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WaveWriter Alpha™ and WaveWriter Alpha™ Prime Systems

Information for Prescribers

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℞ ONLY

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Drawings are for illustration purposes only.

Trademarks

Wavewriter Alpha™ and Wavewriter Alpha™ Prime are registered trademarks of Boston Scientific Corporation or its affiliates.

All other trademarks are the property of their respective owners.

The Bluetooth® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Boston Scientific Neuromodulation Corporation is under license.

Additional Information

For Indications and related information, see the *Indications DFU*. For other device-specific information not included in this manual, labeling symbols, and warranty information, refer to the appropriate DFU for your SCS System as listed on your *Reference Guide.*

Throughout this document, the WaveWriter Alpha™ and WaveWriter Alpha™ 16 Systems will be referred to as the WaveWriter Alpha System. WaveWriter Alpha™ Prime, and WaveWriter Alpha™ Prime 16 Systems will be referred to as the WaveWriter Alpha Prime Systems.

The WaveWriter Alpha System includes a rechargeable Implantable Pulse Generator (IPG). References to the Charging System or charging process are applicable only for rechargeable IPGs.

The WaveWriter Alpha Prime System includes a non-rechargeable IPG.

Labeling Symbols

For an explanation of labeling symbols, refer to the Labeling Symbols document.

Warranty

For device warranty information, visit (www.bostonscientific.com/warranty).

Table of Contents

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Device and Product Description

The WaveWriter Alpha™ and WaveWriter Alpha™ Prime Systems consist of an Implantable Pulse Generator (IPG), temporary and permanent Percutaneous Leads, Surgical Paddle Leads, Lead Extensions, OR Cables, External Trial Stimulator (ETS), Remote Control, and Clinician Programmer, each packaged as a separate kit. Single use accessories and disposable tools are also included in these kits.

Features of the WaveWriter Alpha and WaveWriter Alpha Prime System include:

- Automatic program cycling
- MicroBurst capability between 0 to 1 second range
- Programming of multi-areas at rates greater than 130 Hz
- Patient-provided Therapy Rating
- Stimulation electrode field navigation
- Up to thirty-two independent current-controlled electrodes
- Four programmable stimulation areas per program; sixteen possible programs
- Long-life operation
- High-range parameter capability
- Small size and rounded shape
- Wireless programming capabilities
- This product contains no detectable latex.

Essential Performance

External Trial Stimulator

The stimulation pulse shall meet the requirements for charge balance and amplitude while stimulation is on.

Other External Devices

Failure of the external electrical components will not result in an unacceptable risk to the user.

System Clinical Summary

Determination of the safety and effectiveness of the WaveWriter Alpha and WaveWriter Alpha Prime Systems was based on available published clinical studies for similar implanted spinal cord stimulation systems. The WaveWriter Alpha and WaveWriter Alpha Prime Systems are similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the WaveWriter Alpha and WaveWriter Alpha Prime Systems for the treatment chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Efficacy Evaluation

Three (3) clinical literature studies were used to support the effectiveness of the WaveWriter Alpha and WaveWriter Alpha Prime Systems (Ohnmeiss et al. 1996, Villavincencio et al. 2000, Hassenbach SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system.
A total of approximately 3166 device months of experience was depicted from the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, a totally implantable spinal cord stimulator was used in association with a percutaneous and/or surgical lead. These studies provide the same

diagnostic or therapeutic intervention for the same disease/conditions and patient population as the WaveWriter Alpha and WaveWriter Alpha Prime Systems.

The prospective study by Ohnmeiss et al. 1996, examined the long-term effectiveness of SCS in patients with intractable leg pain. Forty patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP (Sickness Impact Profile), isometric lower extremity testing, and patient questionnaires. An intent-to-treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, 25% of the implanted patients had greater than 50% improvement in pain rating.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 patient had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study performed by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome (CRPS I and II), 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In this study, 27/41 patients, 66%, had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%), reported greater than 50% reduction in pain.

Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, one patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis performed by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opioids. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. Five patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief.

