the generator stimulates is called a duty cycle. To calculate a duty cycle, divide the stimulation time (programmed Normal Mode ON time plus, if frequency is ≥ 10 Hz, 2 seconds of ramp-up time and 2 seconds of ramp-down time) by the sum of the ON time and OFF time.

For details on available parameters, see "Stimulation Parameters and Available Parameter Settings" on page 68.

WARNING: Excessive stimulation is the combination of an excess duty cycle (i.e., one that occurs when ON time is greater than OFF time) and high frequency stimulation (i.e., stimulation at ≥ 50 Hz). Excessive stimulation has resulted in degenerative nerve damage in laboratory animals. While LivaNova limits the maximum programmable frequency to 30 Hz, it is recommended that you do not stimulate with excess duty cycle.

The table below shows duty cycles for typical ON time and OFF time settings.

Table 27.

Duty Cycles for Various ON Time and OFF Time Settings

ON Time (sec)	OFF Time (min)								
	0.2	0.3	0.5	0.8	1.1	1.8	3	5	10
	Duty Cycles* (% ON Time)								
7	58	44	30	20	15	10	6	4	2
14	69	56	41	29	23	15	9	6	3

Table 27. Duty Cycles for Various ON Time and OFF Time Settings (continued)

ON Time (sec)	OFF Time (min)								
	0.2	0.3	0.5	0.8	1.1	1.8	3	5	10
	Duty Cycles* (% ON Time)								
21	76	64	49	36	29	19	12	8	4
30	81	71	57	44	35	25	16	10	5
60	89	82	71	59	51	38	27	18	10

** Duty cycle = (ON time + 2 sec ramp-up + 2 sec ramp-down) / (ON time + OFF time).*

Note: The duty cycles in gray are *not recommended* as they represent parameter combinations with ON time > OFF time.

5.5. Generator Battery Longevity

5.5.1. All Generators

The anticipated longevity of the generator battery depends on the programmed setting choices. Higher output currents, frequencies, pulse widths, and duty cycles generally deplete the battery over a shorter period of time than lower settings. Generally, the increase in battery depletion rate is proportional to the increase in the programmed setting.

⚠ CAUTION: *Undeliverable output currents*: Programming the generator to a high output current that cannot be delivered due to a high lead impedance may disproportionately increase the battery depletion rate and should be avoided.

Other factors, such as lead impedance or use of optional features, also affect the anticipated battery longevity. The anticipated battery longevity decreases as lead impedance increases. Although 1.5 kΩ to 3 kΩ may be a typical lead impedance at implantation, the impedance may increase to 3 kΩ to 5 kΩ during the life of the implant.

The "Battery Longevity Tables" on page 128 provide estimated generator battery lifetimes under a variety of stimulation conditions.

Because of the number of possible parameter combinations, it is impractical to provide the projected life for all possible combinations. The longevity tables should not be used to predict battery EOS, but they give some indication of the effect of various parameter changes on battery life and can be used to assist in the selection of parameter settings. They also indicate that battery life can be maximized at low duty cycles and low frequencies (e.g., 20 Hz) for stimulation.

ⓘ NOTE: For details, see the model-specific programming system manual posted at www.livanova.com.

5.5.2. Battery Status Indicators

The programming software displays a battery indicator for the generator similar to an indicator that may be found in cell phones. The visual indicator illustrates the approximate battery capacity that remains.

The programming software displays warning messages after interrogation or programming of the generator if the battery has been depleted to a level where action is recommended due to near end of service (NEOS) or end of service (EOS).

NOTE: See the VNS Therapy programming system manual for detailed information on these indicators.

CAUTION: *Battery evaluation at cold temperatures*: Low storage temperatures may affect the battery status indicators. In such cases, keep the generator at room or body temperature for 30 minutes, then use the System Diagnostics or Generator Diagnostics to re-evaluate the battery status indicators.

5.6. Generator Replacement

All VNS Therapy generators will eventually require surgical replacement due to battery depletion. Generator replacement does not, of itself, require lead replacement unless a lead discontinuity is suspected. Generator replacement or removal requires dissection to the generator's pocket, with care being taken not to damage or cut the lead. The entire surgical procedure generally requires about 1 hour.

NOTE: See "Revision, Replacement, and Removal Procedure " on page 112 for details.

5.6.1. Signs of End of Service

The most common reason for the absence of stimulation is battery depletion, although there may be other reasons. When end of service (EOS) occurs, the generator will disable stimulation and no output will be delivered. If the generator is not explanted or replaced at end of service (EOS), the battery voltage will continue to gradually decrease and communication with the generator may not be possible.

CAUTION: Generator end of service (EOS) may result in increased frequency, intensity, or duration of signs and symptoms of the patient's disorder, in some cases to levels greater than those reported before stimulation.

5.6.2. Replacement Based on Battery Status Indicators

The generators and the programming system have battery status indicators (see "Battery Status Indicators" above). These indicators provide warnings that a generator battery should be monitored more frequently, is near end of service (NEOS), or has reached end of service (EOS). Once these warning messages appear, see recommendations in the model specific programming system manual posted at www.livanova.com.

CAUTION: *Prompt generator replacement* – LivaNova recommends prompt replacement of the generator at or before end of service (EOS). Prompt replacement may help minimize any possible relapse. See "System Removal" on page 121 for additional information about explanted devices.

CAUTION: *Explanted generator* – A generator explanted for any reason should not be re-implanted. Return explanted generators to LivaNova. For instructions, see Return Product Form.

5.7. Magnet

5.7.1. Magnet Uses

Magnets are supplied by LivaNova. There are two possible uses for the magnet:

- Temporarily inhibit stimulation
- Reset the generator (in combination with the programming system)

NOTE: See also the *Patient Magnet Directions for Use* posted at www.livanova.com.

5.7.2. Inhibit Stimulation

A magnet held in place over the generator temporarily stops any ongoing stimulation. To inhibit the entire stimulation cycle, the magnet must be held in place over the generator for the minimum required time listed in the table below. After the magnet is removed, normal operation will resume after one complete OFF time.

Table 28. Time Needed to Terminate Stimulation

Model	Time
Model 1000 Model 1000-D	10 sec
Model 106	5 sec
Model 105 Model 104 Model 103 Model 8103 Model 102 Model 102R	65 sec

CAUTION: If stimulation becomes painful, the patient should be instructed to stop the stimulation with the magnet.

In the unlikely event of continuous stimulation or other malfunction, advise the patient to apply the magnet, secure it in place, and immediately notify their physician.

NOTE: For details on adverse events, see "Adverse Events" on page 32.

5.8. Generator Reset

The system allows the generator microprocessor to be reset in the event of a malfunction. A reset is necessary only in the rare case of microprocessor memory malfunction, which might be caused by conditions described in "Indications, Warnings and Precautions " on page 16 . A microprocessor reset may be appropriate when the generator and the programming system are unable to communicate.

NOTE: For suggestions in solving communication difficulties, see "Communication Issues" in the programming system manual.

If you have eliminated possible environmental hazards and completed all possible troubleshooting steps, a generator reset may be necessary. Contact "Technical Support" on page 179 for assistance with a generator reset.

Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	⚠ CAUTION: *Generator reset*: When the generator is reset, optional features (e.g., Day-Night Programming) and stimulation output are disabled (0 mA); however, all settings and device history are preserved. After a successful reset, the generator stimulation output may be re-enabled to resume operation at the previously programmed settings and optional features reactivated.
Model 102 Model 102R	⚠ CAUTION: *Generator reset*: When the generator is reset, all device history information is lost, and the reset parameters (0 mA, 10 Hz; 500 µsec; ON time, 30 sec; OFF time, 60 min) are internally programmed. A generator reset turns the device off (**output current** = 0 mA). After a successful reset, the generator stimulation output may be re-enabled to resume operation at the previously programmed settings and optional features reactivated.

5.9. Effects of the Daily Reset of the Internal Clock

The Model 102 and Model 102R generators contain an internal clock that rolls over (i.e., restarts) every 24 hours. This daily rollover of the internal clock is a normal device function. Every time the clock restarts, a stimulation cycle beginning with the programmed ON time is delivered. Patients may notice a shorter OFF time between the last stimulation cycle just prior to the clock restart and the first stimulation cycle after the clock restart.

NOTE: The time that the clock restarts each day corresponds with the time of day the most recent programming event occurred. Holding the magnet over the generator for an extended period of time will put all timekeeping functions on hold and will delay the time that the internal clock rolls over each day.

Some patients may be more sensitive to this shorter OFF time and may exhibit common stimulation related side effects (e.g., coughing, voice changes). These side effects will only occur once a day at the time of the daily clock restart. In the rare reported instances in which side effects occurred with the daily clock restart, it was noted that the most common programmed duty cycle was 30 seconds ON time and 3 minutes OFF time along with a high output current (> 2 mA).

NOTE: For a complete list of side effects, see "Adverse Events" on page 32

As with any normal side effect, adjusting settings for tolerability (i.e., decreasing pulse width, signal frequency, and/or output current) has been shown to be successful in resolving stimulation related side effects associated with the 24-hour rollover event. However, since this 24-hour rollover event is directly related to the programmed ON time and OFF time, adjusting the duty cycle may be a better option. Optimizing the patient's benefit from therapy should be considered when making the decision as to which parameter should be adjusted. For example, if the patient is responding well clinically at a particular output current, adjusting a different parameter or duty cycle may be considered. The table below shows several ON time and OFF time combinations that may be better options when trying to resolve stimulation related side effects associated with the daily clock restart.

Table 29. Optimize Therapy for Patients Affected by the Internal Clock Cycle

ON Time (sec)	OFF Time (min)
7	0.3
14	0.5
21	0.5
7	0.8
14	1.1
30	1.1
60	1.1
30	1.8
7	3.0
14	3.0
60	5.0
14	10.0

NOTE: For details on Duty Cycle, see "Duty Cycle" on page 73.

5.10. Device History

The generator device history consists of the generator serial number, model number, patient ID, implantation date, and other information pertinent to diagnostic and programming events.

Use the programming software to access and view Device History information. For details, see Device History in the model specific programming system manual posted at www.livanova.com.

5.11. Device Diagnostics

5.11.1. Device Diagnostics Introduction

Information from device diagnostic tests can help the physician determine if the following is true:

- Generator output current is delivered at the programmed value
- Generator battery is at a sufficient level
- Lead impedance is within an acceptable range

NOTE: Use the programming software to access and view Device Diagnostics information. For details, see Device Diagnostics in the model specific programming system manual posted at www.livanova.com.

5.11.2. System Diagnostics Test

The System Diagnostics evaluates the lead impedance of the system as well as the generator's ability to deliver the programmed Normal Mode stimulation.

Depending on the generator model and programmed Normal Mode **output current**, different test pulses may be conducted during the test (see table below).

Table 30. System Diagnostics Behavior

Normal Mode Output Current	Model 1000 Model 1000-D	Model 106 Model 105 Model 104 Model 103 Model 8103	Model 102 Model 102R
0 mA	Delivery of programmed output for approximately 4 seconds, followed by one brief pulse at 0.25 mA for less than 130 µsec.*	1 mA, 500 µsec for approximately 14 seconds	1 mA, 500 µsec for approximately 14 seconds
> 0 mA		One brief pulse at 0.25 mA, 130 µsec, followed by delivery of programmed output for the duration of the programmed ON time.	

Table 30. System Diagnostics Behavior (continued)

Normal Mode Output Current	Model 1000 Model 1000-D	Model 106 Model 105 Model 104 Model 103 Model 8103	Model 102 Model 102R
	NOTE: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours.	NOTE: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours.	N/A

*Minor differences in the system diagnostics test exist for Model 1000 with serial numbers < 100,000. For more information, see Model 1000 (Serial Numbers < 100,000 Only) in the indication specific physician's manual.

The programming software reports the lead impedance and whether the programmed stimulus was delivered.

NOTE: For details on available diagnostic tests and how to perform the tests, see Device Diagnostics in the model specific programming system manual posted at www.livanova.com.

5.11.3. High Lead Impedance

High lead impedance is defined as any value ≥ 5300 Ω.

5.11.3.1. Reasons for High Lead Impedance Readings

Possible causes of high lead impedance readings are thought to include:

- Lead discontinuity
- Lead disconnection from the generator
- Fibrosis between the nerve and the electrode
- Electrode detachment from the nerve
- Defective generator

5.11.3.2. High Lead Impedance — Possible Implications

High lead impedance (≥ 5300 Ω), in the absence of other device-related complications, is not an indication of a lead or generator malfunction. High lead impedance in combination with the patient's failure to feel even the maximum output stimulus may indicate a lead wire fracture or other type of electrical discontinuity in the lead.

Patients who experience high lead impedance, no sensation of maximum output stimulation, and an increase in depressive symptoms should be further evaluated for possible lead replacement.

NOTE: For additional instructions on how to perform the System Diagnostics, see the model specific programming system manual posted at www.livanova.com.

NOTE: To troubleshoot high impedance see "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com.

For Models:	Model 102	Model 102R

Use the table below to find the DC DC Code displayed by the System Diagnostics screen to determine an estimate of lead impedance in Ohms (Ω). The use of this table with the DC DC Codes from diagnostic screens other than the System Diagnostics and Generator Diagnostics is not appropriate, unless the generator output parameters are the values indicated in the tables. High lead impedance is defined as any DC DC Code greater than or equal to 4 with 1 mA of diagnostic current.

Table 31. DC DC Code Conversion and Estimated Impedance Range Lead Impedance

DC DC Code	Estimated Impedance Range (Lead Impedance Value at 1 mA, 500 µsec)
0	≤ 1700 Ω
1	1800–2800 Ω
2	2900–4000 Ω
3	4100–5200 Ω
4	5300–6500 Ω
5	6600–7700 Ω
6	7800–8900 Ω
7	≥ 9000 Ω

5.11.4. Low Lead Impedance

Low lead impedance is defined as any value ≤ 600 Ω.

5.11.4.1. Reasons for Low Lead Impedance Readings

Possible causes of low lead impedance readings are thought to include:

- Short-circuit condition within the lead
- Defective generator

5.11.4.2. Low Lead Impedance – Possible Implications

Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	Low lead impedance (≤ 600 Ω) likely indicates the existence of a short-circuit condition, although an impedance value of greater than 600 Ω does not exclude the possibility.
Model 102 Model 102R	Low lead impedance (DC DC Code of "0") likely indicates the existence of a short-circuit condition, although an impedance value of greater than 600 Ω does not exclude the possibility. A significant decrease in DC DC Code value on the System Diagnostics (e.g., "3" to "1") from prior System Diagnostics may also indicate a lead problem.

A sudden decrease in impedance value in combination with device-related complications, listed below, may also indicate a short-circuit condition in the lead:

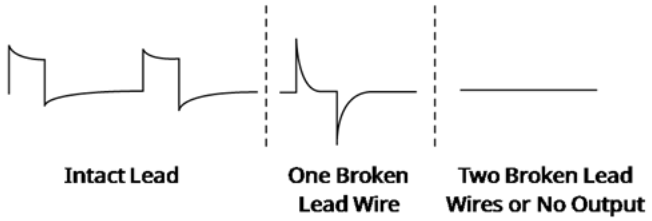
- Increase in depressive symptoms
- Painful stimulation
- Patient perception of feeling erratic, limited, or no stimulation

NOTE: To troubleshoot low impedance see "Lead impedance Issues" in the model specific programming system manual posted at www.livanova.com.

5.11.5. Stimulus Waveform Analysis

Either evoked potential monitoring equipment or an oscilloscope can be used to analyze the stimulus waveform from the neck for verification of an electrical discontinuity. A differentiated waveform with narrowed pulses or no waveform at all can confirm a discontinuity. The figure below shows characteristic waveforms obtained from skin electrodes for a lead that is intact and for a lead that has a fracture in one or both wires. In addition to these approaches, lead discontinuities can sometimes be identified on an x-ray of the implant site.

Figure 13. Typical Waveforms Obtained from Skin Electrodes



5.12. Delivery of Programmed Output Current

5.12.1. Output Current LOW or LIMIT

If the diagnostic tests indicate LOW or LIMIT (Model 102 and Model 102R) output current, the generator may not be delivering the programmed output current. Reasons for failure to deliver the programmed output current include high programmed output current and high lead impedance. The maximum deliverable output current, according to Ohm's Law, equals the maximum output voltage (approximately 12 V) divided by the lead impedance.

5.12.2. Reprogram to a Lower Current

If the generator fails to deliver the programmed output current, you can reprogram the device to a lower output current and attempt to compensate for a decrease in delivered energy by widening the pulse width.

For example, if the output current is at LOW or LIMIT for a generator programmed at 2.5 mA, 30 Hz, 500 µsec with 30 seconds ON time, then lower the output current to 2 mA and widen the pulse width to 750 µsec.

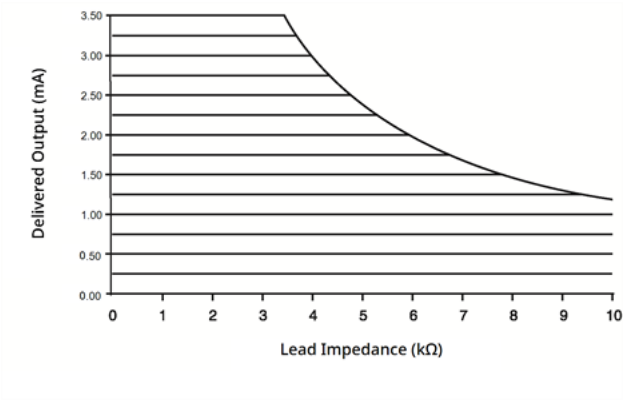
5.13. Charge Delivered per Pulse

The charge delivered per pulse is the most important parameter when stimulation output is evaluated. It is defined as a microcoulomb (µC), which is the product of current and time.

Charge delivered per pulse (µC) = output current (mA) x pulse width (msec[1])

The relationship of programmed output current (mA) to lead impedance for a 1000 µsec pulse with output currents from 0 to 3.5 mA, is shown below.

Figure 14. Relationship of Programmed Output Current to Lead Impedance



[1]Converted from µsec into msec

⚠ CAUTION: Model 100, Model 102 and Model 102R **Do not use frequencies of 5 Hz or below for long-term stimulation.** These frequencies generate an electromagnetic trigger signal, which results in excessive battery depletion of the implanted generator. Therefore, use these low frequencies for short periods of time only.

CHAPTER 6

Implantation

For precautions related to the implantation procedure, see "Precautions—Related to Implantation" on page 24.

This topic includes the following concepts:

6.1. Surgeon Training

Physicians who implant the VNS Therapy system should be experienced with surgery within the carotid sheath and capable of performing the surgical technique used to implant the VNS Therapy system.

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

Physicians who implant the VNS Therapy system should be thoroughly familiar with all associated training materials:

- Physician and patient labeling for the VNS Therapy system
- Electrode practice fixture—a device used to practice placing the helices around the vagus nerve

NOTE: Contact "Technical Support" on page 179 to request other training materials and support.

6.2. Components and Surgical Materials — New Implant

Table 32. Components Needed for New Implant

Components Needed for Surgery	New Implant
Generator	1 primary single-receptacle generator 1 backup single-receptacle generator
Lead	1 primary single-pin lead 1 backup single-pin lead
Accessory Pack	1 accessory pack
Programming System	1 programming system
Tunneler	1 tunneler
Sterile Laser Arm Bag or equivalent*	Required
Soft vessel loops or silicone sheet*	Suggested but optional

* Not provided by LivaNova

NOTE: For lead size availability, see "Physical Characteristics" on page 65.

6.3. How to Open the Sterile Pack

Before any sterile pack is opened, examine it carefully for evidence of damage or compromised sterility. If the outer or inner sterile barrier has been opened or damaged, LivaNova cannot guarantee sterility of the contents, and it should not be used. An opened or damaged product should be returned to LivaNova.

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

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

6.3.1. Generator and Lead

To open the sterile pack, complete the following steps:

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

6.3.2. Tunneler

To open the sterile pack, complete the following steps:

1. Grasp the tab and peel back the outer cover.
2. Use sterile technique to lift out the sterile inner tray.
3. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.
4. Remove all four pieces in the package (shaft, bullet tip, large-diameter sleeve, small-diameter sleeve).

6.3.3. Accessory Pack

To open the sterile pack, complete the following steps:

1. Grasp the tab and peel back the outer cover.
2. Use sterile technique to lift out the sterile inner tray.
3. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.
4. To remove the hex screwdriver, a resistor assembly, or tie-downs, push down on one end of the item and grasp the opposite (raised) end.

6.4. Recommendations for Implantation

In general, implantation of the VNS Therapy system is similar to accepted practice for implantation of a cardiac pacemaker, with the exception of the placement of the helices and the subcutaneous routing of the lead body. The surgical approach and techniques will vary with the preference of the surgeon. To ensure correct lead placement, these instructions provide recommendations for implantation, order of placement of the helical electrodes and anchor tether, and other essential steps.

⚠ CAUTION: To maximize system performance and minimize possible mechanical damage to the nerve or lead, **pay careful attention to helical placement and lead route**.

- The surgeon should ensure that the generator, lead, and tunneler are compatible. See "System—Compatibility" on page 11.
- It is recommended that the patient be given antibiotics pre-operatively and that both incision sites be irrigated frequently with generous amounts of bacitracin or equivalent solution prior to closure. (These incisions should be closed with cosmetic closure techniques to minimize the development of scars.) Also, antibiotics should be administered post-operatively at the discretion of the physician.

  ⚠ CAUTION: **Infections related to any implanted device are difficult to treat** and explant of the VNS Therapy system may be required.

- Critical to the long-term success of the implant are proper techniques both for the attachment of the electrodes and the anchor tether to the vagus nerve, and for the provision of adequate strain relief below and above the sternocleidomastoid muscle. For details on general placement of the generator and lead, see "Lead and Pocket Location" on the next page.
- Coil the lead body and place it in the chest pocket to the side of the generator.
- Adequate exposure of the vagus nerve (> 3 cm) facilitates placement of the helices on the nerve. The nerve may swell temporarily if the nerve is stretched or allowed to dry during implantation. Constriction of the nerve or other nerve damage may result in vocal cord dysfunction.
- It is recommended that output of the generator and performance of the implanted system be tested at the time of implantation. It is recommended that the appropriate version of the programming software and Wand (placed in a sterile drape) be used for routine system verification. For details, see "Test the System" on page 103.
- After the electrode is placed on the nerve, test the electrode-nerve interface impedance. Connect the lead directly to the generator and perform a System Diagnostics. For details, see "Test the System" on page 103.

6.5. Pre-Surgical Steps

Perform the following before surgery and outside of the sterile field.

6.5.1. Interrogate the Generator

To ensure proper device communication, interrogate the device while still in the sterile pack.

For details on generator interrogation, see the model specific programming system manual posted at www.livanova.com.

Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	⚠ CAUTION: If you interrogate a generator that has been exposed to low temperatures within the last 24 hours, a low battery status indicator may be displayed. For details on troubleshooting this problem, see "Troubleshooting" in the model specific programming system manual posted at www.livanova.com.

6.5.2. Program Patient Data

Program the patient identification and implant date into the generator. For details, see the model-specific programming system manual posted at www.livanova.com.

6.6. Implant Procedure

For precautions related to the implantation procedure, see "Precautions—Related to Implantation" on page 24.

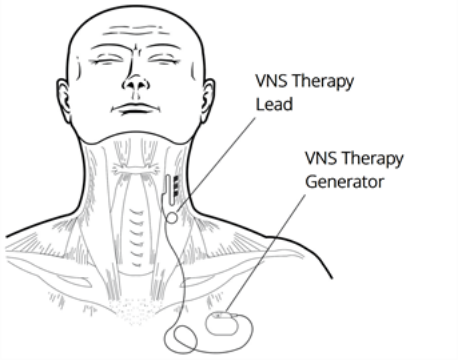
6.6.1. Lead and Pocket Location

The generator is usually implanted just below the clavicle in a subcutaneous pocket in the left upper chest.

ⓘ NOTE: It is preferable to place the generator along the axillary border, at or above anterior rib 4, so the patient can have the maximum flexibility for MRI postoperatively.

Suggested placement for the lead is the area of the vagus nerve half-way between the clavicle and the mastoid process, with the lead subcutaneously tunneled between the incision site in the neck and the pocket formed in the upper chest (see below).

Figure 15. Generator and Lead Placement



It is recommended that both the lead body and the generator be positioned on the same side of the body. The VNS Therapy tunneler is recommended for subcutaneous routing of the lead.

ⓘ NOTE: To ensure device placement follows current MRI guidelines, review the MRI warnings and precautions prior to placement of the system. See MRI Guidance posted at www.livanova.com.

6.6.2. Implantation Procedure Overview

⚠ CAUTION: This procedural overview is not a substitute for the complete implantation procedure.

