

Indications for Use Data Sheet

Abbott Medical Spinal Cord Stimulation Systems

Indications for Use

Abbott Medical spinal cord stimulation (SCS) systems are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Additional Prescription Information

Refer to the clinician's system manual for the appropriate neurostimulation system for additional prescription information, including contraindications. For specific instructions, warnings, precautions, and adverse effects about other system components, see the clinician's manual for those components.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

www.abbott.com



ARTEN600283855 A
2023-04



Clinical Summaries

Spinal Cord Stimulation Systems

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Clinical Studies.	1
Clinical Summary for the Genesis™ (IPG) Neurostimulation System for SCS.	2
Efficacy Evaluation.	2
Safety Evaluation.	3
References.	4
Clinical Summary for BurstDR™ Stimulation.	5
SUNBURST™ Study Design.	5
SUNBURST™ Study Clinical Inclusion and Exclusion Criteria.	5
SUNBURST™ Study Follow-Up Schedule.	6
Clinical Endpoints.	6
Primary Statistical Analysis Plan.	7
Accountability of Subject Cohort.	7
SUNBURST™ Study Demographics and Pain Baseline Characteristics.	8
SUNBURST™ Study Safety Results.	11
Device and Device Usage Data.	15
SUNBURST™ Study Results.	19
Summary of Supplemental Clinical Information.	35
Conclusions Drawn from the Study.	36
References.	37
Clinical Summary for Anatomical Lead Placement.	38
DELIVERY Study.	38
CRISP Study.	47
Clinical Summary for Diabetic Peripheral Neuropathy.	59
Review Design and Methodology.	59
Review Results.	59
Overall Conclusions.	67
References.	68
Clinical Summary for Non-Surgical Back Pain.	71
DISTINCT Study	71
Clinical Inclusion and Exclusion Criteria.	72
Clinical Endpoints.	73
Sample Size Design and Statistical Analysis	74
Accountability of 200-Subject Cohort	74
Study Results.	75
Procedural Results.	78
Primary Effectiveness.	79
Secondary Effectiveness.	80
Descriptive Endpoints and Additional Analysis	82
Adverse Events.	86
Conclusions Drawn from the Study.	88

Clinical Studies

This manual contains summaries of clinical studies conducted with Abbott Medical spinal cord stimulation (SCS) systems. The clinical studies were conducted to assess safety and effectiveness of SCS systems, and will also apply to additional neurostimulation systems that are similar in technology and intended use.

The studies in this manual support the clinical use of the neurostimulation systems identified in the following table. Refer to the clinician's system manual for instructions and other important information, including indications for use, contraindications, warnings, precautions, and adverse effects related to the complete neurostimulation system.

Table 1. Summaries of clinical studies for supported SCS systems and leads

Clinical Summary	Supported SCS Systems	Leads
Genesis™ (IPG) Neurostimulation System for SCS	- Proclaim™ SCS system - Eterna™ SCS system - Prodigy™ SCS system - Prodigy MRI™ SCS system - Prot g™ SCS system - Prot g MRI™ SCS system - St. Jude Medical™ Invisible Trial System*	- Trial leads - Percutaneous leads - Paddle leads
BurstDR™ Stimulation	- Proclaim™ SCS system - Eterna™ SCS system - Prodigy™ SCS system - Prodigy MRI™ SCS system - Prot g™ SCS system - Prot g MRI™ SCS system - St. Jude Medical™ Invisible Trial System*	- Trial leads - Percutaneous leads - Paddle leads
Anatomical Lead Placement	- Proclaim™ SCS system - Eterna™ SCS system - Prodigy™ SCS system - Prodigy MRI™ SCS system - St. Jude Medical™ Invisible Trial System*	- Trial leads - Percutaneous leads
Diabetic Peripheral Neuropathy	- Proclaim™ SCS system - Eterna™ SCS system - Prodigy™ SCS system - Prodigy MRI™ SCS system - St. Jude Medical™ Invisible Trial System*	- Trial leads - Percutaneous leads - Paddle leads
Non-surgical back pain	- Proclaim™ SCS system - Eterna™ SCS system - Prodigy™ SCS system - Prodigy MRI™ SCS system - St. Jude Medical™ Invisible Trial System*	- Trial leads - Percutaneous leads - Paddle leads

* The invisible trial system consists of the external pulse generator, the trial clinician programmer, and the trial patient controller.

Clinical Summary for the Genesis™ (IPG) Neurostimulation System for SCS

The safety and effectiveness of the Genesis™ (IPG) neurostimulation system was determined based on available published clinical studies for similar totally implanted SCS systems. The IPG device is 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 Genesis (IPG) neurostimulation system for use as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain. The studies in this clinical summary support the SCS systems listed in “Clinical Studies” (page 1).

Efficacy Evaluation

Three clinical literature studies were used to assess the safety and effectiveness of the Genesis™ (IPG) neurostimulation system (Ohnmeiss et al. 1996, Villavicencio et al. 2000, Hassenbusch 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 considered in 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, an identified totally implantable spinal cord stimulator was used in association with a quadripolar percutaneous epidural lead or a quadripolar lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the Genesis (IPG) neurostimulation system.

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, 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, SCS was effective in improving intractable leg pain.

In addition, three patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; one patient required two reoperations, one to have 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 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 the study, 27 of 41 (66%) patients 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 of 27 (89%) patients 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 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. A total of 5 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 that 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?" (Hassenbusch SJ et al. 1995) 16 of 26 patients (62%) had greater than 50% pain relief with SCS. A total of 2 of 16 (13%) patients 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

Sixteen studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the Genesis™ (IPG) neurostimulation system (all references in the bibliography were used). The studies included a total of 1253 patients.

The following table depicts the number of patients, the number of events observed, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that several studies include 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 2. Summary of risks identified in the retrospective clinical studies

Risks	Number of Patients	Number of Events	Percent of Patients
Lead migration	1059	144	13.6
Infection	1253	37	3.0
Epidural hemorrhage	1253	0	0
Seroma	1253	0	0
Hematoma	1253	5	0.4
Paralysis	1253	1	0.1
CSF leak	1253	6	0.5
Over/under stim	1059	27	2.6
Intermittent stim	1059	0	0
Pain over implant	1059	12	1.1
Allergic reaction	1059	2	0.2
Skin erosion	1059	1	0.1
Lead breakage	1059	182	17.2
Hardware malfunction	1059	32	3.0
Loose connection	1059	10	1.0
Battery failure	911	17	1.9
Other	1059	24	2.3

References

1. Broggi G, Servello D, Dones I, Carbone G. Italian multicentric study on pain treatment with epidural spinal cord stimulation. *Stereotact Funct Neurosurg*. 62(1994):273–278.
2. Burchiel KJ, Anderson VC, Brown FD, et al. Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain. *Spine*. 21(1996):2786–2793.
3. Devulder J, De Laat M, Van Basterlaere M. Spinal cord stimulation: a valuable treatment for chronic failed back surgery patients. *J Pain Symptom Manage*. 13(1997):296–301.
4. Hassenbusch S, Stanton-Hicks M, Covington EC. Spinal cord stimulation versus spinal infusion for low back and leg pain. *Acta Neurochir*. 64(1995):109–115.
5. Kavar B, Rosenfeld JV, Hutchinson A. The efficacy of spinal cord stimulation for chronic pain. *J Clin Neurosci*. 7(2000):409–413.
6. Kumar K, Toth C, Nath R, Lang P. Epidural spinal cord stimulation for treatment of chronic pain—some predictors of success. A 15 year experience. *Surg Neurol*. 50(1998):110–120.
7. Mazzone P, Rodriguez G, Arrigo A, Nobili F, Pisandi R, Rosadini G. Cerebral haemodynamic changes induced by spinal cord stimulation in man. *Ital J Neurol Sci*. 17(1996):55–57.
8. Meglio M, Cioni B, Rossi GF. Spinal cord stimulation in the management of chronic pain (a 9 year experience). *J Neurosurg*. 70(1989):519–524.
9. Meglio M, Cioni B, Visocchi M, Tancredi A, Pentimalli L. Spinal cord stimulation in low back and leg pain. *Stereotact Funct Neurosurg*. 62(1994):263–266.
10. Ohnmeiss DD, Rashbaum RF, Bogdanffy GM. Prospective outcome evaluation of spinal cord stimulation in patients with intractable leg pain. *Spine*. (1996):1344–1351.
11. Racz GB, McCarron RF, Talboys P. Percutaneous dorsal column stimulator for chronic pain control. *Spine*. 14(1989):1–4.
12. Segal R, Stacey BR, Rudy TE, Baser S, Markham J. Spinal cord stimulation revisited. *Neurol Res*. 20(1998):391–396.
13. Simpson BA. Spinal cord stimulation in 60 cases of intractable pain. *J Neurol Neurosurg Psychiatry*. 54(1991):196–199.
14. Spiegelmeyer R, Friedman WA. Spinal cord stimulation: a contemporary series. *Neurosurg*. 28(1991):65–71.
15. Van de Kelft E, De La Porte C. Long-term pain relief during spinal cord stimulation: the effect of patient selection. *Qual Life Res*. 3(1994):21–27.
16. Villavicencio AT, Leveque JC, Rubin L, Bulsara K, Gorecki JP. Laminectomy versus percutaneous electrode placement for spinal cord stimulation. *Neurosurg*. 46(2000):399–406.

Clinical Summary for BurstDR™ Stimulation

Abbott Medical performed a clinical study to establish reasonable assurance of safety and effectiveness of BurstDR™ stimulation for the treatment of chronic, intractable pain of the trunk and/or limbs. The clinical study supports the SCS systems listed in “Clinical Studies” (page 1). The following sections present information and results for the SUNBURST™ study.

SUNBURST™ Study Design

Subjects began to enroll in the study in January 2014, and treatment has continued through the time of this report. This report includes the data collected through February 2016, accounting for 173 subjects at a total of 20 investigational sites.

The study was a prospective, multicenter, randomized, open-label, crossover study that compared two different stimulation modes:

- Arm 1: tonic-then-burst stimulation (tonic/burst)
- Arm 2: burst-then-tonic stimulation (burst/tonic)

Subjects with chronic intractable pain of the trunk and/or limbs were informed about the study to determine if they were interested in participating. After subjects signed an informed consent agreement, they were screened according to the inclusion and exclusion criteria and underwent a baseline evaluation. Those subjects who met the criteria to participate were scheduled to receive a commercially available Abbott Medical trial neurostimulation system for spinal cord stimulation (SCS). Subjects underwent a trial period using tonic stimulation, and those subjects who completed the trial successfully were scheduled to receive a Prodigy™ neurostimulation system, which is capable of delivering both stimulation modes.

Subjects were implanted with the permanent Prodigy neurostimulation system, and the device remained off during a recovery period. After the recovery period, subjects were randomized to receive either burst stimulation or tonic stimulation. The implanted system was then activated and programmed accordingly. Depending on randomization, a subject experienced either tonic stimulation or burst stimulation first for a total of 12 weeks. At the week-12 visit, the subject was then crossed over to the alternate stimulation mode for another 12 weeks. Subjects reported to the office at 6, 12, 18, and 24 weeks after randomization and activation. After the primary endpoint at the week-24 visit, all subjects were programmed to tonic or burst stimulation based on what the subject and physician preferred, and they continued to attend follow-up visits every 6 months for 2 years or until the study closed, whichever occurred first.

The purpose of the clinical study was to collect the data needed to demonstrate the safety and effectiveness of a neurostimulation system that is capable of both tonic and burst stimulation modes.

SUNBURST™ Study Clinical Inclusion and Exclusion Criteria

Enrollment in the SUNBURST™ study was limited to subjects who met the following selection criteria.

Inclusion Criteria

Subjects were limited to those who met all of the following criteria:

- Subject signed an informed consent to participate in the study.
- Subject was at least 22 years old.
- Subject had chronic intractable pain of the trunk and/or limbs.
- Subject scored a baseline average of 60 or higher for average daily overall pain on the visual analog scale (VAS) 7-day pain diary.
- Subject tried “best” medical therapy, but failed at least three documented, medically supervised treatments (including, but not limited to, physical therapy and acupuncture) and failed medication treatment from at least two different classes.
- Subject’s pain-related medication regimen was stable 4 weeks before the screening evaluation.
- The Investigator evaluated the subject’s medical record to ensure that the subject was a good candidate for a neurostimulation system.
- A psychologist or psychiatrist evaluated the subject and found him or her to be a suitable SCS candidate.
- Subject agreed not to increase the number of or dosage of pain-related medications from activation through the week-24 follow-up visit.

- Subject was willing to cooperate with the study requirements such as complying with the treatment regimen and completing all office visits.
- Subject was female candidate of childbearing potential who agreed to commit to using effective contraception (including, but not limited to, sterilization, barrier devices, oral contraceptives, intrauterine devices (IUDs), condoms, the rhythm method, or abstinence) throughout the study.

Exclusion Criteria

Subjects were excluded if they met any of the following criteria:

- Subject was participating in a clinical investigation that included an active treatment arm.
- Subject had previously been implanted with a neurostimulation system or participated in a trial period for a neurostimulation system.
- Subject had an overall Beck Depression Inventory-II (BDI-II) score greater than 24 or had a score of 3 at the screening visit on question 9, which relates to having suicidal thoughts or wishes. (Beck Depression Inventory and BDI are trademarks of NCS Pearson, Inc.)
- Subject was receiving, applying for, or considering seeking workers compensation or was involved in disability litigation.
- Subject had an infusion pump or any implantable neurostimulator device.
- Subject had a concurrent, clinically significant or disabling chronic pain problem that required additional treatment.
- Subject had an existing medical condition, such as epilepsy, stroke, multiple sclerosis, acoustic neuroma, or a tumor, that was likely to require repetitive evaluations using magnetic resonance imaging (MRI).
- Subject had a history of cancer requiring active treatment in the last 6 months.
- Subject had an existing medical condition that was likely to require the use of diathermy.
- Subject had pain that originated from peripheral vascular disease.
- Subject had an impaired immune system (immunocompromised).
- Subject had a documented history of an allergic response to titanium or silicone.
- Subject had a documented history of substance abuse (with substances such as narcotics or alcohol) or substance dependency within 6 months of the collection of baseline data.
- Subject was a female of childbearing potential who was pregnant (confirmed by a positive urine or blood pregnancy test).

SUNBURST™ Study Follow-Up Schedule

Subjects who met the aforementioned criteria for participation underwent a conventional SCS trial using tonic stimulation. Subjects with an unsuccessful SCS trial exited the study following a safety assessment 2 weeks after the trial. The subjects who remained in the study were implanted with a permanent system, and then they returned to the office after a recovery period of 2 to 3 weeks (2 weeks minimum) for randomization and system activation. After randomization and activation, subjects returned to the office for follow-up at 6 and 12 weeks. During the week-12 visit, subjects crossed over to the alternative stimulation mode. Subjects continued to report to the office at 18 and 24 weeks for follow-up. After the week-24 visit, subjects continued to attend follow-up visits every 6 months for 2 years or until the study closed, whichever occurred first.

Clinical Endpoints

The primary effectiveness endpoint was a non-inferiority test comparing the change in the VAS pain diary score during tonic stimulation with the change in VAS pain diary score during burst stimulation.

The secondary endpoints that were assessed included

- Determining superiority of burst stimulation compared to tonic stimulation using VAS pain diary scores for average daily overall pain (after non-inferiority was demonstrated)
- Comparing the responder rate, which is defined by a 30% decrease in the VAS pain diary scores for average daily overall pain
- Comparing the percentage of paresthesia coverage

The following descriptive endpoints and additional data were assessed:

- Demographics, including gender, age, height, weight, ethnicity, and marital status

- Pain history, including primary diagnosis, pain duration, pain etiology, and prior treatments
- Adverse events
- Summary of adverse events related to tonic and burst stimulation
- Surgery and device information
- Programming and stimulation mode data
- Recharging data
- Comparison of the responder rate, which is defined by a 50% decrease in the VAS pain diary scores for average daily overall pain
- Average daily trunk pain and average daily limb pain as assessed by the VAS
- Comparison of VAS pain diary scores for worst daily overall pain
- Patient satisfaction with the device
- Stimulation mode preference (tonic or burst)
- Patient Global Impression of Change (PGIC)
- Comparison of the quality of life in physical and mental components of Short Form 36 (SF-36)
- Comparison of function in the Oswestry Disability Index (ODI), version 2.1a
- Pain quality as assessed by the Short-Form McGill Pain Questionnaire (SF-MPQ-2)
- Pain catastrophizing as assessed by the Pain Catastrophizing Scale (PCS)
- Depression as assessed by the BDI-II clinical assessment
- Medication usage

Primary Statistical Analysis Plan

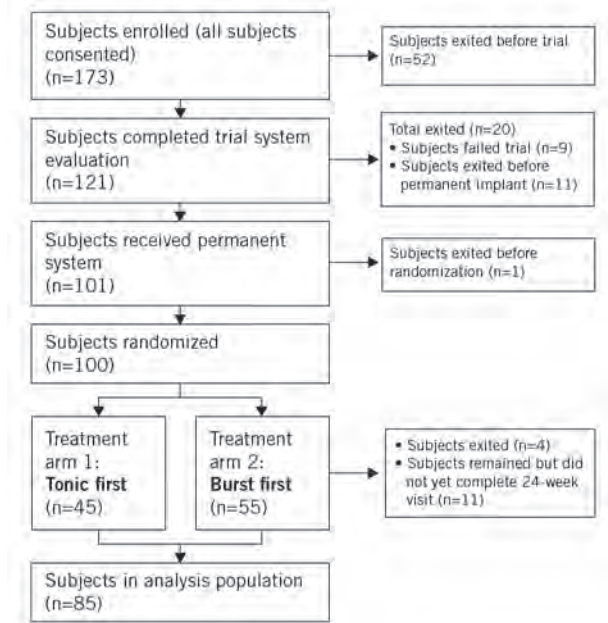
To analyze the primary endpoint: evaluating non-inferiority of burst stimulation to tonic stimulation in overall VAS scores – the non-inferiority margin was set to 7.5 mm for the overall VAS score on a scale of 0 to 100. The standard deviation of the difference between the VAS scores for tonic and burst stimulation was assumed to be 18.4 points. Setting the Type I error rate to 0.05, a minimum sample size of 76 subjects was required to achieve 80% power to demonstrate non-inferiority of burst stimulation to tonic stimulation.

The secondary endpoints were tested if the primary endpoint was met. Each secondary endpoint was tested at a 5% significance level. Statistical tests were not performed for descriptive endpoints and additional data.

Accountability of Subject Cohort

A total of 173 subjects consented and enrolled at 20 investigational sites. Of the 141 subjects completing the baseline evaluation, 121 underwent an evaluation using an SCS trial system with tonic stimulation. After the SCS trial evaluation, 101 subjects met the standard criteria for success and were implanted with the Prodigy™ neurostimulation system. Of these 101 subjects, 100 were randomized and activated. The final subject was randomized in August 2015. A total of 96 subjects completed the week-24 follow-up visit for the primary endpoint. The following figure summarizes the accounting for study subjects.

Figure 1. Subject accounting



SUNBURST™ Study Demographics and Pain Baseline Characteristics

A total of 141 subjects had a baseline visit in this study, 100 of whom were randomized (45 to receive tonic stimulation then burst stimulation [tonic/burst] and 55 to receive burst stimulation then tonic stimulation [burst/tonic]). The following tables show subject demographics and primary diagnosis. Pain duration, origin, and prior treatments are also shown, respectively.

Table 3. Demographics and primary diagnosis

Variable		Subjects with Baseline Visit (N=141)	Randomization		
			Arm 1: Tonic/Burst (N=45)	Arm 2: Burst/Tonic (N=55)	p-value
Age					
Mean ±SD		59.1±13.5 (141)	58.8±13.6 (45)	60.4±13.4 (55)	0.562 ^t
Minimum, Median, Maximum		25.0, 60.0, 88.0	27.0, 62.0, 88.0	25.0, 61.0, 84.0	
Gender, n/N (%)					
Female		85/141 (60.3%)	26/45 (57.8%)	31/55 (56.4%)	0.887 ^c
Male		56/141 (39.7%)	19/45 (42.2%)	24/55 (43.6%)	
Weight (lb)					
Mean ±SD		191.7±48.0 (141)	189.0±42.8 (45)	195.31±47.1 (55)	0.509 ^t
Minimum, Median, Maximum		85.0, 190.0, 350.0	85.0, 184.0, 340.0	113.0, 193.0, 289.0	

Table 3. Demographics and primary diagnosis

Variable		Subjects with Baseline Visit (N=141)	Randomization		p-value
			Arm 1: Tonic/ Burst (N=45)	Arm 2: Burst/ Tonic (N=55)	
Height (in.)					
Mean ±SD		66.7±4.4 (141)	66.2±4.4 (45)	66.8±4.4 (55)	0.502†
Minimum, Median, Maximum		55.0, 66.0, 79.1	57.0, 66.1, 73.0	55.0, 66.0, 76.0	
Race, n/N (%)					
Black or African American		3/141 (2.1%)	0/45 (0.0%)	1/55 (1.8%)	1.000 ^f
White		136/141 (96.5%)	45/45 (100.0%)	54/55 (98.2%)	
Other		2/141 (1.4%)	0/45 (0.0%)	0/55 (0.0%)	
Ethnicity, n/N (%)					
Hispanic or Latino		2/141 (1.4%)	0/45 (0.0%)	0/55 (0.0%)	—
Non-Hispanic or Non-Latino		139/141 (98.6%)	45/45 (100.0%)	55/55 (100.0%)	
Marital Status, n/N (%)					
Married		107/141 (75.9%)	39/45 (86.7%)	41/55 (74.5%)	0.479 ^f
Separated/divorced		13/141 (9.2%)	2/45 (4.4%)	4/55 (7.3%)	
Single		8/141 (5.7%)	2/45 (4.4%)	3/55 (5.5%)	
Widowed		13/141 (9.2%)	2/45 (4.4%)	7/55 (12.7%)	
Diagnosis, n/N (%)					
Arachnoiditis		1/141 (0.7%)	1/45 (2.2%)	0/55 (0.0%)	0.189 ^f
CRPS I/CRPS II		2/141 (1.4%)	0/45 (0.0%)	2/55 (3.6%)	
Degenerative spine disease		7/141 (5.0%)	1/45 (2.2%)	2/55 (3.6%)	
Failed back surgery syndrome (FBSS)		59/141 (41.8%)	15/45 (33.3%)	27/55 (49.1%)	
Neuritis/neuropathy/neuralgia		3/141 (2.1%)	0/45 (0.0%)	2/55 (3.6%)	
Postoperative chronic pain		5/141 (3.5%)	1/45 (2.2%)	2/55 (3.6%)	
Radiculopathies		52/141 (36.9%)	21/45 (46.7%)	17/55 (30.9%)	
Chronic pain (non-postoperative)		12/141 (8.5%)	6/45 (13.3%)	3/55 (5.5%)	