There were 4 (10%) patients who underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" 16/26 patients (62%) had greater than 50% pain relief with SCS. In this study, 2/16 (13%) had greater than 50% pain relief with opioids. Mean follow-up was 2.1 ± 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Eleven studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the WaveWriter Alpha and WaveWriter Alpha Prime Systems. The studies included a total of 1056 patients that were trialed with SCS systems and 880 patients that received implants. The table below depicts the number of patients, the number of events, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that citations cover both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

Table 1: Summary of Risks Identified in the Retrospective Clinical Studies

Risks	# Patients With Adverse Event	Intent-to-Treat Basis N = 1056	Implanted Patient Basis N = 880
Lead Migration	175	16.6%	19.9%
Infection	39	3.7%	4.4%
Epidural Hemorrhage	0	0%	0%
Seroma	0	0%	0%
Hematoma	1	0.1%	0.1%
Paralysis	0	0%	0%
CSF Leak	5	0.5%	0.6%
Over/Under Stimulation, Ineffective Pain Control	46	4.4%	5.2%
Intermittent Stimulation	0	0%	0%
Pain Over Implant	16	1.5%	1.8%
Allergic Reaction	6	0.6%	0.7%
Skin Erosion	0	0%	0%
Lead Breakage	35	3.3%	4.0%
Hardware Malfunction	22	2.1%	2.5%
Loose Connection	0	0%	0%
Battery Failure	2	0.2%	0.2%
Other	45	4.3%	5.1%

Clinical Experience-Safety

Clinical data has been collected during a clinical study of the Precision System. As of January 15, 2004, 35 subjects were enrolled in the study at multiple sites and 26 subjects had a successful trial stimulation period and were implanted with the Precision System. The follow-up period for the 26 implanted patients ranged from two weeks to six months. The following major adverse events were reported.

Table 2: Clinical Experience Safety

Type	Number of Patients	Resolution
Lead Migration	1	Lead repositioning and subsequent replacement
Output malfunction	1	Device replaced
Infection	1	Infection treated
Pain	1	Lead explanted

Other minor adverse events reported by at least one patient included: receiver malfunction, skin irritation, unpleasant stimulation, CSF leak, infection at implant site, lead migration, and OR cable malfunction. Two of the subjects reported multiple events.

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Subperception Therapy - Clinical Summary

Determination of the safety and effectiveness of the Boston Scientific Spinal Cord Stimulator (SCS) Systems for subperception therapy was based on a prospective, randomized, multicenter, crossover study with the primary endpoint of responder rate (proportion of subjects with 50% or greater improvement in overall pain) at 3 month post-device activation. A crossover design provided within-subject comparison between the supra-perception and subperception settings.

The primary objective of this study was to demonstrate sustained clinically significant pain relief in patients with chronic pain when using the Boston Scientific SCS Systems at subperception amplitude.

Of the 197 subjects that provided consent to participate in the study, 136 were randomized to either receive subperception followed by supra-perception settings or vice versa for 90 days post-activation. The study cohort was comprised of subjects who have been treated successfully with paresthesia-inducing stimulation for at least six months.

Efficacy Outcomes

The study successfully met its primary effectiveness endpoint, demonstrating that the proportion of overall pain responders at 90 days post-activation with subperception settings is non-inferior compared to supra-perception settings at a statistically significant level ($p < 0.001$). The study also successfully demonstrated non-inferiority in the Per Protocol group indicating the robustness of the study.

At the end of the crossover period, subjects were asked to choose between supra-perception and subperception settings. Of the 70 subjects included in the primary effectiveness cohort, 53 subjects (76%) chose subperception whereas only 17 (24%) chose supra-perception as their preferred treatment settings. Additionally, 40 subjects (57%) preferred to keep both the stimulation treatments if given the option.

Safety Outcomes

A total of 27 adverse events were reported among 20 subjects across the entire study experience. Of the 27 adverse events, 12 were serious adverse events (SAEs) and 15 nonserious adverse events. All serious adverse events were unrelated to the study-device and/or study-procedure. There were no unanticipated events.

Contraindications

Patients contraindicated for permanent Spinal Cord Stimulation (SCS) therapy are those who:

- are unable to operate the System
- have failed trial stimulation by failing to receive effective pain relief
- are poor surgical candidates
- are pregnant

Safety Information

WARNING: Unauthorized modification to the medical devices is prohibited. System integrity could be compromised and harm or injury to the patient could occur if the medical devices are subjected to unauthorized modification.