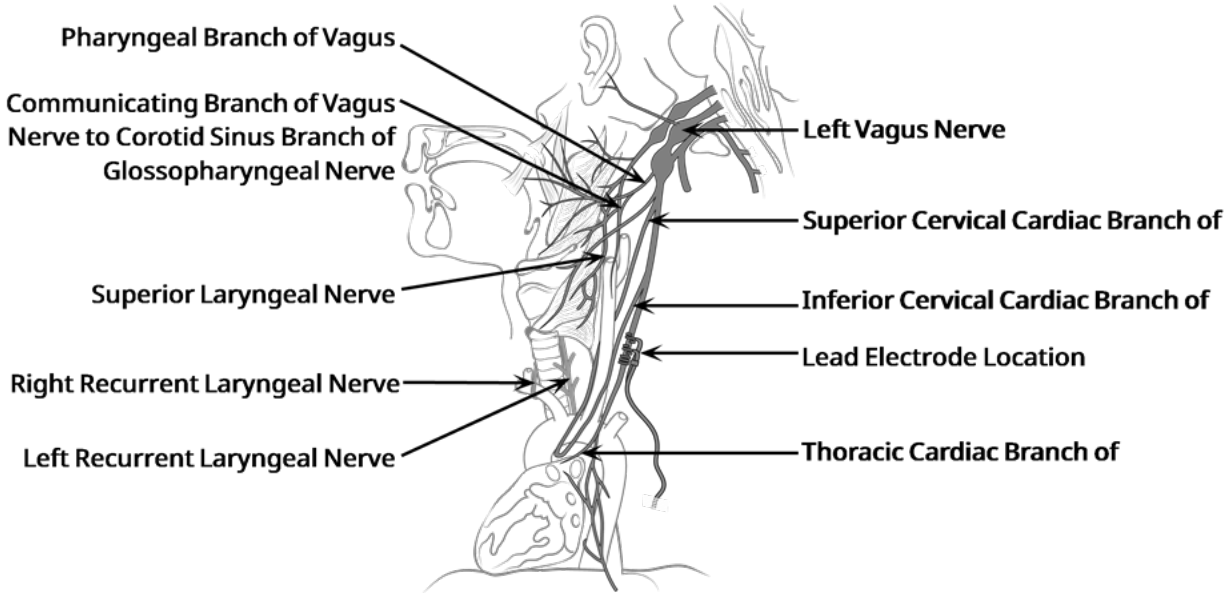
1. Expose the left carotid sheath and vagus nerve.
2. Create a pocket in the left upper chest for the generator.
3. Choose the correct size lead.
4. Tunnel the lead subcutaneously from the neck to the generator pocket in the chest.
5. Attach the electrodes and anchor tether to the vagus nerve.
6. Secure the lead parallel to the nerve.
7. Form the strain relief bend and strain relief loop.
8. Connect the lead to the generator.
9. Verify that the connector pin is fully inserted and tighten the setscrew.
10. Perform System Diagnostics.
11. Place the generator in the chest pocket, with the extra coiled lead to the side of the generator, not behind it.
12. Secure the generator to fascia; do not place sutures directly around or on the lead.
13. Perform the second System Diagnostics.
14. Interrogate the generator to verify current is 0 mA.
15. Irrigate the incision site with bacitracin or other solution.
16. Close the incisions.

6.6.3. Begin the Procedure

6.6.3.1. Anatomy

It is very important that the surgeon who implants the VNS Therapy system be familiar with vagus nerve anatomy, particularly the cardiac branches. The lead electrodes must not be placed on either the superior or the inferior cervical cardiac branches. **Place the lead below where the superior and inferior cardiac branches separate from the vagus nerve.** Stimulation of either of these two branches during the System Diagnostics may cause **bradycardia and/or asystole**. Careful dissection laterally on the vagus nerve should aid the physician in determining proper electrode placement. In most but not all patients, the main vagus nerve is the largest of the three nerves. The image below shows the correct anatomical placement of the helices.

Figure 16. Vagus Nerve Anatomy and Placement of the Lead



⚠ CAUTION: Attachment of lead electrodes must not involve the superior cervical cardiac branch or the inferior cervical cardiac branch of the vagus nerve. Place the electrodes *below* where these two branches separate from the vagus nerve.

⚠ CAUTION: Excessive manipulation of the vagus nerve during placement of the lead can result in noticeable post-operative hoarseness. Under most circumstances, this condition will resolve without additional medical intervention within three to four weeks, depending on the degree of stress applied to the nerve during surgery. LivaNova does not recommend that stimulation treatment be initiated until this condition has resolved, since it could aggravate the condition.

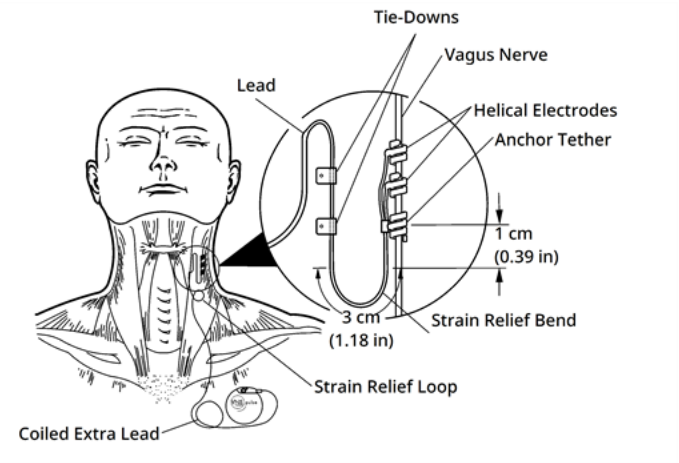
6.6.3.2. Expose the Vagus Nerve

While the specific surgical approach and techniques for lead implantation varies with the implant surgeon, the following detailed instructions are provided for guidance:

1. Administer appropriate anesthesia to the patient.
2. Expose the left carotid sheath as it extends along the anterior border of the sternocleidomastoid muscle.
3. Locate and expose *at least 3 centimeters (1.18 inches)* of the vagus nerve. The recommended stimulation site is a 3-cm section of the vagus nerve, approximately half-way between the clavicle and the mastoid process, where it is clear of branches (below where the superior and inferior cervical cardiac branches separate from the vagus nerve. The nerve usually lies in a posterior groove between the carotid artery and internal jugular vein.

CAUTION: **Do not allow the vagus nerve to become dry** during surgery, because dehydration of the nerve can result in nerve damage and cause the nerve to swell.

Figure 17. Location for Electrode Placement



6.6.3.3. Create a Generator Pocket

Create a subcutaneous pocket in the chest below the clavicle for the generator. The pocket depth should not be deeper than 1 inch beneath the skin. It is not recommended to implant the generator below muscle. Doing so may contribute to communication difficulties once implanted.

NOTE: It is preferable to place the generator along the axillary border, at or above anterior rib 4, so the patient can have the maximum flexibility for MRI postoperatively.

6.6.4. Implant the Lead

CAUTION: To maximize system performance and minimize possible mechanical damage to the nerve or lead, pay careful attention to the lead route, lead stabilization, and electrode placement.

6.6.4.1. Choose a Lead

Choose the appropriately sized lead carefully. It should fit snugly without constriction of the nerve. The lead (2.0 mm/0.08 in.) should accommodate most nerves.

NOTE: For lead size availability, see "Technical Information—Leads" on page 65.

CAUTION: The lead is available in multiple sizes. Since it is not possible to predict in patients what size lead will be needed, **it is recommended that at least one alternate lead size be available in the operating room.** In addition, backups for leads should be available in the event of compromised sterility or damage induced during surgery.

CAUTION: Do not expose the lead to dust or other similar particulates, because its silicone insulation can attract particulate matter.

CAUTION: Do not soak the lead in saline or similar solution before it is implanted, because this may cause the insulated portions of the connector pin to swell and become difficult to insert into the generator.

6.6.4.2. Pass the Tunneler and Lead

The tunneler is used to tunnel the lead connector and lead body subcutaneously between the neck incision site and the generator in the chest pocket.

NOTE: For a detailed description of the tunneler tool, see the Model 402 Tunneler manual at www.livanova.com.

CAUTION: Never route the lead through muscle.

If necessary, the tunneler can be manually shaped to help direct it through the body.

CAUTION: Do not manually shape the tunneler **more than 25 degrees** because doing so may cause the sleeve to bend or kink.

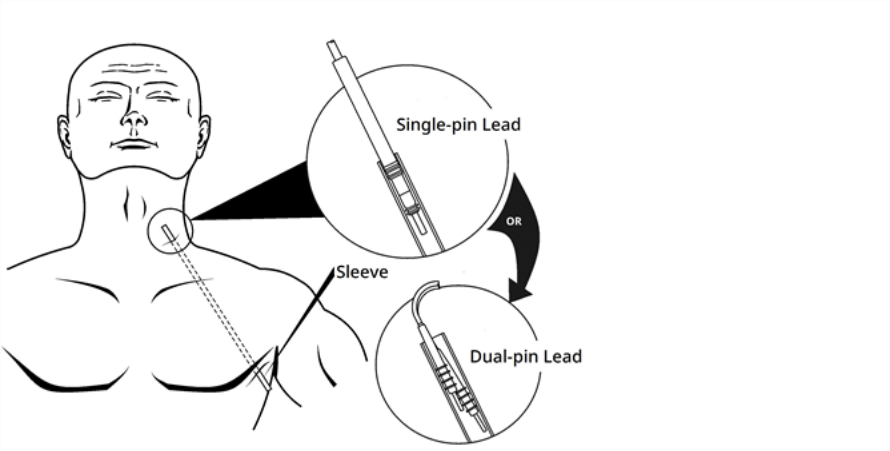
To pass the tunneler follow these steps:

1. Place the bullet-tip end of the tunneler through the neck incision and tunnel subcutaneously toward the chest incision. Exert force on the handle end and direct the tunneler as necessary.

   As an alternative, the lead connector and lead body can be tunneled subcutaneously from the neck incision site to the generator in the chest pocket *after placement of the electrodes and anchor tether on the nerve, and placement of strain relief with the tie-downs*. See "Place the Electrodes" on the next page and "Provide Strain Relief" on page 98, respectively.

2. After the bullet tip has passed from one incision site to the other, unscrew the bullet and withdraw the shaft from the sleeve. Leave the sleeve extended through both incisions.

Figure 18. Position of Sleeve and Lead Connectors



NOTE: Insert the lead into the sleeve at the neck.

3. With the sleeve in place between the two incisions, carefully insert the lead connector inside the end of the sleeve at the neck incision until secure. For a dual-pin lead, the second connector will form a slight compression fit between the first lead connector tubing and the inside of the sleeve.
4. Carefully pull the sleeve, along with the lead connector, from the chest incision end until they completely exit the chest incision.
5. Remove the lead connector from the sleeve and leave the electrode array at the neck incision site.
6. Discard the entire tunneler assembly and unused portions after use.

6.6.4.3. Place the Electrodes

NOTE: For a detailed image of the vagus nerve anatomy, see "Anatomy" on page 90.

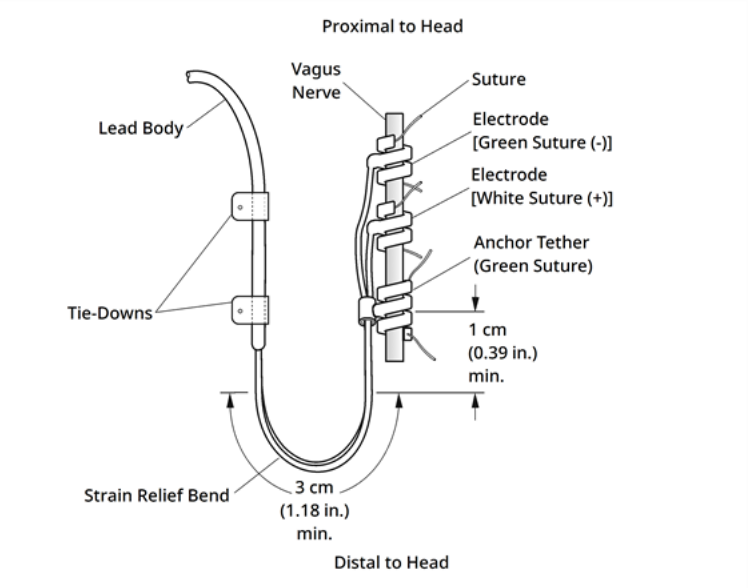
6.6.4.3.1. Electrode Polarity

The helical electrodes and anchor tether are coiled around the nerve. Begin with the electrode that is farthest from the lead bifurcation (with a green suture embedded in the helical material). This electrode should be nearest (proximal to) the patient's head.

Alternately, the surgeon may choose to begin with the anchor tether (distal to head), then the electrode closest to the lead bifurcation (with white suture), and finally the electrode farthest from the lead bifurcation (with green suture).

The polarity of stimulation does not change as long as the electrodes are attached in the final orientation shown below.

Figure 19. Electrode Polarity



6.6.4.3.2. Place the Helicals Around the Nerve

⚠ CAUTION: **The lead and helical electrodes are very delicate**; be careful not to stretch, pinch, or crush them when using forceps, and not to over-straighten or stretch the helices when coiling them around the nerve, because doing so may damage the electrode or tether. Use soft rubber vessel loops to raise, or lift, the nerve, if necessary.

⚠ CAUTION: **Proper techniques** for attachment of the electrodes and the anchor tether to the vagus nerve are critical to the long-term success of the implant.

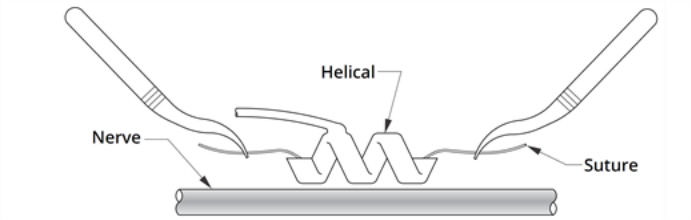
⚠ CAUTION: Sutures that are part of the lead (embedded in the helices of the electrodes and anchor tether) are meant to assist in helical placement around the vagus nerve. These sutures should not be tied to each other or around the nerve, since this may cause nerve damage.

⚠ CAUTION: The suture may become dislodged from the helical if product labeling is not followed (i.e., The elastomer and suture are grasped to manipulate the helical onto the nerve).

Place the helicals on the nerve as described below. As an alternative, each helical can be placed underneath the nerve before it is spread. A silicone sheet may be useful to separate the nerve from tissue during the procedure.

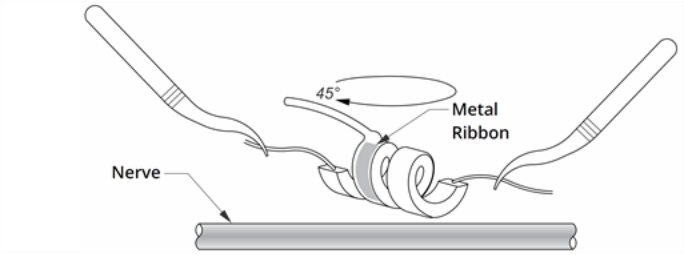
1. Locate the first helical (with green suture).
2. With forceps, gently pull each end of the helical, using the attached sutures to spread the helical.

Figure 20. Spread the Helical



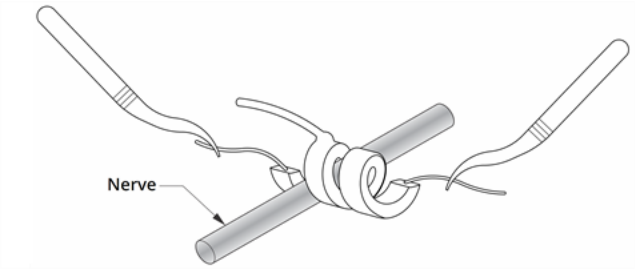
3. Spread the open helical directly above and parallel to the exposed nerve and turn the helical clockwise at a 45 degree angle to the nerve.

Figure 21. Turn the Helical



4. Place the turn of the helical where the lead wire connects to the helical (the section with the metal ribbon) onto the nerve.

Figure 22. Placement of the Turn



5. Pass the *distal* suture portion of the helical under the nerve and back around so that it encircles the nerve.

Figure 23. Initial Placement of the Distal Portion of the Helical

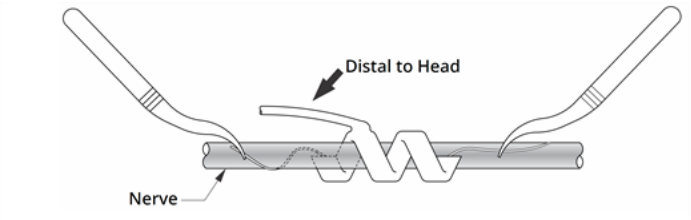
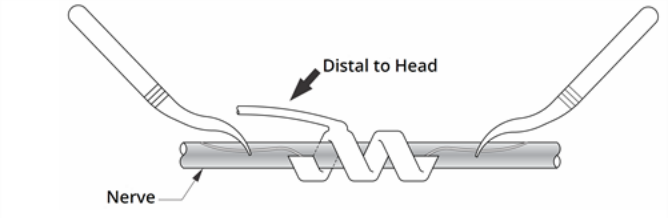
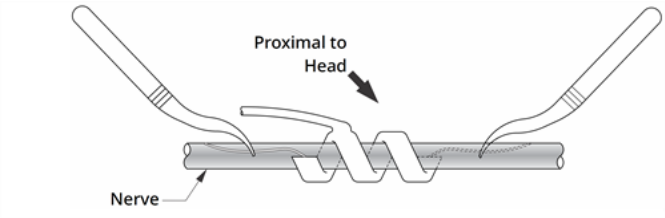


Figure 24. Helical Placement After the Distal Portion Encircles the Nerve



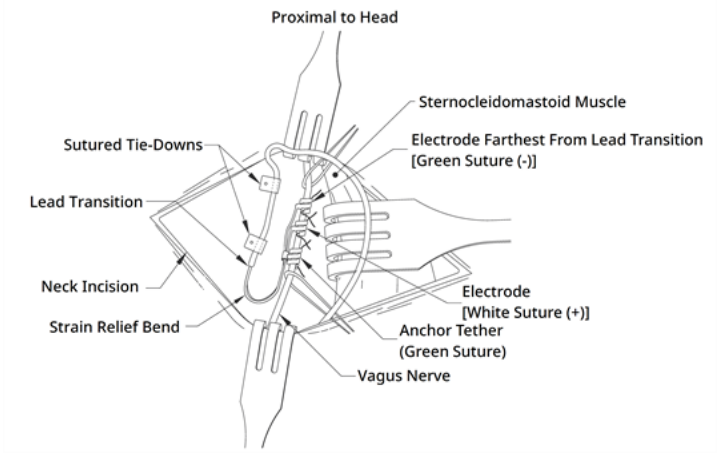
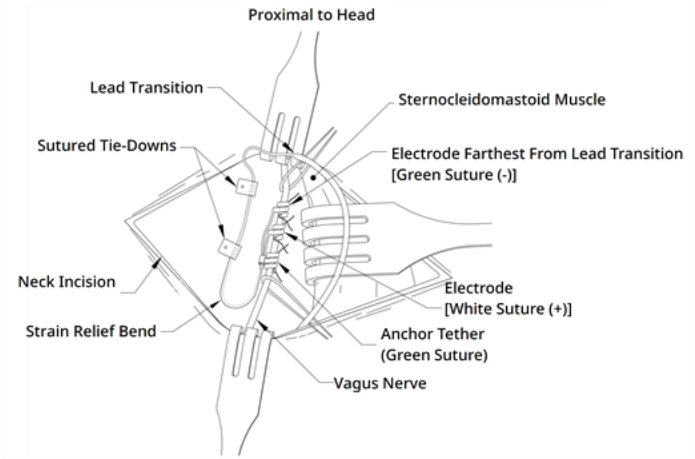
6. Pass the *proximal* suture portion of the helical under the nerve and back around so that it encircles the nerve.

Figure 25. Placement of the Proximal Portion of the Helical



7. Locate the middle helical (with white suture) and repeat steps 2 - 6.
8. Locate the third helical (with green suture) and repeat steps 2 - 6.
9. Verify all three helices have been coiled around the nerve, the lead body exits each helical in the same direction, and the two lead bodies are aligned parallel to each other and the nerve. The correct placement of the two helical electrodes and anchor tether is shown below.

Figure 26. Placement of Electrodes and Anchor Tether

Model 302 Model 304	Model 303
	

6.6.4.3.3. Provide Strain Relief

⚠ CAUTION: **Proper techniques** for providing adequate strain relief below and above the sternocleidomastoid muscle are critical to the long-term success of the implant.

⚠ CAUTION: **The lead wire has a potential for fracture** if the recommended strain relief is not provided as described.

After the two electrodes and anchor tether are attached, form a strain relief bend and a strain relief loop in the lead to provide adequate slack and allow for neck movement.

Form the Strain Relief Bend

⚠ CAUTION: Always use the tie-downs.

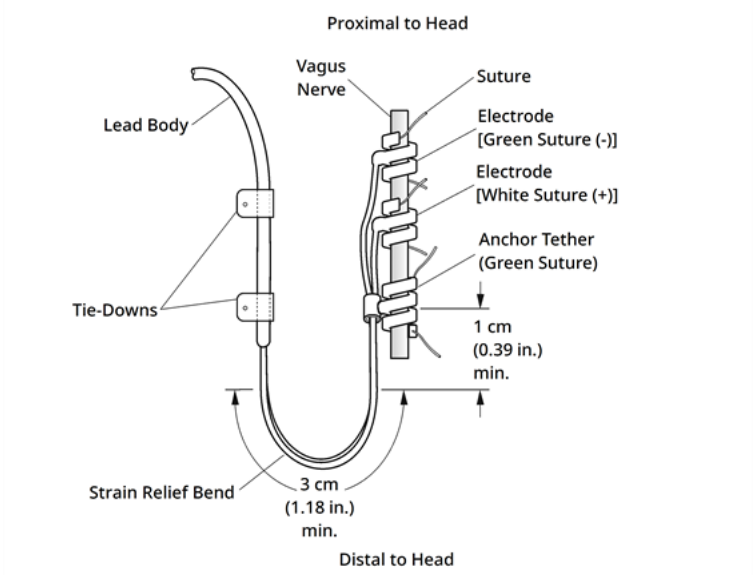
⚠ CAUTION: Never suture the lead or lead body to muscle tissue.

⚠ CAUTION: Do not place the sutures directly around the body of the lead; this could result in insulation failure and system malfunction, and possible lead breakage.

To form the strain relief bend, complete the following steps:

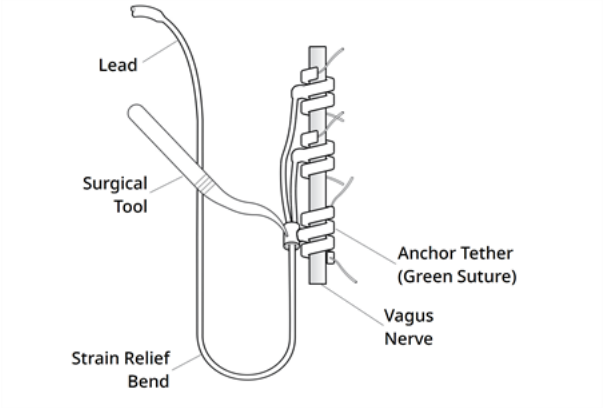
1. Form the lead body into a 3-cm (1.18 in.) strain relief bend with at least 1 cm (0.39 in.) of lead routed parallel to the nerve. The parallel portion can be placed in a pocket formed adjacent to the anchor tether.

Figure 27. Strain Relief Bend



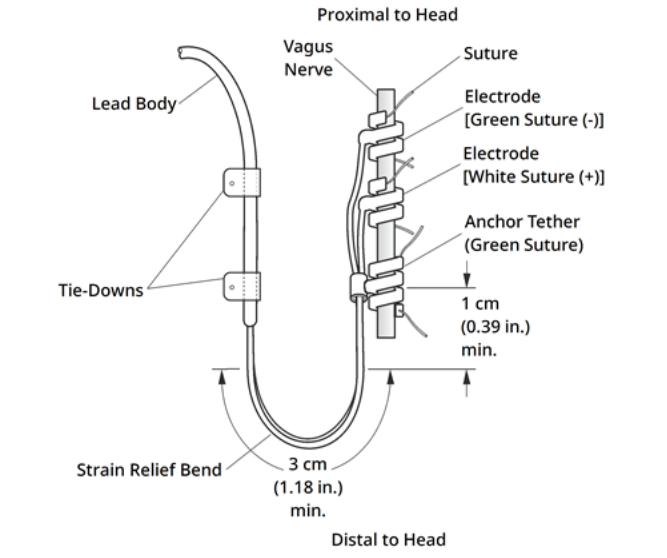
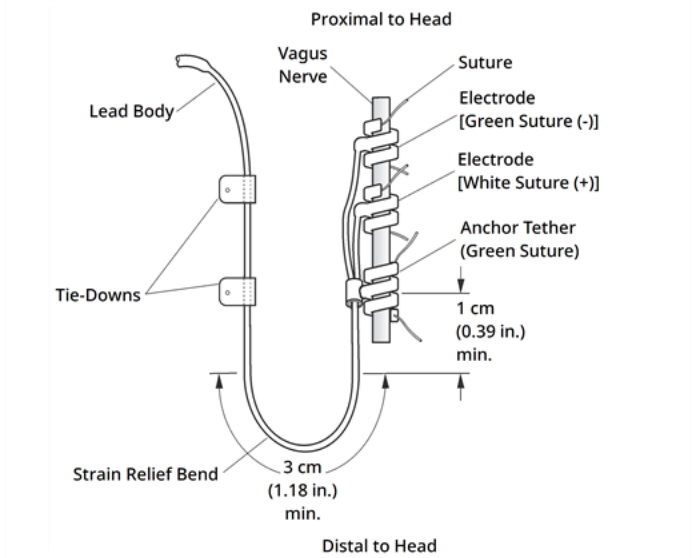
Model 303 lead only: Pay careful attention to the previously placed anchor tether and electrodes so they do not come unattached. Slight pressure may be placed against the anchor tether with a surgical instrument to ensure support to the anchor tether while the strain relief bend is formed).