^t Two-sample t-test^c Chi-square test^f Fisher's exact test

Table 4. Pain duration and origin

Pain History	Subjects with Baseline Visit (N=141)	Randomization		
		Arm 1: Tonic/Burst (N=45)	Arm 2: Burst/Tonic (N=55)	p-value
How long has the subject experienced chronic pain (years)?				
Mean ±SD	12.8±10.9 (141)	11.1±9.5 (45)	15.1±12.1 (55)	0.075 ^w
Minimum, Median, Maximum	0.8, 10.0, 60.0	0.8, 9.0, 50.0	1.3, 10.0, 60.0	
How did the subject's pain start?				
Accident	31/141 (22.0%)	12/45 (26.7%)	12/55 (21.8%)	0.605 ^f
Medical condition	9/141 (6.4%)	0/45 (0.0%)	3/55 (5.5%)	
Motor vehicle accident	5/141 (3.5%)	2/45 (4.4%)	3/55 (5.5%)	
Surgery	13/141 (9.2%)	3/45 (6.7%)	7/55 (12.7%)	
Other	11/141 (7.8%)	5/45 (11.1%)	4/55 (7.3%)	
Unknown	72/141 (51.1%)	23/45 (51.1%)	26/55 (47.3%)	

^w Wilcoxon rank-sum test^f Fisher's exact test

Table 5. Pain treatment history

Pain History		Subjects with Baseline Visit (N=141)	Randomization		
			Arm 1: Tonic/ Burst (N=45)	Arm 2: Burst/ Tonic (N=55)	p-value
Non-Invasive Interventions					
Oral medications		137/141 (97.2%)	43/45 (95.6%)	54/55 (98.2%)	0.587 ^f
Physical therapy		129/141 (91.5%)	41/45 (91.1%)	51/55 (92.7%)	1.000 ^f
Transcutaneous electrical nerve stimulation (TENS)		89/141 (63.1%)	35/45 (77.8%)	29/55 (52.7%)	0.009 ^c
Acupuncture		37/141 (26.2%)	7/45 (15.6%)	17/55 (30.9%)	0.074 ^c
Acupressure		11/141 (7.8%)	3/45 (6.7%)	5/55 (9.1%)	0.727 ^f
Physiological interventions		18/141 (12.8%)	7/45 (15.6%)	4/55 (7.3%)	0.214 ^f
Other		55/141 (39.0%)	19/45 (42.2%)	23/55 (41.8%)	0.968 ^c
At least one non-invasive intervention		141/141 (100.0%)	45/45 (100.0%)	55/55 (100.0%)	—
Invasive Nonsurgical Interventions					
Steroid injections (epidural, facet [zygapophysial] injections, etc.)		130/141 (92.2%)	43/45 (95.6%)	51/55 (92.7%)	0.688 ^f
Therapeutic intradiscal injections		7/141 (5.0%)	4/45 (8.9%)	1/55 (1.8%)	0.171 ^f

Table 5. Pain treatment history

Pain History	Subjects with Baseline Visit (N=141)	Randomization		p-value
		Arm 1: Tonic/Burst (N=45)	Arm 2: Burst/Tonic (N=55)	
Intrathecal therapy	2/141 (1.4%)	0/45 (0.0%)	1/55 (1.8%)	1.000 ^f
Therapeutic medial branch block	33/141 (23.4%)	8/45 (17.8%)	12/55 (21.8%)	0.615 ^c
Botulinum toxin	3/141 (2.1%)	0/45 (0.0%)	3/55 (5.5%)	0.250 ^f
Radiofrequency denervation	33/141 (23.4%)	10/45 (22.2%)	9/55 (16.4%)	0.458 ^c
Intradiscal electrothermal therapy (IDET)	0/141 (0.0%)	0/45 (0.0%)	0/55 (0.0%)	—
Percutaneous intradiscal radiofrequency thermocoagulation	0/141 (0.0%)	0/45 (0.0%)	0/55 (0.0%)	—
Local anesthetic injections (tender or trigger-point injections)	28/141 (19.9%)	7/45 (15.6%)	10/55 (18.2%)	0.728 ^c
Other	30/141 (21.3%)	9/45 (20.0%)	13/55 (23.6%)	0.662 ^c
At least one nonsurgical intervention	138/141 (97.9%)	45/45 (100.0%)	54/55 (98.2%)	1.000^f
Surgical Interventions				
Laminectomy	54/141 (38.3%)	16/45 (35.6%)	23/55 (41.8%)	0.523 ^c
Facetectomy	3/141 (2.1%)	1/45 (2.2%)	2/55 (3.6%)	1.000 ^f
Foraminotomy	1/141 (0.7%)	1/45 (2.2%)	0/55 (0.0%)	0.450 ^f
Laminoplasty	0/141 (0.0%)	0/45 (0.0%)	0/55 (0.0%)	—
Fusion and vertebral disc replacement	56/141 (39.7%)	18/45 (40.0%)	22/55 (40.0%)	1.000 ^c
Discectomy (open, microdiscectomy, laser, coblation nucleoplasty, etc.)	24/141 (17.0%)	11/45 (24.4%)	6/55 (10.9%)	0.073 ^c
Other	26/141 (18.4%)	6/45 (13.3%)	13/55 (23.6%)	0.191 ^c
At least one surgical intervention	102/141 (72.3%)	32/45 (71.1%)	38/55 (69.1%)	0.826^c

^c Chi-square test^f Fisher's exact test

SUNBURST™ Study Safety Results

The analysis of safety was based on the report of adverse events. Serious adverse events (SAEs) were reported after enrollment through study activation. After activation, all adverse events (AEs) were reported whether or not they were considered device- or procedure-related. No unanticipated adverse device effects (UADEs) were reported during the study. Both study-related and non-study related adverse events were collected and monitored through long-term study visits up to 24 months or until study completion.

A total of 158 AEs were reported during the study, 97 (59.5%) of which were considered to be non-study related. Twenty-one (21) events were considered SAEs and were reported in a total of 16 subjects (9.2%). Of all SAEs reported, only two were considered study-related in a total of 2 subjects (1.2%). The following table summarizes all the adverse events.

Table 6. Summary of all AEs

AE Description	Number of Events	Number of Subjects	Percent of Subjects (n/N**)
SAEs			
Study-related	2	2	1.2% (2/173)
Non-study related	19	15	8.7% (15/173)
SAE subtotal	21	16*	9.2% (16/173)
Non-SAEs			
Study-related	62	31	17.9% (31/173)
Non-study related	75	44	25.4% (44/173)
Non-SAE subtotal	137	58*	33.5% (58/173)
All AEs total	158	67*	38.7% (67/173)

* Some subjects experienced more than one event; therefore, the number of subjects experiencing an event is not equal to the number of events in the neighboring column.

** Subjects at risk out of subjects enrolled in study

Two (1.2% of total number of subjects at risk) SAEs were reported that were categorized as study-related. No study-related SAEs occurred following device activation. The following table summarizes the SAEs that occurred before stimulation began.

Table 7. Summary of study-related SAEs

Event Description	Number of Events	Number of Subjects	Percent of Subjects (n/N*)
Enrollment to activation			
Persistent pain and/or numbness	1	1	0.58% (1/173)
Unsuccessful lead placement	1	1	0.58% (1/173)
Total	2	2	1.16% (2/173)

* Subjects at risk out of subjects enrolled in study

The following table shows SAEs that were unrelated to the study. Nineteen (19) events were reported in 15 subjects (8.7%). Thirteen (13) SAEs were reported following device activation.

Table 8. Summary of non-study related SAEs

Event Description	Number of Events	Number of Subjects	Percent of Subjects (n/N)
Enrollment to activation			
Abdominal pain	1	1	0.58% (1/173) ^a
Bowel obstruction	1	1	0.58% (1/173) ^a

Table 8. Summary of non-study related SAEs

Event Description	Number of Events	Number of Subjects	Percent of Subjects (n/N)
Femur fracture	1	1	0.58% (1/173) ^a
Hip pain/replacement	1	1	0.58% (1/173) ^a
Low potassium levels	1	1	0.58% (1/173) ^a
Persistent pain and/or numbness	1	1	0.58% (1/173) ^a
Following activation			
Bladder tumor	1	1	1.04% (1/96) ^b
Broken femur	1	1	1.04% (1/96) ^b
Cancerous tumor on vocal chords	1	1	1.00% (1/100) ^c
Death ^d	1	1	1.04% (1/96) ^b
Infection	1	1	1.00% (1/100) ^c
Loss of speech and memory, and headache	1	1	1.00% (1/100) ^c
Myocardial infarction	1	1	1.04% (1/96) ^b
Scheduled right total-knee arthroplasty	1	1	1.00% (1/100) ^c
Seizure	1	1	1.04% (1/96) ^b
Shortness of breath	1	1	1.00% (1/100) ^c
Somnolence (sleepiness)	1	1	1.00% (1/100) ^c
Temporary paralysis	1	1	1.00% (1/100) ^c
Withdrawal symptoms from tapering off of oxymorphone*	1	1	1.00% (1/100) ^c
Total	19	15**	8.67% (15/173)

* The generic name of the medication, oxymorphone, is used instead of the brand name.

** Some subjects experienced more than one event; therefore, the number of subjects experiencing an event is not equal to the number of events in the neighboring column.

^a Subjects at risk out of all subjects enrolled in study

^b Subjects at risk out of subjects who completed the week-24 visit

^c Subjects at risk out of all subjects who had the implanted system activated

^d Subject died of natural causes at home. No autopsy was performed.

The following table identifies all 62 non-serious AEs that were study-related.

Table 9. Summary of study-related, non-serious AEs (following activation)

Event Description	Number of Events	Number of Subjects	Percent of Subjects (n/N)
Charger stopped working	1	1	1.00% (1/100) ^c
Device pocket heating while charging	1	1	1.00% (1/100) ^c
Diminished or loss of stimulation*	9	7 ^a	7.00% (7/100) ^c
Diminished or loss of symptom relief*	23	14 ^a	14.00% (14/100) ^c
Increased pain	1	1	1.00% (1/100) ^c
Infection	2	2	2.00% (2/100) ^c
Local skin erosion	1	1	1.00% (1/100) ^c
Persistent pain and/or numbness	6	6	6.00% (6/100) ^c
Postoperative low back pain	1	1	1.00% (1/100) ^c
Seroma at the implant site	1	1	1.00% (1/100) ^c
Stimulation in wrong place**	6	4 ^a	4.00% (4/100) ^c
Unpleasant sensations**	7	6 ^a	6.00% (6/100) ^c
Weakness	3	3	3.00% (3/100) ^c
Total	62	31^b	31.00% (31/100)

* Undesirable changes in stimulation

** Unintended effects of stimulation

^a Some subjects experienced more than one event.

^b The total number of subjects who experienced at least one event listed from the previous rows.

^c Subjects at risk out of subjects who had the implanted system activated.

The following table identifies non-serious study-related AEs. Of all the stimulation-related non-serious AEs, 13 occurred with burst stimulation and 16 occurred with tonic stimulation. Fewer non-serious AEs were noted for burst stimulation mode than tonic stimulation mode.

Table 10. Summary of stimulation-related, non-serious AEs (activation to 24 weeks)

Event Description	Number of Events	Number of Subjects	Percent of Subjects (n/N)
Burst stimulation-related			
Diminished or loss of stimulation*	4	3 ^a	3.00% (3/100) ^c
Diminished or loss of symptom relief*	5	5	5.00% (5/100) ^c

Table 10. Summary of stimulation-related, non-serious AEs (activation to 24 weeks)

Event Description	Number of Events	Number of Subjects	Percent of Subjects (n/N)
Unpleasant sensations**	4	4	4.00% (4/100) ^c
Tonic stimulation-related			
Diminished or loss of stimulation*	2	2	2.06% (2/97) ^d
Diminished or loss of symptom relief*	8	6 ^a	6.19% (6/97) ^d
Stimulation in wrong place**	5	4 ^a	4.12% (4/97) ^d
Unpleasant sensations**	1	1	1.03% (1/97) ^d
Total	29	16^b	16.00% (16/100)

* Undesirable changes in stimulation

** Unintended effects of stimulation

^a Some subjects experienced more than one event; therefore, the number of subjects experiencing an event is not equal to the number of events in the neighboring column.

^b The total number of subjects who experienced at least one event listed from the previous rows.

^c Subjects at risk out of the 55 subjects from the burst/tonic arm, as well as the 45 subjects from the tonic/ burst arm who completed the week-12 visit (when they crossed over to burst stimulation).

^d Subjects at risk out of the 45 subjects from the tonic/burst arm, as well as the 52 subjects from the burst/ tonic arm who completed the week-12 visit (when they crossed over to tonic stimulation).

Device and Device Usage Data

Surgery and device data were collected for the 100 subjects that were randomized and received a permanent implant. As shown in the following tables, randomization groups showed a similar number of implanted leads and similar IPG placement.

Table 11. Summary of surgery and device information for all randomized subjects (N=100)

Surgery	Arm 1: Tonic/Burst (N=45)	Arm 2: Burst/Tonic (N=55)
Number of leads implanted		
Mean ±SD (N)	1.8±0.7 (45)	1.7±0.8 (55)
Minimum, Median, Maximum	1.0, 2.0, 4.0	1.0, 2.0, 4.0
1 lead	16/45 (35.6%)	22/55 (40.0%)
2 leads	26/45 (57.8%)	27/55 (49.1%)
3 leads	1/45 (2.2%)	4/55 (7.3%)
4 leads	2/45 (4.4%)	2/55 (3.6%)
IPG placement side		
Left	39/45 (86.7%)	44/55 (80.0%)
Right	6/45 (13.3%)	11/55 (20.0%)
IPG anatomic location		

Table 11. Summary of surgery and device information for all randomized subjects (N=100)

Surgery	Arm 1: Tonic/Burst (N=45)	Arm 2: Burst/Tonic (N=55)
Abdomen	1/45 (2.2%)	2/55 (3.6%)
Lower axilla	0/45 (0.0%)	1/55 (1.8%)
Upper buttock	35/45 (77.8%)	38/55 (69.1%)
Other	9/45 (20.0%)	13/55 (23.6%)
Missing	0/45 (0.0%)	1/55 (1.8%)

Programming and stimulation mode data were collected at follow-up visits including unscheduled programming visits. The following table shows a summary of the burst stimulation settings through 24 weeks. The 100 randomized subjects underwent 350 programming sessions, and the programmed parameters were within the ranges recommended in the protocol (pulse width of 1000 μ s, burst rate of 40 Hz, intra-burst frequency of 500 Hz, and burst train of 5 pulses).

Table 12. Summary of burst stimulation settings for all randomized subjects (N=100)

Number of Programming Sessions	Burst Rate		Intra-Burst Rate	Burst Train	
	40 Hz	20 Hz	500 Hz	5 pulses	Missing
351	350 (99.7%)	1 (0.3%)	351 (100.0%)	350 (99.7%)	1 (0.3%)
	Pulse Width (μ s)	Amplitude			
		Minimum	Target	Maximum	
Mean $\pm$ SD (N)	994.8 $\pm$ 68.6 (348)	0.5 $\pm$ 0.6 (343)	1.6 $\pm$ 1.0 (347)	2.7 $\pm$ 0.8 (346)	
Minimum	0	0	0	1	
Maximum	1000	2	5	5	

Recharging data were collected at follow-up visits including unscheduled programming visits. The following table shows a summary of recharging information through 24 weeks. Recharging instructions for routine care of a typical neurostimulation system (using tonic stimulation) were given at the discretion of the investigator; thus, no differences in recharging for tonic and burst stimulation were expected.

Table 13. Summary of IPG recharging for all available subjects

IPG Recharging		Burst	Tonic
Week 6			
Recharged	Yes	51/52 (98.08%)	44/45 (97.78%)
Frequency	Daily	4/51 (7.84%)	3/44 (6.82%)
	2–3 times a week	15/51 (29.4%)	13/44 (29.5%)
	Weekly	28/51 (54.9%)	23/44 (52.3%)
	Every other week	3/51 (5.88%)	3/44 (6.82%)
	Once a month or less often	1/51 (1.96%)	2/44 (4.55%)
Reason	Battery heats up	1/51 (1.96%)	0/44 (0.0%)
	Low battery message	3/51 (5.88%)	5/44 (11.4%)
	Normal routine	43/51 (84.3%)	39/44 (88.6%)

Table 13. Summary of IPG recharging for all available subjects

IPG Recharging		Burst	Tonic
	Recommended time frame	4/51 (7.84%)	0/44 (0.0%)
Week 12			
Recharged	Yes	52/52 (100.00%)	45/45 (100.00%)
Frequency	Daily	7/52 (13.5%)	1/45 (2.22%)
	2–3 times a week	16/52 (30.8%)	11/45 (24.4%)
	Weekly	23/52 (44.2%)	29/45 (64.4%)
	Every other week	5/52 (9.62%)	2/45 (4.44%)
	Once a month or less often	1/52 (1.92%)	2/45 (4.44%)
Reason	Low battery message	4/52 (7.69%)	1/45 (2.22%)
	Normal routine	46/52 (88.5%)	41/45 (91.1%)
	Recommended time frame	2/52 (3.85%)	2/45 (4.44%)
	Thought it was needed	0/52 (0.0%)	1/45 (2.22%)
Unscheduled before week 12			
Recharged	Yes	15/18 (83.33%)	22/28 (78.57%)
Frequency	Daily	1/15 (6.67%)	0/22 (0.0%)
	2–3 times a week	4/15 (26.7%)	3/22 (13.6%)
	Weekly	8/15 (53.3%)	17/22 (77.3%)
	Every other week	1/15 (6.67%)	2/22 (9.09%)
	Once a month or less often	1/15 (6.67%)	0/22 (0.0%)
Reason	Low battery message	3/15 (20.0%)	4/22 (18.2%)
	Normal routine	10/15 (66.7%)	15/22 (68.2%)
	Patient checks battery and charges when less than 50% depleted	1/15 (6.67%)	0/22 (0.0%)
	Recommended time frame	1/15 (6.67%)	3/22 (13.6%)
Week 18			
Recharged	Yes	44/44 (100.00%)	51/51 (100.00%)
Frequency	Daily	1/44 (2.27%)	3/51 (5.88%)
	2–3 times a week	10/44 (22.7%)	11/51 (21.6%)
	Weekly	28/44 (63.6%)	29/51 (56.9%)
	Every other week	5/44 (11.4%)	6/51 (11.8%)

Table 13. Summary of IPG recharging for all available subjects

IPG Recharging		Burst	Tonic
Reason	Once a month or less often	0/44 (0.0%)	2/51 (3.92%)
	Low battery message	0/44 (0.0%)	3/51 (5.88%)
	Normal routine	44/44 (100%)	45/51 (88.2%)
	Recommended time frame	0/44 (0.0%)	3/51 (5.88%)
Week 24			
Recharged	Yes	45/45 (100.00%)	50/51 (98.04%)
Frequency	Daily	3/45 (6.67%)	2/50 (4.00%)
	2–3 times a week	13/45 (28.9%)	8/50 (16.0%)
	Weekly	25/45 (55.6%)	32/50 (64.0%)
	Every other week	4/45 (8.89%)	7/50 (14.0%)
	Once a month or less often	0/45 (0.0%)	1/50 (2.00%)
Reason	Battery heats up	1/45 (2.22%)	0/50 (0.0%)
	Charged daily due to time it took (1.5 hours daily or more than 3 hours if patient waited)	1/45 (2.22%)	0/50 (0.0%)
	Low battery message	1/45 (2.22%)	3/50 (6.00%)
	Normal routine	42/45 (93.3%)	46/50 (92.0%)
	Recommended time frame	0/45 (0.0%)	1/50 (2.00%)
Unscheduled between weeks 12 and 24			
Recharged	Yes	11/11 (100.00%)	7/7 (100.00%)
Frequency	2–3 times a week	0/11 (0.0%)	3/7 (42.9%)
	Weekly	10/11 (90.9%)	4/7 (57.1%)
	Once a month or less often	1/11 (9.09%)	0/7 (0.0%)
Reason	Normal routine	10/11 (90.9%)	7/7 (100.00%)
	Recommended time frame	1/11 (9.09%)	0/7 (0.0%)

SUNBURST™ Study Results

This section provides results from the SUNBURST™ study.

Primary Effectiveness

The analysis of effectiveness was an intention-to-treat analysis based on the randomization population of 100 subjects.

Statistical methods were used to impute VAS scores for the following subjects and reasons:

- Six (6) subjects increased pain medication in during the 12 weeks following device activation (2 while using tonic and 4 while using burst) and 15 subjects increased pain medication in between weeks 12 and 24 (5 while using burst and 10 while using tonic), and their overall VAS score at the trial baseline was used to impute their overall VAS score for the week-12 or week-24 visit as appropriate per the protocol.
- Four (4) subjects withdrew from the study before week 24, and their overall VAS score was imputed using the hot deck method, which replaces missing values of a visit for a non-respondent with observed values during the same visit from a respondent who shares similar characteristics observed by both cases.
- Three (3) subjects underwent an invasive procedure for a new clinically significant or disabling chronic pain problem, and their overall VAS score was imputed using the hot deck method or the last observation carried forward (LOCF) method, which replaces missing values by using the last value observed for the score.

The following table shows the results of testing the primary endpoint. In both randomization groups, burst stimulation scored lower overall than tonic stimulation on the VAS by 3.6 in the tonic/burst group and 6.5 in the burst/tonic group. The estimated difference in the overall VAS score between burst and tonic stimulation was -5.1, and the 95% upper confidence bound (UCB) for the mean difference between burst and tonic stimulation was -1.14, which is less than the non-inferiority margin of 7.5. Additionally, the *p*-value for the test of the non-inferiority hypothesis was <0.001. Therefore, the primary endpoint was met, and it is concluded that burst stimulation is non-inferior to tonic stimulation.

Table 14. Primary endpoint (overall VAS score)

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Burst			
Mean ±SD (N)	42.7±26.1 (45)	44.2±25.3 (55)	43.5±25.6 (100)
Minimum, Median, Maximum	0.9, 41.1, 100.0	0.0, 45.1, 98.1	–
Tonic			
Mean ±SD (N)	46.3±22.8 (45)	50.0±24.8 (55)	48.7±23.9 (100)
Minimum, Median, Maximum	1.0, 49.3, 88.1	0.0, 49.3, 98.7	–
Burst-Tonic			
Mean ±SD (N)	-3.6±26.3 (45)	-6.5±21.0 (55)	–
Minimum, Median, Maximum	-64.6, -3.7, 79.0	-70.4, -2.6, 48.4	–
Burst-Tonic Average ± Pooled SD Across Arms		-5.1±11.8	
95% UCB on Difference (Burst-Tonic)		-1.14 ^t	
Non-Inferiority Margin		7.5	
<i>p</i>-value for Non-Inferiority Test		<0.001 ^t	
Endpoint Met?		Yes	

^t 95% UCB and *p*-value for non-inferiority are based on a t-distribution with n_1+n_2-2 degrees of freedom, where n_1 and n_2 are the number of subjects in each arm.