Instructions for the Patient

Warnings

Heat Due to Charging (for rechargeable IPGs). Patients should not charge while sleeping. This may result in a burn. While charging, the Charger may become warm. It should be handled with care. Failure to use the Charger with either the Charging Belt or an adhesive patch, may result in a burn. If patients experience pain or discomfort, they should cease charging and contact Boston Scientific.

Magnetic Resonance Imaging (MRI).

- The WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems are “MR Conditional”. An MRI examination can be conducted safely only when using a 1.5 Tesla horizontal closed-bore whole-body MRI system for the MRI scan and following all instructions in the supplemental manual “ImageReady™ MRI Full Body Guidelines for WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems”. The 1.5T MRI system can be configured to use the Full Body, Head, and Extremity transmit/receive RF quadrature coils, and receive only coils of any type. It is important to read the information in the supplemental manual in its entirety before conducting or recommending an MRI examination on a patient with a WaveWriter Alpha or WaveWriter Alpha Prime SCS System. The “ImageReady™ MRI Full Body Guidelines for WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems” manual appears on the Boston Scientific websites (www.bostonscientific.com/ImageReady and www.bostonscientific-elabeling.com). MRI examinations performed on patients with the WaveWriter Alpha or WaveWriter Alpha Prime SCS System using open-sided MRI systems, or other types of MRI systems operating at other static magnetic field strengths (higher or lower), have not been assessed and, as such, should not be performed.
- **External Devices:** External components (for example, the ETS, Remote Control, and Battery Charger) are **MR Unsafe**. They must not be taken into any MR environment such as the MRI scanner room.

Pediatric Use. The safety and effectiveness of stimulation has not been established for pediatric use.

Diathermy. Shortwave, microwave and/ or therapeutic ultrasound diathermy should not be used on SCS patients with a stimulator. The energy generated by diathermy can be transferred through the Stimulator system, causing tissue damage at the lead site and resulting in severe injury or death. The IPG, whether it is turned on or off, may be damaged.

Implanted Stimulation Devices. Stimulators may interfere with the operation of implanted sensing stimulators such as pacemakers or cardioverter defibrillators. The effects of implanted stimulation devices on neurostimulators is unknown.

Stimulator Damage. Burns may result if the pulse generator case is ruptured or pierced and patient tissue is exposed to battery chemicals. Do not implant the device if the case is damaged.

Postural Changes. Patients should be advised that changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level. Patients should be advised to turn down the amplitude or turn off the IPG before making posture changes. If using therapy that does not produce a sensation (subperception), postural changes are less likely to affect the patient.

Important: *If unpleasant sensations occur, the IPG should be turned off immediately.*

Electromagnetic Interference. Strong electromagnetic fields can potentially turn stimulation off, cause temporary unpredictable changes in stimulation, or interfere with Remote Control communication. If an electromagnetic field is strong enough to turn stimulation off, this will be temporary and stimulation will automatically return once the electromagnetic field is removed. Patients should be advised to avoid or exercise care around the following:

- Theft detectors, tag deactivators and RFID devices, such as those used at department stores, libraries, and other public establishments: Patients should proceed with caution, ensuring that they move through the center of the detector as quickly as possible. Interference from these devices should not cause permanent damage to the implanted device.
- Security screeners, such as those used in Airport Security or at entrances to government buildings, including hand-held scanners: Patients should request assistance to bypass the security screener and advise the security staff that they have an implanted medical device. If patients must pass through the security screener, they should move through the security screener quickly and stay as far as allowed from the screener.
- Power lines or power generators.
- Electric steel furnaces and arc welders.
- Large magnetized stereo speakers.
- Strong magnets.
- Automobiles or other motorized vehicles using a LoJack system or other anti-theft systems that can broadcast a radio frequency (RF) signal. The high energy fields produced by these systems may interfere with the operation of the Remote Control and its ability to control stimulation.
- Other sources of electromagnetic disturbance, such as Wi-Fi routers, Cordless Phones, **Bluetooth®** Wireless streaming devices, Baby Monitors, Microwave Ovens.

Note: *When in close proximity, equipment that generate strong electromagnetic fields might cause uncomfortable or jolting stimulation or interfere with wireless communication even if they comply with CISPR requirements.*

Precautions

Physician training is required.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off or may cause permanent damage to the Stimulator, particularly if used in close proximity to the device:

- lithotripsy
- electrocautery (See “Instructions for the Physician” on page 10)
- external defibrillation
- radiation therapy (Any damage to the device by radiation may not be immediately detectable.)
- ultrasonic scanning
- high-output ultrasound

X-ray and CT scans may damage the Stimulator if stimulation is on. X-ray and CT Scans are unlikely to damage the Stimulator if stimulation is turned off.