Figure 28. Model 303 Only – Use of surgical tool (e.g., forceps) to support the anchor tether during strain relief formation



2. Loosely attach the 3-cm strain relief bend to the adjacent fascia with tie-downs before you route the lead over the muscle. The first tie-down should be positioned laterally to the anchor tether tie-downs are provided in the lead sales pack.

Figure 29. Use of Tie-Downs in Electrode Placement

Model 302 Model 304	Model 303
	

Form the Strain Relief Loop

⚠ CAUTION: **Leave enough extra lead** on both sides of the clavicle to prevent damage to the lead caused by tension over the clavicle.

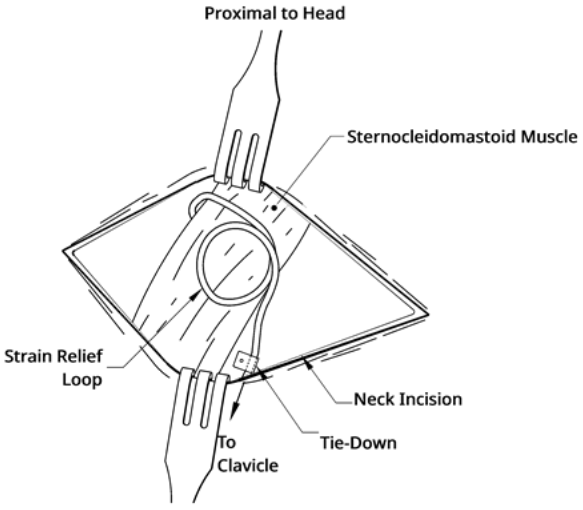
⚠ CAUTION: Do not place the sutures directly around the body of the lead; this could result in insulation failure and system malfunction, and possible lead breakage.

⚠ CAUTION: Use only supplied tie-downs to secure the lead.

To form the strain relief loop above the sternocleidomastoid muscle, complete the following steps:

1. In the neck, form the lead into a large subcutaneous loop.
2. Loosely attach it to fascia with a tie-down before the lead is routed over the clavicle. This strain relief loop should be large enough to provide several inches / centimeters of lead extension when the neck is turned to its maximum stretched position.

Figure 30. Strain Relief Loop



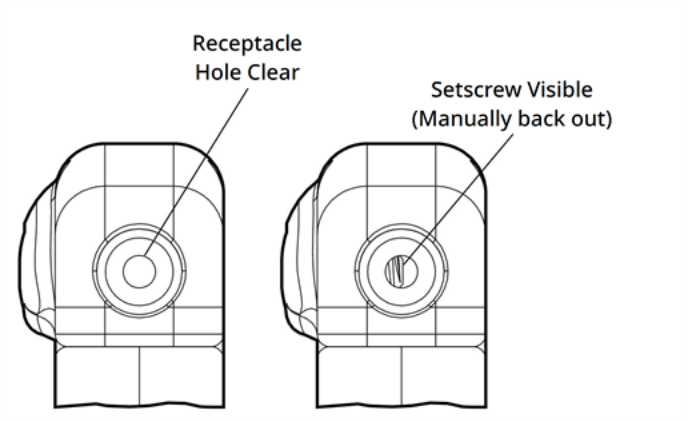
6.6.5. Connect the Lead to the Generator

⚠ CAUTION: Do not use electrosurgical equipment after the generator has been introduced to the sterile field. Exposure to this equipment may damage the generator.

ⓘ NOTE: For the dual-receptacle generator, these directions apply to both receptacles, pins, plugs, and setscrews.

1. Look inside the generator receptacle to verify that no obstruction exists. Ensure that the setscrew is backed out adequately to allow full insertion of the connector pin. Do not back the setscrew out further than needed for lead insertion.

Figure 31. Generator Receptacle and Setscrew



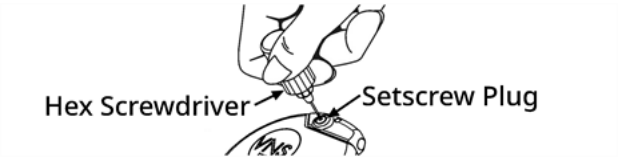
NOTE: Contrast between a clear and a blocked receptacle hole. Applies to single or dual pin headers.

CAUTION: When you use the hex screwdriver, grasp it by the handle only. Do not grasp any other portion of the hex screwdriver during use, as this may affect its proper function. If the metal shaft is touched while the hex screwdriver is engaged with the set screw, an electrostatic discharge into the device circuitry can be conducted, which can damage the generator.

CAUTION: In the steps below, ensure that the hex screwdriver is fully inserted in the setscrew and **always push down on the hex screwdriver while you turn it clockwise until it clicks** (begins to ratchet). Also, the hex screwdriver must be inserted into the center of the silicone rubber setscrew plug and kept perpendicular to the generator to avoid stripping the setscrew and/or dislodging the setscrew plug.

2. Keep the hex screwdriver perpendicular to the generator. Insert the hex screwdriver through the center of the setscrew plug to vent back pressure accumulated during lead insertion.

Figure 32. Hex Screwdriver Position



3. When a single-receptacle generator and single-pin lead is used, insert the lead connector pin fully into the generator header. To allow escape of the back pressure created by insertion, leave the tip of the hex screwdriver in the slit in the setscrew plug.

   When a dual-receptacle generator and dual-pin lead are used, insert the lead connector pins fully into the appropriate generator receptacles in the generator header. To allow escape of the back pressure created by insertion, leave the tip of the hex screwdriver in the slit in the setscrew plug of the connector being inserted. Insert the lead connector with the white marker band and with

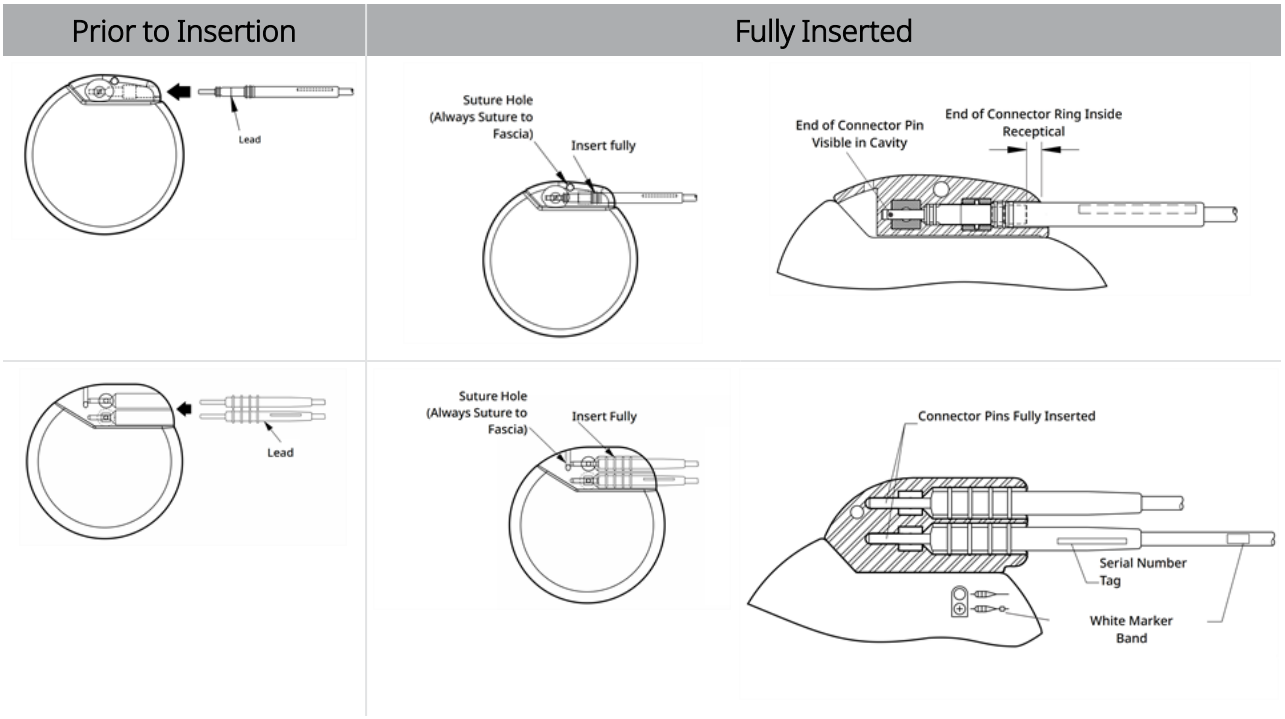
the embedded model number and serial number tag into the generator receptacle labeled "+" (see the dual-receptacle generator portion of the figure below). The other lead connector is inserted into the other generator receptacle.

⚠ CAUTION: Do not back the setscrew out completely. When you loosen during surgery, use no more than two counterclockwise turns.

⚠ CAUTION: **Reversal of lead polarity has been associated with an increased chance of bradycardia** in animal studies. It is important to make sure that the lead connector pins in the VNS Therapy dual-pin lead are correctly inserted (white marker band to + connection) into the generator dual receptacles.

4. With the hex screwdriver still inserted through the setscrew plug, verify that the connector pin is fully inserted. The pin should be visible in the area at the back end of the setscrew connector block. For a dual-receptacle generator, repeat this procedure for each setscrew.

Figure 33. Lead Connectors Prior to Insertion and Fully Inserted



5. If the pin is not visible, remove it. To loosen the setscrew, engage the hex screwdriver into the setscrew, and turn it counterclockwise until the connector pin can be fully inserted. Do not back the setscrew out further than needed for lead insertion. For a dual-receptacle generator, repeat this procedure for each setscrew.
6. After you verify that the connector pin is fully inserted, tighten the setscrew. Engage the hex screwdriver fully, push in, and turn the hex screwdriver clockwise until it begins to click. Always push in on the hex screwdriver as it is turned to ensure that it is fully inserted in the setscrew.

CAUTION:
It is important to do the following:

- Ensure that the generator receptacle is clean and free of obstruction.
- Carefully insert the lead connector pin into the generator receptacle without bending the lead connector.
- Visually inspect that the connector pin is clean and completely inserted.
- **Electrical connection to the generator is not established until the setscrew is completely tightened with the hex screwdriver.** Failure to make a good connection can result in HIGH impedance during a System Diagnostics or erratic stimulation at varying intensity due to rapid, unpredictable changes in lead impedance, which is expected to adversely affect device effectiveness and may have serious safety consequences.
- Gently grasp and pull on lead connector boot (the thick section of the lead) to verify the lead is properly secured inside the generator receptacle. Do not pull on the lead body (thin section) or use excessive pull force, because this may cause lead damage.

6.6.6. Test the System

The System Diagnostics, which should be conducted first, is performed with the lead and the generator connected. Thus, if the System Diagnostics is successful, both components are working properly. However, if the System Diagnostics fails, either of the two components could be defective, or there may not be a good electrical connection between the generator and the lead connector pin. If a defective component is suspected, disconnect the lead and perform the optional Generator Diagnostics. Use the resistor assembly supplied with the accessory pack.

NOTE: The Wand should be placed into a sterile laser arm bag or equivalent (Not provided by LivaNova) in order to introduce the Wand into the sterile field.

WARNING: It is important to follow recommended implantation procedures and intra-operative product tests described in the "Implantation Procedure Overview" on page 90. During the intra-operative System Diagnostics infrequent incidents of bradycardia and/or asystole have occurred. If asystole, severe bradycardia (heart rate < 40 bpm), or a clinically significant change in heart rate is encountered during a System Diagnostics or during initiation of stimulation, physicians should be prepared to follow guidelines consistent with Advanced Cardiac Life Support (ACLS).

Additionally, postoperative bradycardia can occur among patients with certain underlying cardiac arrhythmias. If a patient has experienced asystole, severe bradycardia (heart rate < 40 bpm), or a clinically significant change in heart rate during a System Diagnostics test at the time of initial device implantation, the patient should be placed on a cardiac monitor during initiation of stimulation.

The safety of this therapy has not been systematically established for patients that experience bradycardia or asystole during VNS Therapy system implantation.

6.6.6.1. System Diagnostics

System Diagnostics is performed intraoperatively when the lead and the generator are connected. The test checks the connection between the lead, generator, and the nerve. Depending on the generator model and programmed Normal Mode output current, different test pulses (as shown below) may be conducted during the test.

Table 33. System Diagnostics Behavior

Normal Mode Output Current	Model 1000 Model 1000-D	Model 106 Model 105 Model 104 Model 103 Model 8103	Model 102 Model 102R
0 mA	Delivery of programmed output for approximately 4 seconds, followed by one brief pulse at 0.25 mA for less than 130 µsec.*	1 mA, 500 µsec for approximately 14 seconds	1 mA, 500 µsec for approximately 14 seconds
> 0 mA		One brief pulse at 0.25 mA, 130 µsec, followed by delivery of programmed output for the duration of the programmed ON time.	
	NOTE: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours.	NOTE: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours.	N/A

*Minor differences in the system diagnostics test exist for Model 1000 with serial numbers < 100,000. For more information, see Model 1000 (Serial Numbers < 100,000 Only) in the indication specific physician's manual.

To ensure proper system connection and functionality, perform the test and assess the following:

Model	Assess	
Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	Verify that System Diagnostics is successful (output current and lead impedance are **OK**).	
	IF	**THEN**
	The System Diagnostics fails (output current **LOW** or lead impedance **HIGH** or **LOW**).	See "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com . CAUTION: Electrical connection between the generator and the lead connector pin may be at fault.

<table>
<tr><th>Model</th><th colspan="2">Assess</th></tr>
<tr><td rowspan="3">Model 102
Model 102R</td><td colspan="2">Verify that the lead impedance status is OK.</td></tr>
<tr><td>IF</td><td>THEN</td></tr>
<tr><td>Lead impedance status is not OK.</td><td>See "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com .

⚠ CAUTION: Electrical connection between the generator and the lead connector pin may be at fault.</td></tr>
</table>

6.6.6.2. Generator Diagnostics

The optional Generator Diagnostics is performed when the test resistor is attached to the generator in cases of troubleshooting during surgery. When the System Diagnostics fails (lead impedance HIGH or LOW), the Generator Diagnostics can be used to determine whether the cause of the problem is the lead or the generator. The Generator Diagnostics is performed with the test resistor that is included in the accessory pack. This test verifies that the generator functions properly, independent of the lead.

To connect the test resistor to the generator, perform these steps:

ⓘ NOTE: For the dual-receptacle generator, these directions apply to both receptacles, pins, plugs, and setscrews.

1. Remove the lead connector pin from the generator receptacle. To do so, insert the hex screwdriver through the center of the setscrew plug and loosen the setscrew. Do not back the setscrew out more than necessary to remove the lead. No more than a half turn should be required.
2. Insert the connector pin of the resistor assembly into the generator receptacle. Be careful during the insertion of the test resistor pin into the generator receptacle. If significant resistance is felt or it binds, remove the test resistor, inspect it, and clean it if necessary. Without the use of excessive force, re-insert the test resistor.

   ⓘ NOTE: Fully insert the hex screwdriver into the setscrew and push in on the hex screwdriver whenever the setscrew is tightened or loosened.

3. When the resistor assembly is in place, tighten the setscrew until the hex screwdriver begins to click. Always push in on the hex screwdriver while you turn it to ensure that the hex screwdriver is fully inserted in the setscrew.

Figure 34. Connect the Resistor Assembly

4. Perform Generator Diagnostics and assess the following:

IF	THEN
The Generator Diagnostics is successful (Lead Impedance is **OK**)	The generator is working properly.
The Generator Diagnostics fails (Lead Impedance is **HIGH** or **LOW**)	See "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com .
If the component is damaged	Contact "Technical Support" on page 179, and disinfect and return the item along with a completed Returned Product Form. See Return Product Form to download a copy of the form.

NOTE: See the model-specific programming system manual posted at www.livanova.com.

6.6.6.3. Optional Monitoring

Optional physiologic monitoring of VNS Therapy system operation may be done if surgery is performed under local anesthesia. Monitor the patient's voice for signs of hoarseness while the generator output current is gradually increased. After System Diagnostics is performed and successful results are obtained, reset the current to 0 mA.

6.6.7. Complete the Implant Procedure

After tests have been completed, finish the implantation procedure:

1. If not already performed, place the generator in the chest pocket. Coil the lead slack that remains and place it to the side of the generator. Either side of the generator can face outward.

CAUTION: Do not place the lead slack under the generator, because this could result in insulation failure and system malfunction.

2. Secure the generator: Place a suture through the suture hole and attach it to fascia (not to muscle).

   ⚠ CAUTION: It is important to suture the generator to fascia to stabilize it and prevent manipulation by the patient, which could damage the lead wires.

   ⚠ CAUTION: Do not place the sutures directly around the body of the lead; this could result in insulation failure and system malfunction, and possible lead breakage.

3. Perform the second System Diagnostics and verify lead impedance status remains "OK."
4. Interrogate the generator to verify that output current is 0 mA.

   - Normal current: 0 mA
   - Magnet current: 0 mA
   - AutoStim current: 0 mA Model 1000 Model 1000-D Model 106

   Contact "Technical Support" on page 179.

   ⚠ CAUTION: **Do not program the VNS Therapy system to an ON or periodic stimulation treatment for at least 14 days after the initial or replacement implantation.** Failure to observe this precaution may result in patient discomfort or adverse events.

5. Irrigation of both incision sites with generous amounts of bacitracin or equivalent solution before closure is recommended.
6. Close the surgical incisions. Use cosmetic closure techniques to minimize the development of scars.
7. Administer antibiotics postoperatively (at the discretion of the physician).

A neck brace can be used by the patient for the first week to help ensure proper lead stabilization.

6.7. Post-Implant Patient Materials

6.7.1. Implant Warranty and Registration Form

Included with the generator is an Implant Warranty and Registration Form that *must* be completed. Space is provided to record both the generator and the lead. If the surgery is for a replacement, include explanted device information. Follow the instructions provided on the form to return a copy to LivaNova, retain a copy for the surgical center, and provide a copy to the patient or caregiver.

LivaNova recommends all local privacy laws be followed when this form is completed. This information is required by some government agencies. Completed forms returned to LivaNova are entered into the implant registry and used as a permanent record of implant recipient information. All applicable privacy laws are followed in the maintenance and security of this information.

To download an electronic copy to return or print, see "Implant and Warranty Registration Form" posted at www.livanova.com.

6.7.2. Patient Magnet Kit

Give the patient a Patient Magnet kit, which contains magnets, accessories, and other patient materials.

6.7.3. Patient Implant Card

The implant card contains information about the patient's VNS Therapy system. Give the cards to the patient and/or caregiver after the implant and tell them to complete it with their device information (if not already included), the patient's name, or other identification information (e.g., patient number) and their prescriber name and phone number. Tell them to carry it with them at all times.

CHAPTER 7

Post-Implant Management

This topic includes the following concepts:

7.1. Guidelines for Depression Patient Follow-Up

During the first few weeks after implantation of new or replacement devices, the patient should be seen to confirm wound healing and proper generator operation. The generator's output current for the programmed stimulation in all modes must be 0 mA for the first 14 days after implantation.

The VNS Therapy system is an adjunctive therapy to current (prior to device implantation) antidepressant medications. Physicians are encouraged to keep all antidepressant medications stable for the first 3 months of stimulation before a patient's medication is reduced or changed.

During initial programming, the output current should be programmed to start at nominal parameters (0 mA) and then slowly increased in 0.25 mA increments until the patient feels the stimulation at a comfortable level. Patients who receive replacement generators should also be started at nominal parameters, with 0.25 mA-step increases to allow re-accommodation.

At each patient visit, use the appropriate version of the VNS Therapy programming software to interrogate the generator. After reprogramming and/or diagnostics testing, record and file the data. These data can be used for comparison with a patient's own records to evaluate the VNS Therapy system, to confirm proper system function, and to assess the need to reprogram. At the end of the session, perform a final interrogation to confirm parameters are set to the intended dose before the patient leaves the office.

The median output current used during the clinical studies was about 1 mA. Other standard treatment settings were 20 Hz, 500 µsec pulse width, 30 sec ON time, and 5 min OFF time. There are no data to verify that these are optimal parameters.

There is no proven correlation at present between high output current (mAmps) and device effectiveness, nor is there a standard treatment level that needs to be achieved during treatment ramping. VNS Therapy treatment should not be uncomfortable, nor should it cause bothersome side effects. Patients should be observed for at least 30 minutes after the last stimulation adjustment to make certain that they are comfortable with programmed stimulation.

Although LivaNova recommends adjustment of the output current as necessary, there are no controlled data at this time to indicate that higher current levels are associated with better effectiveness. Patients whose depression is well controlled at follow-up should not have their settings changed unless they experience uncomfortable side effects.

The physician determines the subsequent follow-up schedule and the nature of each examination based on patient response to and tolerance of the implant. In all other respects, follow up is performed in accordance with the standard medical practice for patients with epilepsy.

If intolerable adverse events are reported, try to reduce stimulation parameters to eliminate or reduce the severity. Additionally, instruct patients or caregivers on the application of the magnet to turn the generator off (output current 0 mA) if an adverse event becomes intolerable.

7.2. Individualization of Treatment

Patients should be started on stimulation at a low current output setting (0.25 mA), and the current should be increased gradually to allow accommodation to the stimulation. For patient comfort, the output current should be increased in 0.25 mA increments until a tolerable level is reached, at which improvement in depression symptoms are seen. Physicians should appreciate that some patients will accommodate to stimulation levels over time and should therefore allow further increases (in 0.25 mA steps) in output current, if needed.

Table 34. Stimulation Parameters at 12 Months of VNS Therapy in the Pivotal (D-02) Study

Stimulation Parameters*	Median Value at 12 Months	Range
Output current (mA)	1.0	0 to 2.25
Frequency (Hz)	20 Hz	2 to 30 Hz
Pulse width (µsec)	500 µsec	130 to 750 µsec
ON time (seconds)	30 sec	7 to 60 sec
OFF time (minutes)	5 min	0.3 to 180 min

* The magnet output current should be set to 0 mA.

7.3. Patient Counseling Information

In the unlikely event of uncomfortable adverse events, continuous stimulation, or other malfunction, instruct the patient or caregiver to hold or tape the magnet directly over the implanted generator to prevent additional stimulation. If patients or caregivers find this procedure necessary, they should immediately notify the patient's physician.

CHAPTER 8

Revision, Replacement, and Removal Procedure

This topic includes the following concepts:

8.1. Introduction

Revision, replacement, or removal of the VNS Therapy system or any component of the system may be needed for several reasons:

- Replacement of the generator may be required due to generator NEOS or if EOS has been reached and the generator cannot communicate or provide therapy.
- Revision or replacement of the lead may be necessary if a broken or damaged lead is suspected, based on diagnostic tests or x-ray evaluation.
- Removal of the system may be required in cases of infection or for certain medical procedures.

NOTE: For precautions related to the implantation procedure, see "Precautions—Related to Implantation" on page 24.

NOTE: Return explanted, or opened and unused component(s) of the VNS Therapy system to LivaNova. A Return Product Kit is available from "Technical Support" on page 179. See Return Product Form for an electronic copy of the form.

These instructions are intended to be general guidelines. If you have questions about the procedures, contact "Technical Support" on page 179.

8.2. Components and Surgical Materials

8.2.1. Generator Replacement or Revision

Table 35. Components Needed for Generator Replacement or Revision

Components Needed for Surgery	Single-Receptacle Generator	Dual-Receptacle Generator
Dual-receptacle Generator	N/A	1 primary 1 backup
Single-receptacle Generator	1 primary 1 backup	2 backups (in case lead must also be replaced)
Single-pin Lead	2 backups (in case lead must also be replaced)	2 backups (in case lead must also be replaced)
Accessory Pack	1 accessory pack (test resistors, hex screwdriver and tie-downs)	1 accessory pack (test resistors, hex screwdriver and tie-downs)
Programming System	1 programming system	1 programming system
Tunneler	1 tunneler (if lead is replaced)	1 tunneler (if lead is replaced)
Sterile Laser Arm Bag or equivalent*	Required	Required
Soft vessel loops or silicone sheet*	Used for manipulation of the vagus nerve (suggested but optional)	Used for manipulation of the vagus nerve (suggested but optional)

* Not provided by LivaNova.

8.2.2. Lead Replacement or Revision

Table 36. Components Needed for Lead Replacement or Revision

Components Needed for Surgery	Lead Replacement or Revision
Dual-receptacle generator	Do not use
Single-receptacle generator	2 backups (in case the generator must also be replaced)
Single-pin lead	1 primary 1 backup
Accessory Pack	1 accessory pack (test resistors, hex screwdriver and tie-downs)
Programming System	1 programming system
Tunneler	1 tunneler
Sterile Laser Arm Bag or equivalent*	Required

Table 36. Components Needed for Lead Replacement or Revision (continued)

Components Needed for Surgery	Lead Replacement or Revision
Soft vessel loops or silicone sheet*	Suggested but optional

* Not provided by LivaNova.

NOTE: For lead size availability, see "Physical Characteristics" on page 65.

8.3. How to Open the Sterile Pack

Before any sterile pack is opened, examine it carefully for evidence of damage or compromised sterility. If the outer or inner sterile barrier has been opened or damaged, LivaNova cannot guarantee sterility of the contents, and it should not be used. An opened or damaged product should be returned to LivaNova.

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

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

8.3.1. Generator and Lead

To open the sterile pack, complete the following steps:

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

8.3.2. Tunneler

To open the sterile pack, complete the following steps:

1. Grasp the tab and peel back the outer cover.
2. Use sterile technique to lift out the sterile inner tray.
3. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.
4. Remove all four pieces in the package (shaft, bullet tip, large-diameter sleeve, small-diameter sleeve).