In addition to demonstrating non-inferiority, superiority was also shown. The following table contains the results of testing the superiority hypothesis for burst over tonic stimulation. The difference in the overall VAS score between burst and tonic stimulation is -5 points, with a 95% UCB of -1.14, which is less than 0 and results in a rejection of the hypothesis that burst stimulation is not superior to tonic stimulation (*p*=0.017). Therefore, the results demonstrate that burst stimulation is superior to tonic stimulation.

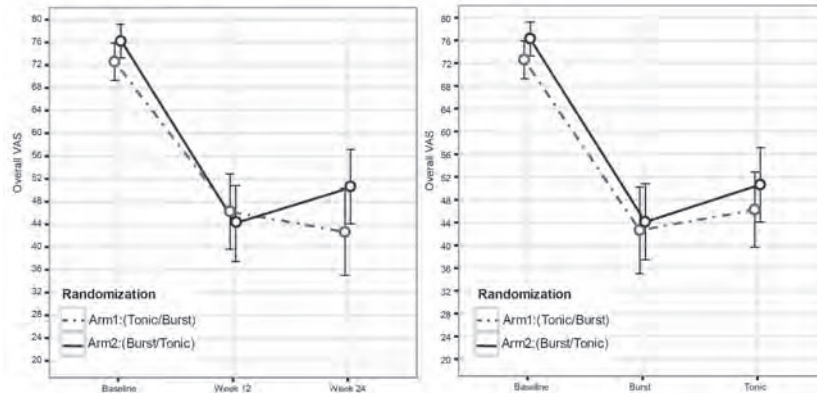
Table 15. Superiority of overall VAS score with burst over tonic

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Burst			
Mean ±SD (N)	42.7±26.1 (45)	44.2±25.3 (55)	43.5±25.6 (100)
Minimum, Median, Maximum	0.9, 41.1, 100.0	0.0, 45.1, 98.1	–
Tonic			
Mean ±SD (N)	46.3±22.8 (45)	50.7±24.8 (55)	48.7±23.9 (100)
Minimum, Median, Maximum	1.0, 49.3, 88.1	0.0, 49.3, 98.7	–
Burst-Tonic			
Mean ±SD (N)	-3.6±26.3 (45)	-6.5±21.0 (55)	–
Minimum, Median, Maximum	-64.6, -3.7, 79.0	-70.4, -2.6, 48.4	–
Burst-Tonic Average ± Pooled SD Across Arms		-5.1±11.8	
95% UCB on Difference (Burst Tonic)		-1.14 ^t	
Superiority Margin		0	
<i>p</i>-value for Superiority Test		0.017 ^t	
Endpoint Met?		Yes	

^t 95% UCB and *p*-value for superiority are based on a t-distribution with n_1+n_2-2 degrees of freedom, where n_1 and n_2 are the number of subjects in each arm.

The following figure presents the overall VAS scores by visit and by stimulation mode. The graph on the left shows that both randomization groups had high overall VAS scores at baseline and, at week 12, both stimulation modes reduced the overall VAS score as expected since all subjects were known responders to tonic stimulation during the stimulation trial period). The graph on the right shows these same data by stimulation method. The figure shows a large reduction in overall VAS score from baseline with burst stimulation and less reduction in VAS during tonic stimulation.

Figure 2. Main overall VAS score with 95% CI by visit (left) and by stimulation mode (right)



Secondary Effectiveness

The following table compares responder rates for burst stimulation versus tonic stimulation, where “responder rate” is defined as a decrease in the overall daily VAS score from baseline by at least 30%. A total of 69 subjects (69%) responded to tonic stimulation, burst stimulation, or both. Responder rates are 60.0% with burst stimulation and 51.0% with tonic stimulation. A cross-tabulation of responders for burst stimulation versus tonic stimulation shows numerically more subjects whose VAS score decreased by at least 30% with burst stimulation than with tonic stimulation (18 versus 9). However, this difference was not statistically significant ($p=0.083$).

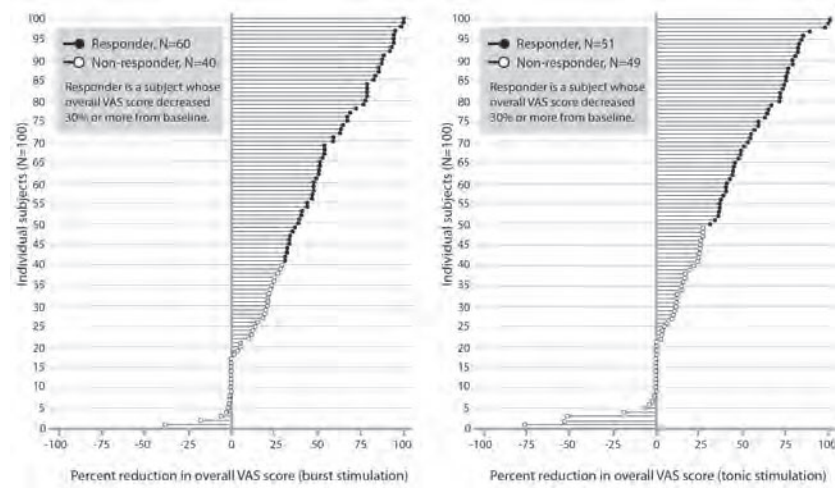
Table 16. Responder rates (decrease of $\geq 30\%$ from baseline) for overall daily VAS score

Overall Responder Rate			
Percent of burst subjects (n/N)		60.0% (60/100)	
Percent of tonic subjects (n/N)		51.0% (51/100)	
Cross-Tabulation of Responders by Stimulation Mode			
Stimulation mode		Tonic	
Burst	Responder	No	Yes
	No	31/100 (31.0%)	9/100 (9.0%)
	Yes	18/100 (18.0%)	42/100 (42.0%)
p-value (Burst vs. Tonic)			
0.083 ^m			

^m McNemar’s test

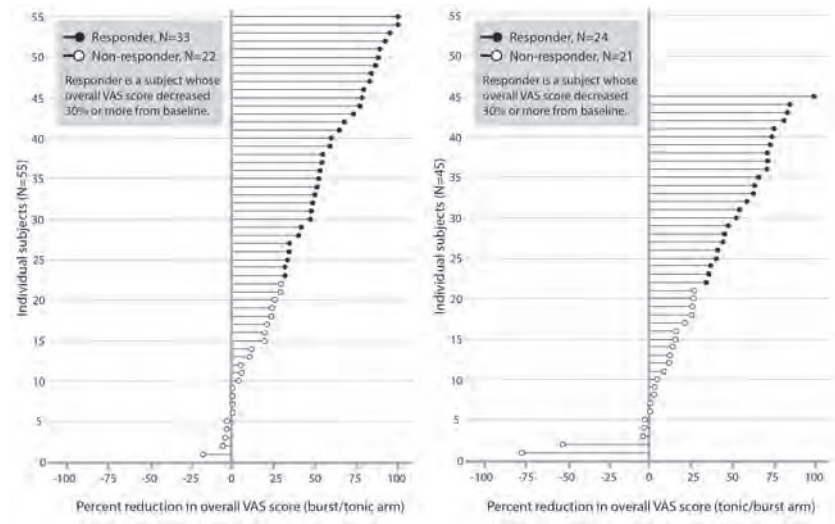
The following figure shows the percentage of pain relief for burst stimulation (left graph) and tonic stimulation (right graph) in individual subjects overall from baseline through week 24. For this figure, the responder rate was defined as a 30% or more reduction in the overall VAS score.

Figure 3. Percentage reduction ($\geq 30\%$ responder rate) in overall VAS score from baseline by stimulation mode



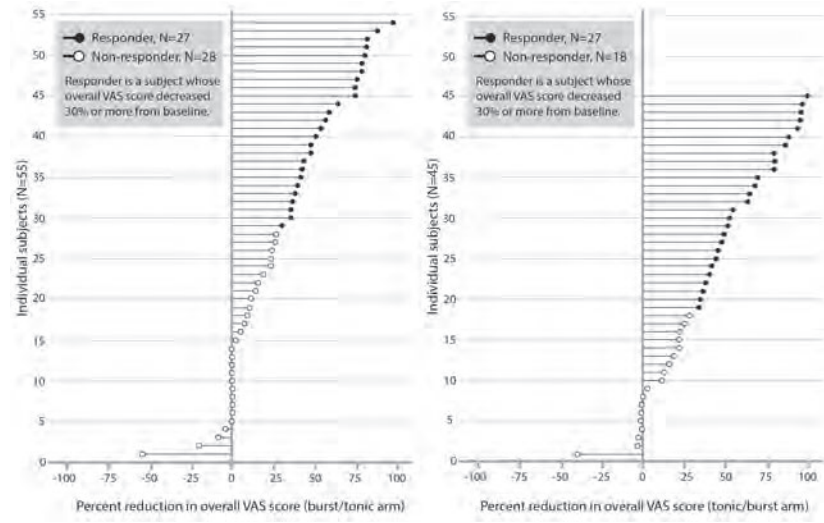
The following figure shows the percentage of pain relief from burst stimulation (left graph) and tonic stimulation (right graph) in the individual subjects for week 12, using a responder rate definition of 30%.

Figure 4. Percentage reduction ($\geq 30\%$ responder rate) in overall VAS score at week 12 from baseline



The following figure shows the percentage of pain relief from tonic stimulation (left graph) and burst stimulation (right graph) in the individual subjects for week 24, using a responder rate definition of 30%.

Figure 5. Percentage reduction ($\geq 30\%$ responder rate) in overall VAS score at week 24 from baseline



Data for paresthesia coverage at both 12 and 24 weeks were available for 73 subjects. More than half of the subjects (45 out of 73 [61.6%]) were paresthesia-free using burst stimulation, while only 2 subjects (2.7%) were paresthesia-free using tonic stimulation. In addition, 89.0% of subjects (65/73) experienced a reduction in paresthesia or no paresthesia with burst stimulation compared to tonic stimulation. The following table summarizes these results.

Table 17. Summary of paresthesia mapping with burst and tonic stimulation

Cross-Tabulation of Paresthesia by Stimulation Mode				
Stimulation mode		Tonic		
	Paresthesia	No	Yes	Overall
Burst	No	2/73 (2.7%)	45/73 (61.6%)	47/73 (64.4%)
	Yes	0/73 (0.0%)	26/73 (35.6%)	26/73 (35.6%)
	Overall	2/73 (2.7%)	71/73 (97.3%)	
Subjects with Reduction of Paresthesia				
Reduction of 100% (No paresthesia)			45/73 (61.6%)	
Reduction of 1%–99%			20/73 (27.4%)	
No Reduction			8/73 (11.0%)	

The mean percentage of paresthesia coverage for burst is significantly lower than that for tonic. The following table summarizes the results of the test of the hypothesis of equality between burst and tonic stimulation. On average, subjects reported only 4.5% of the mapped body segments had paresthesia with burst stimulation compared to 22.7% with tonic stimulation. This difference represents an 80.2% relative reduction in paresthesia coverage with burst stimulation over tonic stimulation.

Table 18. Percentage of paresthesia coverage

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Burst			
Mean $\pm$ SD (N)	3.9 $\pm$ 6.6 (37)	5.0 $\pm$ 10.5 (36)	4.5 $\pm$ 8.7 (73)
Minimum, Median, Maximum	0.0, 0.0, 23.4	0.0, 0.0, 51.1	–
Tonic			
Mean $\pm$ SD (N)	20.1 $\pm$ 14.3 (37)	25.3 $\pm$ 18.1 (36)	22.7 $\pm$ 16.3 (73)
Minimum, Median, Maximum	0.0, 17.0, 59.6	0.0, 20.2, 66.0	–
Burst-Tonic			
Mean $\pm$ SD (N)	-16.2 $\pm$ 14.5 (37)	-20.3 $\pm$ 19.5 (36)	–
Minimum, Median, Maximum	-57.4, -12.8, 8.5	-61.7, -18.1, 12.8	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		-18.2 $\pm$ 8.6	
95% CI		22.2, -14.2	

Additional Nonpowered Effectiveness

The following data consist of descriptive secondary and additional endpoints that were predetermined within the clinical study protocol. See “Clinical Endpoints” (page 6), “Clinical Endpoints” (page 39), “Clinical Endpoints” (page 49), “Clinical Endpoints” (page 73). Additional descriptive (nonpowered) data have also been provided.

Pain Measures

The FDA requested analyses to be performed on overall pain, trunk and limb VAS pain measures from baseline to 12 weeks. Because the study had a crossover design in which subjects were randomized to receive either tonic stimulation or burst stimulation from activation to 12 weeks, these analyses were performed to evaluate study treatment to exclude the possibility of an unequal carryover effect that would influence the results. Within the crossover design of this study, analyses of the data from baseline to 24 weeks would not provide the same meaningful evaluation of the study treatment.

As shown in the following table, the average changes in overall VAS score from baseline to week 12 were -32.1 and -26.4 for burst and tonic stimulation, respectively. The difference was -5.8 with a 95% UCB for a mean difference of 2.9, which is less than the non-inferiority margin of 7.5. Therefore, despite the smaller sample size, the primary endpoint of non-inferiority was met.

Table 19. Change in overall VAS score from baseline to week 12

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic
Stimulation	Tonic	Burst
VAS at Baseline		
Mean $\pm$ SD (N)	72.7 $\pm$ 11.4 (45)	76.3 $\pm$ 11.3 (55)
Minimum, Maximum	44.4, 90.3	43.9, 98.9
VAS at Week 12		
Mean $\pm$ SD (N)	46.3 $\pm$ 22.8 (45)	44.2 $\pm$ 25.3 (55)
Minimum, Maximum	1.0, 88.1	0.0, 98.1

Table 19. Change in overall VAS score from baseline to week 12

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic
Burst-Tonic		
Mean $\pm$ SD (N)	-26.4 $\pm$ 24.9 (45)	-32.1 $\pm$ 26.7 (55)
Minimum, Maximum	87.4, 34.0	87.7, 15.0
Burst-Tonic	-5.8 $\pm$ 25.9	
95% UCB on Difference (Burst-Tonic)	2.9	
Non-Inferiority Margin	7.5	
p-value for Non-Inferiority Test	0.006	
p-value for Superiority Test	0.136	

The following table shows a cross-tabulation of responder rates ($\geq 50\%$ decrease in overall VAS score from baseline) with burst and tonic stimulation. A total of 49 subjects (49%) responded to tonic stimulation, burst stimulation, or both. The overall VAS scores decreased by at least 50% for more subjects with burst stimulation than with tonic stimulation (17 versus 10).

Table 20. Responder rates (decrease of $\geq 50\%$ from baseline) for overall daily VAS score

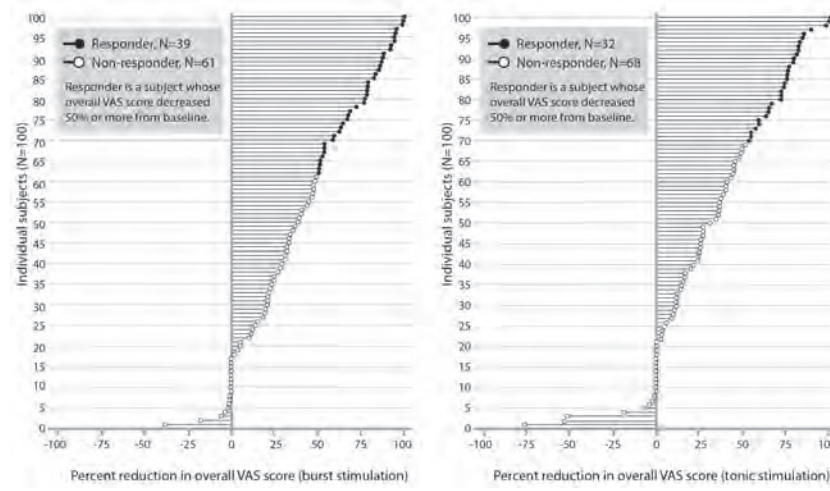
Overall Responder Rate			
Burst subjects (n/N)		39/100 (39.0%)	
Tonic subjects (n/N)		32/100 (32.0%)	
Difference in responder rate with 95% CI* (Burst-Tonic)		7.0% (-1.0%, 19.0%)	
Cross-Tabulation of Responders by Stimulation Mode			
Stimulation mode		Tonic	
Burst	Responder**	No	Yes
	No	51/100 (51.0%)	10/100 (10.0%)
	Yes	17/100 (17.0%)	22/100 (22.0%)

* 95% CI was calculated using asymptotic method without continuity correction. (May and Johnson, 1997; Newcombe, 1998)

** Responder is defined as a subject whose overall VAS score decreased 50% or more from baseline.

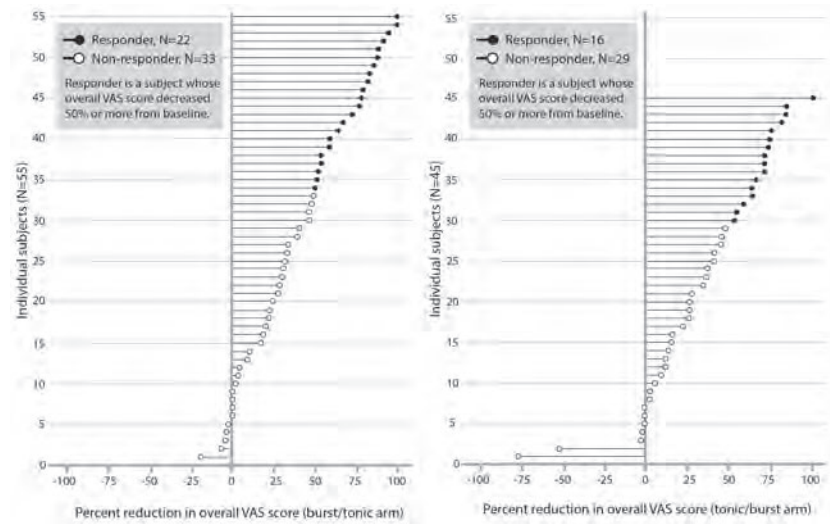
The following figure shows the percentage of pain relief for burst stimulation (left graph) and tonic stimulation (right graph) in individual subjects overall from baseline through week 24. For this figure, the responder rate was defined as a 50% or more reduction in the overall VAS score.

Figure 6. Percentage reduction ($\geq 50\%$ responder rate) in overall VAS score from baseline by stimulation mode



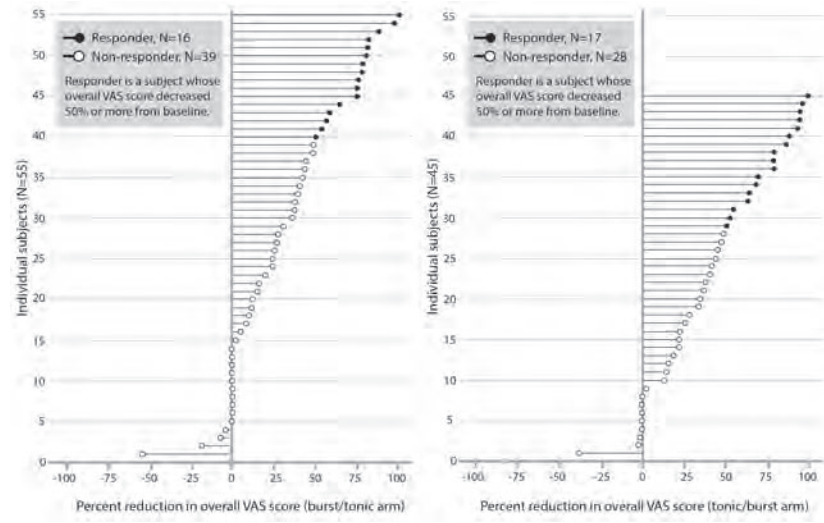
The following figure shows the percentage of pain relief from burst stimulation (left graph) and tonic stimulation (right graph) in the individual subjects at week 12, using a responder rate definition of 50%.

Figure 7. Percentage reduction ($\geq 50\%$ responder rate) in overall VAS score at week 12 from baseline



The following figure shows the percentage of pain relief from burst stimulation (left graph) and tonic stimulation (right graph) in the individual subjects at week 12, using a responder rate definition of 50%.

Figure 8. Percentage reduction ($\geq 50\%$ responder rate) in overall VAS score at week 24 from baseline



The following table summarizes the proportion of subjects with a decrease in overall VAS score by $<30\%$, $\geq 30\%$ and $<50\%$, and $\geq 50\%$ under each stimulation mode. Overall, more subjects experienced a reduction in overall VAS score of $\geq 50\%$ while using burst stimulation than while using tonic stimulation (39 versus 32) and fewer subjects experienced reduction in overall VAS score by $<30\%$ while using burst stimulation (40 versus 49).

Table 21. Summary of decrease in overall VAS score from baseline by three categories

Decrease in Overall VAS From Baseline	Burst	Tonic
Arm 1: Tonic/Burst		
$<30\%$	18/45 (40.0%)	21/45 (46.7%)
$\geq 30\%$, $<50\%$	10/45 (22.2%)	8/45 (17.8%)
$\geq 50\%$	17/45 (37.8%)	16/45 (35.6%)
Arm 2: Burst/Tonic		
$<30\%$	22/55 (40.0%)	28/55 (50.9%)
$\geq 30\%$, $<50\%$	11/55 (20.0%)	11/55 (20.0%)
$\geq 50\%$	22/55 (40.0%)	16/55 (29.1%)
All Subjects		
$<30\%$	40/100 (40.0%)	49/100 (49.0%)
$\geq 30\%$, $<50\%$	21/100 (21.0%)	19/100 (19.0%)
$\geq 50\%$	39/100 (39.0%)	32/100 (32.0%)

The following two tables summarize trunk VAS scores for the randomization subject population and only from baseline to 12 weeks. The complete data show that trunk VAS scores for burst stimulation were lower than

those during tonic stimulation by 5.7. Average changes for trunk VAS scores for baseline to week 12 are also lower for burst stimulation by 8.9.

Table 22. Summary of trunk VAS scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Burst			
Mean $\pm$ SD (N)	39.7 $\pm$ 25.3 (45)	41.8 $\pm$ 25.8 (55)	40.9 $\pm$ 25.5 (100)
Minimum, Median, Maximum	0.6, 38.0, 85.4	0.0, 40.6, 99.0	–
Tonic			
Mean $\pm$ SD (N)	44.2 $\pm$ 21.9 (45)	48.8 $\pm$ 25.6 (55)	46.7 $\pm$ 24.0 (100)
Minimum, Median, Maximum	0.6, 48.9, 84.0	0.0, 51.1, 86.7	–
Burst-Tonic			
Mean $\pm$ SD (N)	-4.5 $\pm$ 22.0 (45)	-7.0 $\pm$ 23.1 (55)	–
Minimum, Median, Maximum	-49.6, -3.7, 57.9	-75.7, -2.3, 36.4	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		-5.7 $\pm$ 11.3	
95% CI		-10.3, -1.2	

Table 23. Change in trunk VAS score from baseline to week 12

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic
Stimulation	Tonic	Burst
VAS at Baseline		
Mean ±SD (N)	70.4±17.2 (45)	77.0±11.6 (55)
Minimum, Maximum	19.3, 98.3	42.6, 97.1
VAS at Week 12		
Mean ±SD (N)	44.2±21.9 (45)	41.8± 25.8 (55)
Minimum, Maximum	0.6, 84.0	0.0, 99.0
Burst-Tonic		
Mean ±SD (N)	26.3±23.4 (45)	35.2±27.0 (55)
Minimum, Maximum	87.0, 36.4	83.7, 7.3
Burst-Tonic		-8.9±25.4
95% CI		-19.2, 1.2

The following two tables summarize limb VAS scores for the randomization subject population and only from baseline to 12 weeks. The complete data show that limb VAS scores for burst stimulation were lower than those during tonic stimulation by 4.7. Average changes for limb VAS scores for baseline to week 12 are also lower for burst stimulation by 5.8.