If any of the above is required by medical necessity, refer to “Instructions for the Physician” on page 10. Ultimately, however, the device may require explantation as a result of damage to the device.

Subperception Therapy. Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months. Full stimulation parameter ranges and options for both paresthesia-based and subperception therapy are available for clinician’s use throughout the patient’s experience and treatment with SCS.

Automobiles and Other Equipment. Patients using therapy that generates paresthesia should not operate motorized vehicles such as automobiles or potentially dangerous machinery and equipment with the stimulation on. Stimulation must be turned off first in such cases. For these patients, any sudden stimulation changes may distract patients from proper operation of the vehicle, machinery, or equipment. For therapy that does not generate paresthesia (e.e., subperception therapy) it is less likely that sudden stimulation changes resulting in distraction could occur while having stimulation on when operating moving vehicles, machinery, and equipment.

Post Operative. During the two weeks following surgery, it is important that patients use extreme care so that appropriate healing will secure the implanted components and close the surgical incisions:

- Patients should not lift objects of more than 2.5 kg (5 lb).
- Patients should not engage in rigorous physical activity such as twisting, bending, or climbing.
- If new leads were implanted, patients should not raise their arms above their head.

Temporarily, there may be some pain in the area of the implant as the incisions heal. Patients should be instructed that if discomfort continues beyond two weeks, they should contact their healthcare provider.

If patients notice excessive redness around the wound areas during this time, they should contact their healthcare provider to check for infection and administer proper treatment. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Patients should consult their healthcare provider before making lifestyle changes due to decreases in pain.

Stimulator Orientation. Patients should never attempt to change the orientation of the Stimulator or turn over the Stimulator. Patients should avoid touching the incisions or Stimulator site. If the Stimulator flips over in the Patient's body, it may be unable to communicate with the Remote Control or Clinician Programmer. If the rechargeable Stimulator flips over in the Patient's body, it cannot be charged. If the Patient knows that the device has turned, or if stimulation cannot be turned on after charging, the Patient should contact his or her physician to arrange an evaluation of the system. In some cases, the skin over the Stimulator may become very thin over time. If this occurs, Patients should contact their healthcare provider.

Lead Location. In some instances a lead can move from its original location, and stimulation at the intended pain site can be lost. If this occurs, Patients should consult their healthcare provider who may able to restore stimulation by reprogramming the Stimulator in the clinic or repositioning the lead during another operation.

Device Failure. Stimulators can fail at any time due to random component failure, loss of battery functionality, or lead breakage. If the device stops working even after complete charging (up to four hours), Patients should turn off the Stimulator and contact their healthcare provider so that the system can be evaluated.

Operating Temperature. The operating temperature of the ETS and Remote Control is 5 to 40 °C (41 to 104 °F). For proper operation, do not use the Charger if the ambient temperature is above 35 °C (95 °F). Non-rechargeable IPGs will enter storage mode if its temperature falls below 8 °C. When the IPG is in storage mode, it will not connect to a Remote Control or Clinician Programmer. To exit storage mode, increase the IPG temperature above 8 °C.

Storage, Handling and Transport. Do not expose the Remote Control or Charging System components to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat.

If the Remote Control or the Charging System is to be stored for a period of time without batteries, the storage temperature should not exceed -20 to 60 °C (-4 to 140 °F).

Handle the system external components and accessories with care. Do not drop them or submerge them in water. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage these components. (See “Limited Warranty - IPG”.)

Upon completion of the Patient Trial, remove the batteries from the ETS.

Component Disposal. Do not dispose of the Remote Control or Charger in fire. The battery in these devices can explode in fire. Dispose of used batteries in accordance with local regulations. The IPG should be explanted in the case of cremation, and returned to Boston Scientific. External devices to be disposed of per local regulatory requirements. Patients should contact their healthcare provider.