8.3.3. Accessory Pack

To open the sterile pack, complete the following steps:

1. Grasp the tab and peel back the outer cover.
2. Use sterile technique to lift out the sterile inner tray.

3. Grasp the inner tray's tab and carefully peel off the cover to expose the contents without dropping them.
4. To remove the hex screwdriver, a resistor assembly, or tie-downs, push down on one end of the item and grasp the opposite (raised) end.

8.4. Revision—Pre-Operative Steps

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

For a list of components and surgical materials, see "Components and Surgical Materials — New Implant" on page 86.

8.4.1. Before Surgery

8.4.1.1. Generator

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

8.4.1.2. Lead

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

8.4.2. Before Patient Enters OR

8.4.2.1. Generator

Interrogate and perform a System Diagnostics on the current generator to confirm generator replacement is required and to determine whether the function of the current lead is normal. For detailed information about System Diagnostics see "Test the System" on page 103.

IF	THEN
Lead Impedance = **OK**	Replace only the generator. See "Generator Replacement—Intra-Operative Steps" on the next page.
Lead Impedance = **HIGH** or **LOW**	The lead requires removal or replacement. See "Lead Replacement—Intra-Operative Steps" on page 118.
The x-ray review shows a gross discontinuity in the lead (i.e., lead break or pin disconnected)	The lead requires removal or replacement. See "Lead Replacement—Intra-Operative Steps" on page 118.

8.4.2.2. Lead

Interrogate and perform a System Diagnostics test on the existing generator to confirm lead replacement is required and to determine whether the function of the existing generator is normal. For detailed information about System Diagnostics see "Test the System" on page 103.

IF	THEN
Lead Impedance = **OK**	The implanted lead is functioning properly. Reassess the need for surgery or if replacement of the generator is desired, see "Generator Replacement—Intra-Operative Steps" below.
There is no gross discontinuity in the lead from the x-ray review	
A short-circuit condition is not suspected	
Lead Impedance = **HIGH** or **LOW**	The lead requires removal or replacement. If replacement of the generator is desired, see "Generator Replacement—Intra-Operative Steps" below
The x-ray review shows a gross discontinuity in the lead [lead break or pin disconnected]	

8.4.3. In the OR Before Generator Replacement

1. Interrogate the replacement generator outside the sterile field in the OR to ensure clear communication.
2. Program the patient data into the new generator.

8.4.4. Replacement

8.4.4.1. Generator

To continue with generator replacement instructions, see "Generator Replacement—Intra-Operative Steps" below.

8.4.4.2. Lead

To continue with lead replacement instructions, see "Lead Replacement—Intra-Operative Steps" on the next page.

8.5. Generator Replacement—Intra-Operative Steps

⚠ CAUTION: Do not use electrosurgical equipment after the new generator has been introduced to the sterile field. Exposure to this equipment may damage the generator.

ⓘ NOTE: For the dual-receptacle generator, these directions apply to both receptacles, pins, plugs, and setscrews.

1. With the lead pin still connected, remove the existing generator from the pocket.
2. Open the new generator sales pack.
3. Use the hex screwdriver to disconnect the existing generator from the implanted lead. Remove the lead connector pin from the generator receptacle. Insert the hex screwdriver through the center of the setscrew plug and loosen the setscrew. Do not back the setscrew out more than necessary to remove the lead. No more than half a turn should be required.

   ⚠ CAUTION: When you use the hex screwdriver, grasp it by the handle only. Do not grasp any other portion of the hex screwdriver during use, as this may affect its proper function. If the metal shaft is touched while the hex screwdriver is engaged with the set screw, an electrostatic discharge into the device circuitry can be conducted, which can damage the generator.

   ⓘ NOTE: Extraneous pocket space left behind from the replacement of a larger generator with a smaller generator may increase the likelihood of certain adverse events (e.g., seroma, device manipulation, and device migration).

   ⓘ NOTE: Replacement of a smaller generator with a larger generator may require enlargement of the generator pocket during surgery. Physicians should assess the potential impact to post-surgical recovery time and likelihood of temporary patient discomfort due to surgical alteration of the generator pocket.

   ⓘ NOTE: It is preferable to place the generator along the axillary border, at or above anterior rib 4, so the patient can have the maximum flexibility for MRI postoperatively.

4. Connect the replacement generator to the lead.
5. To continue with generator replacement instructions, see "Connect the Lead to the Generator" on page 100.

8.6. Lead Replacement—Intra-Operative Steps

ⓘ NOTE: For the dual-receptacle generator, these directions apply to both receptacles, pins, plugs, and setscrews.

ⓘ NOTE: For complete troubleshooting steps, see "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com.

8.6.1. System Diagnostics Reports “HIGH” Lead Impedance

If “HIGH” lead impedance is reported, perform the following steps:

1. With the lead pin still connected, remove the existing generator from the pocket.
2. Open the accessory pack and remove the hex screwdriver and test resistor.

3. Remove the lead connector pin from the generator receptacle. Insert the hex screwdriver through the center of the setscrew plug and loosen the setscrew. Do not back the setscrew out more than necessary to remove the lead. No more than a half turn should be required.
4. If foreign material (e.g., blood) is observed in the generator receptacle, flush the receptacle with saline to remove the foreign material. Drain the excess fluid from the receptacle. Do not place any object (other than the connector pin) into the receptacle. Use saline to clean the lead connector pin, then wipe dry.
5. Follow proper lead insertion techniques to re-insert the existing lead connector pin into the existing generator.

   ⚠ CAUTION: Visually inspect that the connector pin is clean and completely inserted.

   ⓘ NOTE: For proper lead insertion techniques, see "Connect the Lead to the Generator" on page 100.
6. Introduce the programming system into the sterile field with a sterile laser arm bag (or equivalent) and perform an interrogation followed by System Diagnostics.
7. Record System Diagnostics results.

IF	THEN	
Lead Impedance = **OK**	The previous **HIGH** lead impedance is resolved and the system appears to function properly. Assess replacement of the generator.	
	IF	THEN
	Replacement of the generator *is not desired*	Verify that all relevant steps outlined in "Test the System" on page 103 have been completed. Finish the procedure. See "Complete the Implant Procedure" on page 106.
	Replacement of the generator *is desired*	Open an new compatible generator sales pack. Follow the steps in "Connect the Lead to the Generator" on page 100 to connect the replacement generator to the lead, then complete the remainder of the implantation procedure. Ensure appropriate patient data has been programmed into the new generator.
Results continue to report **HIGH** lead impedance	Perform Generator Diagnostics to verify that the generator functions properly, independent of the lead. Follow the steps in "Generator Diagnostics" on the next page.	

8.6.2. System Diagnostics Reports “LOW” Lead Impedance

IF	THEN
System Diagnostics reports **LOW** lead impedance	Perform Generator Diagnostics to verify that the generator functions properly, independent of the lead. Follow the steps in "Generator Diagnostics" on the next page.

8.6.3. Generator Diagnostics

1. Remove the lead connector pin from the generator receptacle. To do so, insert the hex screwdriver through the center of the setscrew plug and loosen the setscrew. Do not back the setscrew out more than necessary to remove the lead. No more than a half turn should be required.
2. Insert the connector pin of the resistor assembly into the generator receptacle. Be careful during the insertion of the test resistor pin into the generator receptacle. If significant resistance is felt or it binds, remove the test resistor, inspect it, and clean it if necessary. Without the use of excessive force, re-insert the test resistor.
3. When the resistor assembly is in place, tighten the setscrew until the hex screwdriver begins to click. Always push in on the hex screwdriver while you turn it to ensure that the hex screwdriver is fully inserted in the setscrew.

Figure 35. Resistor Assembly Connection for Single and Dual Receptacle Generators

4. Perform Generator Diagnostics and assess the following:

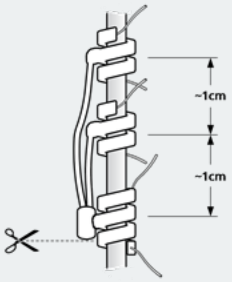
IF	THEN
Generator Diagnostics results indicate **HIGH** or **LOW** lead Impedance	See "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com
Generator Diagnostics results indicate **OK** lead Impedance	The implanted lead should be replaced and generator replacement assessed.

8.6.4. Remove Helices and Lead

⚠ CAUTION: Lead replacement or removal is a medical judgment that must be carefully weighed against the known and unknown risks of surgery. At present there are no known long-term hazards or risks associated with leaving the lead implanted, beyond those mentioned in this physician's manual.

1. Open the neck incision and locate the vagus nerve / helices interface.
2. Assess the degree of fibrotic encapsulation to determine if the entire lead can be removed safely.

IF	THEN
Complete removal of the existing helices can be accomplished.	The new helices may be placed in the same location.

IF	THEN
Complete removal of the helices from the nerve *is not possible* 	Transect as much of the lead as possible. If ≤ 2 cm of the lead remains, a full body MRI using the body coil to transmit RF is allowable. If it is not possible to leave ≤ 2 cm, then MRI can still be performed for brain or extremity imaging with the appropriate type of T/R coil. For additional details, see the MRI Guidance posted at www.livanova.com.

3. The replacement helices can be placed above or below the existing helices if they must remain.

8.6.5. Complete the Procedure

To continue with lead replacement instructions, see "Place the Electrodes" on page 94. Pay particular attention to all warnings and precautions that pertain to the cardiac branches.

NOTE: The physician (prescriber) will program the stimulation parameters post-operatively after the recommended 2-week recovery period to allow the nerve to heal.

8.7. System Removal

CAUTION: Explanted generators and leads are medical waste and should be handled in accordance with local laws. They should be returned to LivaNova for examination and proper disposal, along with a completed Return Product Form. Before device components are returned, disinfect them with Betadine®, Cidex® soak, or other similar disinfectant, and double seal them in a pouch or other container properly labeled with a biohazard warning. For directions, see "Contacts and Resources" on page 179.

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

If removal is medically necessary, LivaNova recommends removing as much of the VNS Therapy system as can be safely accomplished:

- Assess the degree of fibrotic in-growth in and around the helices.
- Remove the entire system, if possible.
- If fibrotic encapsulation hinders safe removal of the entire system, transect as much of the lead wire as possible. See "Remove Helices and Lead" on the previous page.
- Removal of the generator alone does not alter the hazards associated with certain MRI procedures.

  NOTE: For details, see MRI Guidance posted at www.livanova.com.

- Diathermy procedures are contraindicated for patients with any portion of the VNS Therapy system that remains in the body. For details, see "Contraindications" on page 17.

A Returned Product Form is used for the return of any VNS Therapy system component. See Return Product Form to access an electronic copy.

CHAPTER 9

Troubleshooting

This section provides solution steps to resolve error conditions with the programming system components. For other programming system issues not included in this section, contact "Technical Support" on page 179.

This topic includes the following concepts:

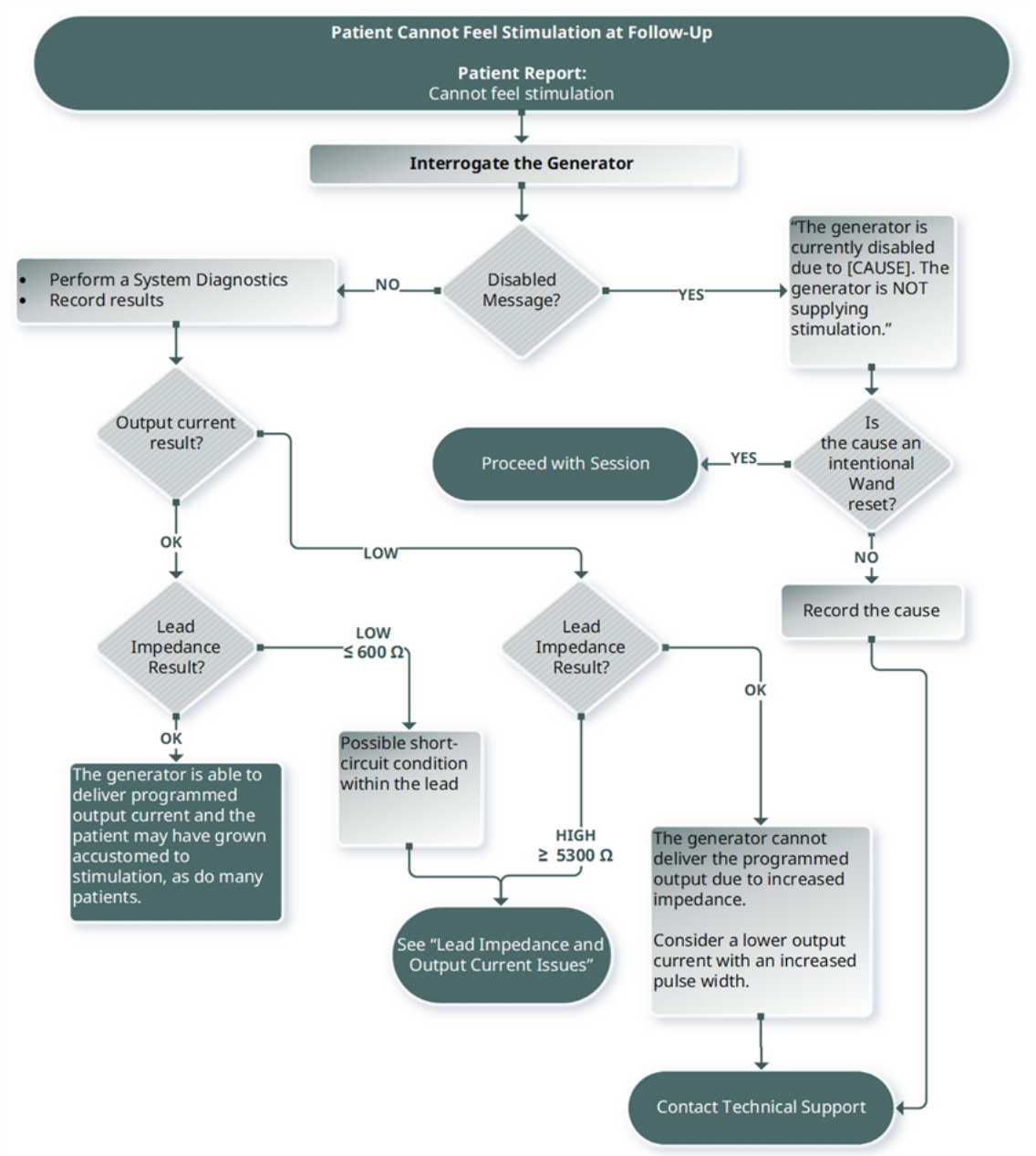
9.1. Patient Cannot Feel Stimulation at Follow-Up

9.1.1. Possible Causes

- Patient has become accustomed to the programmed setting
- Generator battery at end of service (EOS)
- High lead impedance
- Defective generator
- Disabled generator
- Short-circuit condition within the lead

9.1.2. Solution Steps

Applicable Models:	Model 1000	Model 1000-D	Model 106	Model 105	Model 104	Model 103	Model 8103



Applicable Models: Model 102 Model 102R

STEP 1	Interrogate the generator.	
STEP 2	Perform a System Diagnostics and record the results.	
	IF	THEN
	Model 250 V11.0 and below—The DC-DC Converter Code is 0 or there has been a significant decrease in DC-DC Converter Code value (e.g., 3 to 1) in respect to prior System Diagnostics **Model 3000 V1.0 and above**—The impedance is ≤ 1700 Ω or if there has been a sudden change in impedance range (e.g., 4100–5200 Ω to 1800–2800 Ω) in respect to prior System Diagnostics	A short-circuit condition may be present within the lead and the patient may not receive the intended therapy.
	Model 250 V11.0 and below—The DC-DC Converter Code is not 0, there has been no significant decrease in DC-DC Converter Code value (e.g., 3 to 1) in respect to prior tests, and the System Diagnostics test indicates the lead impedance is **OK** **Model 3000 V1.0 and above**—The System Diagnostics test indicates the lead impedance is **OK**	The system is functioning properly and the patient could have become accustomed to the settings, as do many patients.
	System Diagnostics indicates the lead impedance is **HIGH**	For troubleshooting, see "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com.
	⚠ CAUTION: For the system, the software automatically programs the generator to 1 mA, 500 µsec, and 20 Hz. Patients whose generator output current is normally *less than* these values may experience increased sensation, cough, flushed face, or other effects.	

STEP 3	Perform a Normal Mode Diagnostics test and record the results.	
	IF	THEN
	The Normal Mode Diagnostics test indicates the output current is **LIMIT.**	The generator cannot deliver programmed output. Consider a reduction in the output current or frequency, and a wider pulse width.
	The Normal Mode Diagnostics test indicates the output current is **OK.**	The generator can deliver the programmed output current. NOTE: To obtain accurate information from the device diagnostics, the generator must be programmed to a **minimum** of 0.75 mA, 15 Hz, and **at least** 30 seconds ON time.
	The Normal Mode Diagnostics test indicates **HIGH** lead impedance.	For troubleshooting, see "Lead Impedance Issues" in the model specific programming system manual posted at www.livanova.com.

If further assistance is needed, contact "Technical Support" on page 179.

CHAPTER 10

Battery Longevity Tables

This topic includes the following concepts:

10.1. Model 1000 / Model 1000-D Battery Longevity and Programmed Setting Choices

10.1.1. AutoStim Feature Disabled

AutoStim Feature Disabled Model 1000 Model 1000-D											
Parameters at 3 kΩ			Normal Mode Duty Cycle								
			10% (30s ON / 5 min OFF)			35% (30s ON / 1.1 min OFF)			51% (60s ON / 1.1 min OFF)		
			BOL to IFI	IFI to NEOS	NEOS to EOS	BOL to IFI	IFI to NEOS	NEOS to EOS	BOL to IFI	IFI to NEOS	NEOS to EOS
mA	Hz	µS	Years	Years	Years	Years	Years	Years	Years	Years	Years
0.5	20	250	11.9	1.2	1.2	6.1	0.6	0.6	4.6	0.5	0.5
0.5	20	500	11.8	1.2	1.2	6.0	0.6	0.6	4.5	0.5	0.5
0.5	30	250	10.2	1.0	1.0	4.7	0.5	0.5	3.5	0.4	0.4
0.5	30	500	10.1	1.0	1.0	4.6	0.5	0.5	3.4	0.3	0.3
1	20	250	11.7	1.2	1.2	5.9	0.6	0.6	4.5	0.5	0.4
1	20	500	11.6	1.2	1.1	5.8	0.6	0.5	4.4	0.4	0.4
1	30	250	10.0	1.0	1.0	4.5	0.5	0.5	3.3	0.3	0.3
1	30	500	9.9	1.0	1.0	4.4	0.4	0.4	3.2	0.3	0.3
1.5	20	250	11.4	1.1	1.1	5.7	0.6	0.5	4.2	0.4	0.4
1.5	20	500	9.4	0.9	0.8	4.1	0.4	0.3	3.0	0.3	0.2
1.5	30	250	9.8	1.0	0.9	4.4	0.4	0.4	3.2	0.3	0.3
1.5	30	500	7.7	0.7	0.7	3.1	0.3	0.2	2.2	0.2	0.2
2	20	250	9.7	0.9	0.8	4.3	0.4	0.3	3.2	0.3	0.2
2	20	500	7.2	0.7	0.6	2.8	0.3	0.2	2.0	0.2	0.2
2	30	250	8.2	0.8	0.7	3.3	0.3	0.3	2.4	0.2	0.2
2	30	500	5.6	0.5	0.5	2.0	0.2	0.2	1.4	0.1	0.1
2.5	20	250	7.9	0.7	0.7	3.2	0.3	0.2	2.3	0.2	0.2
2.5	20	500	5.5	0.5	0.4	1.9	0.2	0.1	1.4	0.1	0.1
2.5	30	250	6.5	0.6	0.5	2.4	0.2	0.2	1.7	0.2	0.1
2.5	30	500	4.2	0.4	0.3	1.4	0.1	0.1	1.0	0.1	0.1
3	20	250	6.4	0.6	0.5	2.4	0.2	0.2	1.7	0.2	0.1
3	20	500	4.2	0.4	0.3	1.4	0.1	0.1	1.0	0.1	0.1
3	30	250	5.1	0.5	0.4	1.8	0.2	0.1	1.2	0.1	0.1
3	30	500	3.1	0.3	0.2	1.0	0.1	0.1	0.7	0.1	0.1

AutoStim Feature Disabled
Model 1000
Model 1000-D

Parameters at 3 kΩ			Normal Mode Duty Cycle								
			10% (30s ON / 5 min OFF)			35% (30s ON / 1.1 min OFF)			51% (60s ON / 1.1 min OFF)		
			BOL to IFI	IFI to NEOS	NEOS to EOS	BOL to IFI	IFI to NEOS	NEOS to EOS	BOL to IFI	IFI to NEOS	NEOS to EOS
mA	Hz	µS	Years	Years	Years	Years	Years	Years	Years	Years	Years
3.5	20	250	5.2	0.5	0.4	1.8	0.2	0.1	1.3	0.1	0.1
3.5	20	500	3.2	0.3	0.2	1.0	0.1	0.1	0.7	0.1	0.1
3.5	30	250	4.0	0.4	0.3	1.3	0.1	0.1	0.9	0.1	0.1
3.5	30	500	2.3	0.2	0.2	0.7	0.1	0.1	0.5	0.0	0.0

10.2. Model 106 Battery Longevity and Programmed Setting Choices

10.2.1. AutoStim Feature Disabled

AutoStim Feature Disabled Model 106											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
0.5	10	130	>10	>10	>10	3.0	2.5	2.2	2.2	1.8	1.6
0.5	10	250	>10	>10	>10	2.9	2.3	2.0	2.2	1.7	1.5
0.5	10	500	>10	>10	>10	2.7	1.9	1.6	2.0	1.4	1.2
0.5	10	750	>10	>10	>10	2.6	1.7	1.3	1.9	1.2	1.0
0.5	10	1000	>10	>10	>10	2.4	1.5	1.1	1.8	1.1	0.8
0.5	15	130	>10	>10	>10	2.9	2.2	1.9	2.1	1.6	1.4
0.5	15	250	>10	>10	>10	2.8	2.0	1.7	2.1	1.5	1.2
0.5	15	500	>10	>10	>10	2.5	1.6	1.3	1.9	1.2	0.9
0.5	15	750	>10	>10	>10	2.3	1.4	1.0	1.7	1.0	0.8
0.5	15	1000	>10	>10	>10	2.1	1.2	0.9	1.6	0.9	0.6
0.5	20	130	>10	>10	>10	2.8	2.0	1.7	2.1	1.5	1.2
0.5	20	250	>10	>10	>10	2.7	1.8	1.5	2.0	1.3	1.1
0.5	20	500	>10	>10	>10	2.4	1.4	1.1	1.7	1.0	0.8
0.5	20	750	>10	>10	>10	2.1	1.1	0.9	1.6	0.8	0.6
0.5	20	1000	>10	>10	9.3	1.9	1.0	0.7	1.4	0.7	0.5
0.5	25	130	>10	>10	>10	2.7	1.8	1.5	2.0	1.4	1.1
0.5	25	250	>10	>10	>10	2.5	1.6	1.3	1.9	1.2	1.0
0.5	25	500	>10	>10	>10	2.2	1.2	0.9	1.6	0.9	0.7
0.5	25	750	>10	>10	9.6	1.9	1.0	0.7	1.4	0.7	0.5
0.5	25	1000	>10	>10	7.8	1.7	0.8	0.6	1.3	0.6	0.4
0.5	30	130	>10	>10	>10	2.6	1.7	1.3	1.9	1.3	1.0
0.5	30	250	>10	>10	>10	2.4	1.5	1.2	1.8	1.1	0.9
0.5	30	500	>10	>10	>10	2.1	1.1	0.8	1.5	0.8	0.6
0.5	30	750	>10	>10	8.3	1.8	0.9	0.6	1.3	0.6	0.5
0.5	30	1000	>10	9.5	6.7	1.6	0.7	0.5	1.2	0.5	0.4
1	10	130	>10	>10	>10	2.7	1.8	1.5	1.9	1.2	1.0
1	10	250	>10	>10	>10	2.5	1.6	1.2	1.7	1.0	0.8