Table 24. Summary of limb VAS scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Burst			
Mean $\pm$ SD (N)	37.2 $\pm$ 27.8 (44)	35.9 $\pm$ 27.1 (54)	36.5 $\pm$ 27.3 (98)
Minimum, Median, Maximum	0.7, 38.2, 100.0	0.0, 30.0, 98.9	–
Tonic			
Mean $\pm$ SD (N)	37.2 $\pm$ 24.2 (44)	45.2 $\pm$ 27.3 (54)	41.6 $\pm$ 26.1 (98)
Minimum, Median, Maximum	0.7, 36.2, 82.6	0.0, 43.6, 99.0	–
Burst-Tonic			
Mean $\pm$ SD (N)	-0.0 $\pm$ 22.2 (44)	-9.3 $\pm$ 22.9 (54)	–
Minimum, Median, Maximum	-44.0, -0.1, 82.0	-69.3, -5.2, 40.1	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		-4.7 $\pm$ 11.3	
95% CI		-9.2, -0.1	

NOTE: This analysis includes only subjects who reported limb pain at baseline.

Table 25. Change in limb VAS score from baseline to week 12

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic
Stimulation	Tonic	Burst
VAS at Baseline		
Mean $\pm$ SD (N)	68.1 $\pm$ 21.0 (44)	72.5 $\pm$ 21.6 (54)
Minimum, Maximum	0.4, 93.0	2.1, 98.3
VAS at Week 12		
Mean $\pm$ SD (N)	37.2 $\pm$ 24.2 (44)	35.9 $\pm$ 27.1 (54)
Minimum, Maximum	0.7, 82.6	0.0, 98.9
Burst-Tonic		
Mean $\pm$ SD (N)	30.9 $\pm$ 25.1 (44)	36.6 $\pm$ 29.7 (54)
Minimum, Maximum	88.0, 13.3	89.1, 16.1
Burst-Tonic		-5.8 $\pm$ 27.7
95% CI		-16.9, 5.4

The following table summarizes worst VAS scores for the randomization subject population. The data shows that burst stimulation worst VAS scores were lower than those during tonic stimulation by 4.1 points.

Table 26. Summary of worst VAS scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Burst			
Mean $\pm$ SD (N)	52.2 $\pm$ 27.9 (45)	52.3 $\pm$ 26.9 (55)	52.3 $\pm$ 27.2 (100)

Table 26. Summary of worst VAS scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Minimum, Median, Maximum	0.4, 54.4, 100.0	0.0, 50.1, 97.7	–
Tonic			
Mean ±SD (N)	54.3±24.4 (45)	58.5±26.1 (55)	56.6±25.3 (100)
Minimum, Median, Maximum	0.8, 54.1, 99.0	0.0, 63.3, 99.3	–
Burst-Tonic			
Mean ±SD (N)	-2.1±25.8 (45)	-6.2±22.8 (55)	–
Minimum, Median, Maximum	-57.0, -0.4, 83.1	-70.1, -2.4, 54.6	–
Burst-Tonic Average ± Pooled SD Across Arms		-4.1±12.1	
95% CI		-9.0, 0.7	

Device Satisfaction and Stimulation Preference

At each follow-up visit, subjects specified their overall level of satisfaction with the device, and they specified their preference with the stimulation mode at the week-24 visit. The following tables show that most subjects were satisfied with the device therapy during both stimulation modes (78.1%), few subjects were dissatisfied with the device (4.2%), and a similar number of subjects had opposite responses for burst and tonic. These data are reflected more clearly in the summary of stimulation preference, which shows that more than two-thirds of subjects (70.8%) preferred burst stimulation over tonic stimulation. While most subjects preferred burst stimulation, 18 subjects (18.8%) still preferred tonic stimulation. This is important to note because the investigational device is capable of both stimulation modes.

Table 27. Subject satisfaction summary at week 24

Satisfaction Level	Burst	Tonic	
Burst subjects (n/N)	85/96 (88.5%)	82/96 (85.4%)	
Tonic subjects (n/N)	11/96 (11.5%)	14/96 (14.6%)	
Difference in satisfaction rate (burst-tonic)		3.1%	
95% CI of difference in satisfaction rate (lower bound, upper bound)		-5.3%, -11.5%	
Cross-Tabulation of Satisfaction Level by Stimulation Mode			
Stimulation mode		Tonic	
Burst	Satisfaction Level	Dissatisfied*	Satisfied**
	Dissatisfied*	4/96 (4.2%)	7/96 (7.3%)
	Satisfied**	10/96 (10.4%)	75/96 (78.1%)

* Dissatisfied is a combination of “very dissatisfied,” “dissatisfied,” and “neither satisfied nor dissatisfied.”

** Satisfied is a combination of “satisfied and very satisfied.”

Table 28. Summary of subject stimulation preferences at week 24

	Stimulation Preference			95% CI*
	Burst Stimulation	Tonic Stimulation	No Preference	
Arm 1: Tonic/Burst	37/45 (82.2%)	3/45 (6.7%)	5/45 (11.1%)	–
Arm 2: Burst/Tonic	31/51 (60.8%)	15/51 (29.4%)	5/51 (9.8%)	–
All Subjects	68/96 (70.8%)	18/96 (18.8%)	10/96 (10.4%)	60.7%, 97.7%

* 95% CI of proportion of subjects preferring burst stimulation

Psychosocial Health and Physical Function Measures

The PGIC questionnaire was completed at the week-12 and week-24 visits and was used to evaluate the subject's impression of change since beginning the study treatment. The following table shows the summary of responses to this questionnaire pooled across the two arms. Overall, the proportion of subjects whose global impression was moderately better, better, or a great deal better was comparable between the two stimulation modes (72/97 for burst versus 71/96 for tonic).

Table 29. Summary of PGIC questionnaire

PGIC	Burst	Tonic
No change (or condition has got worse)	6/97 (6.2%)	1/96 (1.0%)
Almost the same, hardly any change at all	7/97 (7.2%)	11/96 (11.5%)
A little better, but no noticeable change	7/97 (7.2%)	3/96 (3.1%)
Somewhat better, but the change has not made any real difference	5/97 (5.2%)	10/96 (10.4%)
Moderately better, and a slight but noticeable change	20/97 (20.6%)	16/96 (16.7%)
Better, and a definite improvement that has made a real and worthwhile difference	35/97 (36.1%)	43/96 (44.8%)
A great deal better, and a considerable improvement that has made all the difference	17/97 (17.5%)	12/96 (12.5%)

The following table presents the physical and mental component scores for the SF-36 quality of life survey. Burst stimulation had higher pooled scores than tonic stimulation with a difference of 0.4 for the physical component score and 0.7 for the mental component score. It is important to note that baseline scores for the mental component of the SF-36 (48.7) are near the normative mean (50.0) for this subscale (Ware, 2000), indicating that the subject's quality of life based on mental health was about the same as the general population (Bell, 2015; Verkerk, 2015) and were not representative of chronic pain patients (Elliott et al, 2003).

Table 30. Components of SF-36 quality of life physical and mental scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Physical Component Scores			
Baseline			
Mean $\pm$ SD (N)	29.0 $\pm$ 6.5 (42)	28.3 $\pm$ 8.3 (47)	28.6 $\pm$ 7.5 (89)

Table 30. Components of SF-36 quality of life physical and mental scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Minimum, Median, Maximum	16.2, 27.7, 45.6	12.9, 27.7, 49.3	–
Burst			
Mean ±SD (N)	37.3±8.4 (42)	35.3±8.3 (47)	36.2±8.4 (89)
Minimum, Median, Maximum	23.2, 37.8, 53.6	20.7, 34.8, 51.2	–
Tonic			
Mean ±SD (N)	36.1±8.0 (42)	35.6±10.1 (47)	35.8±9.2 (89)
Minimum, Median, Maximum	22.3, 36.1, 55.6	18.9, 34.4, 64.6	–
Burst-Tonic			
Mean ±SD (N)	1.1±7.3 (42)	-0.3±7.0 (47)	–
Minimum, Median, Maximum	-15.4, 2.1, 19.1	-17.8, 0.6, 19.5	–
Burst-Tonic Average ± Pooled SD Across Arms		0.4±3.6	
95% CI		-1.1, -1.9	
Mental Component Scores			
Baseline			
Mean ±SD (N)	47.1±12.9 (42)	50.2±11.6 (47)	48.7±12.3 (89)
Minimum, Median, Maximum	18.6, 48.4, 71.4	24.5, 54.4, 69.5	–
Burst			
Mean ±SD (N)	50.2±12.6 (42)	52.3±9.6 (47)	51.3±11.1 (89)
Minimum, Median, Maximum	16.1, 50.9, 72.5	31.2, 56.2, 68.6	–
Tonic			
Mean ±SD (N)	49.1±11.9 (42)	52.0±9.8 (47)	50.6±10.9 (89)
Minimum, Median, Maximum	19.3, 49.6, 67.7	25.6, 53.5, 64.2	–
Burst-Tonic			
Mean ±SD (N)	1.1±8.4 (42)	-0.3±7.9 (47)	–
Minimum, Median, Maximum	-26.5, 1.5, 21.3	-20.1, -0.3, 19.3	–
Burst-Tonic Average ± Pooled SD Across Arms		0.7±4.1	
95% CI		-1.0, 2.5	

The following table shows a summary of ODI scores. Subjects experienced a reduction in ODI scores from baseline during both stimulation modes. However, neither burst nor tonic stimulation produced clinically

meaningful changes on the ODI. One reason for this observation may be the relatively low baseline scores observed in this population. The baseline score for the ODI was 49.1, which is less than what is typical for chronic pain patients. Typical scores are in the 61- to 80-point range (Kumar, 2007). Thus, in light of the low baseline ODI scores, a significant improvement would not necessarily be expected.

Table 31. Summary of ODI scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Baseline			
Mean $\pm$ SD (N)	48.9 $\pm$ 11.3 (45)	49.2 $\pm$ 10.6 (50)	49.1 $\pm$ 10.9 (95)
Minimum, Median, Maximum	24.0, 50.0, 80.0	17.8, 50.0, 72.0	–
Burst			
Mean $\pm$ SD (N)	33.4 $\pm$ 16.9 (45)	37.5 $\pm$ 15.6 (50)	35.6 $\pm$ 16.3 (95)
Minimum, Median, Maximum	0.0, 32.0, 80.0	4.0, 41.0, 70.0	–
Tonic			
Mean $\pm$ SD (N)	34.4 $\pm$ 15.3 (45)	36.5 $\pm$ 14.3 (50)	35.5 $\pm$ 14.8 (95)
Minimum, Median, Maximum	0.0, 34.0, 74.0	0.0, 37.9, 72.0	–
Burst-Tonic			
Mean $\pm$ SD (N)	-1.0 $\pm$ 12.5 (45)	1.0 $\pm$ 11.8 (50)	–
Minimum, Median, Maximum	28.0, -2.0, 40.0	24.0, 2.0, 44.0	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		0.0 $\pm$ 6.1	
95% CI		-2.5, 2.5	

The Short Form McGill Pain Questionnaire (SF MPQ-2) assesses pain quality and the intensity or severity of those qualities. The following table shows a summary of the mean SF MPQ-2 score. Both burst and tonic stimulation show improvement from baseline scores.

Table 32. Summary of SF MPQ-2 scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Baseline			
Mean $\pm$ SD (N)	4.5 $\pm$ 1.8 (44)	4.6 $\pm$ 1.2 (51)	4.5 $\pm$ 1.5 (95)
Minimum, Median, Maximum	0.5, 4.4, 7.7	1.5, 4.5, 7.4	–
Burst			
Mean $\pm$ SD (N)	2.0 $\pm$ 2.0 (44)	2.2 $\pm$ 1.4 (51)	2.1 $\pm$ 1.7 (95)
Minimum, Median, Maximum	0.0, 1.3, 8.0	0.0, 2.2, 5.3	–
Tonic			
Mean $\pm$ SD (N)	2.2 $\pm$ 1.8 (44)	2.4 $\pm$ 1.7 (51)	2.3 $\pm$ 1.8 (95)

Table 32. Summary of SF MPQ-2 scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Minimum, Median, Maximum	0.0, 1.7, 8.5	0.0, 2.4, 8.0	–
Burst-Tonic			
Mean $\pm$ SD (N)	-0.2 $\pm$ 1.6 (44)	-0.2 $\pm$ 1.2 (51)	–
Minimum, Median, Maximum	4.3, -0.1, 5.3	-3.0, -0.2, 2.0	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		-0.2 $\pm$ 0.7	
95% CI		-0.5, 0.1	

The PCS measures negative thoughts and feelings associated with pain. The following table shows the overall PCS scores. Both burst and tonic stimulation reduced the PCS score; however, neither produced clinically meaningful changes on the PCS. Again, the reason for this observation may be the relatively low baseline scores observed in the study population. The average baseline PCS score of 20.4 was well below what is considered to reflect a clinically relevant level of pain catastrophizing, which is a score that is more than 30 (Sullivan, 2009).

Table 33. Summary of PCS scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Baseline			
Mean $\pm$ SD (N)	21.0 $\pm$ 11.9 (45)	20.0 $\pm$ 11.8 (51)	20.4 $\pm$ 11.8 (96)
Minimum, Median, Maximum	1.0, 20.0, 47.0	0.0, 20.0, 44.0	–
Burst			
Mean $\pm$ SD (N)	10.3 $\pm$ 11.1 (45)	14.6 $\pm$ 10.9 (51)	12.6 $\pm$ 11.1 (96)
Minimum, Median, Maximum	0.0, 8.0, 50.0	0.0, 15.0, 52.0	–
Tonic			
Mean $\pm$ SD (N)	12.5 $\pm$ 11.2 (45)	11.5 $\pm$ 11.6 (51)	12.0 $\pm$ 11.4 (96)
Minimum, Median, Maximum	0.0, 12.0, 43.0	0.0, 9.0, 45.0	–
Burst-Tonic			
Mean $\pm$ SD (N)	-2.2 $\pm$ 10.3 (45)	3.1 $\pm$ 11.8 (51)	–
Minimum, Median, Maximum	-24.0, 0.0, 31.0	-22.0, 2.0, 52.0	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		0.5 $\pm$ 5.6	
95%CI		-1.8, 2.7	

The BDI-II was completed at baseline, week 12, and week 24. Higher scores indicate higher levels of depression symptoms. Subjects with moderate to severe depression symptoms, with a score of 24 or more at baseline, were not eligible to continue in the study. The mean baseline score (10.1) indicates the subject population had minimal depression symptoms. The minimal depression symptoms that were observed at baseline continued to be observed under both stimulation modes at follow-up. The BDI-II scores may have

remained the same because those subjects with clinically significant depression symptoms were excluded from the study. Further, an improvement from minimal depression symptoms would not necessarily be expected. The following table shows a summary of BDI-II scores.

Table 34. Summary of BDI-II scores

Randomization	Arm 1: tonic/burst	Arm 2: burst/tonic	Pooled
Baseline			
Mean $\pm$ SD (N)	10.5 $\pm$ 6.6 (45)	9.8 $\pm$ 5.5 (51)	10.1 $\pm$ 6.0 (96)
Minimum, Median, Maximum	0.0, 9.0, 24.0	0.0, 9.0, 23.0	–
Burst			
Mean $\pm$ SD (N)	9.0 $\pm$ 9.4 (45)	8.9 $\pm$ 5.7 (51)	8.9 $\pm$ 7.6 (96)
Minimum, Median, Maximum	0.0, 7.0, 50.0	0.0, 9.0, 24.0	–
Tonic			
Mean $\pm$ SD (N)	9.8 $\pm$ 7.6 (45)	9.5 $\pm$ 6.5 (51)	9.6 $\pm$ 7.0 (96)
Minimum, Median, Maximum	0.0, 9.0, 35.0	0.0, 9.0, 27.0	–
Burst-Tonic			
Mean $\pm$ SD (N)	-0.8 $\pm$ 6.1 (45)	-0.5 $\pm$ 5.0 (51)	–
Minimum, Median, Maximum	-12.0, -2.0, 17.0	-18.0, -1.0, 13.0	–
Burst-Tonic Average $\pm$ Pooled SD Across Arms		-0.7 $\pm$ 2.8	
95% CI		-1.8, 0.4	

Pain Medication

In the first 12 weeks, 6 subjects (2 using tonic stimulation, 4 using burst stimulation) increased pain medication. Between weeks 12 and 24, 15 subjects (5 using burst stimulation, 10 using tonic stimulation) increased pain medication. Altogether, 12 tonic stimulation subjects and 9 burst stimulation subjects increased pain medication. More subjects decreased pain medication during the study than increased it, and more subjects decreased medication while receiving burst stimulation (31 subjects) than while receiving tonic stimulation (27 subjects). The following table shows a summary of medication changes from activation for each stimulation mode.

Table 35. Summary of medication changes from activation

Medication Change	Burst	Tonic
Decreased	31/96 (32.3%)	27/96 (28.1%)
Increased	9/96 (9.4%)	12/96 (12.5%)
No change	56/96 (58.3%)	57/96 (59.4%)

Summary of Supplemental Clinical Information

This pivotal, prospective, multicenter, randomized, crossover study assessed the safety and effectiveness of a neurostimulation system which enables the use of both tonic and burst stimulation modes. Twenty (20) experienced pain centers in the United States participated in the study. One hundred seventy-three (173) subjects were enrolled across the 20 sites, and all were diagnosed with chronic, intractable pain of the trunk

and/or limbs; had an average overall VAS pain score of at least 60 on a 0-to-100 scale; and had attempted and previously failed at least 3 medically supervised treatments.

Conclusions Drawn from the Study

This section provides study conclusions based on stimulation effectiveness, safety, and risks and benefits, as well as overall conclusions.

Effectiveness Conclusions

This section provides conclusions on stimulation effectiveness.

- **Pain measures.** The primary effectiveness endpoint of non-inferiority was met (43.5 versus 48.7, $p < 0.001$), and burst stimulation was found to be superior to tonic stimulation ($p = 0.017$). Differences in VAS scores for burst stimulation and tonic stimulation from baseline were assessed for carryover effect, with no statistical difference ($p = 0.883$). Burst stimulation was preferred by over two-thirds of subjects (70.8%) who had responded to tonic stimulation during an SCS trial period.

The mean VAS scores for trunk and limb pain were lower with burst stimulation than with tonic stimulation (40.9 versus 46.7 for trunk and 36.5 versus 41.6 for limb, respectively). The percentage of subjects reporting at least a 30% decrease in VAS pain diary scores for the average overall pain was higher with burst stimulation than with tonic stimulation (60.0% compared to 51.0%). A higher percentage was also observed in subjects reporting at least a 50% decrease in VAS pain diary scores (39.0% compared to 32.0%).

- **Paresthesia.** More than half of subjects (61.6%) reported no paresthesia during burst stimulation while 97.3% of subjects reported paresthesia during tonic stimulation. When compared to tonic stimulation, burst stimulation was associated with a reduction of paresthesia or no paresthesia, representing a relative reduction of 80.2% in average paresthesia from tonic stimulation to burst stimulation.

Programming parameters for tonic stimulation are based on long-term experience and subject-optimization needs, while burst programming parameters for pulse width and frequency were selected from feasibility studies and did not allow subject-specific customization except for amplitude adjustment. Future studies that optimize burst programming may show additional reduction in paresthesia.

- **Pain medication.** The use of pain medications decreased more often during burst stimulation (32.3%) than during tonic stimulation (28.1%). In addition, the use of pain medications increased less often during burst stimulation (9.4%) than during tonic stimulation (12.5%).

- **Psychosocial measures.** Based on the study exclusion criteria, only subjects with a BDI-II score of less than 24 could be enrolled. The exclusion of subjects with a BDI-II score of 24 or more most likely contributed to the observed low baseline scores for the other psychosocial measures, as depression has been shown to be directly related to quality of life, disability, and catastrophizing (Brenes, 2007; Currie & Wang, 2004; Richardson et al., 2009; Tennen et al., 2006). Other pain studies that have shown clinically significant changes for these domains have generally included such patients.

The baseline scores for the SF-36 physical component (28.6), ODI (49.1), and PCS (20.4) in the study population were also below clinically relevant levels of impairment typically seen in SCS candidates in quality of life, disability (Kumar et al., 2007), and catastrophizing (Sullivan, 2009), respectively. Neither burst stimulation nor tonic stimulation produced clinically meaningful changes for any of these psychosocial measures. Based on the baseline scores, an improvement of the scores would not be expected.

Safety Conclusions

No device- or stimulation-related SAEs or any events categorized as unanticipated adverse device effects (UADEs) were reported during the study. Fewer stimulation-related events occurred during burst stimulation than tonic stimulation (13 events in 11 subjects and 16 events in 10 subjects, respectively).

Benefit-Risk Conclusions

The probable benefits of the device are based on this clinical study for burst stimulation. Effectiveness was demonstrated by the primary and powered secondary study endpoints. Burst stimulation was also shown to be safe as described in the safety conclusions.

- **Limitations.** The open label crossover design did not blind subjects as to whether they were receiving burst or tonic stimulation. The only randomized variable was the order in which a subject would experience each stimulation mode: burst stimulation first or tonic stimulation first. Blinding the stimulation mode was not feasible because subjects may have experienced different sensations with each mode. Since the mode was not blinded, investigator and subject bias may have affected the results for both tonic and burst stimulation modes.

In addition, the study design did not allow an assessment of the placebo response. Placebo response is well known in pain studies due to the subjective nature of the pain assessment, and the duration of the placebo response may be long lasting. Finally, subjects in the study were required to maintain stable doses of their adjunctive pain medications. However, some subjects in both groups required additional pain medications; these subjects were considered non-responders for the stimulation mode in which they increased their medications and were accounted for in the statistical plan.

Subjects had to complete a successful SCS trial using tonic stimulation before being implanted with a permanent system and the success of tonic stimulation during the trial period may have resulted in investigator and subject bias. Additionally, a washout phase was not included before switching between stimulation modes.

Overall Conclusions

The nonclinical laboratory testing performed on the SCS leads, SCS extensions, IPG, charger, patient programmer, and accessories demonstrates that the individual components, as well as the combined system, are reliable and that the probable health benefits from using the device outweigh any probable injury or illness from such use.