Remote Control, Charging System, and External Trial Stimulator Cleaning. The charging system components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. The Remote Control and ETS can be cleaned using a mild detergent applied with a lightly dampened cloth or tissue. Residue from soapy detergents should be removed with a cloth lightly dampened with water. Do not use abrasive cleansers for cleaning. Cleaning wipes for the External Trial Stimulator can also be ordered through Boston Scientific customer service. As an operator of the external devices, perform only the following service and maintenance tasks on the external devices:

- Changing the battery
- Charging the battery
- Cleaning

Ensure that the devices are not in use while performing service and maintenance tasks. Do not clean any of the accessories while they are directly or indirectly connected to a power outlet.

Cell Phones. While we do not anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time. Portable RF communications equipment (for example mobile phones) should be kept a minimum distance of 6 inches (15 centimeters) from the area of the implanted device. If there is a concern or a problem is encountered, the patients should contact their healthcare provider.

Adverse Effects

Potential risks are involved with any surgery.

The possible risks of implanting a pulse generator as part of a system to deliver spinal cord stimulation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include device failure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.
- Tissue reaction to implanted materials can occur. In some cases, the formation of reactive tissue around the lead in the epidural space can result in delayed onset of spinal cord compression and neurological/sensory deficit, including paralysis. Time to onset is variable, possibly ranging from weeks to years after implant.
- Skin erosion at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.

- Exposure to magnetic resonance imaging (MRI) can result in discomfort or injury due to heat near the Stimulator or the leads, tugging or vibration of the implanted system, induced stimulation, damage to the device requiring its replacement, and may distort the image needed for diagnosis.
- Undesirable stimulation may occur over time due to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections and/or lead failure.
- The patient may experience painful electrical stimulation of the chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, the Stimulator may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.

In any event, instruct the patient to contact their healthcare provider to inform him/her.

Instructions for the Physician

Implanted Stimulation Devices. If such implanted devices are indicated for the patient, careful screening is required to determine if safe results can be achieved before permanently implementing concurrent electrical therapies.

Postural Changes. Depending on the activity level of the patient, postural changes may affect stimulation intensity. Instruct patients to keep the Remote Control on hand at all times, and ensure that they understand how to adjust stimulation levels. Refer to Postural Changes in the Instructions for Patients section of this manual, page 6, for additional information. If using therapy that does not produce a sensation (subperception), postural changes are less likely to affect the patient.

Medical Devices/Therapies. If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, high-output ultrasound, X-Ray or CT Scan:

- Turn off stimulation at least five minutes before the procedure or application.
- All equipment, including ground plates and paddles, must be used as far away as possible from the IPG and all external devices (i.e. ETS, Remote Control, OR cables, and Charger).
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG and all external devices.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm IPG functionality following treatment by turning on the IPG and gradually increasing stimulation to the desired level.

Quality of Wireless Service

The WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems use a Half-Duplex, direct point-to-point, primary-secondary communication system based on Bluetooth Low Energy technology with the following typical communication range:

• Between the Remote Control and IPG: 3 meters	• Between the Clinician Programmer and IPG: 3 meters
• Between the Remote Control and ETS: 6 meters	• Between the Clinician Programmer and ETS: 6 meters

Data will be resent if not successfully received on supported devices. Sources of in-band high interference may result in slow connection, difficulty when pairing devices, or both. If you experience any of these, you may need to decrease the distance between the communicating devices. For information on how to improve connection issues, see “Troubleshooting Wireless Coexistence Issues” on page 11.

Timing

When a user initiates a communication session, the system will typically respond in 1 to 6 seconds. The typical data throughput during active programming session will be more than 10 kbs.

Troubleshooting Wireless Coexistence Issues

Other wireless and RF technology based equipments operating in the close proximity that uses similar frequency band may degrade the range and responsiveness of the System. If you experience issues with the wireless communication behavior between the Remote Control or Clinician Programmer and IPG or ETS, try the following steps to correct the behavior:

- Decrease the distance between the two devices if possible.
- Ensure there are no objects between the communicating devices.
- Move the communicating devices away from other equipment or devices that may be causing interference, such as Wi-Fi routers, Cordless Phones, Bluetooth Wireless streaming devices, Baby Monitors, Microwave Ovens.

Wireless Security

The WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems utilize Bluetooth Low Energy for communication. The WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems supported devices implement the following Bluetooth Low Energy security features:

- LE Privacy
- LE Secure Connections

Additionally, the WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems implement proprietary authentication and encryption that supports:

- Authenticated pairing sequences that are initiated by the healthcare provider
- Establishing a bonded connection only after successfully completing the authentication sequence
- Creating a validated and encrypted communication link during each connection with a previously paired device

The additional application level authentication and encryption ensures that communication with the Stimulator is only accomplished by authorized Boston Scientific devices.