AutoStim Feature Disabled
Model 106

Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	10	500	>10	>10	>10	2.2	1.2	0.9	1.5	0.8	0.6
1	10	750	>10	>10	>10	2.0	1.0	0.7	1.3	0.6	0.4
1	10	1000	>10	>10	9.7	1.8	0.8	0.6	1.1	0.5	0.4
1	15	130	>10	>10	>10	2.6	1.7	1.4	1.8	1.2	0.9
1	15	250	>10	>10	>10	2.4	1.4	1.1	1.6	0.9	0.7
1	15	500	>10	>10	>10	2.0	1.1	0.8	1.3	0.7	0.5
1	15	750	>10	>10	8.7	1.7	0.8	0.6	1.1	0.5	0.4
1	15	1000	>10	9.8	7.0	1.5	0.7	0.5	1.0	0.4	0.3
1	20	130	>10	>10	>10	2.5	1.6	1.3	1.8	1.1	0.9
1	20	250	>10	>10	>10	2.3	1.3	1.0	1.6	0.8	0.6
1	20	500	>10	>10	9.3	1.8	0.9	0.7	1.2	0.6	0.4
1	20	750	>10	9.7	6.9	1.5	0.7	0.5	1.0	0.4	0.3
1	20	1000	>10	7.8	5.5	1.3	0.5	0.4	0.8	0.3	0.2
1	25	130	>10	>10	>10	2.4	1.5	1.2	1.7	1.0	0.8
1	25	250	>10	>10	>10	2.1	1.2	0.9	1.5	0.8	0.6
1	25	500	>10	>10	7.8	1.7	0.8	0.6	1.1	0.5	0.3
1	25	750	>10	8.2	5.7	1.4	0.6	0.4	0.9	0.4	0.2
1	25	1000	>10	6.5	4.5	1.2	0.5	0.3	0.7	0.3	0.2
1	30	130	>10	>10	>10	2.4	1.4	1.1	1.7	1.0	0.7
1	30	250	>10	>10	>10	2.0	1.0	0.8	1.4	0.7	0.5
1	30	500	>10	9.5	6.7	1.5	0.7	0.5	1.0	0.4	0.3
1	30	750	>10	7.0	4.9	1.2	0.5	0.3	0.8	0.3	0.2
1	30	1000	>10	5.6	3.8	1.0	0.4	0.3	0.7	0.2	0.2
1.5	10	130	>10	>10	>10	2.3	1.3	1.0	1.6	0.9	0.7
1.5	10	250	>10	>10	>10	2.0	1.0	0.8	1.4	0.7	0.5
1.5	10	500	>10	>10	7.9	1.6	0.7	0.5	1.1	0.5	0.3
1.5	10	750	>10	8.1	5.7	1.2	0.5	0.4	0.8	0.3	0.2
1.5	10	1000	>10	6.4	4.4	1.0	0.4	0.3	0.7	0.3	0.2
1.5	15	130	>10	>10	>10	2.2	1.2	0.9	1.5	0.8	0.6
1.5	15	250	>10	>10	9.7	1.8	0.9	0.6	1.3	0.6	0.4
1.5	15	500	>10	8.5	6.0	1.3	0.5	0.4	0.9	0.4	0.3
1.5	15	750	>10	6.1	4.2	1.0	0.4	0.3	0.7	0.3	0.2
1.5	15	1000	>10	4.7	3.2	0.8	0.3	0.2	0.6	0.2	0.1
1.5	20	130	>10	>10	>10	2.0	1.1	0.8	1.5	0.7	0.6

AutoStim Feature Disabled Model 106											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	20	250	>10	>10	8.5	1.7	0.8	0.5	1.1	0.5	0.4
1.5	20	500	>10	7.2	5.0	1.2	0.5	0.3	0.8	0.3	0.2
1.5	20	750	>10	5.0	3.4	0.9	0.3	0.2	0.6	0.2	0.1
1.5	20	1000	>10	3.8	2.6	0.7	0.2	0.2	0.5	0.2	0.1
1.5	25	130	>10	>10	>10	1.9	1.0	0.7	1.4	0.7	0.5
1.5	25	250	>10	>10	7.5	1.5	0.7	0.5	1.1	0.5	0.3
1.5	25	500	>10	6.3	4.4	1.0	0.4	0.3	0.7	0.3	0.2
1.5	25	750	>10	4.3	2.9	0.8	0.3	0.2	0.5	0.2	0.1
1.5	25	1000	9.2	3.3	2.2	0.6	0.2	0.1	0.4	0.1	0.1
1.5	30	130	>10	>10	9.8	1.8	0.9	0.7	1.3	0.6	0.4
1.5	30	250	>10	9.5	6.8	1.4	0.6	0.4	1.0	0.4	0.3
1.5	30	500	>10	5.5	3.8	0.9	0.4	0.2	0.6	0.2	0.2
1.5	30	750	>10	3.8	2.6	0.7	0.2	0.2	0.5	0.2	0.1
1.5	30	1000	8.2	2.8	1.9	0.5	0.2	0.1	0.4	0.1	0.1
2	10	130	>10	>10	>10	2.0	1.0	0.8	1.4	0.7	0.5
2	10	250	>10	>10	8.2	1.6	0.7	0.5	1.1	0.5	0.3
2	10	500	>10	7.2	5.0	1.2	0.5	0.3	0.8	0.3	0.2
2	10	750	>10	5.2	3.6	0.9	0.3	0.2	0.6	0.2	0.1
2	10	1000	>10	4.0	2.8	0.7	0.3	0.2	0.5	0.2	0.1
2	15	130	>10	>10	9.5	1.8	0.9	0.6	1.3	0.6	0.4
2	15	250	>10	8.9	6.3	1.4	0.6	0.4	0.9	0.4	0.3
2	15	500	>10	5.3	3.7	0.9	0.3	0.2	0.6	0.2	0.2
2	15	750	>10	3.8	2.6	0.7	0.2	0.2	0.5	0.2	0.1
2	15	1000	8.3	2.9	2.0	0.5	0.2	0.1	0.4	0.1	0.1
2	20	130	>10	>10	8.1	1.6	0.8	0.5	1.1	0.5	0.4
2	20	250	>10	7.3	5.1	1.2	0.5	0.3	0.8	0.3	0.2
2	20	500	>10	4.2	2.9	0.8	0.3	0.2	0.5	0.2	0.1
2	20	750	8.4	2.9	2.0	0.6	0.2	0.1	0.4	0.1	0.1
2	20	1000	6.6	2.2	1.5	0.4	0.1	0.1	0.3	0.1	0.1
2	25	130	>10	>10	7.2	1.5	0.7	0.5	1.1	0.5	0.3
2	25	250	>10	6.4	4.4	1.1	0.4	0.3	0.7	0.3	0.2
2	25	500	>10	3.6	2.4	0.7	0.2	0.2	0.5	0.2	0.1
2	25	750	7.2	2.5	1.7	0.5	0.2	0.1	0.3	0.1	0.1
2	25	1000	5.6	1.9	1.2	0.4	0.1	0.1	0.2	0.1	0.1

AutoStim Feature Disabled
Model 106

Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	30	130	>10	9.0	6.4	1.4	0.6	0.4	1.0	0.4	0.3
2	30	250	>10	5.6	3.9	1.0	0.4	0.3	0.7	0.2	0.2
2	30	500	8.9	3.1	2.1	0.6	0.2	0.1	0.4	0.1	0.1
2	30	750	6.4	2.1	1.4	0.4	0.1	0.1	0.3	0.1	0.1
2	30	1000	4.9	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	130	>10	>10	9.9	1.8	0.9	0.7	1.3	0.6	0.4
2.5	10	250	>10	9.3	6.6	1.4	0.6	0.4	1.0	0.4	0.3
2.5	10	500	>10	5.8	4.0	1.0	0.4	0.3	0.6	0.2	0.2
2.5	10	750	>10	4.1	2.8	0.7	0.3	0.2	0.5	0.2	0.1
2.5	10	1000	9.1	3.2	2.2	0.6	0.2	0.1	0.4	0.1	0.1
2.5	15	130	>10	>10	8.0	1.6	0.7	0.5	1.1	0.5	0.3
2.5	15	250	>10	7.2	5.0	1.2	0.5	0.3	0.8	0.3	0.2
2.5	15	500	>10	4.2	2.9	0.8	0.3	0.2	0.5	0.2	0.1
2.5	15	750	8.5	2.9	2.0	0.5	0.2	0.1	0.4	0.1	0.1
2.5	15	1000	6.7	2.3	1.5	0.4	0.1	0.1	0.3	0.1	0.1
2.5	20	130	>10	9.3	6.6	1.4	0.6	0.4	1.0	0.4	0.3
2.5	20	250	>10	5.8	4.0	1.0	0.4	0.3	0.7	0.3	0.2
2.5	20	500	9.3	3.3	2.2	0.6	0.2	0.1	0.4	0.1	0.1
2.5	20	750	6.8	2.3	1.5	0.4	0.1	0.1	0.3	0.1	0.1
2.5	20	1000	5.3	1.7	1.2	0.3	0.1	0.1	0.2	0.1	0.0
2.5	25	130	>10	8.1	5.7	1.3	0.5	0.4	0.9	0.4	0.3
2.5	25	250	>10	4.9	3.4	0.9	0.3	0.2	0.6	0.2	0.1
2.5	25	500	7.9	2.7	1.8	0.5	0.2	0.1	0.4	0.1	0.1
2.5	25	750	5.7	1.9	1.3	0.4	0.1	0.1	0.3	0.1	0.1
2.5	25	1000	4.4	1.4	1.0	0.3	0.1	0.1	0.2	0.1	0.0
2.5	30	130	>10	7.2	5.1	1.2	0.5	0.3	0.8	0.3	0.2
2.5	30	250	>10	4.3	2.9	0.8	0.3	0.2	0.5	0.2	0.1
2.5	30	500	7.0	2.4	1.6	0.5	0.2	0.1	0.3	0.1	0.1
2.5	30	750	4.9	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
2.5	30	1000	3.8	1.2	0.8	0.2	0.1	0.1	0.2	0.1	0.0
3	10	130	>10	>10	8.4	1.7	0.8	0.6	1.1	0.5	0.4
3	10	250	>10	7.5	5.3	1.2	0.5	0.3	0.8	0.3	0.2
3	10	500	>10	4.4	3.0	0.8	0.3	0.2	0.5	0.2	0.1
3	10	750	8.6	3.0	2.0	0.6	0.2	0.1	0.4	0.1	0.1

AutoStim Feature Disabled
Model 106

Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3	10	1000	6.8	2.3	1.5	0.4	0.1	0.1	0.3	0.1	0.1
3	15	130	>10	9.3	6.6	1.4	0.6	0.4	1.0	0.4	0.3
3	15	250	>10	5.7	3.9	1.0	0.4	0.3	0.7	0.2	0.2
3	15	500	9.0	3.2	2.1	0.6	0.2	0.1	0.4	0.1	0.1
3	15	750	6.4	2.2	1.5	0.4	0.1	0.1	0.3	0.1	0.1
3	15	1000	5.0	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
3	20	130	>10	7.7	5.4	1.2	0.5	0.4	0.8	0.3	0.2
3	20	250	>10	4.6	3.1	0.8	0.3	0.2	0.5	0.2	0.1
3	20	500	7.3	2.5	1.7	0.5	0.2	0.1	0.3	0.1	0.1
3	20	750	5.1	1.7	1.1	0.3	0.1	0.1	0.2	0.1	0.0
3	20	1000	3.9	1.3	0.8	0.3	0.1	0.1	0.2	0.1	0.0
3	25	130	>10	6.6	4.6	1.1	0.4	0.3	0.8	0.3	0.2
3	25	250	>10	3.9	2.6	0.7	0.2	0.2	0.5	0.2	0.1
3	25	500	6.1	2.1	1.4	0.4	0.1	0.1	0.3	0.1	0.1
3	25	750	4.3	1.4	0.9	0.3	0.1	0.1	0.2	0.1	0.0
3	25	1000	3.3	1.0	0.7	0.2	0.1	0.0	0.1	0.0	0.0
3	30	130	>10	5.8	4.0	1.0	0.4	0.3	0.7	0.3	0.2
3	30	250	9.3	3.3	2.2	0.6	0.2	0.1	0.4	0.1	0.1
3	30	500	5.3	1.7	1.2	0.3	0.1	0.1	0.2	0.1	0.0
3	30	750	3.7	1.2	0.8	0.2	0.1	0.0	0.2	0.0	0.0
3	30	1000	2.8	0.9	0.6	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	130	>10	7.2	5.1	1.3	0.5	0.4	0.9	0.4	0.3
3.5	10	250	>10	4.7	3.2	0.9	0.3	0.2	0.6	0.2	0.2
3.5	10	500	7.3	2.5	1.7	0.5	0.2	0.1	0.4	0.1	0.1
3.5	10	750	5.3	1.7	1.2	0.4	0.1	0.1	0.2	0.1	0.1
3.5	10	1000	4.5	1.4	1.0	0.3	0.1	0.1	0.2	0.1	0.0
3.5	15	130	>10	6.1	4.2	1.1	0.4	0.3	0.8	0.3	0.2
3.5	15	250	>10	3.7	2.5	0.7	0.3	0.2	0.5	0.2	0.1
3.5	15	500	5.9	2.0	1.3	0.4	0.1	0.1	0.3	0.1	0.1
3.5	15	750	4.2	1.4	0.9	0.3	0.1	0.1	0.2	0.1	0.0
3.5	15	1000	3.4	1.1	0.7	0.2	0.1	0.0	0.2	0.0	0.0
3.5	20	130	>10	5.2	3.6	1.0	0.4	0.2	0.7	0.3	0.2
3.5	20	250	8.9	3.1	2.1	0.6	0.2	0.1	0.4	0.1	0.1
3.5	20	500	5.0	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0

AutoStim Feature Disabled Model 106											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	20	750	3.5	1.1	0.7	0.2	0.1	0.0	0.2	0.0	0.0
3.5	20	1000	2.8	0.9	0.6	0.2	0.1	0.0	0.1	0.0	0.0
3.5	25	130	>10	4.6	3.1	0.9	0.3	0.2	0.6	0.2	0.1
3.5	25	250	7.7	2.7	1.8	0.5	0.2	0.1	0.3	0.1	0.1
3.5	25	500	4.3	1.4	0.9	0.3	0.1	0.1	0.2	0.1	0.0
3.5	25	750	2.9	0.9	0.6	0.2	0.1	0.0	0.1	0.0	0.0
3.5	25	1000	2.4	0.7	0.5	0.2	0.0	0.0	0.1	0.0	0.0
3.5	30	130	>10	4.1	2.8	0.8	0.3	0.2	0.5	0.2	0.1
3.5	30	250	6.8	2.3	1.6	0.5	0.2	0.1	0.3	0.1	0.1
3.5	30	500	3.7	1.2	0.8	0.2	0.1	0.1	0.2	0.1	0.0
3.5	30	750	2.6	0.8	0.5	0.2	0.1	0.0	0.1	0.0	0.0
3.5	30	1000	2.0	0.6	0.4	0.1	0.0	0.0	0.1	0.0	0.0

10.3. Model 105 Battery Longevity and Programmed Setting Choices

Battery Longevity and Programmed Setting Choices Model 105												
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
0.5	10	130	>10	>10	>10	2.5	1.6	1.3	1.9	1.2	0.9
0.5	15	130	>10	>10	>10	2.5	1.5	1.2	1.8	1.1	0.9
0.5	20	130	>10	>10	>10	2.4	1.4	1.1	1.7	1.0	0.8
0.5	25	130	>10	>10	>10	2.2	1.3	1.0	1.7	1.0	0.7
0.5	30	130	>10	>10	>10	2.2	1.2	0.9	1.6	0.9	0.7
0.5	10	250	>10	>10	>10	2.5	1.6	1.3	1.9	1.2	1.0
0.5	15	250	>10	>10	>10	2.4	1.4	1.1	1.8	1.1	0.8
0.5	20	250	>10	>10	>10	2.3	1.3	1.0	1.7	1.0	0.7
0.5	25	250	>10	>10	>10	2.2	1.2	0.9	1.6	0.9	0.7
0.5	30	250	>10	>10	>10	2.1	1.1	0.8	1.5	0.8	0.6
0.5	10	500	>10	>10	>10	2.4	1.4	1.1	1.7	1.0	0.8
0.5	15	500	>10	>10	>10	2.2	1.2	0.9	1.6	0.9	0.7
0.5	20	500	>10	>10	>10	2.0	1.1	0.8	1.5	0.8	0.6
0.5	25	500	>10	>10	9.0	1.9	0.9	0.7	1.4	0.7	0.5
0.5	30	500	>10	>10	8.6	1.8	0.9	0.6	1.3	0.7	0.5
0.5	10	750	>10	>10	>10	2.2	1.3	1.0	1.7	0.9	0.7
0.5	15	750	>10	>10	>10	2.0	1.1	0.8	1.5	0.8	0.6
0.5	20	750	>10	>10	8.9	1.9	0.9	0.7	1.4	0.7	0.5
0.5	25	750	>10	>10	7.7	1.7	0.8	0.6	1.3	0.6	0.4
0.5	30	750	>10	9.6	6.8	1.6	0.7	0.5	1.2	0.5	0.4
0.5	10	1000	>10	>10	>10	2.1	1.2	0.9	1.6	0.9	0.6
0.5	15	1000	>10	>10	8.9	1.9	0.9	0.7	1.4	0.7	0.5
0.5	20	1000	>10	>10	7.3	1.7	0.8	0.6	1.2	0.6	0.4
0.5	25	1000	>10	9.2	6.5	1.5	0.7	0.5	1.1	0.5	0.4
0.5	30	1000	>10	8.0	5.7	1.4	0.6	0.4	1.0	0.4	0.3
1	10	130	>10	>10	>10	2.4	1.4	1.1	1.7	0.9	0.7
1	15	130	>10	>10	>10	2.3	1.4	1.0	1.6	0.9	0.7
1	20	130	>10	>10	>10	2.3	1.3	1.0	1.6	0.9	0.7
1	25	130	>10	>10	>10	2.2	1.2	0.9	1.5	0.8	0.6

Battery Longevity and Programmed Setting Choices Model 105											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	30	130	>10	>10	>10	2.1	1.1	0.8	1.5	0.8	0.6
1	10	250	>10	>10	>10	2.2	1.2	0.9	1.5	0.8	0.6
1	15	250	>10	>10	>10	2.1	1.1	0.8	1.5	0.8	0.6
1	20	250	>10	>10	>10	2.0	1.0	0.7	1.4	0.7	0.5
1	25	250	>10	>10	9.7	1.9	0.9	0.7	1.3	0.6	0.5
1	30	250	>10	>10	8.9	1.8	0.8	0.6	1.2	0.6	0.4
1	10	500	>10	>10	>10	2.0	1.0	0.7	1.3	0.6	0.5
1	15	500	>10	>10	9.6	1.8	0.8	0.6	1.2	0.5	0.4
1	20	500	>10	>10	7.8	1.6	0.7	0.5	1.1	0.5	0.3
1	25	500	>10	9.3	6.6	1.4	0.6	0.4	1.0	0.4	0.3
1	30	500	>10	8.4	5.9	1.3	0.6	0.4	0.9	0.4	0.3
1	10	750	>10	>10	9.7	1.7	0.8	0.6	1.2	0.5	0.4
1	15	750	>10	>10	7.4	1.5	0.7	0.5	1.0	0.4	0.3
1	20	750	>10	8.6	6.0	1.3	0.6	0.4	0.9	0.4	0.3
1	25	750	>10	7.3	5.1	1.2	0.5	0.3	0.8	0.3	0.2
1	30	750	>10	6.4	4.4	1.1	0.4	0.3	0.7	0.3	0.2
1	10	1000	>10	>10	8.0	1.5	0.7	0.5	1.0	0.4	0.3
1	15	1000	>10	8.8	6.2	1.3	0.5	0.4	0.9	0.4	0.2
1	20	1000	>10	7.1	4.9	1.1	0.5	0.3	0.8	0.3	0.2
1	25	1000	>10	6.0	4.1	1.0	0.4	0.3	0.7	0.3	0.2
1	30	1000	>10	5.1	3.5	0.9	0.3	0.2	0.6	0.2	0.2
1.5	10	130	>10	>10	>10	2.0	1.1	0.8	1.5	0.7	0.6
1.5	15	130	>10	>10	>10	1.9	1.0	0.7	1.4	0.7	0.5
1.5	20	130	>10	>10	9.4	1.8	0.9	0.7	1.3	0.6	0.5
1.5	25	130	>10	>10	8.8	1.8	0.8	0.6	1.3	0.6	0.4
1.5	30	130	>10	>10	7.8	1.7	0.8	0.6	1.2	0.6	0.4
1.5	10	250	>10	>10	9.3	1.8	0.9	0.6	1.3	0.6	0.4
1.5	15	250	>10	>10	7.9	1.6	0.7	0.5	1.1	0.5	0.4
1.5	20	250	>10	>10	7.6	1.6	0.7	0.5	1.1	0.5	0.3
1.5	25	250	>10	9.1	6.5	1.4	0.6	0.4	1.0	0.4	0.3
1.5	30	250	>10	8.5	6.0	1.3	0.6	0.4	0.9	0.4	0.3
1.5	10	500	>10	9.4	6.6	1.4	0.6	0.4	1.0	0.4	0.3
1.5	15	500	>10	7.4	5.2	1.2	0.5	0.3	0.8	0.3	0.2
1.5	20	500	>10	6.5	4.5	1.1	0.4	0.3	0.7	0.3	0.2

Battery Longevity and Programmed Setting Choices Model 105											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	25	500	>10	5.7	4.0	1.0	0.4	0.3	0.7	0.2	0.2
1.5	30	500	>10	5.1	3.5	0.9	0.3	0.2	0.6	0.2	0.1
1.5	10	750	>10	7.2	5.0	1.2	0.5	0.3	0.8	0.3	0.2
1.5	15	750	>10	5.5	3.8	1.0	0.4	0.2	0.7	0.2	0.2
1.5	20	750	>10	4.7	3.2	0.8	0.3	0.2	0.6	0.2	0.1
1.5	25	750	>10	4.0	2.7	0.7	0.3	0.2	0.5	0.2	0.1
1.5	30	750	10.0	3.6	2.4	0.7	0.2	0.2	0.4	0.2	0.1
1.5	10	1000	>10	5.7	4.0	1.0	0.4	0.3	0.7	0.2	0.2
1.5	15	1000	>10	4.3	2.9	0.8	0.3	0.2	0.5	0.2	0.1
1.5	20	1000	9.9	3.5	2.4	0.7	0.2	0.2	0.4	0.2	0.1
1.5	25	1000	8.7	3.1	2.1	0.6	0.2	0.1	0.4	0.1	0.1
1.5	30	1000	7.8	2.7	1.8	0.5	0.2	0.1	0.3	0.1	0.1
2	10	130	>10	>10	9.4	1.8	0.9	0.6	1.3	0.6	0.4
2	15	130	>10	>10	8.0	1.7	0.8	0.5	1.2	0.5	0.4
2	20	130	>10	9.8	7.0	1.5	0.7	0.5	1.1	0.5	0.3
2	25	130	>10	8.8	6.2	1.4	0.6	0.4	1.0	0.4	0.3
2	30	130	>10	8.1	5.7	1.3	0.6	0.4	0.9	0.4	0.3
2	10	250	>10	9.7	6.9	1.5	0.7	0.5	1.0	0.4	0.3
2	15	250	>10	8.2	5.7	1.3	0.5	0.4	0.9	0.4	0.3
2	20	250	>10	6.8	4.7	1.1	0.5	0.3	0.8	0.3	0.2
2	25	250	>10	5.9	4.1	1.0	0.4	0.3	0.7	0.3	0.2
2	30	250	>10	5.2	3.6	0.9	0.4	0.2	0.6	0.2	0.2
2	10	500	>10	6.5	4.5	1.1	0.4	0.3	0.7	0.3	0.2
2	15	500	>10	5.0	3.4	0.9	0.3	0.2	0.6	0.2	0.1
2	20	500	>10	4.0	2.7	0.7	0.3	0.2	0.5	0.2	0.1
2	25	500	9.6	3.4	2.3	0.7	0.2	0.2	0.4	0.2	0.1
2	30	500	8.7	3.0	2.1	0.6	0.2	0.1	0.4	0.1	0.1
2	10	750	>10	4.8	3.3	0.9	0.3	0.2	0.6	0.2	0.1
2	15	750	>10	3.6	2.4	0.7	0.2	0.2	0.4	0.2	0.1
2	20	750	8.1	2.8	1.9	0.5	0.2	0.1	0.4	0.1	0.1
2	25	750	7.0	2.4	1.6	0.5	0.2	0.1	0.3	0.1	0.1
2	30	750	6.2	2.1	1.4	0.4	0.1	0.1	0.3	0.1	0.1
2	10	1000	>10	3.8	2.6	0.7	0.2	0.2	0.5	0.2	0.1
2	15	1000	8.0	2.8	1.9	0.5	0.2	0.1	0.4	0.1	0.1

Battery Longevity and Programmed Setting Choices Model 105											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	20	1000	6.5	2.2	1.5	0.4	0.1	0.1	0.3	0.1	0.1
2	25	1000	5.5	1.8	1.2	0.4	0.1	0.1	0.2	0.1	0.1
2	30	1000	4.8	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	130	>10	>10	8.3	1.7	0.8	0.6	1.2	0.5	0.4
2.5	15	130	>10	9.6	6.8	1.5	0.6	0.5	1.0	0.4	0.3
2.5	20	130	>10	8.5	6.0	1.4	0.6	0.4	0.9	0.4	0.3
2.5	25	130	>10	7.4	5.2	1.2	0.5	0.4	0.9	0.3	0.2
2.5	30	130	>10	6.7	4.7	1.1	0.5	0.3	0.8	0.3	0.2
2.5	10	250	>10	8.3	5.9	1.3	0.6	0.4	0.9	0.4	0.3
2.5	15	250	>10	6.5	4.5	1.1	0.4	0.3	0.8	0.3	0.2
2.5	20	250	>10	5.5	3.8	1.0	0.4	0.3	0.7	0.2	0.2
2.5	25	250	>10	4.6	3.2	0.8	0.3	0.2	0.6	0.2	0.1
2.5	30	250	>10	4.1	2.8	0.8	0.3	0.2	0.5	0.2	0.1
2.5	10	500	>10	5.4	3.7	0.9	0.4	0.2	0.6	0.2	0.2
2.5	15	500	>10	4.0	2.7	0.7	0.3	0.2	0.5	0.2	0.1
2.5	20	500	9.0	3.2	2.1	0.6	0.2	0.1	0.4	0.1	0.1
2.5	25	500	7.8	2.7	1.8	0.5	0.2	0.1	0.3	0.1	0.1
2.5	30	500	6.8	2.3	1.5	0.5	0.2	0.1	0.3	0.1	0.1
2.5	10	750	>10	3.9	2.7	0.7	0.3	0.2	0.5	0.2	0.1
2.5	15	750	8.2	2.9	1.9	0.5	0.2	0.1	0.4	0.1	0.1
2.5	20	750	6.6	2.2	1.5	0.4	0.1	0.1	0.3	0.1	0.1
2.5	25	750	5.5	1.8	1.2	0.4	0.1	0.1	0.2	0.1	0.1
2.5	30	750	4.9	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	1000	8.8	3.1	2.1	0.6	0.2	0.1	0.4	0.1	0.1
2.5	15	1000	6.5	2.2	1.5	0.4	0.1	0.1	0.3	0.1	0.1
2.5	20	1000	5.2	1.7	1.1	0.3	0.1	0.1	0.2	0.1	0.0
2.5	25	1000	4.3	1.4	0.9	0.3	0.1	0.1	0.2	0.1	0.0
2.5	30	1000	3.7	1.2	0.8	0.2	0.1	0.1	0.2	0.1	0.0
3	10	130	>10	>10	7.3	1.5	0.7	0.5	1.1	0.5	0.3
3	15	130	>10	8.5	6.0	1.3	0.6	0.4	0.9	0.4	0.3
3	20	130	>10	7.4	5.1	1.2	0.5	0.3	0.8	0.3	0.2
3	25	130	>10	6.2	4.3	1.1	0.4	0.3	0.7	0.3	0.2
3	30	130	>10	5.5	3.8	1.0	0.4	0.3	0.7	0.2	0.2
3	10	250	>10	6.9	4.8	1.2	0.5	0.3	0.8	0.3	0.2