Further, the nonclinical laboratory studies that Abbott Medical conducted, when combined with the clinical experience, provide assurance that a Prodigy™ neurostimulation system using burst stimulation is safe and effective when treating chronic pain. The clinical experience also shows that burst stimulation is superior to tonic stimulation in reducing overall pain and provides additional advantages over tonic stimulation including patient preference and reduced paresthesia.

References

1. Bell JA, DiBonaventura Md, Witt EA, et al. Feasibility of using the SF-36 v2 health survey to screen for risk of major depressive disorder. Presented at: ISPOR 20th Annual International Meeting; 2015 May 16-20; Philadelphia, PA.
2. Brenes GA. Anxiety, depression, and quality of life in primary care patients. *Prim Care Companion J Clin Psychiatry*. 2007;9(6):437–443.
3. Currie SR, Wang J. Chronic back pain and major depression in the general Canadian population. *Pain*. 2004 Jan;107(1-2):54-60.
4. Elliott TE, Renier CM, Palcher, JA. Chronic pain, depression, and quality of life: correlations and predictive value of the SF-36. *Pain Med*. 2003;4(4):331–339.
5. Kumar K, Taylor R, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain*. 2007;132(1-2):179–188.
6. May WL, Johnson WD. Confidence intervals for differences in correlated binary proportions. *Stat Med*. 1997;16:2127–2136.
7. Newcombe RG. Improved confidence intervals for the difference between binomial proportions based on paired data. *Stat Med*. 1998;17:2635–2650.
8. Richardson EJ, Ness TJ, Doleys DM, Banos JH, Cianfrini L, Richards JS. Depressive symptoms and pain evaluations among persons with chronic pain: catastrophizing, but not pain acceptance, shows significant effects. *Pain*. 2009;147:147–152. doi:10.1016/j.pain.2009.08.030. pmid:19773126.
9. Sullivan MJ. PCS: *The Pain Catastrophizing Scale User Manual*. http://sullivan-painresearch.mcgill.ca/pdf/pcs/PCSMannual_English.pdf. 2009, Accessed March 18, 2016.
10. Tennen H, Affleck G, Zautra A. Depression history and coping with chronic pain: a daily process analysis. *Health Psychol*. 2006;25:370–379.
11. Verkerk PT, Luijsterburg PAJ, Pool-Goudzwaard A, Heymans MW, Ronchetti I, Miedema HS, Koes BW. Prognosis and course of work-participation in patients with chronic non-specific low back pain: a 12-month follow-up cohort study. *J Rehabil Med*. 2015;47:854–859.
12. Ware JE. SF-36 health survey update. *Spine (Phila Pa 1986)*. 2000;25(24):3130–3139.

Clinical Summary for Anatomical Lead Placement

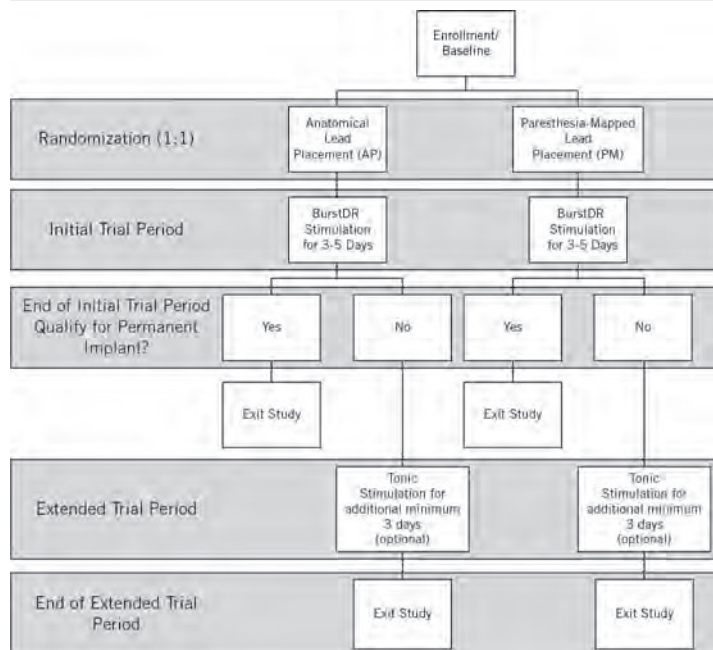
Abbott Medical conducted two clinical studies to compare effectiveness of BurstDR™ spinal cord stimulation (SCS) using traditional paresthesia-mapped lead placement or anatomical lead placement. DELIVERY evaluated the trial success rate for anatomical lead placement compared to traditional paresthesia-mapped lead placement in patients with chronic, intractable pain of the trunk and/or lower limbs. CRISP was performed to evaluate trial pain relief and outcomes up to one year after permanent implant from anatomically placed and paresthesia-mapped leads in patients with failed back surgery syndrome and predominant low back pain. The clinical studies support the SCS systems listed in “Clinical Studies” (page 1). The following sections present information and results for the two studies.

DELIVERY Study

Study Design

DELIVERY was a multicenter, randomized, controlled, single-blind, clinical study. The purpose was to compare trial success rate between anatomical lead placement (AP) and paresthesia-mapped (PM) lead placement techniques with the St. Jude Medical™ Invisible Trial System using BurstDR™ stimulation. Enrollment in the DELIVERY study (NCT03277378 on clinicaltrials.gov) began September 22, 2017 and ended August 23, 2018. A total of 288 subjects were enrolled at 23 sites in the United States, Europe, and Australia. The following figure shows the flow of study design.

Figure 9. DELIVERY study design flow



Patients who met the inclusion/exclusion criteria of the study signed the informed consent and were enrolled in the study. The enrolled subjects underwent baseline assessment prior to the trial. The subjects were blinded to treatment group and randomized in a 1:1 ratio. Trial procedures were as follows:

- AP group: When using one lead, the tip was placed at the superior endplate of T9. When using two leads, one lead was placed at the mid-body of T8 and the second was placed at the superior endplate of T9. Lead position was confirmed using fluoroscopy. This was followed by BurstDR stimulation during an initial trial evaluation period.

- PM group: The implanting physician confirmed coverage of the patient's primary pain location using intraoperative testing. This was followed by BurstDR stimulation during an initial trial evaluation period.

Subjects who successfully completed the trial exited the clinical study and continued treatment per the physician's standard of care. Any subject who did not qualify for a permanent system implant after the initial trial evaluation period was offered to participate in an extended trial evaluation period, at physician discretion, during which they were programmed with tonic stimulation. These subjects were followed through the completion of the extended trial period and exited the clinical study at the end of this period.

Clinical Inclusion and Exclusion Criteria

Inclusion Criteria

Subjects were limited to those who met all of the following criteria:

- Subject signed an informed consent to participate in the study.
- Subject was at least 18 years old.
- Subject had chronic, intractable pain of the trunk and/or lower limbs.
- Subject indicated for SCS therapy in accordance with the approved labelling.
- Indication of subject's pain profile to appropriate lead placement at one or more levels from T7 to T10 to achieve pain coverage.
- Subject scored a baseline of 6 or higher on the numeric rating scale (NRS) over the past 24 hours for "average overall pain" specific to the area(s) of chronic pain that could be treated with spinal cord stimulation.
- The Investigator evaluated the subject's medical record to ensure that the subject was a good candidate for implantation of a spinal cord stimulation system according to the system's Instructions for Use.
- Subject was willing to cooperate with the study requirements such as complying with the treatment regimen and completing all office visits.

Exclusion Criteria

Subjects were excluded if they met any of the following criteria:

- Subject had a spinal cord stimulation system currently implanted.
- Subject had previously failed a spinal cord stimulation therapy (either trial system evaluation or permanent system implant).
- Subject had a primary diagnosis of peripheral vascular disease, angina pectoris, or chronic migraine.
- Subject was scheduled to undergo an on-the-table trial evaluation (all-in-one procedure).
- Subject was scheduled to be implanted with one or more surgical paddle trial leads.
- Subject was participating in a clinical investigation that included an active treatment arm.
- Subject was unable to read and/or write.

Clinical Endpoints

The primary endpoint was the trial success rate for permanent system implant at the end of the trial evaluation period, defined by a composite where a subject met all the following conditions:

- Subject with >50% patient-reported pain relief (PRP) at the end of the trial evaluation.
- Trial evaluation period lasted a minimum of 3 days.
- Physician recommended subject for permanent system implant.
- Subject was willing to pursue a permanent system implant.

Subjects did not qualify for permanent system implant if there was <50% PRP at the end of a trial that lasted at least 5 days.

The secondary endpoint was the rate of physician preference for anatomical placement versus paresthesia-mapped placement at the end of the study. There were also descriptive endpoints reported using summary statistics:

- Overall procedure time (in-room to out-room), implant procedure time (needle-in to needle-out), and total time of intraoperative fluoroscopy exposure for each randomized group and stratified by number of leads and lead type (permanent lead or temporary lead).

- Programming time required for each randomized group.
- Change from pre-implant NRS in each randomized group to end of initial trial evaluation period and to the end of the extended trial evaluation period, as applicable.
- Number of subjects in each randomized group who have affirmative assessment for each of the independent criteria required for trial success.
- Proportion of subjects in each randomized group who do not qualify for permanent implant, but proceed with permanent implant per physician discretion.
- Time from trial system implant to >50% PRP measured by the number of days (also known as “wash-in period”).
- Rate of serious adverse device effects (SADE) in each group.
- Number and proportion of meaningful lead migrations during the initial trial evaluation periods by treatment group. A meaningful lead migration is defined as a lead migration resulting in the inability to program for therapeutic response.
- Number and proportion of meaningful lead migrations during the initial trial evaluation period in subjects who have a temporary trial lead implant compared to subjects who have a permanent trial lead implant.
- Clinician assessment of anesthesia related difficulty (assessed primarily in the procedure room for the trial) on a 5-point Likert scale for each randomized group.
- Clinician assessment of lead placement difficulty on a 5-point Likert scale for each randomized group.
- Clinician affinity for lead placement technique at the end of the trial implant procedure.
- Trial success rate at the end of extended trial period.

Statistical Plan

The primary objective was to evaluate non-inferiority of trial success rate for anatomical lead placement, compared to paresthesia-mapped lead placement, at the end of the initial trial evaluation period. The non-inferiority margin was set at 15% with a significance level of 5%. The analysis required the 95% lower confidence bound on the difference of trial success rates using the Farrington-Manning method to exceed -15%.

The secondary objective was to demonstrate physician preference for anatomical placement over paresthesia-mapped placement. The analysis required the 95% lower confidence bound on the percentage of physicians who preferred anatomical placement over paresthesia-mapped placement to exceed 60%, using the Clopper-Pearson exact method.

Study Results

Demographics and Baseline Assessments

Between September 2017 and August 2018, 288 subjects at 23 investigational sites were enrolled; 18 subjects were withdrawn before randomization as shown in the following table. The average age of the randomized subjects was 63 ±14 years and 61% of the subjects were female. Subjects experienced pain for an average of 11.5 ±11.5 years at the time of study enrollment. Demographics and baseline characteristics were statistically comparable between the two randomized arms (all $p > 0.05$). Many randomized subjects had a pain diagnosis of either radiculopathy (49.1%) or post laminectomy syndrome commonly known as failed back surgery syndrome (40.2%). In the sites located outside of the United States (OUS), the predominant pain diagnosis among the subjects was failed back surgery syndrome (68.6%).

Table 36. Demographics and baseline characteristics

Variable	All Randomized Subjects	Anatomical Lead Placement	Paresthesia-Mapped Lead Placement
Age (years)	(N=270)	(N=135)	(N=135)
Mean ±SD	62.8±13.5	61.8±13.2	63.9±13.8
Range (Min, Max)	(25, 89)	(31, 86)	(25, 89)
Gender, n (%)	(N=270)	(N=135)	(N=135)
Female	165 (61.1%)	78 (57.8%)	87 (64.4%)

Table 36. Demographics and baseline characteristics

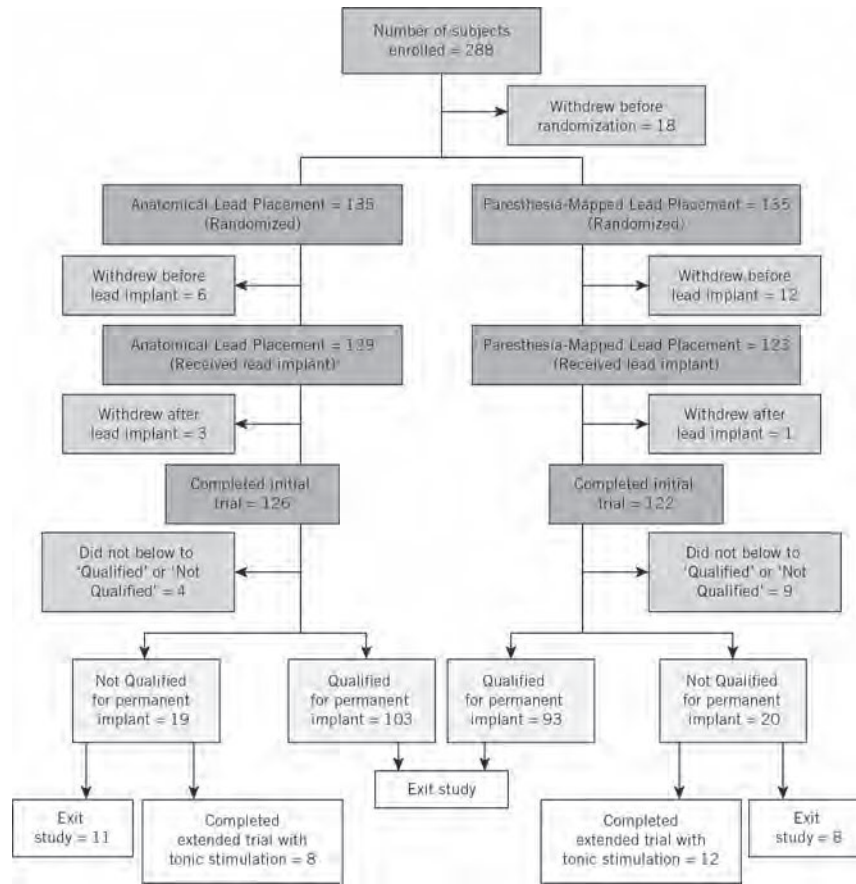
Variable	All Randomized Subjects	Anatomical Lead Placement	Paresthesia-Mapped Lead Placement
Male	105 (38.9%)	57 (42.2%)	48 (35.6%)
Race, US and Australia Only, n (%)	(N=232)	(N=116)	(N=116)
Black or African American	8 (3.4%)	5 (4.3%)	3 (2.6%)
Native Hawaiian or Other Pacific Islander	2 (0.9%)	1 (0.9%)	1 (0.9%)
White	201 (86.6%)	103 (88.8%)	98 (84.5%)
Other	21 (9.1%)	7 (6.0%)	14 (12.1%)
Years of having chronic pain	(N=270)	(N=135)	(N=135)
Mean $\pm$ SD	11.46 $\pm$ 11.48	12.23 $\pm$ 11.83	10.69 $\pm$ 11.11
Range (Min, Max)	(0.08, 60.00)	(0.33, 58.08)	(0.08, 60.00)
Pain Primary Diagnosis, US Patients, n (%)	(N=218)	(N=109)	(N=109)
Chronic pain due to trauma	23 (10.6%)	16 (14.7%)	7 (6.4%)
Chronic pain syndrome	119 (54.6%)	53 (48.6%)	66 (60.6%)
Other chronic post procedural pain	32 (14.7%)	17 (15.6%)	15 (13.8%)
Other chronic pain	44 (20.2%)	23 (21.1%)	21 (19.3%)
Pain Secondary Diagnosis, US Patients, n (%)*	(N=214)	(N=106)	(N=108)
None	2 (0.9%)	1 (0.9%)	1 (0.9%)
Causalgia	6 (2.8%)	3 (2.8%)	3 (2.8%)
Post-laminectomy syndrome	86 (40.2%)	44 (41.5%)	42 (38.9%)
Lumbosacral plexus disorders	1 (0.5%)	0 (0.0%)	1 (0.9%)
Radiculopathy	105 (49.1%)	52 (49.1%)	53 (49.1%)
Intervertebral disc disorder with/without radiculopathy	20 (9.3%)	8 (7.5%)	12 (11.1%)
Complex regional pain syndrome	5 (2.3%)	3 (2.8%)	2 (1.9%)
Other	45 (21.0%)	22 (20.8%)	23 (21.3%)
Pain Diagnosis, Non-US Patients, n (%)*	(N=51)	(N=26)	(N=25)

Table 36. Demographics and baseline characteristics

Variable	All Randomized Subjects	Anatomical Lead Placement	Paresthesia-Mapped Lead Placement
Failed back surgery syndrome	35 (68.6%)	18 (69.2%)	17 (68.0%)
Causalgia	1 (2.0%)	0 (0.0%)	1 (4.0%)
Post-laminectomy syndrome	3 (5.9%)	1 (3.8%)	2 (8.0%)
Radiculopathy	7 (13.7%)	5 (19.2%)	2 (8.0%)
Lumbosacral plexus disorders	1 (2.0%)	0 (0.0%)	1 (4.0%)
Complex regional pain syndrome	1 (2.0%)	1 (3.8%)	0 (0.0%)
Other	3 (5.9%)	1 (3.8%)	2 (8.0%)

*Subjects may have more than one diagnosis.

Figure 10. DELIVERY study disposition of subjects



Procedural Results

Operative conditions and patient preparation were performed according to routine practice for each participating investigator. Implanters used either one or two trial or permanent leads at their discretion. Since most of the participating study sites were in the US, a majority of subjects were implanted with two trial leads. Implantation of permanent leads during the SCS trial procedure is sometimes done outside the US. The following table shows the number of leads implanted per subject.

Table 37. Number of leads implanted per subject (N=252)

Number of Leads Implanted	Trial Leads Implanted n (%)	Permanent Leads Implanted n (%)
2	203 (80.6%)	6 (2.4%)
1	24 (9.5%)	19 (7.5%)

Primary Effectiveness

Trial success was achieved in 84% (103/122) of patients undergoing AP lead placement and in 82% (93/113) of patients with PM lead placement. The estimated difference between the trial success rates for the AP and PM groups was 2.1%, and the 95% lower confidence bound of -6.1% was above the pre-specified non-inferiority

margin of -15%. Therefore, the primary endpoint indicating non-inferiority of AP lead placement compared to PM lead placement was satisfied ($p < 0.001$).

Secondary Effectiveness

Physicians who performed both techniques preferred anatomical lead placement in 70% of cases, compared to paresthesia-mapped placement for 30% of cases. The 95% lower confidence bound was 49.2%, but did not exceed the pre-specified performance goal of 60%.

Descriptive Endpoint Results

- The study noted differences in lead placement and total procedure times for anatomical placement compared to paresthesia-mapped placement in 203 subjects who received two trial leads.
 - Average lead placement time (needle-in to needle-out) was reduced by 31% for AP (14 ±9 minutes) compared with PM technique (21 ±11 minutes).
 - Average total procedure time (room-in to room-out) was reduced by 12% for AP (40 ±12 minutes) compared with PM technique (46 ±14 minutes).
- In 24 subjects who received a single trial lead:
 - Average lead placement time was reduced by 19% for AP (21 ±15 minutes) compared with PM technique (26 ±15 minutes).
 - Average total procedure time was reduced by 10% for AP (45 ±14 minutes) compared with PM technique (50 ±18 minutes).
- There were 25 cases with leads placed that would remain in for permanent implant, including 6 using two leads and 19 using a single lead. Average lead placement time for a single lead was 12 ±9 minutes for AP placement compared to a PM placement of 23 ±12 minutes. For implants with two leads, average lead placement time was 19 ±5 minutes for AP placement compared to 27 ±7 minutes for PM placement.
- Programming time for anatomical lead placement was 5.0 ±6.4 minutes, compared to 6.0 ±6.0 minutes for paresthesia-mapped lead placement.
- Decrease in mean NRS pain score was similar between groups (53.2% for AP and 53.8% for PM) at the end of initial trial evaluation period, and after extended trial evaluation period.
- The wash-in period to reach 50% patient-reported pain relief was 3.0 ±2.0 days for AP, compared to 3.3 ±2.8 days for PM placement.
- Both groups had one meaningful lead migration resulting in inability to program for therapeutic response during the initial evaluation period.
- No differences were observed between groups in anesthesia-related difficulty or lead placement difficulty.
- Compared to usual clinical practice, 35.7% of clinicians declared the highest affinity, for anatomical lead placement, meaning it was “very much” liked. Clinicians rated paresthesia-mapped lead placement “very much” liked 8.9% of the time compared to usual practice. Paresthesia-mapped lead placement was considered a usual practice for clinicians in 82.1% of trial procedures, and anatomical lead placement was already considered a usual practice 45.7% of the time.

Adverse Events

A total of 13 adverse events were reported during the study. There were two serious device-related adverse effects (SADEs), ten adverse device effects (ADEs), and one non-device related serious adverse event (SAE). The following table summarizes adverse events.

Table 38. Adverse events for each group, as reported by site investigators

Event Type	Number of Events	Anatomical Lead Placement	Paresthesia-Mapped Lead Placement
SADE	2	1	1
ADE	10	4	6
SAE	1	1	0
Total	13	6	7

One non-device-related SAE occurred in the AP group undergoing permanent lead implant in which a patient was hospitalized for stroke.

Two device- or procedure-related serious adverse events were reported. There was one spinal cord compression in the AP group, and one occurrence of stimulation in unwanted places in the PM group, as shown in the following table.

Table 39. Summary of serious adverse device effects (SADEs)

Event Description	Related to	Subjects with Events n (%)	Number of Events
Spinal cord compression	Procedure, Lead	1 (0.3%)	1
Stimulation in unwanted places	Procedure	1 (0.3%)	1

Ten non-serious adverse device effects were reported at the time of study close-out, as shown in the following table.

Table 40. Summary of adverse device effects (ADEs)

Event Description	Related to	Subjects with Events n (%)	Number of Events
Cerebrospinal fluid leakage	Procedure	1 (0.3%)	1
Hematoma	Procedure	1 (0.3%)	1
Lead migration, causing changes in stimulation or reduced pain relief	Leads (4), Procedure (1)	4 (1.4%)	4
New leg pain on walking instead of original dysaesthetic sensation	Procedure, EPG, Lead, Accessory	1 (0.3%)	1
Persistent pain at the lead site	Procedure (2)	2 (0.7%)	2
Unpleasant sensations or motor disturbances	Procedure	1 (0.3%)	1

There were no deaths reported in the study. The AEs reported in this study were anticipated for the study population and are considered acceptable.

Conclusions Drawn from the Study

Effectiveness

Leads placed using an anatomical approach resulted in equivalent SCS trial success when compared with leads placed using paresthesia mapping. Physicians who performed both implant techniques preferred AP over PM placement by 70% to 30%, although the difference did not reach statistical significance. When two trial leads were used, average lead placement time (needle-in to needle-out) was reduced by 31% for AP compared with PM technique. Furthermore, average total procedure time (room-in to room-out) was reduced by 12% for AP compared with PM technique. Anatomical placement technique resulted in a less complex procedure and more predictable lead placements.