Clinician Programmer Security

The Clinician Programmer (CP) is a hardened computer with the following security controls:

- Access to the CP is restricted to authorized users and the CP screen locks out if there is no activity and may only be unlocked with a password to prevent unauthorized access.
- The CP Platform enforces a password lockout duration after a predefined number of unsuccessful login attempts.
- Only authorized incoming connections are allowed.
- The encrypted file system restricts access of the data in the file system to authorized users only.
- Non-whitelisted applications cannot be installed.
- All BSN applications are code signed so that any compromise to their integrity via USB or other data channels may be detected and prevented from execution.
- User actions and login attempts are logged by Windows Event Log.
- The CP logs and notifies the user upon detection of malicious software.

Boston Scientific has developed a process to receive potential product security vulnerabilities from external sources in order to validate their existence and determine how to best respond to improve product security and safety. Please refer to the following webpage to report potential product security vulnerabilities to the Boston Scientific Product Security team:

https://www.bostonscientific.com/en-US/customer-service/product-security/responsible-disclosure.html

Telemetry Information

The following parameters describe the wireless communication link between the Remote Control or Clinician Programmer and IPG or ETS.

Frequency Band: 2.402 GHz to 2.480 GHz

Modulation Type: GFSK

Maximum Radiated Power: 5 dBm

Protocol: Bluetooth Low Energy technology (Version 4.2)

Wireless Charging Information

Charging Frequency: 77 – 90 kHz

The charging distance between the Charger and the IPG is between 0.5 cm to 2 cm. Centering the charger over the stimulator ensures the shortest charging time. The Charger will beep as it searches for the IPG and will stop beeping when it is aligned with the IPG. Please refer to the instructions provided in the "Charging Steps" Section of IPG Directions for Use for instructions on aligning the Charger.

Electromagnetic Compatibility - EN 60601-1-2 Classification Information

- Internally Powered Equipment
- Continuous Operation
- Ordinary Equipment
- Class II

<table>
<tr><td colspan="3">Guidance and Manufacturer's Declaration - electromagnetic emissions - for all ME Equipment and ME Systems</td></tr>
<tr><td colspan="3">The WaveWriter Alpha and WaveWriter Alpha Prime Systems are intended for use in the electromagnetic environment specified below. The customer or user of the IPG should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic Environment Guide</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The WaveWriter Alpha and WaveWriter Alpha Prime Systems use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="2">The WaveWriter Alpha and WaveWriter Alpha Prime Systems are suitable for use in all establishments. Including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class B</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The WaveWriter Alpha and WaveWriter Alpha Prime Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the WaveWriter Alpha or WaveWriter Alpha Prime System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. Note: Applies to external devices.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device.

Guidance and manufacturer's declaration – electromagnetic immunity			
The WaveWriter Alpha and WaveWriter Alpha Prime Systems are intended for use in the electromagnetic environment specified below. The customer or the user of the WaveWriter Alpha or WaveWriter Alpha Prime System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 -1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - guidance**
Conducted RF IEC 61000-4-6 (ETS only)	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	Professional healthcare facility environment and home healthcare environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	Professional healthcare facility environment and home healthcare environment. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol shown below: 

NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WaveWriter Alpha or WaveWriter Alpha Prime System is used exceeds the applicable RF compliance level above, the WaveWriter Alpha or WaveWriter Alpha Prime System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WaveWriter Alpha or WaveWriter Alpha Prime System.

Immunity Testing - RFID Readers

The external electrical components of the WaveWriter Alpha and WaveWriter Alpha Prime Systems have been tested for immunity to interference from RFID readers per the following specifications.

RFID Spec Per AIM 7351731	Frequency	Test Level (RMS)
ISO 14223	134.2 kHz	65 A/m
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m
ISOAEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m
ISO 18000-3 Mode 3	13.56 MHz	12 A/m
ISO/IEC 18000-7	433 MHz	3 V/m
ISO/IEC 18000-63 Type C[a]	860-960 MHz	54 V/m
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m

Manufacturer's declaration for proximity fields

The WaveWriter Alpha and WaveWriter Alpha Prime SCS Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The users of the WaveWriter Alpha or WaveWriter Alpha Prime SCS System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WaveWriter Alpha or WaveWriter Alpha Prime SCS System as recommended below, according to the maximum output power of the communications equipment.