Battery Longevity and Programmed Setting Choices Model 105											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3	15	250	>10	5.3	3.7	0.9	0.4	0.2	0.6	0.2	0.2
3	20	250	>10	4.4	3.0	0.8	0.3	0.2	0.5	0.2	0.1
3	25	250	>10	3.7	2.5	0.7	0.2	0.2	0.5	0.2	0.1
3	30	250	9.2	3.2	2.2	0.6	0.2	0.1	0.4	0.1	0.1
3	10	500	>10	4.1	2.8	0.8	0.3	0.2	0.5	0.2	0.1
3	15	500	8.7	3.1	2.1	0.6	0.2	0.1	0.4	0.1	0.1
3	20	500	7.1	2.4	1.6	0.5	0.2	0.1	0.3	0.1	0.1
3	25	500	6.1	2.0	1.4	0.4	0.1	0.1	0.3	0.1	0.1
3	30	500	5.3	1.7	1.2	0.3	0.1	0.1	0.2	0.1	0.0
3	10	750	8.4	2.9	2.0	0.6	0.2	0.1	0.4	0.1	0.1
3	15	750	6.3	2.1	1.4	0.4	0.1	0.1	0.3	0.1	0.1
3	20	750	5.1	1.7	1.1	0.3	0.1	0.1	0.2	0.1	0.0
3	25	750	4.2	1.4	0.9	0.3	0.1	0.1	0.2	0.1	0.0
3	30	750	3.6	1.2	0.8	0.2	0.1	0.1	0.2	0.0	0.0
3	10	1000	6.6	2.2	1.5	0.4	0.1	0.1	0.3	0.1	0.1
3	15	1000	4.9	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
3	20	1000	3.9	1.3	0.8	0.3	0.1	0.1	0.2	0.1	0.0
3	25	1000	3.2	1.0	0.7	0.2	0.1	0.0	0.1	0.0	0.0
3	30	1000	2.7	0.9	0.6	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	130	>10	6.7	4.7	1.2	0.5	0.3	0.9	0.4	0.2
3.5	15	130	>10	6.0	4.1	1.1	0.4	0.3	0.8	0.3	0.2
3.5	20	130	>10	5.0	3.4	0.9	0.4	0.2	0.7	0.2	0.2
3.5	25	130	>10	4.6	3.1	0.8	0.3	0.2	0.6	0.2	0.1
3.5	30	130	>10	4.1	2.8	0.8	0.3	0.2	0.5	0.2	0.1
3.5	10	250	>10	4.6	3.1	0.9	0.3	0.2	0.6	0.2	0.1
3.5	15	250	>10	3.6	2.5	0.7	0.2	0.2	0.5	0.2	0.1
3.5	20	250	8.7	3.0	2.1	0.6	0.2	0.1	0.4	0.1	0.1
3.5	25	250	7.5	2.6	1.7	0.5	0.2	0.1	0.3	0.1	0.1
3.5	30	250	6.7	2.3	1.5	0.5	0.2	0.1	0.3	0.1	0.1
3.5	10	500	7.2	2.4	1.6	0.5	0.2	0.1	0.4	0.1	0.1
3.5	15	500	5.9	2.0	1.3	0.4	0.1	0.1	0.3	0.1	0.1
3.5	20	500	5.0	1.6	1.1	0.3	0.1	0.1	0.2	0.1	0.0
3.5	25	500	4.3	1.4	0.9	0.3	0.1	0.1	0.2	0.1	0.0
3.5	30	500	3.7	1.2	0.8	0.2	0.1	0.1	0.2	0.1	0.0

Battery Longevity and Programmed Setting Choices Model 105											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	10	750	5.2	1.7	1.1	0.4	0.1	0.1	0.3	0.1	0.1
3.5	15	750	4.1	1.3	0.9	0.3	0.1	0.1	0.2	0.1	0.0
3.5	20	750	3.4	1.1	0.7	0.2	0.1	0.0	0.2	0.0	0.0
3.5	25	750	3.0	0.9	0.6	0.2	0.1	0.0	0.1	0.0	0.0
3.5	30	750	2.6	0.8	0.5	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	1000	4.4	1.4	1.0	0.3	0.1	0.1	0.2	0.1	0.0
3.5	15	1000	3.4	1.1	0.7	0.2	0.1	0.0	0.2	0.0	0.0
3.5	20	1000	2.8	0.9	0.6	0.2	0.1	0.0	0.1	0.0	0.0
3.5	25	1000	2.3	0.7	0.5	0.2	0.0	0.0	0.1	0.0	0.0
3.5	30	1000	2.0	0.6	0.4	0.1	0.0	0.0	0.1	0.0	0.0

10.4. Model 103 / Model 104 Battery Longevity and Programmed Setting Choices

Battery Longevity and Programmed Setting Choices Model 103 Model 104											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
0.5	10	130	>10	>10	>10	2.8	2.5	2.4	2.2	2.0	1.9
0.5	15	130	>10	>10	>10	2.7	2.2	1.9	2.1	1.7	1.5
0.5	20	130	>10	>10	>10	2.5	1.9	1.7	2.0	1.5	1.3
0.5	25	130	>10	>10	>10	2.4	1.7	1.4	1.9	1.4	1.2
0.5	30	130	>10	>10	9.5	2.3	1.6	1.3	1.8	1.3	1.0
0.5	10	250	>10	>10	>10	2.7	2.3	2.0	2.1	1.8	1.6
0.5	15	250	>10	>10	>10	2.5	1.9	1.6	2.0	1.5	1.3
0.5	20	250	>10	>10	>10	2.4	1.7	1.4	1.9	1.3	1.1
0.5	25	250	>10	>10	8.7	2.3	1.5	1.2	1.8	1.2	0.9
0.5	30	250	>10	9.8	7.6	2.1	1.3	1.0	1.7	1.0	0.8
0.5	10	500	>10	>10	>10	2.5	1.9	1.6	1.9	1.5	1.2
0.5	15	500	>10	>10	8.9	2.3	1.5	1.2	1.8	1.2	0.9
0.5	20	500	>10	9.3	7.2	2.1	1.2	1.0	1.6	1.0	0.8
0.5	25	500	>10	8.1	6.1	1.9	1.1	0.8	1.5	0.9	0.6
0.5	30	500	>10	7.1	5.2	1.8	0.9	0.7	1.4	0.8	0.6
0.5	10	750	>10	>10	9.4	2.3	1.6	1.3	1.8	1.2	1.0
0.5	15	750	>10	9.1	7.0	2.1	1.2	0.9	1.6	1.0	0.7
0.5	20	750	>10	7.5	5.6	1.9	1.0	0.7	1.5	0.8	0.6
0.5	25	750	>10	6.4	4.7	1.7	0.9	0.6	1.3	0.7	0.5
0.5	30	750	>10	5.5	4.0	1.5	0.7	0.5	1.2	0.6	0.4
0.5	10	1000	>10	>10	7.9	2.2	1.4	1.1	1.7	1.1	0.8
0.5	15	1000	>10	7.7	5.8	1.9	1.0	0.8	1.5	0.8	0.6
0.5	20	1000	>10	6.3	4.6	1.7	0.8	0.6	1.3	0.7	0.5
0.5	25	1000	>10	5.3	3.8	1.5	0.7	0.5	1.2	0.6	0.4
0.5	30	1000	>10	4.6	3.2	1.4	0.6	0.4	1.1	0.5	0.3
1	10	130	>10	>10	>10	2.6	2.1	1.9	2.0	1.5	1.3
1	15	130	>10	>10	>10	2.5	1.9	1.6	1.9	1.4	1.1
1	20	130	>10	>10	>10	2.4	1.6	1.3	1.8	1.2	0.9

Battery Longevity and Programmed Setting Choices Model 103 Model 104											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	25	130	>10	>10	9.3	2.2	1.5	1.2	1.7	1.1	0.8
1	30	130	>10	>10	8.2	2.1	1.3	1.0	1.6	1.0	0.8
1	10	250	>10	>10	>10	2.4	1.7	1.4	1.8	1.3	1.0
1	15	250	>10	>10	8.9	2.2	1.4	1.1	1.7	1.1	0.9
1	20	250	>10	9.4	7.2	2.1	1.2	0.9	1.6	0.9	0.7
1	25	250	>10	8.1	6.1	1.9	1.1	0.8	1.5	0.8	0.6
1	30	250	>10	7.1	5.3	1.8	0.9	0.7	1.4	0.7	0.5
1	10	500	>10	>10	7.9	2.1	1.2	1.0	1.5	0.9	0.7
1	15	500	>10	7.8	5.8	1.8	1.0	0.7	1.4	0.7	0.5
1	20	500	>10	6.3	4.6	1.6	0.8	0.6	1.2	0.6	0.4
1	25	500	>10	5.3	3.8	1.5	0.7	0.5	1.1	0.5	0.4
1	30	500	>10	4.6	3.2	1.3	0.6	0.4	1.0	0.4	0.3
1	10	750	>10	8.0	6.0	1.8	1.0	0.7	1.3	0.7	0.5
1	15	750	>10	6.0	4.3	1.5	0.7	0.5	1.1	0.5	0.4
1	20	750	>10	4.7	3.4	1.3	0.6	0.4	1.0	0.4	0.3
1	25	750	9.3	3.9	2.8	1.2	0.5	0.3	0.9	0.4	0.3
1	30	750	8.3	3.4	2.3	1.1	0.4	0.3	0.8	0.3	0.2
1	10	1000	>10	6.6	4.9	1.6	0.8	0.6	1.2	0.5	0.4
1	15	1000	>10	4.8	3.4	1.3	0.6	0.4	1.0	0.4	0.3
1	20	1000	9.0	3.8	2.7	1.1	0.5	0.3	0.8	0.3	0.2
1	25	1000	7.8	3.1	2.2	1.0	0.4	0.3	0.7	0.3	0.2
1	30	1000	6.9	2.7	1.8	0.9	0.3	0.2	0.6	0.2	0.2
1.5	10	130	>10	>10	8.8	2.2	1.4	1.1	1.6	1.0	0.8
1.5	15	130	>10	>10	7.9	2.1	1.3	1.0	1.6	0.9	0.7
1.5	20	130	>10	9.3	7.1	2.0	1.1	0.9	1.5	0.8	0.6
1.5	25	130	>10	8.3	6.3	1.9	1.0	0.8	1.4	0.7	0.5
1.5	30	130	>10	7.6	5.7	1.8	0.9	0.7	1.3	0.6	0.5
1.5	10	250	>10	>10	8.8	2.1	1.3	1.0	1.5	0.8	0.6
1.5	15	250	>10	8.9	6.8	1.9	1.0	0.8	1.3	0.7	0.5
1.5	20	250	>10	7.5	5.6	1.7	0.9	0.6	1.2	0.6	0.4
1.5	25	250	>10	6.4	4.7	1.6	0.8	0.5	1.1	0.5	0.4
1.5	30	250	>10	5.6	4.0	1.4	0.7	0.5	1.0	0.5	0.3
1.5	10	500	>10	7.3	5.4	1.7	0.8	0.6	1.2	0.6	0.4
1.5	15	500	>10	5.7	4.1	1.4	0.7	0.5	1.0	0.4	0.3

Battery Longevity and Programmed Setting Choices Model 103 Model 104											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	20	500	>10	4.7	3.3	1.2	0.5	0.4	0.9	0.4	0.2
1.5	25	500	9.2	3.9	2.7	1.1	0.4	0.3	0.8	0.3	0.2
1.5	30	500	8.2	3.3	2.3	1.0	0.4	0.3	0.7	0.3	0.2
1.5	10	750	>10	5.3	3.8	1.4	0.6	0.4	0.9	0.4	0.3
1.5	15	750	9.5	4.1	2.9	1.1	0.5	0.3	0.8	0.3	0.2
1.5	20	750	8.1	3.3	2.3	1.0	0.4	0.3	0.6	0.2	0.2
1.5	25	750	7.0	2.7	1.9	0.8	0.3	0.2	0.6	0.2	0.1
1.5	30	750	6.2	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
1.5	10	1000	9.7	4.2	3.0	1.1	0.5	0.3	0.8	0.3	0.2
1.5	15	1000	7.8	3.1	2.2	0.9	0.4	0.2	0.6	0.2	0.2
1.5	20	1000	6.5	2.5	1.7	0.8	0.3	0.2	0.5	0.2	0.1
1.5	25	1000	5.6	2.1	1.4	0.7	0.2	0.2	0.4	0.2	0.1
1.5	30	1000	4.9	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
2	10	130	>10	8.7	6.6	1.9	1.1	0.8	1.4	0.7	0.5
2	15	130	>10	7.2	5.3	1.7	0.9	0.6	1.2	0.6	0.4
2	20	130	>10	6.2	4.5	1.6	0.8	0.5	1.1	0.5	0.4
2	25	130	>10	5.5	4.0	1.4	0.7	0.5	1.0	0.5	0.3
2	30	130	>10	5.0	3.5	1.3	0.6	0.4	1.0	0.4	0.3
2	10	250	>10	6.4	4.7	1.6	0.8	0.6	1.2	0.5	0.4
2	15	250	>10	5.2	3.8	1.4	0.6	0.4	1.0	0.4	0.3
2	20	250	>10	4.4	3.1	1.2	0.5	0.4	0.9	0.4	0.3
2	25	250	9.1	3.8	2.7	1.1	0.5	0.3	0.8	0.3	0.2
2	30	250	8.3	3.4	2.3	1.0	0.4	0.3	0.7	0.3	0.2
2	10	500	9.5	4.1	2.9	1.2	0.5	0.3	0.8	0.3	0.2
2	15	500	7.8	3.1	2.2	1.0	0.4	0.3	0.7	0.3	0.2
2	20	500	6.7	2.6	1.8	0.8	0.3	0.2	0.6	0.2	0.1
2	25	500	5.9	2.2	1.5	0.7	0.3	0.2	0.5	0.2	0.1
2	30	500	5.2	1.9	1.3	0.6	0.2	0.1	0.4	0.1	0.1
2	10	750	7.5	2.9	2.0	0.9	0.3	0.2	0.6	0.2	0.2
2	15	750	5.9	2.2	1.5	0.7	0.3	0.2	0.5	0.2	0.1
2	20	750	5.0	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
2	25	750	4.3	1.5	1.0	0.5	0.2	0.1	0.3	0.1	0.1
2	30	750	3.7	1.3	0.9	0.4	0.1	0.1	0.3	0.1	0.1
2	10	1000	6.1	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1

Battery Longevity and Programmed Setting Choices Model 103 Model 104											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	15	1000	4.7	1.7	1.1	0.6	0.2	0.1	0.4	0.1	0.1
2	20	1000	3.9	1.3	0.9	0.5	0.2	0.1	0.3	0.1	0.1
2	25	1000	3.3	1.1	0.8	0.4	0.1	0.1	0.3	0.1	0.1
2	30	1000	2.9	1.0	0.6	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	130	>10	7.2	5.3	1.7	0.9	0.6	1.3	0.6	0.5
2.5	15	130	>10	6.0	4.4	1.5	0.7	0.5	1.1	0.5	0.4
2.5	20	130	>10	5.1	3.7	1.4	0.6	0.4	1.0	0.4	0.3
2.5	25	130	>10	4.5	3.2	1.2	0.5	0.4	0.9	0.4	0.3
2.5	30	130	9.3	4.0	2.8	1.1	0.5	0.3	0.8	0.3	0.2
2.5	10	250	>10	5.4	3.9	1.4	0.6	0.5	1.0	0.4	0.3
2.5	15	250	9.6	4.1	2.9	1.2	0.5	0.3	0.8	0.3	0.2
2.5	20	250	8.4	3.4	2.4	1.0	0.4	0.3	0.7	0.3	0.2
2.5	25	250	7.4	2.9	2.0	0.9	0.3	0.2	0.6	0.2	0.2
2.5	30	250	6.7	2.5	1.7	0.8	0.3	0.2	0.5	0.2	0.1
2.5	10	500	8.0	3.2	2.2	1.0	0.4	0.3	0.7	0.3	0.2
2.5	15	500	6.3	2.4	1.6	0.8	0.3	0.2	0.5	0.2	0.1
2.5	20	500	5.3	1.9	1.3	0.6	0.2	0.2	0.4	0.2	0.1
2.5	25	500	4.6	1.6	1.1	0.5	0.2	0.1	0.4	0.1	0.1
2.5	30	500	4.0	1.4	0.9	0.5	0.2	0.1	0.3	0.1	0.1
2.5	10	750	6.1	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
2.5	15	750	4.7	1.7	1.1	0.6	0.2	0.1	0.4	0.1	0.1
2.5	20	750	3.9	1.3	0.9	0.5	0.2	0.1	0.3	0.1	0.1
2.5	25	750	3.3	1.1	0.7	0.4	0.1	0.1	0.3	0.1	0.1
2.5	30	750	2.8	0.9	0.6	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	1000	5.0	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
2.5	15	1000	3.7	1.3	0.9	0.4	0.1	0.1	0.3	0.1	0.1
2.5	20	1000	3.0	1.0	0.7	0.4	0.1	0.1	0.2	0.1	0.1
2.5	25	1000	2.5	0.8	0.6	0.3	0.1	0.1	0.2	0.1	0.0
2.5	30	1000	2.2	0.7	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3	10	130	>10	6.3	4.6	1.6	0.7	0.5	1.1	0.5	0.4
3	15	130	>10	5.0	3.6	1.3	0.6	0.4	1.0	0.4	0.3
3	20	130	9.6	4.2	2.9	1.2	0.5	0.3	0.8	0.3	0.2
3	25	130	8.6	3.6	2.5	1.0	0.4	0.3	0.7	0.3	0.2
3	30	130	7.8	3.1	2.2	0.9	0.4	0.3	0.7	0.2	0.2

Battery Longevity and Programmed Setting Choices Model 103 Model 104											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3	10	250	>10	4.4	3.1	1.2	0.5	0.4	0.8	0.3	0.2
3	15	250	8.1	3.3	2.3	1.0	0.4	0.3	0.7	0.3	0.2
3	20	250	6.8	2.6	1.8	0.8	0.3	0.2	0.6	0.2	0.1
3	25	250	5.9	2.2	1.5	0.7	0.3	0.2	0.5	0.2	0.1
3	30	250	5.3	1.9	1.3	0.6	0.2	0.2	0.4	0.1	0.1
3	10	500	6.6	2.5	1.7	0.8	0.3	0.2	0.5	0.2	0.1
3	15	500	5.0	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
3	20	500	4.0	1.4	0.9	0.5	0.2	0.1	0.3	0.1	0.1
3	25	500	3.4	1.2	0.8	0.4	0.1	0.1	0.3	0.1	0.1
3	30	500	3.0	1.0	0.7	0.3	0.1	0.1	0.2	0.1	0.1
3	10	750	4.9	1.7	1.2	0.6	0.2	0.1	0.4	0.1	0.1
3	15	750	3.6	1.2	0.8	0.4	0.1	0.1	0.3	0.1	0.1
3	20	750	2.8	0.9	0.6	0.3	0.1	0.1	0.2	0.1	0.0
3	25	750	2.4	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3	30	750	2.0	0.7	0.4	0.2	0.1	0.1	0.2	0.1	0.0
3	10	1000	3.8	1.3	0.9	0.4	0.2	0.1	0.3	0.1	0.1
3	15	1000	2.8	0.9	0.6	0.3	0.1	0.1	0.2	0.1	0.0
3	20	1000	2.2	0.7	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3	25	1000	1.8	0.6	0.4	0.2	0.1	0.0	0.1	0.0	0.0
3	30	1000	1.5	0.5	0.3	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	130	>10	4.7	3.4	1.3	0.6	0.4	0.9	0.4	0.3
3.5	15	130	9.0	3.8	2.6	1.1	0.4	0.3	0.8	0.3	0.2
3.5	20	130	7.7	3.1	2.1	0.9	0.4	0.3	0.6	0.2	0.2
3.5	25	130	6.8	2.6	1.8	0.8	0.3	0.2	0.6	0.2	0.1
3.5	30	130	6.1	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
3.5	10	250	8.0	3.2	2.2	1.0	0.4	0.3	0.7	0.3	0.2
3.5	15	250	6.4	2.4	1.7	0.8	0.3	0.2	0.5	0.2	0.1
3.5	20	250	5.3	1.9	1.3	0.6	0.2	0.2	0.4	0.2	0.1
3.5	25	250	4.6	1.6	1.1	0.5	0.2	0.1	0.4	0.1	0.1
3.5	30	250	4.0	1.4	0.9	0.5	0.2	0.1	0.3	0.1	0.1
3.5	10	500	4.7	1.7	1.1	0.6	0.2	0.1	0.4	0.1	0.1
3.5	15	500	3.6	1.2	0.8	0.4	0.1	0.1	0.3	0.1	0.1
3.5	20	500	3.0	1.0	0.7	0.3	0.1	0.1	0.2	0.1	0.1
3.5	25	500	2.5	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0

Battery Longevity and Programmed Setting Choices Model 103 Model 104											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	30	500	2.1	0.7	0.5	0.2	0.1	0.1	0.2	0.1	0.0
3.5	10	750	3.2	1.1	0.7	0.4	0.1	0.1	0.3	0.1	0.1
3.5	15	750	2.4	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3.5	20	750	2.0	0.6	0.4	0.2	0.1	0.0	0.2	0.1	0.0
3.5	25	750	1.7	0.5	0.4	0.2	0.1	0.0	0.1	0.0	0.0
3.5	30	750	1.4	0.5	0.3	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	1000	2.4	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3.5	15	1000	1.9	0.6	0.4	0.2	0.1	0.0	0.2	0.0	0.0
3.5	20	1000	1.5	0.5	0.3	0.2	0.1	0.0	0.1	0.0	0.0
3.5	25	1000	1.3	0.4	0.3	0.1	0.0	0.0	0.1	0.0	0.0
3.5	30	1000	1.1	0.3	0.2	0.1	0.0	0.0	0.1	0.0	0.0

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Battery Longevity and Programmed Setting Choices Model 8103												
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
0.5	10	130	>10	>10	>10	2.8	2.5	2.4	2.2	2.0	1.9
0.5	15	130	>10	>10	>10	2.7	2.2	1.9	2.1	1.7	1.5
0.5	20	130	>10	>10	>10	2.5	1.9	1.7	2.0	1.5	1.3
0.5	25	130	>10	>10	>10	2.4	1.7	1.4	1.9	1.4	1.2
0.5	30	130	>10	>10	9.5	2.3	1.6	1.3	1.8	1.3	1.0
0.5	10	250	>10	>10	>10	2.7	2.3	2.0	2.1	1.8	1.6
0.5	15	250	>10	>10	>10	2.5	1.9	1.6	2.0	1.5	1.3
0.5	20	250	>10	>10	>10	2.4	1.7	1.4	1.9	1.3	1.1
0.5	25	250	>10	>10	8.7	2.3	1.5	1.2	1.8	1.2	0.9
0.5	30	250	>10	9.8	7.6	2.1	1.3	1.0	1.7	1.0	0.8
0.5	10	500	>10	>10	>10	2.5	1.9	1.6	1.9	1.5	1.2
0.5	15	500	>10	>10	8.9	2.3	1.5	1.2	1.8	1.2	0.9
0.5	20	500	>10	9.3	7.2	2.1	1.2	1.0	1.6	1.0	0.8
0.5	25	500	>10	8.1	6.1	1.9	1.1	0.8	1.5	0.9	0.6
0.5	30	500	>10	7.1	5.2	1.8	0.9	0.7	1.4	0.8	0.6
0.5	10	750	>10	>10	9.4	2.3	1.6	1.3	1.8	1.2	1.0
0.5	15	750	>10	9.1	7.0	2.1	1.2	0.9	1.6	1.0	0.7
0.5	20	750	>10	7.5	5.6	1.9	1.0	0.7	1.5	0.8	0.6
0.5	25	750	>10	6.4	4.7	1.7	0.9	0.6	1.3	0.7	0.5
0.5	30	750	>10	5.5	4.0	1.5	0.7	0.5	1.2	0.6	0.4
0.5	10	1000	>10	>10	7.9	2.2	1.4	1.1	1.7	1.1	0.8
0.5	15	1000	>10	7.7	5.8	1.9	1.0	0.8	1.5	0.8	0.6
0.5	20	1000	>10	6.3	4.6	1.7	0.8	0.6	1.3	0.7	0.5
0.5	25	1000	>10	5.3	3.8	1.5	0.7	0.5	1.2	0.6	0.4
0.5	30	1000	>10	4.6	3.2	1.4	0.6	0.4	1.1	0.5	0.3
1	10	130	>10	>10	>10	2.6	2.1	1.9	2.0	1.5	1.3
1	15	130	>10	>10	>10	2.5	1.9	1.6	1.9	1.4	1.1
1	20	130	>10	>10	>10	2.4	1.6	1.3	1.8	1.2	0.9
1	25	130	>10	>10	9.3	2.2	1.5	1.2	1.7	1.1	0.8