Safety

No deaths were reported during the study. There were similar rates of AEs between the two groups.

Study Limitations

The study was designed to collect data during the initial trial period only. However, CRISP was a prospective, multicenter, randomized, double-blinded, crossover study that collected data up to one year after permanent implant.

Benefit-Risk Conclusions

This clinical study established non-inferiority of the trial success rate for anatomical placement of leads compared with paresthesia-mapped placement. An acceptable rate of events occurred in the DELIVERY study.

Overall Conclusions

When using BurstDR™ stimulation, the anatomical placement of leads during the trial phase is a viable alternative to paresthesia-mapped lead placement.

CRISP Study

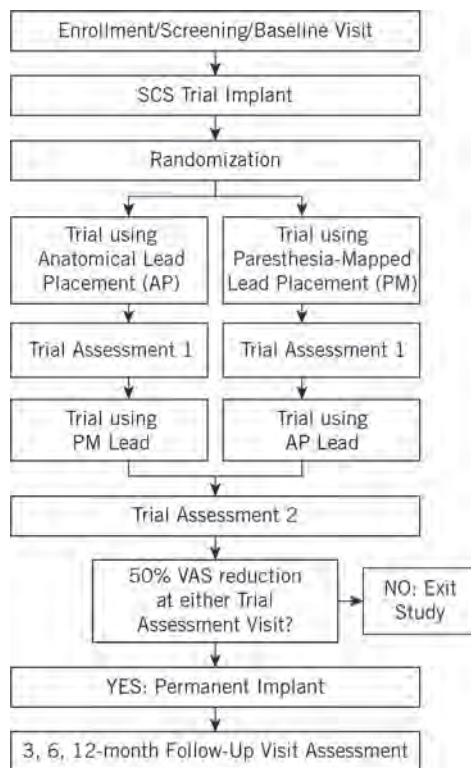
Study Design

The study was a prospective, multicenter, randomized, double-blinded, crossover feasibility study that consisted of two phases: spinal cord stimulation (SCS) trial and permanent implant follow-up. Subjects were evaluated at SCS trial followed by evaluation at 3, 6, and 12 months post-permanent implantation.

Subjects began to enroll in the study on October 28, 2016 with the study enrollment completing on June 5, 2018. All follow-up visits were completed on August 19, 2019. The study included a total of 60 subjects at two investigational sites in Europe (NCT02986074 on clinicaltrials.gov).

The study compared the therapeutic efficacy of the conventional, paresthesia mapping-based BurstDR™ stimulation implantation strategy to a more novel, anatomical approach. The following figure shows the flow of study design.

Figure 11. CRISP study design flow



Subjects with failed back surgery syndrome (FBSS) with predominant low back pain were informed about the study to determine if they were interested in participating. After subjects signed an informed consent agreement, they were screened according to the inclusion and exclusion criteria and underwent a baseline evaluation to collect primary and secondary outcome measures prior to the SCS trial. Subjects scored pain ratings using visual analog scale (VAS), quality of life using EuroQol-5D instrument (EQ-5D), and functionality using Oswestry disability index (ODI) during the course of the study. Those subjects who met the criteria to participate were scheduled to receive a St. Jude Medical™ Invisible Trial System for spinal cord stimulation (SCS). During the trial implant, two SCS leads were implanted using standard surgical techniques. One lead was implanted using paresthesia mapping to maximize the overlap between painful regions and evoked paresthesia according to standard clinical practice. A second lead was implanted using a novel anatomical

approach. Under fluoroscopic guidance, the lead was positioned above the anatomical midline such that it extends over the T9-T10 junction.

Subjects underwent BurstDR stimulation therapy using both leads. Subjects were randomized 1:1 to decide which lead they would evaluate first (lead placed using paresthesia mapping first and then lead placed by anatomical approach or vice versa) and were blinded to the randomization order. The SCS trial consisted of two phases and lasted for a total of 4 weeks. During the first trial phase, BurstDR stimulation was delivered for two weeks using the first lead in the randomization sequence. Subjects were then crossed over to the second trial phase during which BurstDR stimulation was delivered for an additional two weeks using the second lead in the randomization sequence. If the VAS score during either of the two trial assessments is reduced by at least 50% compared to the baseline score, the subject was considered for permanent SCS implant.

Subjects who underwent a successful trial ($\geq 50\%$ overall pain relief) were implanted with a Proclaim™, Prodigy™, or Prodigy MRI™ neurostimulation system. The lead that was activated depended on the subject's preference following the trial. For subjects without a preference, the lead placed using the anatomical technique was activated. Subjects were followed for 12 months to assess the long-term treatment outcome.

Clinical Inclusion and Exclusion Criteria

Inclusion Criteria

Subjects were limited to those who met all of the following criteria:

- Subject signed an informed consent to participate in the study.
- Subject was at least 18 years old.
- Subject had failed to respond to at least 6 months of conventional treatment including pharmacological treatment, physical therapy, epidural injections and/or radiofrequency therapy as per NICE Tag 0159.
- Subject with failed back surgery syndrome (FBSS) had predominant low back pain.
- Subject scored a baseline of at least 6.0 out of 10.0 for low back and pain intensity on the visual analog scale (VAS).
- Subject's pain-related medication regimen with a total opioid equivalent of 120 mg/day or less was stable for at least 28 days before enrolling in the study, and was willing to stay on the medication with no dose adjustments until activation of the permanently implanted SCS device.
- The Investigator evaluated the subject's medical record to ensure that the subject was a good candidate for a neurostimulation system.
- Subject was willing to cooperate with the study requirements such as complying with the treatment regimen and completing all office visits.
- Subject was female candidate of childbearing potential who agreed to commit to using effective contraception (including, but not limited to, sterilization, barrier devices, oral contraceptives, intrauterine devices (IUDs), condoms, the rhythm method, or abstinence) throughout the study.

Exclusion Criteria

Subjects were excluded if they met any of the following criteria:

- Subject had significant scoliosis even if surgically corrected.
- Subject was participating in a clinical investigation that included an active treatment arm.
- Subject had previously been implanted with a neurostimulation system or participated in a trial period for a neurostimulation system.
- Subject had an infusion pump.
- Subject had evidence of standard care for an active disruptive psychological or psychiatric disorder.
- Subject had a current diagnosis of a coagulation disorder, bleeding diathesis, progressive peripheral vascular disease, or uncontrolled diabetes mellitus.
- The Investigator determined the subject had a current diagnosis of a progressive neurological disease.
- Subject had an existing medical condition, such as epilepsy, stroke, multiple sclerosis, acoustic neuroma, or a tumor, that was likely to require repetitive evaluations using magnetic resonance imaging (MRI).
- Subject had a history of cancer requiring active treatment in the last 12 months.
- Subject had an existing medical condition that was likely to require the use of diathermy.

- Subject had an impaired immune system (immunocompromised).
- Subject had a documented history of an allergic response to titanium or silicone.
- Subject had a documented history of substance abuse (with substances such as narcotics or alcohol) or substance dependency within 6 months of the collection of baseline data.
- Subject was a female of childbearing potential who was pregnant (confirmed by a positive urine or blood pregnancy test).

Follow-up Schedule

Subjects were followed through 12 months post-permanent implant with follow-up visits at 3, 6, and 12 months. Subjects who did not pass the stimulation trial (with <50% pain relief or did not express a desire for the permanent implant) were exited from the study.

Clinical Endpoints

The primary effectiveness endpoint was evaluating the change in pain intensity between baseline and trial using the VAS assessment. The first SCS trial assessment was up to 2 weeks after electrodes implantation, and the second SCS trial assessment was up to 2 weeks after the first trial assessment.

The secondary endpoints that were assessed included:

- Comparing the subject preference between the two lead implantation techniques during the SCS trial.
- Evaluating changes in lower back and lower limbs pain between baseline and 3, 6, and 12 months after permanent implant (VAS assessments).
- Evaluating changes in quality of life assessed using the EuroQol (EQ-5D) questionnaire, and disability assessed using the Oswestry Disability Index (ODI) between baseline, trial assessments, and at 3, 6, and 12 months after permanent implant.
- Evaluating subject satisfaction at 3, 6, and 12 months after permanent implant.

This study did not have any descriptive endpoints.

Primary Statistical Analysis Plan

The primary analysis assessed improvements in pain intensity, using VAS, was conducted using repeated measures ANOVA (RMANOVA). Post-hoc Tukey's pairwise comparisons followed to determine specific differences between follow-up visits. Secondary analyses assessed improvements in quality of life, disability, and satisfaction was conducted using repeated measures ANOVA (RMANOVA).

Study Results

Demographics and Pain Baseline Characteristics

The following table shows subject demographics and baseline characteristics of the CRISP study.

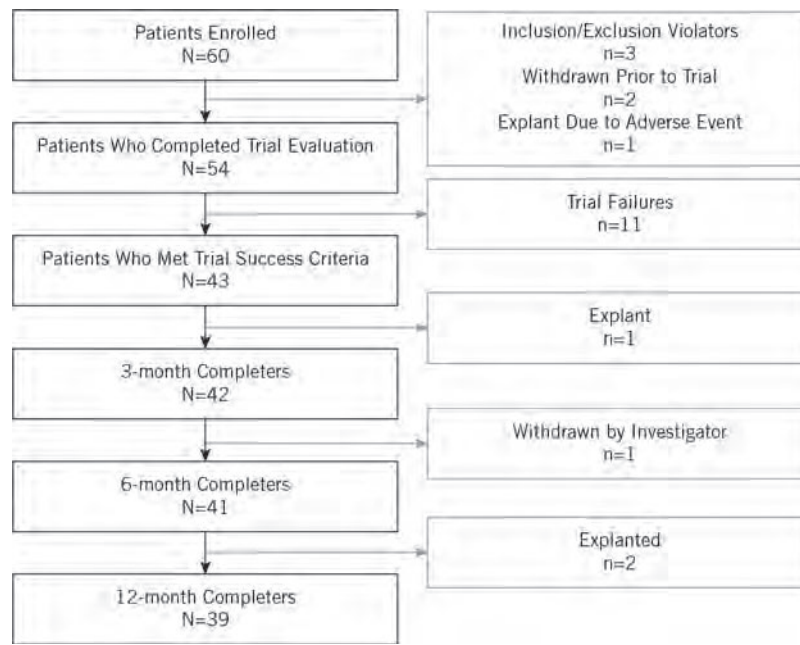
Table 41. Demographics and baseline characteristics

Variable	Subjects Starting Trial (N=60)
Age	
Mean ±SD	51.6±12.1
Gender, n (%)	
Female	34 (56.7%)
Male	26 (43.3%)

Disposition of Subjects

A total of 60 subjects were enrolled in this study, 54 of whom completed the trial phase, and 43 subjects continued into the follow-up after a successful trial completion. The following figure shows the disposition of all subjects.

Figure 12. CRISP study disposition of subjects



Procedural Results

Forty three (43) out of the 54 subjects who underwent the trial received at least 50% reduction in pain and continued to the follow-up phase of the study. Twenty one (21) subjects (48.8%) preferred the lead placed through paresthesia mapping, and 21 subjects (48.8%) preferred the lead placed using anatomical positioning. One subject (2.4%) had no preference, so the anatomical lead was activated for the follow up phase as per protocol.

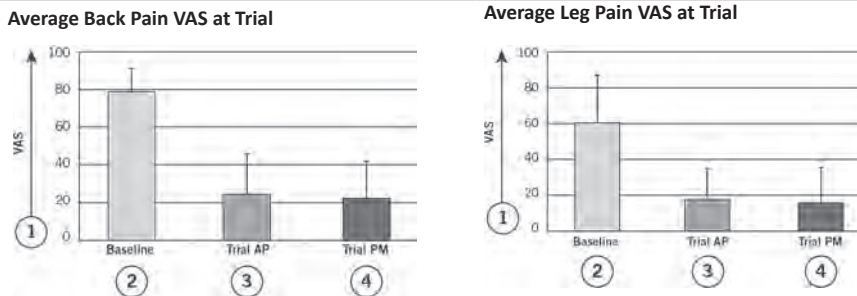
Primary Effectiveness

The primary effectiveness endpoint was the change in pain intensity, as assessed by VAS, between baseline and end of trial. During the trial, all subjects underwent testing with both implantation strategies: the anatomically implanted lead and the paresthesia implanted lead in a cross over design. The study demonstrated a significant improvement ($p < 0.001$) in the average back and leg pain scores (VAS) from the baseline to the end of the trial period in both AP and PM lead activation, as shown in the following table and figure. No significant difference was observed in pain scores (Back pain, $p=0.85$; Leg pain, $p=0.91$) between the AP and PM lead.

Table 42. Average pain scores of subjects at the baseline and end of trial period for AP and PM-based leads (n=43)

Evaluated Parameters	Baseline	Anatomical Placement	Paresthesia Mapping
Back average VAS score in mm $\pm$ SD; number of subjects (n)	78.9 $\pm$ 12.5	24.6 $\pm$ 21.3	22.5 $\pm$ 19.2
Leg average VAS score in mm $\pm$ SD; number of subjects (n)	60.4 $\pm$ 26.9	17.7 $\pm$ 17.5	15.7 $\pm$ 19.5

Figure 13. Average back and leg pain scores of subjects at the baseline and end of trial period for AP and PM-based leads (markers indicate average $\pm$ SD)



1. Average VAS score
2. Baseline
3. Trial anatomical placement (AP)
4. Trial paresthesia mapping (PM)

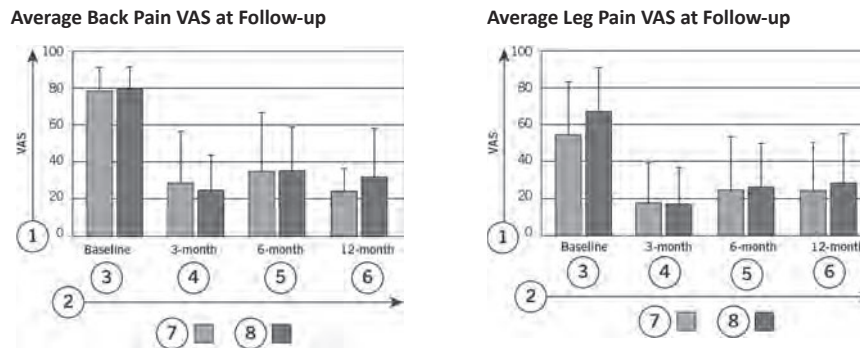
Secondary Effectiveness

The study demonstrated a significant improvement ($p < 0.0001$) in the average back and the average leg pain scores (VAS) from the baseline to follow-up at 3, 6, and 12 months respectively in both AP and PM lead groups, as shown in the following table and figure. No significant difference was observed in pain scores (back pain; leg pain) between the AP and PM lead groups at all time points considered for the study. The following table summarizes the follow-up assessments of pain intensity by back and leg average VAS score.

Table 43. Average pain scores at the baseline and follow-up for AP and PM-based lead groups

Evaluated Parameters	Follow-up Visit	Anatomical Placement	Paresthesia Mapping
Back average VAS score in mm $\pm$ SD; number of subjects (n)	Baseline	78.4 $\pm$ 13.1; n=22	79.4 $\pm$ 12.0; n=21
	3 month	28.5 $\pm$ 28.1; n=21	24.6 $\pm$ 19.0; n=20
	6 month	34.8 $\pm$ 32; n=19	35.2 $\pm$ 23.7; n=19
	12 month	24.0 $\pm$ 24.5; n=19	31.8 $\pm$ 26.4; n=20
Leg average VAS score in mm $\pm$ SD; number of subjects (n)	Baseline	54.2 $\pm$ 28.7; n=22	66.9 $\pm$ 23.8; n=21
	3 month	17.6 $\pm$ 21.6; n=19	17.0 $\pm$ 19.5; n=21
	6 month	24.3 $\pm$ 29.1; n=18	26.0 $\pm$ 23.8; n=19
	12 month	24.2 $\pm$ 26.3; n=19	28.2 $\pm$ 26.7; n=20

Figure 14. Average back and leg pain scores of subjects at the baseline and follow-up visits for AP and PM-based leads (markers indicate average $\pm$ SD)



1. Average VAS score
2. Follow-up visit
3. Baseline
4. 3 month
5. 6 month
6. 12 month
7. Anatomical placement
8. Paresthesia mapping

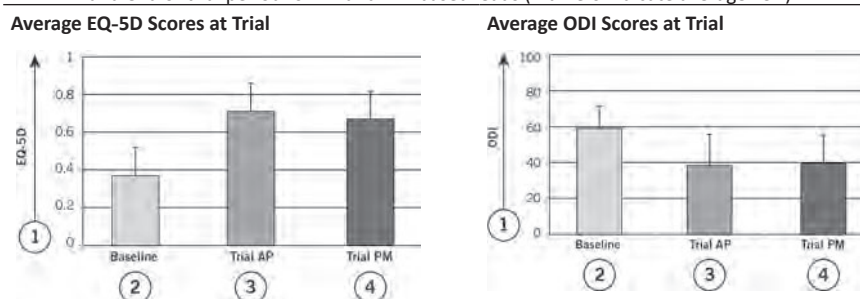
Quality of Life and Functionality Assessments – SCS Trial Results

The average EQ-5D score and ODI score significantly improved ($p < 0.001$) from baseline to the end of trial period in both AP and PM lead activation, as shown in the following table and figure. No significant difference was observed in the quality of life and disability scores between the AP and PM lead.

Table 44. Average pain scores of subjects at the baseline and end of trial period for AP and PM-based leads

Evaluated Parameters	Baseline	Anatomical Placement	Paresthesia Mapping
Average EQ-5D score; number of subjects (n)	0.4±0.1; n=43	0.7±0.2; n=42	0.7±0.2; n=43
Average ODI score; number of subjects (n)	59.0±12.3; n=43	38.4±17.5; n=43	39.6±16.1; n=43

Figure 15. Average quality of life (left) and functionality assessment (right) scores of subjects at the baseline and end of trial period for AP and PM-based leads (markers indicate average ±SD)



1. Average score
2. Baseline
3. Trial anatomical placement (AP)
4. Trial paresthesia mapping (PM)

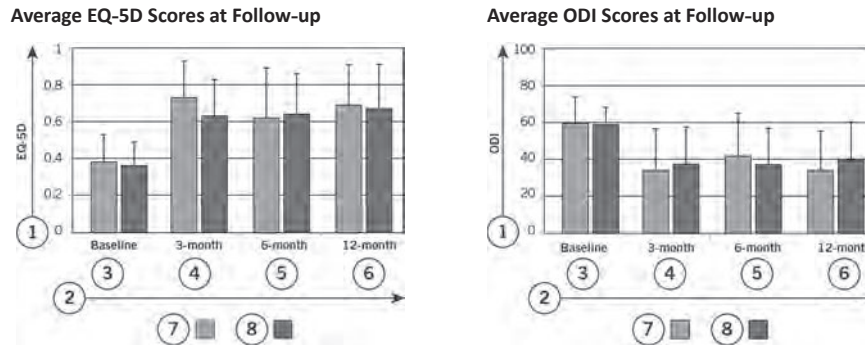
Quality of Life and Functionality Assessments – Follow-up Results

The study demonstrated significant improvement ($p < 0.0001$) in the average quality of life (assessed by EQ-5D) in the average functionality scores (assessed by ODI) from baseline to follow-up at 3, 6, and 12 months, respectively in both AP and PM lead groups, as shown in the following table and figure. No significant difference was observed in quality of life ($p=0.58$) and in disability ($p=0.66$) between the AP and PM lead groups at all time points considered for the study.

Table 45. Average quality of life and disability scores at the baseline and follow-up for AP and PM-based lead groups

Evaluated Parameters	Follow-up Visit	Anatomical Placement	Paresthesia Mapping
EQ-5D score $\pm$ SD; number of subjects (n)	Baseline	0.4 $\pm$ 0.2; n=22	0.4 $\pm$ 0.1; n=21
	3 month	0.7 $\pm$ 0.2; n=20	0.6 $\pm$ 0.2; n=19
	6 month	0.6 $\pm$ 0.3; n=19	0.6 $\pm$ 0.2; n=21
	12 month	0.7 $\pm$ 0.2; n=19	0.7 $\pm$ 0.2; n=20
ODI score $\pm$ SD; number of subjects (n)	Baseline	59.4 $\pm$ 14.5; n=22	58.7 $\pm$ 9.7; n=21
	3 month	33.8 $\pm$ 22.6; n=21	37.3 $\pm$ 20.5; n=21
	6 month	41.5 $\pm$ 23.5; n=19	36.9 $\pm$ 20.2; n=21
	12 month	33.9 $\pm$ 21.5; n=19	39.4 $\pm$ 20.8; n=20

Figure 16. Average quality of life (left) and functionality assessment (right) scores of subjects at the baseline and end of trial period for AP and PM-based leads (markers indicate average $\pm$ SD)



Satisfaction Assessment

At the 12 month follow-up, 94% of the patients who used AP leads and 85% of the patients who used PM lead were reported to be either satisfied or very satisfied, as shown in the following table.

Table 46. Subject satisfaction scores for AP and PM-based lead groups during follow-up

Subject Satisfaction	Follow-up Visit	Anatomical Placement	Paresthesia Mapping
Very Dissatisfied	3 month	–	–
	6 month	5.9%	–
	12 month	–	–
Dissatisfied	3 month	–	–
	6 month	5.9%	9.5%
	12 month	5.6%	5%
Neither Satisfied or Dissatisfied	3 month	19.1%	5%
	6 month	23.5%	14.3%
	12 month	–	10%
Satisfied	3 month	33.3%	40%
	6 month	23.5%	23.8%
	12 month	50%	20%
Very Satisfied	3 month	46.6%	55%
	6 month	41.2%	52.4%
	12 month	44.4%	65%

Adverse Events

A total of 58 adverse events were reported in 24 subjects during the study. Of these, 40 were classified as serious or non-serious adverse events. These are summarized below.

There were 6 serious adverse device effects reported in 5 subjects, as shown in the following table.

Table 47. Summary of serious adverse device effects (SADEs)

Event Description	Related to	Subjects with Events	Number of Events
Difficulty with urination and unable to weight bear on the right leg associated with pre-existing cauda equina	Device	1	1
Worsening of right leg pain after implant	Device, Procedure	1	1
Photophobia	Procedure	1	1
Explant due to suspicion of infection	Device	1	1
Right leg numbness	Procedure	1	1

Table 47. Summary of serious adverse device effects (SADEs)

Event Description	Related to	Subjects with Events	Number of Events
Wound exploration due to weeping wound at the IPG site	Device	1	1
Total		5*	6

* Some subjects experienced more than one event.

There was 1 serious adverse event in 1 subject classified by investigators as not related to a device or procedure, as shown in the following table.

Table 48. Summary of serious adverse events (SAEs)

Event Description	Subjects with Events	Number of Events
Acute abdominal pain due to gall stones	1	1

A total of 26 non-serious adverse device effects were reported in a total of 15 subjects, as shown in the following table.