Proximity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guide
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended separation distance d = 30 cm
	450 MHz: 28 V/m @ FM modulation	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	

IEC 61000-4-3	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	Recommended separation distance d = 30 cm
	2450 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
NOTE: For the frequency bands in this table, use the specified recommended separation distance. The recommended minimum separation distance of 30 cm between portable and mobile RF communications equipment (transmitters) and the WaveWriter Alpha or WaveWriter Alpha Prime SCS System apply to all other frequencies within the specified ranges. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Sterilization

All implantable and surgical components of the WaveWriter Alpha and WaveWriter Alpha Prime Systems, are sterilized with ethylene oxide.

- Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.
- Do not use any component that shows signs of damage.
- Do not resterilize the package or the contents. Obtain a sterile package from Boston Scientific.
- Do not use if the product is past the labeled expiration date.
- All components are for single use only. Do not reuse.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.

WARNING: *Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.*

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

FCC Rules

The following is federal government communications regulation information about the WaveWriter Alpha and WaveWriter Alpha Prime System.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The WaveWriter Alpha and WaveWriter Alpha Prime System components should only be serviced by Boston Scientific. Do not attempt to open or repair any of the components. Unauthorized opening of or attempts to repair the components will void the warranty.

Changes of modifications to this product not authorized by Boston Scientific Corporation could void the FCC Certification and negate your authority to operate this product.

FCC ID

WW Alpha Rechargeable IPG
FCC ID: Q4D-SC1232

WW Alpha Non-Rechargeable IPG
FCC ID: Q4D-SC1432

Technical Service

Boston Scientific has highly trained service professionals located worldwide to assist you. The Technical Service Department is available to provide technical consultation 24 hours a day.

In North America, please call (866) 566-8913 to speak to a representative.

End of Programmed Service

The WaveWriter Alpha and WaveWriter Alpha Prime Systems use a software programs the IPG to end service after 12 years. As the IPG nears the end of the programmed period, the Remote Control and Clinician Programmer provide the following indicators to inform the user that end of the programmed period is approaching:

- Remote Control - Approximately six months before the end of programmed period, the Remote Control displays a weekly message indicating the number of service days remaining. Approximately one month before the end of the programmed period, the message displays daily.
- Clinician Programmer - When less than six months of service period remain, an indicator displays on the Connect screen of the Clinician Programmer. When end of the programmed period has been reached, a message displays when connecting to the Stimulator to indicate that end of the programmed period has been reached and programming is not allowed.

Patients should contact their health care provider upon first receiving a message regarding the number of programmed service days remaining.

Note: *End of Programmed Service is applicable to the WaveWriter Alpha Prime System only when battery longevity is greater than 12 years.*

IPG Battery Life

Rechargeable Systems

The rechargeable battery in the WaveWriter Alpha System IPG should provide at least five years of service.[1] Battery life is dependent on your stimulation settings and conditions. In most cases, the Stimulator will need to be recharged at intervals ranging from once a week to once a month. Over time, the IPG battery will need more frequent recharges. Like all rechargeable batteries, use over time and repeated recharge cycles reduce the maximum charge capacity of the IPG battery.

The WaveWriter Alpha System's programming software gives you an estimate of charging time based on 24 hours per day of stimulation at the programmed settings. Depending on the program parameters, the patient may expect daily recharging times from as low as 10 minutes up to four hours, or weekly recharging times from as low as one hour up to four hours. Battery life is dependent on your stimulation settings and conditions

Non-Rechargeable Systems

The WaveWriter Alpha Prime IPG has a non-rechargeable battery. The longevity of the non-rechargeable IPG battery depends on the following factors:

- Programmed parameters (i.e., amplitude, rate, pulse width, number of electrodes used, and number of stimulation areas)
- System impedance
- Use of cycling or burst settings
- Hours per day of stimulation
- Changes made by the patient to programmed parameters

It is possible to estimate the battery longevity of a new IPG based on usage over 12 or 24 hours per day with a selected Program. The estimate is based on the settings of a program, the system impedance at time of estimation, and the hours per day of stimulation.