Battery Longevity and Programmed Setting Choices Model 8103											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	30	130	>10	>10	8.2	2.1	1.3	1.0	1.6	1.0	0.8
1	10	250	>10	>10	>10	2.4	1.7	1.4	1.8	1.3	1.0
1	15	250	>10	>10	8.9	2.2	1.4	1.1	1.7	1.1	0.9
1	20	250	>10	9.4	7.2	2.1	1.2	0.9	1.6	0.9	0.7
1	25	250	>10	8.1	6.1	1.9	1.1	0.8	1.5	0.8	0.6
1	30	250	>10	7.1	5.3	1.8	0.9	0.7	1.4	0.7	0.5
1	10	500	>10	>10	7.9	2.1	1.2	1.0	1.5	0.9	0.7
1	15	500	>10	7.8	5.8	1.8	1.0	0.7	1.4	0.7	0.5
1	20	500	>10	6.3	4.6	1.6	0.8	0.6	1.2	0.6	0.4
1	25	500	>10	5.3	3.8	1.5	0.7	0.5	1.1	0.5	0.4
1	30	500	>10	4.6	3.2	1.3	0.6	0.4	1.0	0.4	0.3
1	10	750	>10	8.0	6.0	1.8	1.0	0.7	1.3	0.7	0.5
1	15	750	>10	6.0	4.3	1.5	0.7	0.5	1.1	0.5	0.4
1	20	750	>10	4.7	3.4	1.3	0.6	0.4	1.0	0.4	0.3
1	25	750	9.3	3.9	2.8	1.2	0.5	0.3	0.9	0.4	0.3
1	30	750	8.3	3.4	2.3	1.1	0.4	0.3	0.8	0.3	0.2
1	10	1000	>10	6.6	4.9	1.6	0.8	0.6	1.2	0.5	0.4
1	15	1000	>10	4.8	3.4	1.3	0.6	0.4	1.0	0.4	0.3
1	20	1000	9.0	3.8	2.7	1.1	0.5	0.3	0.8	0.3	0.2
1	25	1000	7.8	3.1	2.2	1.0	0.4	0.3	0.7	0.3	0.2
1	30	1000	6.9	2.7	1.8	0.9	0.3	0.2	0.6	0.2	0.2
1.5	10	130	>10	>10	8.8	2.2	1.4	1.1	1.6	1.0	0.8
1.5	15	130	>10	>10	7.9	2.1	1.3	1.0	1.6	0.9	0.7
1.5	20	130	>10	9.3	7.1	2.0	1.1	0.9	1.5	0.8	0.6
1.5	25	130	>10	8.3	6.3	1.9	1.0	0.8	1.4	0.7	0.5
1.5	30	130	>10	7.6	5.7	1.8	0.9	0.7	1.3	0.6	0.5
1.5	10	250	>10	>10	8.8	2.1	1.3	1.0	1.5	0.8	0.6
1.5	15	250	>10	8.9	6.8	1.9	1.0	0.8	1.3	0.7	0.5
1.5	20	250	>10	7.5	5.6	1.7	0.9	0.6	1.2	0.6	0.4
1.5	25	250	>10	6.4	4.7	1.6	0.8	0.5	1.1	0.5	0.4
1.5	30	250	>10	5.6	4.0	1.4	0.7	0.5	1.0	0.5	0.3
1.5	10	500	>10	7.3	5.4	1.7	0.8	0.6	1.2	0.6	0.4
1.5	15	500	>10	5.7	4.1	1.4	0.7	0.5	1.0	0.4	0.3
1.5	20	500	>10	4.7	3.3	1.2	0.5	0.4	0.9	0.4	0.2

Battery Longevity and Programmed Setting Choices Model 8103											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	25	500	9.2	3.9	2.7	1.1	0.4	0.3	0.8	0.3	0.2
1.5	30	500	8.2	3.3	2.3	1.0	0.4	0.3	0.7	0.3	0.2
1.5	10	750	>10	5.3	3.8	1.4	0.6	0.4	0.9	0.4	0.3
1.5	15	750	9.5	4.1	2.9	1.1	0.5	0.3	0.8	0.3	0.2
1.5	20	750	8.1	3.3	2.3	1.0	0.4	0.3	0.6	0.2	0.2
1.5	25	750	7.0	2.7	1.9	0.8	0.3	0.2	0.6	0.2	0.1
1.5	30	750	6.2	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
1.5	10	1000	9.7	4.2	3.0	1.1	0.5	0.3	0.8	0.3	0.2
1.5	15	1000	7.8	3.1	2.2	0.9	0.4	0.2	0.6	0.2	0.2
1.5	20	1000	6.5	2.5	1.7	0.8	0.3	0.2	0.5	0.2	0.1
1.5	25	1000	5.6	2.1	1.4	0.7	0.2	0.2	0.4	0.2	0.1
1.5	30	1000	4.9	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
2	10	130	>10	8.7	6.6	1.9	1.1	0.8	1.4	0.7	0.5
2	15	130	>10	7.2	5.3	1.7	0.9	0.6	1.2	0.6	0.4
2	20	130	>10	6.2	4.5	1.6	0.8	0.5	1.1	0.5	0.4
2	25	130	>10	5.5	4.0	1.4	0.7	0.5	1.0	0.5	0.3
2	30	130	>10	5.0	3.5	1.3	0.6	0.4	1.0	0.4	0.3
2	10	250	>10	6.4	4.7	1.6	0.8	0.6	1.2	0.5	0.4
2	15	250	>10	5.2	3.8	1.4	0.6	0.4	1.0	0.4	0.3
2	20	250	>10	4.4	3.1	1.2	0.5	0.4	0.9	0.4	0.3
2	25	250	9.1	3.8	2.7	1.1	0.5	0.3	0.8	0.3	0.2
2	30	250	8.3	3.4	2.3	1.0	0.4	0.3	0.7	0.3	0.2
2	10	500	9.5	4.1	2.9	1.2	0.5	0.3	0.8	0.3	0.2
2	15	500	7.8	3.1	2.2	1.0	0.4	0.3	0.7	0.3	0.2
2	20	500	6.7	2.6	1.8	0.8	0.3	0.2	0.6	0.2	0.1
2	25	500	5.9	2.2	1.5	0.7	0.3	0.2	0.5	0.2	0.1
2	30	500	5.2	1.9	1.3	0.6	0.2	0.1	0.4	0.1	0.1
2	10	750	7.5	2.9	2.0	0.9	0.3	0.2	0.6	0.2	0.2
2	15	750	5.9	2.2	1.5	0.7	0.3	0.2	0.5	0.2	0.1
2	20	750	5.0	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
2	25	750	4.3	1.5	1.0	0.5	0.2	0.1	0.3	0.1	0.1
2	30	750	3.7	1.3	0.9	0.4	0.1	0.1	0.3	0.1	0.1
2	10	1000	6.1	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
2	15	1000	4.7	1.7	1.1	0.6	0.2	0.1	0.4	0.1	0.1

Battery Longevity and Programmed Setting Choices Model 8103											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	20	1000	3.9	1.3	0.9	0.5	0.2	0.1	0.3	0.1	0.1
2	25	1000	3.3	1.1	0.8	0.4	0.1	0.1	0.3	0.1	0.1
2	30	1000	2.9	1.0	0.6	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	130	>10	7.2	5.3	1.7	0.9	0.6	1.3	0.6	0.5
2.5	15	130	>10	6.0	4.4	1.5	0.7	0.5	1.1	0.5	0.4
2.5	20	130	>10	5.1	3.7	1.4	0.6	0.4	1.0	0.4	0.3
2.5	25	130	>10	4.5	3.2	1.2	0.5	0.4	0.9	0.4	0.3
2.5	30	130	9.3	4.0	2.8	1.1	0.5	0.3	0.8	0.3	0.2
2.5	10	250	>10	5.4	3.9	1.4	0.6	0.5	1.0	0.4	0.3
2.5	15	250	9.6	4.1	2.9	1.2	0.5	0.3	0.8	0.3	0.2
2.5	20	250	8.4	3.4	2.4	1.0	0.4	0.3	0.7	0.3	0.2
2.5	25	250	7.4	2.9	2.0	0.9	0.3	0.2	0.6	0.2	0.2
2.5	30	250	6.7	2.5	1.7	0.8	0.3	0.2	0.5	0.2	0.1
2.5	10	500	8.0	3.2	2.2	1.0	0.4	0.3	0.7	0.3	0.2
2.5	15	500	6.3	2.4	1.6	0.8	0.3	0.2	0.5	0.2	0.1
2.5	20	500	5.3	1.9	1.3	0.6	0.2	0.2	0.4	0.2	0.1
2.5	25	500	4.6	1.6	1.1	0.5	0.2	0.1	0.4	0.1	0.1
2.5	30	500	4.0	1.4	0.9	0.5	0.2	0.1	0.3	0.1	0.1
2.5	10	750	6.1	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
2.5	15	750	4.7	1.7	1.1	0.6	0.2	0.1	0.4	0.1	0.1
2.5	20	750	3.9	1.3	0.9	0.5	0.2	0.1	0.3	0.1	0.1
2.5	25	750	3.3	1.1	0.7	0.4	0.1	0.1	0.3	0.1	0.1
2.5	30	750	2.8	0.9	0.6	0.3	0.1	0.1	0.2	0.1	0.0
2.5	10	1000	5.0	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
2.5	15	1000	3.7	1.3	0.9	0.4	0.1	0.1	0.3	0.1	0.1
2.5	20	1000	3.0	1.0	0.7	0.4	0.1	0.1	0.2	0.1	0.1
2.5	25	1000	2.5	0.8	0.6	0.3	0.1	0.1	0.2	0.1	0.0
2.5	30	1000	2.2	0.7	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3	10	130	>10	6.3	4.6	1.6	0.7	0.5	1.1	0.5	0.4
3	15	130	>10	5.0	3.6	1.3	0.6	0.4	1.0	0.4	0.3
3	20	130	9.6	4.2	2.9	1.2	0.5	0.3	0.8	0.3	0.2
3	25	130	8.6	3.6	2.5	1.0	0.4	0.3	0.7	0.3	0.2
3	30	130	7.8	3.1	2.2	0.9	0.4	0.3	0.7	0.2	0.2
3	10	250	>10	4.4	3.1	1.2	0.5	0.4	0.8	0.3	0.2

Battery Longevity and Programmed Setting Choices Model 8103											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3	15	250	8.1	3.3	2.3	1.0	0.4	0.3	0.7	0.3	0.2
3	20	250	6.8	2.6	1.8	0.8	0.3	0.2	0.6	0.2	0.1
3	25	250	5.9	2.2	1.5	0.7	0.3	0.2	0.5	0.2	0.1
3	30	250	5.3	1.9	1.3	0.6	0.2	0.2	0.4	0.1	0.1
3	10	500	6.6	2.5	1.7	0.8	0.3	0.2	0.5	0.2	0.1
3	15	500	5.0	1.8	1.2	0.6	0.2	0.1	0.4	0.1	0.1
3	20	500	4.0	1.4	0.9	0.5	0.2	0.1	0.3	0.1	0.1
3	25	500	3.4	1.2	0.8	0.4	0.1	0.1	0.3	0.1	0.1
3	30	500	3.0	1.0	0.7	0.3	0.1	0.1	0.2	0.1	0.1
3	10	750	4.9	1.7	1.2	0.6	0.2	0.1	0.4	0.1	0.1
3	15	750	3.6	1.2	0.8	0.4	0.1	0.1	0.3	0.1	0.1
3	20	750	2.8	0.9	0.6	0.3	0.1	0.1	0.2	0.1	0.0
3	25	750	2.4	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3	30	750	2.0	0.7	0.4	0.2	0.1	0.1	0.2	0.1	0.0
3	10	1000	3.8	1.3	0.9	0.4	0.2	0.1	0.3	0.1	0.1
3	15	1000	2.8	0.9	0.6	0.3	0.1	0.1	0.2	0.1	0.0
3	20	1000	2.2	0.7	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3	25	1000	1.8	0.6	0.4	0.2	0.1	0.0	0.1	0.0	0.0
3	30	1000	1.5	0.5	0.3	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	130	>10	4.7	3.4	1.3	0.6	0.4	0.9	0.4	0.3
3.5	15	130	9.0	3.8	2.6	1.1	0.4	0.3	0.8	0.3	0.2
3.5	20	130	7.7	3.1	2.1	0.9	0.4	0.3	0.6	0.2	0.2
3.5	25	130	6.8	2.6	1.8	0.8	0.3	0.2	0.6	0.2	0.1
3.5	30	130	6.1	2.3	1.6	0.7	0.3	0.2	0.5	0.2	0.1
3.5	10	250	8.0	3.2	2.2	1.0	0.4	0.3	0.7	0.3	0.2
3.5	15	250	6.4	2.4	1.7	0.8	0.3	0.2	0.5	0.2	0.1
3.5	20	250	5.3	1.9	1.3	0.6	0.2	0.2	0.4	0.2	0.1
3.5	25	250	4.6	1.6	1.1	0.5	0.2	0.1	0.4	0.1	0.1
3.5	30	250	4.0	1.4	0.9	0.5	0.2	0.1	0.3	0.1	0.1
3.5	10	500	4.7	1.7	1.1	0.6	0.2	0.1	0.4	0.1	0.1
3.5	15	500	3.6	1.2	0.8	0.4	0.1	0.1	0.3	0.1	0.1
3.5	20	500	3.0	1.0	0.7	0.3	0.1	0.1	0.2	0.1	0.1
3.5	25	500	2.5	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3.5	30	500	2.1	0.7	0.5	0.2	0.1	0.1	0.2	0.1	0.0

Battery Longevity and Programmed Setting Choices Model 8103											
Parameters at 3 kΩ			Time from BOL to IFI (Years)			Time from IFI to NEOS (Years)			Time from NEOS to EOS (Years)		
mA	Hz	µS	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle	10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	10	750	3.2	1.1	0.7	0.4	0.1	0.1	0.3	0.1	0.1
3.5	15	750	2.4	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3.5	20	750	2.0	0.6	0.4	0.2	0.1	0.0	0.2	0.1	0.0
3.5	25	750	1.7	0.5	0.4	0.2	0.1	0.0	0.1	0.0	0.0
3.5	30	750	1.4	0.5	0.3	0.2	0.1	0.0	0.1	0.0	0.0
3.5	10	1000	2.4	0.8	0.5	0.3	0.1	0.1	0.2	0.1	0.0
3.5	15	1000	1.9	0.6	0.4	0.2	0.1	0.0	0.2	0.0	0.0
3.5	20	1000	1.5	0.5	0.3	0.2	0.1	0.0	0.1	0.0	0.0
3.5	25	1000	1.3	0.4	0.3	0.1	0.0	0.0	0.1	0.0	0.0
3.5	30	1000	1.1	0.3	0.2	0.1	0.0	0.0	0.1	0.0	0.0

10.6. Model 102 / Model 102R Battery Longevity and Programmed Setting Choices

10.6.1. Nominal Estimates – Beginning of Life (BOL) to End of Service (EOS)

Nominal Estimates – Beginning of Life (BOL) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	10	130	2	15.3	11.3	9.5
1	10	130	3	15.1	11.1	9.2
1	10	130	5	14.8	10.5	8.7
1	10	130	7	14.4	9.8	8.0
1	10	500	2	14.2	9.6	7.7
1	10	500	3	13.8	8.9	7.1
1	10	500	5	13.0	7.9	6.1
1	10	500	7	12.4	7.3	5.6
1	10	1000	2	12.8	7.6	5.9
1	10	1000	3	12.2	6.9	5.3
1	10	1000	5	10.9	5.7	4.2
1	10	1000	7	10.3	5.2	3.8
1	20	130	2	14.2	9.5	7.6
1	20	130	3	13.8	9.0	7.2
1	20	130	5	13.4	8.5	6.7
1	20	130	7	12.7	7.6	5.9
1	20	500	2	12.3	7.1	5.4
1	20	500	3	11.7	6.5	4.9
1	20	500	5	10.6	5.5	4.0
1	20	500	7	10.0	4.9	3.6
1	20	1000	2	10.3	5.2	3.8
1	20	1000	3	9.6	4.6	3.3
1	20	1000	5	8.2	3.6	2.6
1	20	1000	7	7.5	3.2	2.3
1	30	130	2	13.1	8.1	6.3
1	30	130	3	12.7	7.6	5.9
1	30	130	5	12.2	7.0	5.3
1	30	130	7	11.4	6.2	4.6
1	30	500	2	10.9	5.7	4.2
1	30	500	3	10.2	5.1	3.7

Nominal Estimates – Beginning of Life (BOL) to End of Service (EOS)
Model 102
Model 102R

Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	30	500	5	9.0	4.2	3.0
1	30	500	7	8.3	3.7	2.6
1	30	1000	2	8.7	3.9	2.8
1	30	1000	3	7.9	3.5	2.4
1	30	1000	5	6.6	2.7	1.8
1	30	1000	7	5.9	2.3	1.6
1.5	10	130	2	14.7	10.3	8.4
1.5	10	130	3	14.4	9.8	7.9
1.5	10	130	5	13.7	8.8	7.0
1.5	10	130	7	13.8	8.9	7.1
1.5	10	500	2	12.4	7.3	5.6
1.5	10	500	3	12.0	6.7	5.1
1.5	10	500	5	10.9	5.7	4.3
1.5	10	500	7	11.2	6.0	4.5
1.5	10	1000	2	10.3	5.2	3.8
1.5	10	1000	3	9.6	4.6	3.3
1.5	10	1000	5	8.4	3.8	2.7
1.5	10	1000	7	8.9	4.1	2.9
1.5	20	130	2	13.1	8.0	6.2
1.5	20	130	3	12.6	7.5	5.8
1.5	20	130	5	11.8	6.5	4.9
1.5	20	130	7	11.8	6.6	5.0
1.5	20	500	2	10.0	5.0	3.6
1.5	20	500	3	9.4	4.5	3.2
1.5	20	500	5	8.2	3.7	2.6
1.5	20	500	7	8.6	3.9	2.8
1.5	20	1000	2	7.5	3.2	2.2
1.5	20	1000	3	6.8	2.8	2.0
1.5	20	1000	5	5.7	2.2	1.5
1.5	20	1000	7	6.2	2.4	1.7
1.5	30	130	2	11.8	6.5	4.9
1.5	30	130	3	11.3	6.1	4.5
1.5	30	130	5	10.3	5.2	3.8
1.5	30	130	7	10.4	5.3	3.9

Nominal Estimates – Beginning of Life (BOL) to End of Service (EOS)
Model 102
Model 102R

Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	30	500	2	8.4	3.8	2.7
1.5	30	500	3	7.7	3.3	2.4
1.5	30	500	5	6.6	2.7	1.9
1.5	30	500	7	7.0	2.9	2.0
1.5	30	1000	2	5.9	2.3	1.6
1.5	30	1000	3	5.3	2.0	1.4
1.5	30	1000	5	4.3	1.6	1.1
1.5	30	1000	7	4.7	1.8	1.2
2	10	130	2	14.1	9.4	7.5
2	10	130	3	13.5	8.5	6.7
2	10	130	5	13.5	8.5	6.7
2	10	130	7	13.7	8.8	7.0
2	10	500	2	11.2	6.0	4.4
2	10	500	3	10.1	5.0	3.6
2	10	500	5	10.5	5.4	3.9
2	10	500	7	11.1	5.9	4.3
2	10	1000	2	8.4	3.8	2.7
2	10	1000	3	7.4	3.1	2.2
2	10	1000	5	7.9	3.5	2.4
2	10	1000	7	8.6	3.9	2.8
2	20	130	2	12.2	7.0	5.3
2	20	130	3	11.3	6.0	4.5
2	20	130	5	11.4	6.2	4.6
2	20	130	7	11.7	6.5	4.9
2	20	500	2	8.4	3.8	2.7
2	20	500	3	7.3	3.1	2.2
2	20	500	5	7.8	3.4	2.4
2	20	500	7	8.4	3.8	2.7
2	20	1000	2	5.5	2.1	1.5
2	20	1000	3	4.8	1.8	1.2
2	20	1000	5	5.3	2.0	1.4
2	20	1000	7	5.9	2.3	1.6
2	30	130	2	10.8	5.6	4.1
2	30	130	3	9.7	4.7	3.4

Nominal Estimates – Beginning of Life (BOL) to End of Service (EOS)
Model 102
Model 102R

Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	30	130	5	9.9	4.9	3.5
2	30	130	7	10.2	5.1	3.8
2	30	500	2	6.8	2.8	1.9
2	30	500	3	5.7	2.2	1.5
2	30	500	5	6.2	2.5	1.7
2	30	500	7	6.8	2.8	1.9
2	30	1000	2	4.0	1.4	1.0
2	30	1000	3	3.6	1.3	0.8
2	30	1000	5	4.0	1.4	1.0
2	30	1000	7	4.6	1.7	1.1
3.5	10	130	2	12.6	7.5	5.7
3.5	10	130	3	12.9	7.8	6.0
3.5	10	130	5	13.3	8.3	6.5
3.5	10	130	7	13.5	8.6	6.8
3.5	10	500	2	8.6	3.9	2.8
3.5	10	500	3	9.2	4.4	3.1
3.5	10	500	5	10.1	5.0	3.7
3.5	10	500	7	10.8	5.6	4.1
3.5	10	1000	2	5.8	2.3	1.6
3.5	10	1000	3	6.5	2.6	1.8
3.5	10	1000	5	7.5	3.2	2.3
3.5	10	1000	7	8.3	3.7	2.6
3.5	20	130	2	10.2	5.1	3.8
3.5	20	130	3	10.6	5.5	4.0
3.5	20	130	5	11.1	5.9	4.4
3.5	20	130	7	11.5	6.3	4.7
3.5	20	500	2	5.9	2.3	1.6
3.5	20	500	3	6.5	2.6	1.8
3.5	20	500	5	7.4	3.1	2.2
3.5	20	500	7	8.1	3.5	2.5
3.5	20	1000	2	3.6	1.3	0.9
3.5	20	1000	3	4.1	1.5	1.0
3.5	20	1000	5	5.0	1.9	1.3
3.5	20	1000	7	5.6	2.2	1.5

Nominal Estimates – Beginning of Life (BOL) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	30	130	2	8.6	3.9	2.8
3.5	30	130	3	9.0	4.2	3.0
3.5	30	130	5	9.6	4.6	3.3
3.5	30	130	7	10.0	4.9	3.6
3.5	30	500	2	4.5	1.7	1.1
3.5	30	500	3	5.0	1.9	1.3
3.5	30	500	5	5.8	2.3	1.6
3.5	30	500	7	6.5	2.6	1.8
3.5	30	1000	2	2.7	0.9	0.6
3.5	30	1000	3	3.0	1.0	0.7
3.5	30	1000	5	3.7	1.3	0.9
3.5	30	1000	7	4.3	1.6	1.1

10.6.2. Worst Case Estimates – Beginning of Life (BOL) to Near End of Service (NEOS)

Worst Case Estimates – Beginning of Life (BOL) to Near End of Service (NEOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	10	130	2	9.3	7.1	6.0
1	10	130	3	9.3	7.2	6.1
1	10	130	5	8.8	6.2	5.1
1	10	130	7	8.8	6.2	5.0
1	10	500	2	9.1	6.8	5.7
1	10	500	3	8.9	6.4	5.2
1	10	500	5	8.2	5.3	4.2
1	10	500	7	8.0	5.0	3.9
1	10	1000	2	8.3	5.4	4.3
1	10	1000	3	8.0	5.1	4.0
1	10	1000	5	7.2	4.1	3.1
1	10	1000	7	6.8	3.7	2.8
1	20	130	2	9.1	6.7	5.6
1	20	130	3	8.9	6.4	5.3
1	20	130	5	8.6	5.9	4.8
1	20	130	7	8.2	5.3	4.2
1	20	500	2	8.2	5.2	4.2
1	20	500	3	7.8	4.8	3.7
1	20	500	5	6.9	3.8	2.8
1	20	500	7	6.7	3.6	2.7
1	20	1000	2	6.9	3.7	2.8
1	20	1000	3	6.6	3.5	2.6
1	20	1000	5	5.7	2.8	2.0
1	20	1000	7	5.2	2.4	1.7
1	30	130	2	8.6	5.9	4.7
1	30	130	3	8.4	5.6	4.4
1	30	130	5	8.0	5.0	3.9
1	30	130	7	7.5	4.5	3.4
1	30	500	2	7.4	4.3	3.3
1	30	500	3	7.0	3.9	2.9

Worst Case Estimates – Beginning of Life (BOL) to Near End of Service (NEOS)
Model 102
Model 102R

Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	30	500	5	6.1	3.0	2.2
1	30	500	7	5.7	2.8	2.0
1	30	1000	2	5.8	2.8	2.0
1	30	1000	3	5.6	2.7	1.9
1	30	1000	5	4.7	2.1	1.5
1	30	1000	7	4.1	1.7	1.2
1.5	10	130	2	9.2	6.9	5.9
1.5	10	130	3	8.9	6.5	5.4
1.5	10	130	5	8.3	5.4	4.3
1.5	10	130	7	8.3	5.5	4.4
1.5	10	500	2	7.9	4.9	3.8
1.5	10	500	3	7.8	4.8	3.7
1.5	10	500	5	7.1	4.0	3.0
1.5	10	500	7	7.2	4.1	3.1
1.5	10	1000	2	7.0	3.9	2.9
1.5	10	1000	3	6.6	3.5	2.6
1.5	10	1000	5	5.8	2.8	2.0
1.5	10	1000	7	6.0	3.0	2.2
1.5	20	130	2	8.5	5.7	4.6
1.5	20	130	3	8.2	5.3	4.2
1.5	20	130	5	7.6	4.5	3.5
1.5	20	130	7	7.6	4.6	3.5
1.5	20	500	2	6.9	3.8	2.8
1.5	20	500	3	6.5	3.4	2.5
1.5	20	500	5	5.7	2.7	2.0
1.5	20	500	7	5.9	2.9	2.1
1.5	20	1000	2	5.3	2.5	1.8
1.5	20	1000	3	4.9	2.2	1.5
1.5	20	1000	5	4.2	1.7	1.2
1.5	20	1000	7	4.5	1.9	1.3
1.5	30	130	2	7.8	4.8	3.8
1.5	30	130	3	7.5	4.5	3.4
1.5	30	130	5	6.9	3.7	2.8
1.5	30	130	7	6.9	3.8	2.8

Worst Case Estimates – Beginning of Life (BOL) to Near End of Service (NEOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	30	500	2	5.9	2.9	2.1
1.5	30	500	3	5.5	2.6	1.9
1.5	30	500	5	4.8	2.1	1.5
1.5	30	500	7	5.0	2.2	1.6
1.5	30	1000	2	4.3	1.8	1.3
1.5	30	1000	3	3.9	1.6	1.1
1.5	30	1000	5	3.3	1.2	0.8
1.5	30	1000	7	3.5	1.4	1.0
2	10	130	2	8.8	6.3	5.2
2	10	130	3	8.0	5.0	4.0
2	10	130	5	8.2	5.3	4.2
2	10	130	7	8.3	5.5	4.4
2	10	500	2	7.4	4.3	3.3
2	10	500	3	6.6	3.5	2.6
2	10	500	5	6.9	3.7	2.8
2	10	500	7	7.2	4.0	3.1
2	10	1000	2	5.6	2.6	1.9
2	10	1000	3	5.1	2.3	1.7
2	10	1000	5	5.5	2.6	1.9
2	10	1000	7	5.9	2.9	2.1
2	20	130	2	8.0	5.0	3.9
2	20	130	3	7.3	4.2	3.2
2	20	130	5	7.4	4.3	3.3
2	20	130	7	7.6	4.5	3.4
2	20	500	2	5.8	2.8	2.0
2	20	500	3	5.2	2.3	1.7
2	20	500	5	5.4	2.5	1.8
2	20	500	7	5.8	2.8	2.0
2	20	1000	2	3.7	1.4	1.0
2	20	1000	3	3.6	1.4	1.0
2	20	1000	5	3.9	1.6	1.1
2	20	1000	7	4.3	1.8	1.3
2	30	130	2	7.3	4.1	3.1
2	30	130	3	6.5	3.4	2.5

Worst Case Estimates – Beginning of Life (BOL) to Near End of Service (NEOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	30	130	5	6.7	3.5	2.6
2	30	130	7	6.8	3.7	2.8
2	30	500	2	4.7	2.1	1.5
2	30	500	3	4.2	1.7	1.2
2	30	500	5	4.5	1.9	1.3
2	30	500	7	4.9	2.1	1.5
2	30	1000	2	2.9	1.0	0.7
2	30	1000	3	2.7	1.0	0.7
2	30	1000	5	3.1	1.1	0.8
2	30	1000	7	3.4	1.3	0.9
3.5	10	130	2	7.9	4.9	3.8
3.5	10	130	3	8.0	5.1	4.0
3.5	10	130	5	8.2	5.3	4.2
3.5	10	130	7	8.3	5.5	4.4
3.5	10	500	2	5.9	2.9	2.1
3.5	10	500	3	6.2	3.1	2.3
3.5	10	500	5	6.7	3.6	2.7
3.5	10	500	7	7.0	3.9	2.9
3.5	10	1000	2	4.2	1.8	1.2
3.5	10	1000	3	4.6	2.0	1.4
3.5	10	1000	5	5.2	2.4	1.7
3.5	10	1000	7	5.7	2.7	2.0
3.5	20	130	2	6.8	3.7	2.7
3.5	20	130	3	7.0	3.9	2.9
3.5	20	130	5	7.3	4.2	3.2
3.5	20	130	7	7.4	4.4	3.3
3.5	20	500	2	4.3	1.8	1.3
3.5	20	500	3	4.7	2.0	1.4
3.5	20	500	5	5.2	2.4	1.7
3.5	20	500	7	5.6	2.7	1.9
3.5	20	1000	2	2.8	1.0	0.7
3.5	20	1000	3	3.1	1.2	0.8
3.5	20	1000	5	3.7	1.5	1.0
3.5	20	1000	7	4.1	1.7	1.2

Worst Case Estimates – Beginning of Life (BOL) to Near End of Service (NEOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Estimated Battery Life (Years)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	30	130	2	6.0	2.9	2.1
3.5	30	130	3	6.2	3.1	2.3
3.5	30	130	5	6.5	3.4	2.5
3.5	30	130	7	6.7	3.6	2.7
3.5	30	500	2	3.4	1.3	0.9
3.5	30	500	3	3.7	1.5	1.0
3.5	30	500	5	4.3	1.8	1.2
3.5	30	500	7	4.7	2.0	1.4
3.5	30	1000	2	2.1	0.7	0.5
3.5	30	1000	3	2.4	0.8	0.6
3.5	30	1000	5	2.9	1.1	0.7
3.5	30	1000	7	3.2	1.2	0.8

10.6.3. Nominal Time Estimates – Near End of Service (NEOS) to End of Service (EOS)

Nominal Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	10	130	2	9.4	6.7	5.5
1	10	130	3	9.3	6.5	5.3
1	10	130	5	9.1	6.2	5.0
1	10	130	7	8.8	5.8	4.6
1	10	500	2	8.7	5.6	4.4
1	10	500	3	8.4	5.2	4.1
1	10	500	5	7.9	4.6	3.5
1	10	500	7	7.5	4.2	3.2
1	10	1000	2	7.7	4.4	3.4
1	10	1000	3	7.3	4.0	3.1
1	10	1000	5	6.5	3.3	2.5
1	10	1000	7	6.2	3.0	2.2
1	20	130	2	8.6	5.5	4.4
1	20	130	3	8.4	5.3	4.1
1	20	130	5	8.2	4.9	3.8
1	20	130	7	7.7	4.4	3.4
1	20	500	2	7.4	4.1	3.1
1	20	500	3	7.0	3.8	2.8
1	20	500	5	6.3	3.2	2.3
1	20	500	7	5.9	2.9	2.1
1	20	1000	2	6.2	3.0	2.2
1	20	1000	3	5.7	2.7	2.0
1	20	1000	5	4.8	2.1	1.5
1	20	1000	7	4.4	1.9	1.4
1	30	130	2	8.0	4.7	3.6
1	30	130	3	7.7	4.4	3.4
1	30	130	5	7.4	4.1	3.1
1	30	130	7	6.9	3.6	2.7
1	30	500	2	6.5	3.3	2.4
1	30	500	3	6.1	3.0	2.2

Nominal Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	30	500	5	5.3	2.4	1.8
1	30	500	7	4.9	2.2	1.6
1	30	1000	2	5.1	2.3	1.7
1	30	1000	3	4.7	2.0	1.5
1	30	1000	5	3.9	1.6	1.1
1	30	1000	7	3.3	1.3	0.9
1.5	10	130	2	9.0	6.0	4.9
1.5	10	130	3	8.8	5.7	4.6
1.5	10	130	5	8.4	5.2	4.0
1.5	10	130	7	8.4	5.2	4.1
1.5	10	500	2	7.5	4.2	3.2
1.5	10	500	3	7.2	3.9	3.0
1.5	10	500	5	6.6	3.3	2.5
1.5	10	500	7	6.7	3.5	2.6
1.5	10	1000	2	6.1	3.0	2.2
1.5	10	1000	3	5.7	2.7	2.0
1.5	10	1000	5	5.0	2.2	1.6
1.5	10	1000	7	5.3	2.4	1.7
1.5	20	130	2	7.9	4.7	3.6
1.5	20	130	3	7.6	4.4	3.3
1.5	20	130	5	7.1	3.8	2.8
1.5	20	130	7	7.1	3.8	2.9
1.5	20	500	2	6.0	2.9	2.1
1.5	20	500	3	5.6	2.6	1.9
1.5	20	500	5	4.9	2.2	1.6
1.5	20	500	7	5.1	2.3	1.7
1.5	20	1000	2	4.4	1.9	1.4
1.5	20	1000	3	4.0	1.7	1.2
1.5	20	1000	5	3.1	1.3	0.9
1.5	20	1000	7	3.6	1.5	1.1
1.5	30	130	2	7.1	3.8	2.9
1.5	30	130	3	6.8	3.5	2.6
1.5	30	130	5	6.1	3.0	2.2
1.5	30	130	7	6.2	3.1	2.3

Nominal Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	30	500	2	5.0	2.2	1.6
1.5	30	500	3	4.6	2.0	1.4
1.5	30	500	5	3.9	1.6	1.2
1.5	30	500	7	4.1	1.7	1.2
1.5	30	1000	2	3.2	1.3	0.9
1.5	30	1000	3	2.9	1.1	0.8
1.5	30	1000	5	2.4	0.9	0.7
1.5	30	1000	7	2.6	1.0	0.7
2	10	130	2	8.6	5.5	4.3
2	10	130	3	8.2	5.0	3.9
2	10	130	5	8.2	5.0	3.9
2	10	130	7	8.3	5.1	4.0
2	10	500	2	6.7	3.5	2.6
2	10	500	3	6.0	2.9	2.1
2	10	500	5	6.3	3.1	2.3
2	10	500	7	6.6	3.4	2.5
2	10	1000	2	5.0	2.2	1.6
2	10	1000	3	4.3	1.8	1.3
2	10	1000	5	4.7	2.0	1.5
2	10	1000	7	5.1	2.3	1.7
2	20	130	2	7.4	4.1	3.1
2	20	130	3	6.8	3.5	2.6
2	20	130	5	6.9	3.6	2.7
2	20	130	7	7.0	3.8	2.8
2	20	500	2	5.0	2.2	1.6
2	20	500	3	4.3	1.8	1.3
2	20	500	5	4.6	2.0	1.4
2	20	500	7	5.0	2.2	1.6
2	20	1000	2	3.0	1.2	0.9
2	20	1000	3	2.6	1.0	0.7
2	20	1000	5	2.9	1.2	0.8
2	20	1000	7	3.3	1.3	0.9
2	30	130	2	6.4	3.2	2.4
2	30	130	3	5.8	2.8	2.0

Nominal Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	30	130	5	5.9	2.8	2.1
2	30	130	7	6.1	3.0	2.2
2	30	500	2	4.0	1.7	1.2
2	30	500	3	3.2	1.3	0.9
2	30	500	5	3.6	1.5	1.1
2	30	500	7	4.0	1.7	1.2
2	30	1000	2	2.2	0.9	0.6
2	30	1000	3	2.0	0.8	0.6
2	30	1000	5	2.2	0.9	0.6
2	30	1000	7	2.5	1.0	0.7
3.5	10	130	2	7.6	4.3	3.3
3.5	10	130	3	7.8	4.5	3.5
3.5	10	130	5	8.1	4.8	3.7
3.5	10	130	7	8.2	5.0	3.9
3.5	10	500	2	5.1	2.3	1.7
3.5	10	500	3	5.5	2.5	1.8
3.5	10	500	5	6.0	2.9	2.1
3.5	10	500	7	6.4	3.2	2.4
3.5	10	1000	2	3.2	1.3	0.9
3.5	10	1000	3	3.8	1.6	1.1
3.5	10	1000	5	4.4	1.9	1.4
3.5	10	1000	7	4.9	2.2	1.6
3.5	20	130	2	6.1	3.0	2.2
3.5	20	130	3	6.3	3.2	2.3
3.5	20	130	5	6.7	3.4	2.6
3.5	20	130	7	6.9	3.6	2.7
3.5	20	500	2	3.3	1.3	0.9
3.5	20	500	3	3.8	1.6	1.1
3.5	20	500	5	4.3	1.9	1.3
3.5	20	500	7	4.8	2.1	1.5
3.5	20	1000	2	2.0	0.8	0.6
3.5	20	1000	3	2.3	0.9	0.6
3.5	20	1000	5	2.7	1.1	0.8
3.5	20	1000	7	3.1	1.2	0.9

Nominal Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Nominal Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	30	130	2	5.1	2.3	1.7
3.5	30	130	3	5.4	2.5	1.8
3.5	30	130	5	5.7	2.7	2.0
3.5	30	130	7	6.0	2.9	2.1
3.5	30	500	2	2.5	1.0	0.7
3.5	30	500	3	2.8	1.1	0.8
3.5	30	500	5	3.2	1.3	0.9
3.5	30	500	7	3.8	1.6	1.1
3.5	30	1000	2	1.5	0.6	0.4
3.5	30	1000	3	1.7	0.7	0.5
3.5	30	1000	5	2.1	0.8	0.6
3.5	30	1000	7	2.4	0.9	0.7

10.6.4. Worst Case Time Estimates – Near End of Service (NEOS) to End of Service (EOS)

Worst Case Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	10	130	2	7.7	5.6	4.7
1	10	130	3	7.8	5.7	4.8
1	10	130	5	7.2	4.9	4.0
1	10	130	7	7.2	4.9	3.9
1	10	500	2	7.6	5.4	4.4
1	10	500	3	7.3	5.0	4.1
1	10	500	5	6.7	4.2	3.3
1	10	500	7	6.5	3.9	3.0
1	10	1000	2	6.8	4.2	3.3
1	10	1000	3	6.6	4.0	3.1
1	10	1000	5	5.9	3.2	2.4
1	10	1000	7	5.5	2.9	2.2
1	20	130	2	7.5	5.3	4.4
1	20	130	3	7.4	5.1	4.1
1	20	130	5	7.1	4.7	3.7
1	20	130	7	6.7	4.1	3.2
1	20	500	2	6.7	4.1	3.2
1	20	500	3	6.4	3.8	2.9
1	20	500	5	5.6	3.0	2.2
1	20	500	7	5.4	2.8	2.1
1	20	1000	2	5.6	2.9	2.2
1	20	1000	3	5.3	2.8	2.1
1	20	1000	5	4.6	2.2	1.6
1	20	1000	7	4.1	1.9	1.4
1	30	130	2	7.1	4.6	3.7
1	30	130	3	6.9	4.4	3.5
1	30	130	5	6.5	3.9	3.0
1	30	130	7	6.1	3.5	2.7
1	30	500	2	6.0	3.4	2.6
1	30	500	3	5.7	3.0	2.3

Worst Case Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1	30	500	5	4.9	2.4	1.8
1	30	500	7	4.6	2.2	1.6
1	30	1000	2	4.6	2.2	1.6
1	30	1000	3	4.5	2.1	1.6
1	30	1000	5	3.8	1.7	1.2
1	30	1000	7	3.1	1.3	0.9
1.5	10	130	2	7.6	5.5	4.6
1.5	10	130	3	7.4	5.1	4.2
1.5	10	130	5	6.8	4.3	3.4
1.5	10	130	7	6.8	4.3	3.4
1.5	10	500	2	6.4	3.8	3.0
1.5	10	500	3	6.4	3.8	2.9
1.5	10	500	5	5.7	3.1	2.3
1.5	10	500	7	5.9	3.3	2.5
1.5	10	1000	2	5.6	3.0	2.3
1.5	10	1000	3	5.3	2.7	2.0
1.5	10	1000	5	4.6	2.2	1.6
1.5	10	1000	7	4.8	2.4	1.7
1.5	20	130	2	7.0	4.5	3.6
1.5	20	130	3	6.7	4.2	3.3
1.5	20	130	5	6.2	3.5	2.7
1.5	20	130	7	6.2	3.6	2.7
1.5	20	500	2	5.6	3.0	2.2
1.5	20	500	3	5.2	2.7	2.0
1.5	20	500	5	4.6	2.2	1.6
1.5	20	500	7	4.7	2.3	1.7
1.5	20	1000	2	4.3	2.0	1.4
1.5	20	1000	3	3.9	1.7	1.3
1.5	20	1000	5	3.1	1.3	0.9
1.5	20	1000	7	3.5	1.5	1.1
1.5	30	130	2	6.4	3.8	2.9
1.5	30	130	3	6.1	3.5	2.7
1.5	30	130	5	5.5	2.9	2.2
1.5	30	130	7	5.6	3.0	2.2

Worst Case Time Estimates – Near End of Service (NEOS) to End of Service (EOS)
Model 102
Model 102R

Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
1.5	30	500	2	4.8	2.3	1.7
1.5	30	500	3	4.4	2.1	1.5
1.5	30	500	5	3.8	1.7	1.2
1.5	30	500	7	4.0	1.8	1.3
1.5	30	1000	2	3.3	1.4	1.0
1.5	30	1000	3	2.9	1.2	0.9
1.5	30	1000	5	2.4	1.0	0.7
1.5	30	1000	7	2.6	1.1	0.8
2	10	130	2	7.3	4.9	4.0
2	10	130	3	6.5	4.0	3.1
2	10	130	5	6.7	4.2	3.3
2	10	130	7	6.8	4.3	3.4
2	10	500	2	6.0	3.4	2.6
2	10	500	3	5.4	2.8	2.1
2	10	500	5	5.5	2.9	2.2
2	10	500	7	5.8	3.2	2.4
2	10	1000	2	4.5	2.1	1.5
2	10	1000	3	4.1	1.9	1.3
2	10	1000	5	4.4	2.1	1.5
2	10	1000	7	4.7	2.3	1.7
2	20	130	2	6.5	3.9	3.1
2	20	130	3	5.9	3.3	2.5
2	20	130	5	6.0	3.4	2.6
2	20	130	7	6.1	3.5	2.7
2	20	500	2	4.7	2.2	1.6
2	20	500	3	4.1	1.9	1.4
2	20	500	5	4.3	2.0	1.5
2	20	500	7	4.6	2.2	1.6
2	20	1000	2	2.7	1.1	0.8
2	20	1000	3	2.7	1.1	0.8
2	20	1000	5	2.9	1.2	0.9
2	20	1000	7	3.2	1.4	1.0
2	30	130	2	5.9	3.3	2.5
2	30	130	3	5.3	2.7	2.0

Worst Case Time Estimates – Near End of Service (NEOS) to End of Service (EOS)
Model 102
Model 102R

Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
2	30	130	5	5.4	2.8	2.1
2	30	130	7	5.5	2.9	2.2
2	30	500	2	3.8	1.7	1.2
2	30	500	3	3.1	1.3	0.9
2	30	500	5	3.6	1.5	1.1
2	30	500	7	3.9	1.7	1.2
2	30	1000	2	2.1	0.8	0.6
2	30	1000	3	2.0	0.8	0.6
2	30	1000	5	2.3	0.9	0.7
2	30	1000	7	2.6	1.0	0.7
3.5	10	130	2	6.4	3.8	3.0
3.5	10	130	3	6.6	4.0	3.1
3.5	10	130	5	6.7	4.2	3.3
3.5	10	130	7	6.8	4.3	3.4
3.5	10	500	2	4.7	2.3	1.7
3.5	10	500	3	5.0	2.5	1.8
3.5	10	500	5	5.4	2.8	2.1
3.5	10	500	7	5.7	3.1	2.3
3.5	10	1000	2	3.2	1.3	1.0
3.5	10	1000	3	3.7	1.6	1.2
3.5	10	1000	5	4.2	1.9	1.4
3.5	10	1000	7	4.6	2.2	1.6
3.5	20	130	2	5.5	2.9	2.2
3.5	20	130	3	5.7	3.0	2.3
3.5	20	130	5	5.9	3.3	2.5
3.5	20	130	7	6.1	3.4	2.6
3.5	20	500	2	3.2	1.4	1.0
3.5	20	500	3	3.7	1.6	1.2
3.5	20	500	5	4.2	1.9	1.4
3.5	20	500	7	4.5	2.1	1.5
3.5	20	1000	2	2.1	0.8	0.6
3.5	20	1000	3	2.3	0.9	0.7
3.5	20	1000	5	2.8	1.1	0.8
3.5	20	1000	7	3.1	1.3	0.9

Worst Case Time Estimates – Near End of Service (NEOS) to End of Service (EOS) Model 102 Model 102R						
Output Current (mA)	Frequency (Hz)	Pulse Width (µsec)	DC-DC Converter Code	Worst Case Time from NEOS to EOS (Months)		
				10% Duty Cycle	33% Duty Cycle	50% Duty Cycle
3.5	30	130	2	4.8	2.3	1.7
3.5	30	130	3	5.0	2.5	1.8
3.5	30	130	5	5.2	2.7	2.0
3.5	30	130	7	5.4	2.8	2.1
3.5	30	500	2	2.5	1.0	0.7
3.5	30	500	3	2.8	1.1	0.8
3.5	30	500	5	3.2	1.3	1.0
3.5	30	500	7	3.7	1.6	1.2
3.5	30	1000	2	1.6	0.6	0.5
3.5	30	1000	3	1.8	0.7	0.5
3.5	30	1000	5	2.1	0.8	0.6
3.5	30	1000	7	2.4	1.0	0.7

LivaNova Forms

Return Product Form

A Returned Product Form is used for the return of any VNS Therapy system component. Call first for a Return Goods Authorization (RGA) number, available from "Technical Support" on page 179. Before device components are returned, disinfect them with Betadine®, Cidex® soak, or other similar disinfectant, and double seal them in a pouch or other container properly labeled with a biohazard warning.

Return Product Forms are posted at www.livanova.com.

Implant and Warranty Registration Form

Download a copy of the Implant and Warranty Registration form at www.livanova.com.

Find your preferred language and complete the form online (or print and complete by hand).

Print 3 copies of the completed form:

- Return one to LivaNova
- Keep one for the patient chart
- Give one to the patient

NOTE: A pre-printed triplicate copy is provided in the generator sales pack.

Limited Replacement Warranty

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

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

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

1. A properly completed Implant and Warranty Registration form for both the VNS Therapy generator and the VNS Therapy lead must be returned to LivaNova USA, Inc. within sixty (60) days of device implantation;
2. The battery in the VNS Therapy generator cannot have been depleted as a result of programming to unusually high output currents, pulse widths, or duty cycles, which will cause a high energy / current drain;
3. The VNS Therapy lead cannot have been cut or damaged due to excessive handling or abuse during surgical implantation;
4. The product must have been used and prescribed in accordance with the VNS Therapy and programming system physician's manuals;
5. The VNS Therapy generator or lead must have been implanted prior to its "use by date";
6. The defective VNS Therapy generator or lead must be returned to LivaNova USA, Inc. with an accompanying Authorization number and confirmed defective by the Quality Assurance Department;
7. To obtain an authorization number contact "Technical Support" on page 179;
8. All returned VNS Therapy generators and leads shall become the property of LivaNova USA, Inc.

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

If the VNS Therapy generator or lead becomes defective within the warranty period, contact LivaNova USA, Inc. Customer Service for a no-cost replacement. LivaNova USA, Inc. reserves the right to replace a defective product with the most comparable product currently available. Returned biohazardous product should be

clearly identified as such on the outside surface of the package. To access an electronic copy, see "Contacts and Resources" on the next page.

No implied warranty, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose, shall extend beyond the period specified above. This replacement warranty shall be the exclusive remedy available to any person. No person has any authority to bind LivaNova USA, Inc. to any representation, condition, or warranty except this Limited Replacement Warranty.

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

Contacts and Resources

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

Contacts

	 LivaNova USA, Inc. 100 Cyberonics Blvd Houston, Texas 77058 USA	 LivaNova Belgium NV Ikaroslaan 83 B-1930 Zaventem BELGIUM	 LivaNova Switzerland Rue de Grand-Pont 12 CH-1003 Lausanne SWITZERLAND
Tel:	+1 281 228 7200 (Worldwide)	+32 2 720 95 93	
Toll free:	+1 800 332 1375 (US/Canada)		
Fax:	+1 281 218 9332	+32 2 720 60 53	
Website:	www.livanova.com	www.livanova.com	www.livanova.com

Technical Support

Available 24 hours per day	
Toll free:	+1 866 882 8804 (US/Canada)
Tel:	+1 281 228 7330 (Worldwide)
Tel:	+32 2 790 27 73 (Europe/EMMEA)

Regulatory Authority Websites

Report all adverse events related to the device to LivaNova and to your local regulatory authority.

Australia	https://www.tga.gov.au/
Canada	https://www.canada.ca/en/health-canada.html
UK	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
EU	https://ec.europa.eu/growth/sectors/medical-devices/contacts_en