Table 49. Summary of non-serious adverse device effects (ADEs)

Adverse Device Event	Subjects with Events	Number of Events
IPG unpairing	2	2
Increase in pain due to lead migration	1	1
Suspect infection	1	1
Numbness in leg on change of program	1	1
Ache at base of skull when lying down	1	1
Pain at IPG site	2	2
Tremor and weakness	1	1
Worsening of back pain symptoms	1	1
Short IPG battery life span	1	1
Rib pain	1	1
Anchor revision due to pain at the anchor site	1	1
Irritation around surgery site	1	2
Skin suture remains in-situ	1	1
Knee pain	1	1
Leg cramps	1	1
Leakage at wound site/IPG scar	1	2
Tingling in right leg	1	1
Bleeding from back wound	1	1
Headache	3	3
Lead explanted due to light growth of bacillus cereus on lead exit	1	1

Table 49. Summary of non-serious adverse device effects (ADEs)

Adverse Device Event	Subjects with Events	Number of Events
Total	15*	26

* Some subjects experienced more than one event.

A total of 7 non-serious adverse events were reported in a total of 5 subjects, as described in the following table. Although formal event adjudication was not performed, several events related to lead explant, wound site, and pain would likely be considered device-related.

Table 50. Summary of non-serious adverse events

Adverse Event	Subjects with Events	Number of Events
Diarrhea	1	1
Vomiting	1	1
Pain due to falling	2	2
Swelling on right side of face, leg, and ankle	1	1
Complains of palpitation	1	1
Acquired shingles	1	1
Total	5*	7

* Some subjects experienced more than one event.

There were no unanticipated serious adverse device effects. There were no deaths reported in the study. There were no device deficiencies reported in the study.

Conclusions Drawn from the Study

Effectiveness

There were similar results using BurstDR™ stimulation from trial leads implanted with paresthesia-mapping and anatomical placement. Back and leg pain scores, quality of life and disability measures improved, and there were no statistical differences between the lead groups. At the end of the trial, there was an even distribution of preferences for the leads. No order effect was observed.

The study demonstrated equivalent long-term clinical outcomes with BurstDR SCS treatment regardless of lead placement method. Back and leg pain scores, quality of life and disability measures improved from baseline to 3-, 6-, and 12-month follow-up for leads positioned through paresthesia-mapping as well anatomical placement. There were no statistical differences between the lead groups.

Safety

No deaths or any events categorized as unanticipated serious adverse or device effects were reported during the study. A total of 58 adverse events were reported in 24 subjects during the study. Of these, 40 were classified as serious or non-serious adverse events.

Study Limitations

This study has a limited size, and may lack statistical power to detect differences in pain rating between the groups. However, the even split in blinded subjects' preferences at the end of the trial suggest that both implant techniques provide equivalent therapeutic outcomes that are sustained over 12 months.

Paresthesia mapping typically involves the use of two leads to improve pain-paresthesia overlap. However, this study had used only one lead for mapping. While the use of a single lead could have resulted in sub-optimal paresthesia coverage, the long-term results have demonstrated clinically and statistically significant improvement from baseline with both approaches. Moreover, as BurstDR stimulation is programmed at amplitudes that do not evoke sensory percepts, optimal pain-paresthesia overlap may not be necessary to produce effective pain relief with this waveform.

Benefit-Risk Conclusions

This clinical study demonstrated equivalent outcomes with BurstDR™ stimulation delivered through the positioning of leads using paresthesia mapping and anatomical placement in both trial phase and long-term follow-up.

Overall Conclusions

The study reported equivalent long-term clinical outcomes with BurstDR™ stimulation treatment regardless of the lead placement method. Implanting physicians could employ either of the lead placement methods based on the specific circumstances and patient characteristics. Anatomical placement of lead does not require paresthesia or require patient input or feedback for effective stimulation. This placement may bypass the need to reduce sedation or analgesia during the procedure, contributing to the reduction of patient discomfort and stress.

Clinical Summary for Diabetic Peripheral Neuropathy

Diabetic peripheral neuropathy (DPN) pain is often associated with a history of poorly controlled diabetes that presents as pain in the extremities. It will typically begin in the toes and progress upward to the foot and legs. The pain is described as uncomfortable “tingling,” “shooting,” or “burning” pain.

The recommended primary course of treatment for DPN is for patients to improve their glycemic control through diet, exercise, and medical management. If those approaches are unsuccessful, secondary treatments include medications for neuropathic pain, topical treatments, physical therapy, and noninvasive neuromodulation. Patients may benefit from invasive neuromodulation approaches if they are refractory to those more conservative measures.

Review Design and Methodology

The safety and effectiveness of the Abbott implantable neurostimulation system to treat DPN was based on clinical safety outcome data from a systematic review of published scientific literature reporting on the use of any commercially available spinal cord stimulation (SCS) systems for the treatment of chronic intractable pain in a diabetic population and Medicare claims data collected from patients implanted with Abbott SCS devices.

The systematic review of published literature was conducted by searching EMBASE and PubMed for terms relating to SCS and for the term diabetes. Two reviewers independently screened 503 search results, ultimately selecting 103 publications for full text review. In addition, a retrospective real world evidence (RWE) study was conducted based on Medicare claims data to provide supplementary safety information on the use of SCS for DPN.

The analysis included patients implanted with an Abbott SCS system between January 1, 2014 and September 30, 2020, identified in the Medicare databases and categorized into two cohorts based on Medicare claims diagnosis codes: 1) DPN patients with a primary diagnosis of DPN or a secondary diagnosis of DPN and a primary being chronic pain and 2) non-DPN patients without any DPN diagnosis on the implant date or any evidence of a diagnosis in the year prior to implant. The incidence rate and cumulative incidence of common safety events up to 12 months following implantation were compared between the two cohorts to determine whether patients with DPN, who are implanted with SCS exhibited an increased risk of particular safety events when compared to the general population of SCS patients. For both cohorts, the incidence of safety events potentially associated with device related surgeries (i.e., device removal, reimplant, or revision) following implantation were also evaluated.

Safety

Safety objective: Identify risks relevant to SCS to which diabetic patients are predisposed and to characterize the safety profile of SCS to treat DPN.

The safety profile of Abbott SCS systems to treat DPN was characterized through analysis of data from the published scientific literature and Medicare claims data relevant to the use of Abbott SCS devices. The analysis characterized the overall safety profile by common adverse events, as well as specifically examining the risks to which the diabetic population are predisposed such as inherent surgical complications that may occur more frequently or have greater impact in these patients.

Effectiveness

Effectiveness objective: Characterize the clinical benefits related to pain relief for SCS used to treat DPN, when compared to the standard-of-care.

The effectiveness of Abbott SCS systems to treat DPN was demonstrated through analysis of clinical study results from the systematic review of published scientific literature. Effectiveness was demonstrated by the probability of treatment success. The probability of treatment success (responder rate or proportion of successfully treated subjects) was defined by a specified percent reduction in pain rating or Patient Global Impression of Change (PGIC) rating.

Review Results

Safety

Literature Search Results

Selection criteria were 1) treatment with SCS and 2) a distinctly identifiable diabetic population with either (a) an analysis of the impact of a diabetic state on a safety related outcome, or (b) a comprehensive listing of

adverse events. After full text review of 103 publications, 22 publications on 16 studies were included for analysis. Three studies resulted in multiple publications; safety information was extracted from the publication with the longest follow-up from each study that included comprehensive adverse event information.

Real World Evidence Evaluation of Medicare Claims Data

Available data on 36,004 patients (DPN: 507 and non-DPN: 35,497) implanted with Abbott SCS systems were included in the safety analysis. Incidence rates and cumulative incidence up to 12 months following implantation for a total of 23 common safety events were calculated. The safety events were identified from International Statistical Classification of Diseases and Related Health Problems (ICD) 9 and ICD 10 diagnosis codes that are used by the Center for Medicare and Medicaid Services (CMS) for diagnostic, billing, and reporting purposes. A systematic review of ICD-9 and ICD-10 codes was conducted to identify diagnostic codes that are either associated with known SCS risks (e.g., infection and CSF leak) or are specific to nervous system implants or neurostimulators for the spinal cord. These safety events include device related events (e.g., lead migration, stimulator failure), negative device or procedure effects (e.g., infections, thrombosis, and hemorrhages that are specific to an implanted nervous system device), and general adverse events that are not specific to the device (e.g., CSF leak, infection due to any cause).

The results indicate low incidences of device or procedure related safety events in DPN patients implanted with SCS, including incidence rates of 2.6% for device specific infections (compared to 1.8% for non-DPN patients), 2.2% for lead migration (compared to 2.9% for non-DPN patients), 7.5% for lead failure (compared to 8.6% for non-DPN patients), and 4.9% for stimulation issues that require adjustment of the stimulation settings (compared to 3.4% for non-DPN patients). Furthermore, there was no statistically reliable evidence of a difference between DPN and non-DPN patients in the incidence and cumulative incidence rates for any safety events that were specific to the device or procedure. The incidence and cumulative incidence rates for safety events that are associated with device related surgical procedures (i.e., revision, replacement, or removal) were also not significantly different between DPN and non-DPN patients. This suggests that the use of SCS in this patient population does not lead to increased risk of device related safety events or safety events that may be associated with a device related surgery following initial implantation.

Common Adverse Events

Studies which included detailed adverse event information were pooled to assess common adverse event occurrences. The table below presents study data grouped by reports of common patient cohorts and by populations defined specifically by DPN or by those reporting on patients with diabetes mellitus (DM) in general. Studies that did not include AE information specific to the diabetic or DPN population were not included in this table.

Table 51. Common Adverse Events

Adverse Event Counts (%)								
	Sample size	Infection	Lead migration	Lead failure	Device site swelling or pain	Hematoma, Erosion, Wound dehiscence	CSF leak, Dural tear	Uncomfortable stimulation, Stimulation issues
DPN	DPN SCS RWE study on Abbott devices ^a	n ⁱ = 507	13 (2.6) ^b	11 (2.2) ^c	38 (7.5) ^d	<11 (0.2–2.0) ^e		25 (4.9) ^f
	Petersen (2021)	n ^{t,i} = 104	8 (7.7)	1 (1.0)		2 (1.9)	4 (3.8)	1 (1.0)
	Petersen (2022)							
	Pluijms (2012)	n ^{t,i} = 49	2 (4.1)	5 (10.2)	4 (8.2)	10 (20.4)		9 (18.4)
	Slangen (2013, 2014)						1 (2.0) ^h	
	van Beek (2015, 2018)							
	Galan (2020)	n ^{t,i} = 9				1 (11.1) ⁱ	1 (11.1)	
DM	de Vos (2014)	n ^{t,i} = 40	3 (7.5) ^g	1 (2.5)		2 (5)		2 (5)
	de Vos (2009)	n ^{t,i} = 11	1 (9.1)		2 (18.2)			
	Tesfaye (1996)	n ^{t,i} = 10	2 (20)	2 (20)	1 (10)		1 (10)	
	Daousi (2005)							
	Falowski (2019)	n ^{t,i} = 1663	59 (3.5)					
	Hoelzer (2017)	n ^{t,i} = 452	9 (2.0)					
	Mekhail (2011)	n ^{t,i} = 56	5 (8.9)					
Range	Petrakis (1999)	n ^{t,i} = 64	2 (3.1)	2 (3.1)				
	Range		2.0–20%	1.0–20%	7.5–18.2%	0.2–20.4%	3.8–11.1%	2.0%

DPN: Diabetic peripheral neuropathy

DM: Diabetes mellitus

nⁱ Sample size reflects patients with DPN who were implanted with a permanent implantable pulse generator (IPG).

n^{t,i} Sample size reflects subjects exposed to either the trial stimulation or permanent IPG implant as described in the individual publications.

^a Incidence rates at 12 month post-implant based on Abbott real world evidence study of Medicare claims based on Medicare ICD-9 and ICD-10 diagnosis codes.

^b Based on diagnosis codes that are specific to an implanted nervous system device, infection related to an implanted neurostimulator lead and infection related to an implanted neurostimulator IPG.

^c Based on diagnosis codes that are specific to displacement of implanted nervous system lead.

^d Based on diagnosis codes that are for mechanical breakdown of implanted nervous system lead and other mechanical complication of implanted nervous system lead.

^e Based on diagnosis codes that are for pain due to implanted nervous system device.

^f Based on diagnosis codes that are for encounters for adjustment and management of neurostimulator.

^g Two patients with infection also had fluctuations in their blood glucose levels.

^h CSF leak reported in one subject during aborted trial lead placement and reported in Slangen (2014).

ⁱ Based on report of implant site seroma.

Three publications reported sub-analyses on the impact of diabetes on a specific safety related outcome (without detailed adverse event information).

- TenVaarwerk et al. (1999)¹ was a retrospective, multicenter study of patients with angina pectoris treated with spinal cord stimulation to evaluate risk factors associated with morbidity and mortality in SCS. Insulin dependent diabetes was reported as the only important risk factor between survivors and non-survivors (p=0.05). Additionally, a multivariate analysis showed that diabetes was significantly correlated with mortality (p=0.01).
- Bir et al. (2016)² was a retrospective study of SCS in patients with chronic back pain to evaluate potential predictors of SCS revisions. The authors conducted an analysis of the effect of diabetes on revision free survival (RFS). RFS in patients with diabetes was 35 months, and in patients without diabetes it was 43 months; however, this difference was not statistically significant (log-rank, p=0.98).
- Antonovich et al. (2021)³ was a single center, retrospective analysis of SCS re-operation rates for specific lead types (paddle vs. percutaneous). Of the study participants, 22.34% had diabetes, and patient data was collected over a 10 year period. The authors evaluated whether or not there was an association between diabetes and lead type and time to re-operation but found none (p=0.197).

Published literature describing treatment of DPN with SCS and published clinical practice guidelines on perioperative care of diabetic patients provide information on specific inherent risks that may be of concern for diabetic patients when it comes to the delivery and management of SCS therapy.

Infection

Data on device or procedure related infections in DPN and diabetic patients reported in the literature indicate an infection rate ranging from 2–20%. The incidence of infection is comparable to overall rates of infection associated with SCS of 4.89% (range: 2.5% to 10%) as reported in a systematic literature review by Eldabe et al. (2016)⁴. In the literature, infections were either resolved using solely antibiotics or through removal of the infected components of the SCS system, followed by administration of antibiotics. Data from the RWE study suggest that in general patients diagnosed with DPN have higher risk of infection at 12 months following implantation and higher cumulative incidence of infection during the 12 month period following implantation than subjects who were not diagnosed with DPN. However, these infections are not necessarily device or procedure related.

The results of the RWE study indicate that the incidence of device specific infections is 2.6%. The device specific infection rate falls within the 2–20% incidence range reported in the literature. Additionally, device specific infections and infections that may be associated with device related surgical procedures (i.e., revision, replacement, or removal) were not significantly different between DPN and non-DPN patients (device related infections: risk difference of 0.7%, 95% CI: -0.6% to 2.1%; infections associated with device related surgical procedures post implant: risk difference of 1.0%, 95% CI: -0.7% to 2.7%). This suggests that while DPN subjects have elevated all-cause infection rates, device specific infection and infections that may be associated with device related post-implant surgeries are not significantly different among patients with DPN as compared to non-DPN patients implanted with SCS. This finding is consistent with the results of three large

retrospective studies on SCS, which also reported no significant difference in the rate of device specific infection for patients with diabetes^{5, 6, 7}.

Data from the RWE study, however, suggest that patients diagnosed with DPN in general have a higher risk of infection at 12 months following implantation and higher cumulative incidence of infection during the 12 month period following implantation than subjects who were not diagnosed with DPN. Therefore, the various sources of evidence are consistent and show DPN subjects in general do not have a higher risk of device or procedure related infections. The data also suggests that diabetic patients have an increased risk of all-cause infection; however, this risk can be appropriately communicated through device labeling and clinical guidelines.

The only complications as a result of infections explicitly mentioned in the literature include device explantation, abscess formation, and changes in glucose level stability. Another infection related complication that is of note is an increased risk of blood glucose fluctuations. This risk is highlighted by de Vos et al. (2014)⁸ in which two subjects experienced fluctuations in blood glucose levels in response to an infection. Although the study did not attribute these infections to the device, the impact of blood glucose fluctuations in diabetic patients that may arise from device related infections can lead to increased morbidity and mortality in this patient population.

Hematoma, Erosion, Wound Dehiscence

Based on the literature, the incidence rate of hematoma, erosion, and wound dehiscence ranged from 3.8% to 11.1%. Diabetes is known to be a potential risk factor for hematoma, erosion, and wound dehiscence, which can lead to infection. However, these rates may be underreported due to greater attention to infections that may result from this adverse event.

Cardiovascular Events

Several reports of subject or patient death attributed to myocardial infarction (n=4) or heart failure (n=1) were included in the available data on SCS to treat DPN^{9, 10}. While none were reported to be related to SCS procedures or therapy, patients with poorly controlled diabetes may have an elevated risk for cardiovascular events in the perioperative period. In an analysis of outcomes in patients undergoing elective orthopedic surgery (Marchant et al., 2009)¹¹, patients with poor glycemic control showed a nonsignificant trend towards greater odds of myocardial infarction and significantly greater odds of stroke (odds ratio 3.42 CI: 1.87–6.25; p <0.001).

Dural Puncture and CSF Leak

Only one of the studies reviewed in the literature reported CSF leak. Specifically, Slangen et al. (2014) reported one death due to subdural hematoma after dural puncture during the trial. A review of the literature was conducted to identify publications that reported CSF leak in patients with diabetes. Specifically data from craniotomy procedures in Ha et al. (2016)¹² and Hutter et al. (2014)¹³ suggest that diabetes may be a risk factor for CSF leaks. However, the more invasive nature of craniotomy procedures described in Hutter et al. and Ha et al. limits the translation of this concern to SCS procedures. Wang et al. (2014)¹⁴ also reported a 1.57-fold higher incidence of subdural hematoma in general (rates were not specific to SCS procedures) in diabetic patients than in non-diabetic patients (2.04 vs. 1.30 per 1000 person-years), with an adjusted hazard ratio of 1.63 [95% confidence interval (CI) 1.43–1.85].

It should be noted that although CSF leak was evaluated in the RWE study, results of the study were not included in the previous table since the common adverse events presented in the table are device or procedure related. The CSF leak safety event that was evaluated in the RWE study included all diagnosis codes that were related to CSF leak without regard to device or procedure causality. This approach was taken to induce a level of conservativeness in the incidence rate associated with this serious adverse event.

Out of the 507 DPN patients, there were fewer than 11 patients that were identified with CSF leaks from the medical claims data. Due to confidentiality concerns and per CMS cell suppression policy¹⁵, we are unable to report on patient data that have fewer than 11 subjects. As such, CSF leak in the DPN patients may have occurred in one subject or in 10 subjects; this range corresponds to an incidence rate ranging from 0.2–2%. Additionally, there was no statistically reliable evidence of a difference in the incidence in CSF leak between DPN and non-DPN subjects implanted with an SCS system (risk difference=0.0% to 1.8%, 95% CI: -0.4, 3.0%).

Glycemic Control

de Vos et al. (2014)¹ reported 2 subjects experiencing fluctuations in blood glucose levels following infections. While these were assessed by authors as unrelated to SCS, the physiologic stress of surgery or any adverse event may impact glycemic control.

Effectiveness

Literature Search Results

Selection criteria were 1) treatment of DPN with SCS systems delivering therapy at frequencies of 0 to 1200 Hz, and 2) a distinctly identifiable DPN population with quantifiable effectiveness data on pain related outcomes including the proportion of patients assessed as treatment success (responder rate), the magnitude of pain relief, or improvements in quality of life. After full text review, 14 publications on 8 studies were included for analysis. Three studies produced multiple publications, and one publication combined 2 separately studied cohorts.

Noncomparative Studies

Ten publications include data from 6 single-arm studies that evaluated the use of SCS to treat DPN^{16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26}. SCS trial success rates ranged from 73% to 93%. The proportion of subjects assessed as successfully treated ranged from 55% to 100% with average pain relief ranging from 41% to 80% (up to 12 months). Successful treatment during long term follow-up ranged from 40% to 77% (24 months to 7.5 years).

Comparative Studies

Two randomized controlled trials (RCT) investigated the use of SCS to treat DPN; results from these studies were described in 5 publications^{27, 28, 29, 30, 31}. The following table presents a comparison of the two initial studies that reported on the primary outcomes.

Table 52. Details of publications describing randomized studies on DPN

	Publication	
	Slangen et al., 2014 ³²	de Vos et al., 2014 ³³
Sponsor	Maastricht University Medical Center (NCT01162993)	Medisch Spectrum Twente (ISRCTN03269533)
Population	Diabetic patients with moderate to severe DPN in the lower limbs, who were refractory to conventional medical treatments for more than 12 months; NPRS pain rating ≥ 5 , 18 and 80 years of age	Patients with DPN in the lower extremities for more than 1 year and refractory to conventional treatments; VAS pain rating ≥ 50 mm ≥ 18 years of age
Design-allocation	Open Label, Randomized, Parallel assignment (3:2)	Open Label, Randomized, Parallel assignment (2:1)
Comparator	Best medical treatment (BMT)	Best conventional medical practice (BCMP)
Sample size (countries)	36 from 2 centers (NL)	60 from 7 centers (NL, BE, DK, DE)
Primary endpoint	$\geq 50\%$ pain reduction during daytime or nighttime or a score of ≥ 6 on a 7-point Likert scale of the PGIC scale for pain and sleep	Treatment success at 6 months $\geq 50\%$ pain reduction
Publication date	Nov 2014	Nov 2014

The demographic characteristics for subjects participating in both studies were comparable for most categories. Fewer Type I diabetic subjects were included in Slangen et al. though in both studies the majority

of subjects were diagnosed as Type II diabetics. Subject demographics for each study are presented in the following table.

Table 53. Comparison of study demographics

Demographic	Slangen et al. ²¹	de Vos et al. ²⁴
Age (years)	56.9	59.0
Duration of diabetes mellitus (years)	12.7	16.3
Duration of pain (years)	5.5	7.0
Male	67%	63%
Female	33%	37%
Type I	11%	25%
Type II	89%	75%

Primary pain related outcome measures between the two trials were compared to determine if the trials demonstrated similar effectiveness levels within the two similar populations; the subject measure averages are shown in the following table. Pain related outcomes were similar between studies with slightly greater reductions in pain reported by de Vos et al. Control groups from both studies did not achieve any notable reduction in average pain; however, one subject in the control arm reported treatment success.

Table 54. Comparison of pain measure (95% CI)

	Pain Rating ^a			
	Slangen et al. ²¹	de Vos et al. ²⁴		
	SCS (n=22)	Control (n=14)	SCS (n=40)	Control (n=20)
Baseline	7.1 (6.3–7.9)	6.5 (5.5–7.5)	7.3 (6.8–7.8)	6.7 (5.9–7.5)
6 month	4 ^d (2.6–5.4)	6.5 (5.4–7.6)	3.1 (2.2–4.0)	6.7 (5.7–7.7)
Pain relief ^b	44%	0%	58%	0%
Responder rate ^c	59% (36%–79%)	7% (0%–34%)	63% (46%–77%)	5% (0%–25%)

^a VAS (0–100 mm) and NRS (0–10) were normalized to a 0–10 scale.