These estimates will not reflect adjustments to stimulation parameters or changes in impedance. The estimate functions as a reference value to approximate the period that a new WaveWriter Alpha Prime stimulator will last (see Estimating Longevity section). Battery life is dependent on your stimulation settings and conditions.

Note: *If the WaveWriter Alpha Prime System is being considered for permanent implant, it is recommended that the battery longevity of the WaveWriter Alpha Prime IPG be estimated during the trial. It is also recommended to estimate the battery longevity at the initial programming of the implant.*

Note: *Estimations made after initial programming of the IPG may overestimate the longevity of its battery.*

When the IPG battery is fully depleted, the End of Service (EOS) indicator will be displayed on the Remote Control and Clinician Programmer. Stimulation will not be available. Surgery is required to replace the implanted non-rechargeable stimulator to continue providing stimulation.

Estimating Longevity (for Non-Rechargeable Systems)

After the optimal settings have been identified for a program, click on Battery Estimate in the Program Options Menu in the Bionic Navigator™ 3D software to obtain the Energy Use Index. Use Figure 1 (if estimated usage of stimulation is 12 hours) or Figure 2 (if estimated usage of stimulation is 24 hours) to

1 The expected years of battery operation are defined as the longer of either:
A.Typical case: the time at which therapy cannot be maintained with daily charging.
OR
B.High energy case: when the maximum recharge interval has decreased by more than 50 % from the initial recharge interval.

identify the longevity that corresponds to this Energy Use Index. Figures 1 and 2 take into account nominal non-therapy power consumption, including shelf-life and patient remote control use. If the estimate for longevity obtained by these Figures is below 12 months, consider evaluating a Boston Scientific rechargeable system.

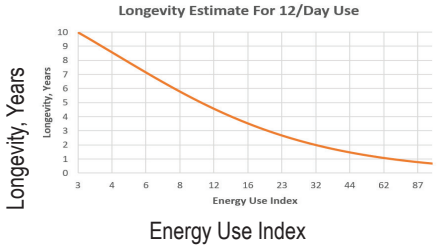

Figure 1: *Longevity estimates based on 12 hour per day usage*

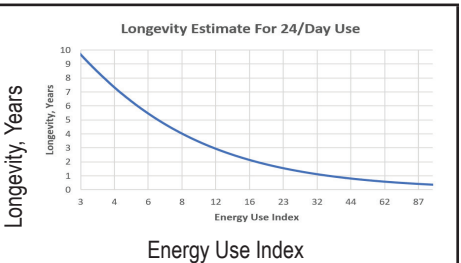

Figure 2: *Longevity estimates based on 24 hour per day usage*

Example: Estimating Battery Longevity with Nominal Program Settings

Nominal Program Settings*	Energy Use Index	Mode of Operation	Battery Longevity
4.1 mA, 280 us, 40 Hz, 1 area, 730 Ohms, 2 contacts	10	Hours of stimulation per day: 12	Approximately 5.1 years

*Nominal settings based on Oakley et al. Stimulation Power by Disease Diagnosis in Spinal Cord Stimulation. Presented at American Academy of Pain, 2006.

Elective Replacement (for Non-Rechargeable Systems)

When the battery is nearing depletion, the IPG will enter the Elective Replacement mode. The Elective Replacement Indicator (ERI) will appear on the Remote Control and Clinician Programmer. Failure to replace the IPG may lead to reduced programming capabilities, limited communication with the stimulator, and stimulation not being available soon. The stimulator must be replaced to continue receiving stimulation. Batteries that have lasted 12 months or more without entering ERI mode will have a minimum of 4 weeks between entering ERI mode and reaching End of Battery Life. Surgery is required to replace the implanted non-rechargeable Stimulator, although leads may stay in place while the stimulator is exchanged.

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Boston Scientific

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Legal Manufacturer

Boston Scientific Neuromodulation Corporation
25155 Rye Canyon Loop
Valencia, CA 91355 USA
(866) 789-5899 in US and Canada
(661) 949-4000, (661) 949-4022 Fax
(866) 789-6364 TTY
www.bostonscientific.com
Email: neuro.info@bsci.com

AUS Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

EC REP EU Authorized Representative

Boston Scientific Limited
Ballybrit Business Park
Galway, Ireland
T: +33 (0) 1 39 30 97 00
F: +33 (0) 1 39 30 97 99

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