^b 95% CI not provided due to required distributional assumptions.

^c Study design defined successful pain relief by different measures.

^d N=19 subjects with available data for pain scores at 6 months.

Combined Data from Comparative Studies

Because the two RCTs had highly similar trial designs, and patient populations and both compared SCS to conventional medical management with primary endpoints at 6 months, data from both studies were pooled and are presented in the following table. Average values were weighted by the number of subjects in the respective SCS and control treatment groups for each study.

Table 55. Combined subject measures (95% CI)

Measure	SCS (n=62)	Control (n=34)
Age (years)	57.7	59.1
Duration of DM (years)	14.8	15.2
Duration of pain (years)	6.6	6.1

Table 55. Combined subject measures (95% CI)

Measure	SCS (n=62)	Control (n=34)
Male	65%	65%
Female	35%	35%
Type I	21%	18%
Type II	79%	82%
Average baseline pain rating	7.2 (6.5–10)	6.6 (5.7–9.6)
Average 6 month pain rating	3.4 (2.1–4.4)	6.6 (5.6–9.5)
Average pain reduction ^a	53%	0%
Responder rate per protocol ^{b,c}	61% (48%–73%)	6% (0%–20%)
Responder rate ≥50% reduction in pain ^c	55% (42%–68%)	3% (0%–15%)
Responder rate per protocol as-treated ^d	70% (56%–82%)	6% (0%–20%)
Responder rate ≥50% reduction in pain as-treated ^d	63% (49%–76%)	3% (0%–15%)

^a 95% CI not provided due to required distributional assumptions.

^b Each study design defined successful pain relief by different measures.

^c Analysis of all randomized subjects in an intent-to-treat approach.

^d Including only subjects who received an SCS system implant.

Meta-analysis for Comparative Studies

A meta-analysis of responder rate (≥50% pain relief) from the two RCTs was performed. A random effects analysis of heterogeneity between studies supported homogenization (Cochran's $Q=0.113$, p -value=0.737; Higgin's I^2 test=0.0%). The confidence intervals of these studies overlap, and the estimate of odds ratios are consistent, demonstrating subjects treated with SCS for DPN are more likely to achieve ≥50% pain relief at 6 months. The overall mean logOR is 3.21 (95% CI 1.68 to 4.73), corresponding to an odds ratio of 24.8 in favor of treatment success with SCS treatment of DPN.

A second analysis based on a fixed effects model on the risk differences was performed. Similar to the random effects analysis, there is no statistically reliable evidence of heterogeneity between the studies $I^2=0.0\%$, and $Q=0.129$ ($p=0.719$). The fixed effects model estimates a group difference of 55.3% with a 95% CI from 40.8% to 69.9%. The data pooled from both studies showed that the binomial responder rates (defined as ≥50% reduction in pain at 6 months) for all subjects randomized to receive SCS treatment was 62.9% and supports probability of treatment success.

Long Term Effectiveness

Van Beek et al. (2018)³⁴ published long term follow-up results for subjects from the studies reported by Pluijms et al. (2012)³⁵ and Slangen et al. (2014)³⁶. Forty-eight subjects (40 with permanent implant) were included in the analysis for follow-up to 5 years. Treatment success was defined as ≥50% pain relief in day or nighttime pain or a PGIC rating of “much improved” or “very much improved”. Treatment success was observed in 86%, 71%, 77%, 67%, and 55% at 1 (n=36), 2 (n=35), 3 (n=34), 4 (n=30), and 5 (n=22) years, respectively. A Michigan Diabetic Neuropathy Score (0 to 3 scale) of 3 at baseline was associated with treatment failure during the 5 year follow-up (hazard ratio 3.9; p -value=0.014). This suggests patients with severe neuropathy may be less likely to experience treatment success.

Summary of Articles with Meta-analyses

There were 6 meta-analyses^{37, 38, 39, 40, 41, 42}, which included reviews of 77 publications, covering a range of study types from randomized controlled trials to case series. There is significant overlap in studies that were included in each publication, and many of the articles cited were included in the previous discussions of results for the safety and efficacy literature search; therefore, only high level conclusions were pulled from the analyses.

The adverse events identified in these meta-analyses included infections, meningitis, hematoma, lead migration or failure, and IPG failure requiring revision. Other adverse events mentioned in Hou et al. (2016) included dizziness, headache, or a sensation of heaviness or warmth in the legs. One death from subdural hematoma was originally reported in Slangen et al., 2014. Two meta-analyses reported infection rates of 4% (Raghu et al., 2021) and 14% for infections requiring antibiotics (Pluijms et al., 2011).

From an effectiveness perspective, these meta-analyses provide reasonable evidence of the effectiveness for the use of SCS in DPN. As reviewed in Raghu et al., 2021 and Duarte et al., 2021, two RCTs demonstrated that SCS provided superior treatment over best medical therapy at 6 months follow-up with continued significant improvement compared to baseline for many years. Xu et al., 2022 and D'Souza et al., 2022 concluded that the studies reviewed provided moderate to strong support of SCS to treat refractory DPN. Pluijms et al., 2011 compared long term effectiveness across multiple studies and determined that SCS provided continued pain relief at 7 years in DPN patients. At this point, 57% of patients (4 of 7) achieved $\geq 50\%$ pain relief, and 30% reported stoppage of analgesic use. Based on the collected information in the meta-analyses, there is general support on the use of SCS for DPN.

Overall Conclusions

Safety

The clinical evidence supporting the safety of Abbott implantable SCS systems to treat DPN includes a systematic literature review of published scientific articles reporting SCS as treatment for chronic intractable pain in patients with diabetes in general, and Medicare claims data on patients treated with SCS for DPN. Safety data from 730 subjects treated with SCS for their DPN was included. An additional 2235 patients were included across 4 studies that reported on diabetic patients treated with SCS.

The rates of common adverse events in the DPN population were similar to that of the general SCS population. The literature highlighted some inherent risks that are associated with spinal cord stimulation in DPN subjects, including but not limited to infection, delayed wound healing, cardiovascular events, dural puncture and subsequent subdural hematoma, and fluctuations in glycemic control. These events can be mitigated through appropriate patient selection, or with the use of appropriate surgical techniques and procedures.

Device labeling has been updated to provide information on warnings, advice on appropriate selection of patients healthy enough to receive SCS, and steps to take to avoid or reduce the impact of complications with SCS for patients with DPN. Refer to the system related clinician manuals for safety information specifically addressing the diabetic population. Underlying health conditions related to diabetes or other diseases may disqualify some patients from receiving SCS.

Published literature describing SCS as treatment for DPN and published clinical practice guidelines on perioperative care of diabetic patients provide information on specific inherent risks for the diabetic patient in the delivery and management of SCS therapy. These inherent risks include, but are not limited to delayed wound healing, cardiovascular events, dural puncture and subsequent subdural hematoma, and fluctuations in glycemic control. These events may be avoided by appropriate patient selection, or by the use of appropriate surgical techniques and procedures. There were an additional 5 meta-analyses that independently reviewed safety information and determined that risks of SCS in the diabetic population were similar to conclusions from previously published studies.

Effectiveness

A total of 14 publications from 8 studies (several publications reported alternative analyses or long term follow-up) described effectiveness outcomes associated with SCS to treat DPN. Four prospective studies without a comparator included a total of 84 subjects. Two retrospective studies contained data on 68 patients with diabetic neuropathy, and 2 RCTs comparing SCS to the standard-of-care included a total of 96 subjects.

Two independent RCTs evaluating SCS to treat DPN compared to standard-of-care included a total of 62 subjects in the treatment group and 34 subjects in the control group. At the 6 month primary endpoint, the outcomes for subjects randomized to receive SCS treatment were consistent between both studies with

treatment success rates of 59% and 63%, and an average pain relief of 44% and 58% in Slangen et al. (2014) and de Vos et al. (2014), respectively. The overall mean logOR is 3.21 (95% CI 1.68 to 4.73), corresponding to an odds ratio of 24.8 is in favor of treatment success with SCS treatment for DPN. The data pooled from both studies showed that the binomial responder rates (defined as $\geq 50\%$ reduction in pain at 6 months) for all subjects randomized to receive SCS treatment was 62.9% and supports probability of treatment success. Long term efficacy data on subjects treated with SCS to treat DPN from one nonrandomized study and one RCT, reflecting outcomes after 5 years of treatment showed a sustained pain relief at clinically meaningful levels. There were an additional 6 meta-analyses that independently reviewed effectiveness from previously published studies and determined that there was sufficiently strong evidence to support the use of SCS to treat DPN.

Limitations

Limitations of the available data include lack of a placebo control in the 2 randomized studies, no impact of medication use on criteria for treatment success, and the open-label design of long term follow-up reports. Studies without a placebo control arm are unable to measure the contribution of the placebo effect to the overall outcomes reported by subjects. While study data may reflect an average reduction in medication use, an individual patient's treatment success with SCS could be attributed to changes in pain medication. Data from open-label studies or long term, non-randomized follow-up may result in an overestimation of the treatment effect.

A limitation of data on the safety and effectiveness of SCS to treat DPN based on published literature and claims data is the lack of access to primary source data on patient-reported outcomes such as pain scores and detailed adverse event descriptions. In the absence of primary source data, analyses of associated variables (for example, diabetes type, baseline pain scores, or relevant pre-enrollment diagnoses) are not possible. While some published reports of studies of SCS to treat DPN provide covariate analyses, data included in these publications do not allow for verification of the analyses. Variation in diagnosis descriptions and criteria for inclusion of adverse events reported in publications limits the resolution of safety information that can be extracted from the published literature.

NOTE: The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

References

1. TenVaarwerk, I. A., et al. (1999). "Clinical outcome of patients treated with spinal cord stimulation for therapeutically refractory angina pectoris. The Working Group on Neurocardiology." *Heart* 82(1): 82-88.
2. Bir, S. C., et al. (2016). "Neuromodulation in intractable pain management: outcomes and predictors of revisions of spinal cord stimulators." *Neurosurg Focus* 40(5): E4
3. Antonovich, D. D., et al. (2021). "Reoperation Rates of Percutaneous and Paddle Leads in Spinal Cord Stimulator Systems: A Single-Center Retrospective Analysis." *Pain Med* 22(1): 34-40.
4. Eldabe S, Buchser E, Duarte RV. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature. *Pain Med*. 2016;17(2):325-336.
5. Falowski SM, Provenzano DA, Xia Y, Doth AH. Spinal Cord Stimulation Infection Rate and Risk Factors: Results From a United States Payer Database. *Neuromodulation*. 2019;22(2):179-189.
6. Hoelzer BC, Bendel MA, Deer TR, et al. Spinal Cord Stimulator Implant Infection Rates and Risk Factors: A Multicenter Retrospective Study. *Neuromodulation*. 2017;20(6):558-562.
7. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract*. 2011;11(2):148-153.
8. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. *Pain*. 2014;155(11):2426-2431.
9. Daousi C, Benbow SJ, MacFarlane IA. Electrical spinal cord stimulation in the long-term treatment of chronic painful diabetic neuropathy. *Diabet Med*. 2005;22(4):393-398. doi:10.1111/j.1464-5491.2004.01410.x
10. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial. *Pain*. 2014;155(11):2426-2431. doi:10.1016/j.pain.2014.08.031
11. Marchant MH, Jr., Viens NA, Cook C, Vail TP, Bolognesi MP. The impact of glycemic control and diabetes mellitus on perioperative outcomes after total joint arthroplasty. *J Bone Joint Surg Am*. 2009;91(7):1621-1629.

12. Ha B-J, Cheong JH, Yi H-J. Risk Factors for Cerebrospinal Fluid Leakage after Craniotomy and the Efficacy of Dural Sealants Application versus Dural Suturing Alone. *Nerve*. 2016;2(2):22-25.
13. Hutter G, von Felten S, Sailer MH, Schulz M, Mariani L. Risk factors for postoperative CSF leakage after elective craniotomy and the efficacy of fleece-bound tissue sealing against dural suturing alone: a randomized controlled trial. *J Neurosurg*. 2014;121(3):735-744.
14. Wang I-K, Chen H-J, Cheng Y-K, et al. Subdural hematoma in diabetic patients. *Eur J Neurol*. 2015;22(1):99-105. doi:10.1111/ene.12538
15. <https://www.hhs.gov/guidance/document/cms-cell-suppression-policy>
16. Tesfaye S, Watt J, Benbow SJ, Pang KA, Miles J, MacFarlane IA. Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy. *Lancet*. 1996;348(9043):1698-1701. doi:10.1016/S0140-6736(96)02467-1
17. Daousi C, Benbow SJ, MacFarlane IA. Electrical spinal cord stimulation in the long-term treatment of chronic painful diabetic neuropathy. *Diabet Med*. 2005;22(4):393-398. doi:10.1111/j.1464-5491.2004.01410.x
18. de Vos CC, Rajan V, Steenbergen W, van der Aa HE, Buschman HPI. Effect and safety of spinal cord stimulation for treatment of chronic pain caused by diabetic neuropathy. *J Diabetes Complications*. 2009;23(1):40-45. doi:10.1016/j.jdiacomp.2007.08.002
19. de Vos, C. C., et al. (2014). "Burst spinal cord stimulation evaluated in patients with failed back surgery syndrome and painful diabetic neuropathy." *Neuromodulation* 17(2): 152-159.
20. Pluijms WA. Pain relief and quality-of-life improvement after spinal cord stimulation in painful diabetic polyneuropathy: A pilot study. *Br J Anaesth*. 2012;109(4):623-629. doi:10.1093/bja/aes251
21. Slangen R, Pluijms WA, Faber CG, Dirksen CD, Kessels AGH, van Kleef M. Sustained effect of spinal cord stimulation on pain and quality of life in painful diabetic peripheral neuropathy. *Br J Anaesth*. 2013;111(6):1030-1031. doi: 10.1093/bja/aet397
22. Pluijms, W. A., et al. (2015). "Increased contact heat evoked potential stimulation latencies in responders to spinal cord stimulation for painful diabetic polyneuropathy." *Neuromodulation* 18(2): 126-132; discussion 132.
23. van Beek M, Geurts JW, Slangen R, et al. Severity of neuropathy is associated with long-term spinal cord stimulation outcome in painful diabetic peripheral neuropathy: Five-year follow-up of a prospective two-center clinical trial. *Diabetes Care*. 2018;41(1):32-38. doi:10.2337/dc17-0983
24. Petrakis IE, Sciacca V. Epidural spinal cord electrical stimulation in diabetic critical lower limb ischemia. *Journal of Diabetes and its Complications* JO - J Diabetes Complications. 1999;13(5-6):293-299.
25. Kumar, K., et al. (1996). "Spinal cord stimulation for chronic pain in peripheral neuropathy." *Surg Neurol* 46(4): 363-369.
26. de Vos CC, Bom MJ, Vanneste S, Lenders MW, de Ridder D. Burst spinal cord stimulation evaluated in patients with failed back surgery syndrome and painful diabetic neuropathy. *Neuromodulation*. 2014;17(2):152-159.
27. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial. *Pain*. 2014;155(11):2426-2431. doi:10.1016/j.pain.2014.08.031
28. Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: A prospective two-center randomized controlled trial. *Diabetes Care*. 2014;37(11):3016-3024. doi:10.2337/dc14-0684
29. van Beek M, Slangen R, Schaper NC, et al. Sustained Treatment Effect of Spinal Cord Stimulation in Painful Diabetic Peripheral Neuropathy: 24-Month Follow-up of a Prospective Two-Center Randomized Controlled Trial. *Diabetes Care*. 2015;38(9):e132-4. doi:10.2337/dc15-0740
30. Duarte RV, Andronis L, Lenders MWPM, de Vos CC. Quality of life increases in patients with painful diabetic neuropathy following treatment with spinal cord stimulation. *Qual Life Res*. 2016;25(7):1771-1777. doi:10.1007/s11136-015-1211-4
31. van Beek M, Geurts JW, Slangen R, et al. Severity of neuropathy is associated with long-term spinal cord stimulation outcome in painful diabetic peripheral neuropathy: Five-year follow-up of a prospective two-center clinical trial. *Diabetes Care*. 2018;41(1):32-38. doi:10.2337/dc17-0983
32. Slangen, R., et al. (2014). "Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial." *Diabetes Care* 37(11): 3016-3024.
33. de Vos, C. C., et al. (2014). "Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial." *Pain* 155(11): 2426-2431.

34. van Beek M, Geurts JW, Slangen R, et al. Severity of Neuropathy Is Associated With Long-term Spinal Cord Stimulation Outcome in Painful Diabetic Peripheral Neuropathy: Five-Year Follow-up of a Prospective Two-Center Clinical Trial. *Diabetes Care*. 2018;41(1):32-38.
35. Pluijms WA, Slangen R, Bakkers M, et al. Pain relief and quality-of-life improvement after spinal cord stimulation in painful diabetic polyneuropathy: a pilot study. *Br J Anaesth*. 2012;109(4):623-629.
36. Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. *Diabetes Care*. 2014;37(11):3016-3024.
37. Hou S, Kemp K, Grabis M. A Systematic Evaluation of Burst Spinal Cord Stimulation for Chronic Back and Limb Pain. *Neuromodulation*. 2016;19(4):398-405.
38. Raghu ALB, Parker T, Aziz TZ, et al. Invasive Electrical Neuromodulation for the Treatment of Painful Diabetic Neuropathy: Systematic Review and Meta-Analysis. *Neuromodulation*. 2021;24(1):13-21.
39. Xu L, Sun Z, Casserly E, Nasr C, Cheng J, Xu J. Advances in Interventional Therapies for Painful Diabetic Neuropathy: A Systematic Review. *Anesth Analg*. 2022;134(6):1215-1228.
40. D'Souza RS, Langford B, Dombrovsky-Johnson M, Abd-Elseyed A. Neuromodulation Interventions for the Treatment of Painful Diabetic Neuropathy: a Systematic Review. *Curr Pain Headache Rep*. 2022;26(5):365-377.
41. Pluijms WA, Slangen R, Joosten EA, et al. Electrical spinal cord stimulation in painful diabetic polyneuropathy, a systematic review on treatment efficacy and safety. *Eur J Pain*. 2011;15(8):783-788.
42. Duarte, R. V., et al. (2021). "Spinal cord stimulation for the management of painful diabetic neuropathy: a systematic review and meta-analysis of individual patient and aggregate data." *Pain* 162(11): 2635-2643.

Clinical Summary for Non-Surgical Back Pain

Abbott Medical conducted a clinical study, DISTINCT (Dorsal spinal cord STimulation vs mediCal management for the Treatment of non-surgical low back pain), to evaluate the effectiveness of spinal cord stimulation (SCS) compared with conventional medical management (CMM) in the treatment of chronic back pain for patients who have not undergone and who are not candidates for back surgery. Specifically, the efficacy of SCS, delivered by BurstDR™ stimulation therapy-capable devices, compared with CMM in improving pain relief, emotional suffering, and back pain-related physical functioning improvement was evaluated in non-surgical back pain patients. The clinical study supports the SCS systems listed in “Clinical Studies” (page 1) and the following sections present information and results.

DISTINCT Study

Study Design

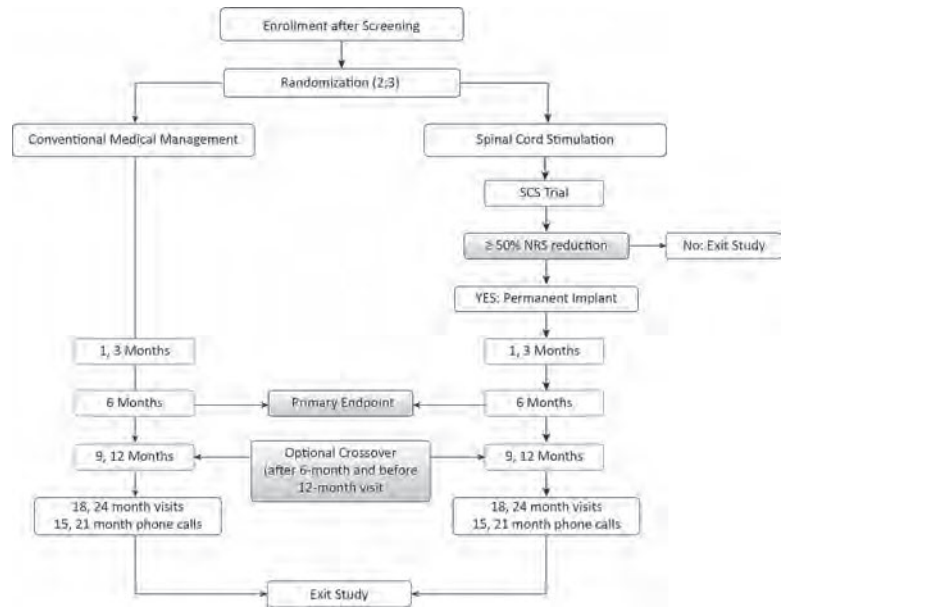
DISTINCT is a prospective, multicenter, randomized, controlled, clinical study with an optional crossover component. It is designed to evaluate the efficacy of SCS using systems that can be programmed with BurstDR™ stimulation therapy, along with relevant leads and accessories, in the treatment of chronic back pain, compared to conventional medical management (CMM). This clinical investigation (NCT04479787 on ClinicalTrials.gov) enrolled subjects without underlying pathology that can be effectively treated with surgery and who have not had prior lumbar spine surgery. Only patients who met the inclusion/exclusion criteria were enrolled in the study. Any subject that did not meet all inclusion criteria or met any of the exclusion criteria was considered a screening failure. An independent board-certified spine surgeon acted as a medical monitor and evaluated each enrolled subject for suitability.

After enrollment, subjects were randomized between two treatment arms:

- Conventional medical management (CMM)
During the follow-up period, subjects in the CMM arm received supervised medical care, including medication optimization, and supervised non-interventional therapy. Medication optimizations include use of non-steroidal anti-inflammatories, muscle relaxants, anti-neuropathic agents, opioids, and other analgesics as appropriate. Supervised non-interventional therapy may include, but is not limited to, physical therapy, chiropractic care, cognitive behavioral therapy, and acupuncture. Interventional therapies such as injections and radiofrequency ablation were included.
- Spinal cord stimulation (SCS)
Subjects randomized to receive spinal cord stimulation first undergo a trial of the therapy. A successful trial, defined as 50% decrease in pain recorded on the Numerical Rating Scale (NRS) for low back pain, is required for a subject to receive a permanent implant.

Subjects are followed in-clinic at 1, 3, 6, 9, 12, 18, and 24 months and via phone call or optional clinic visit at 15 and 21 months. The primary endpoint is assessed at the 6-month follow-up visit. Upon completion of the 6-month follow-up visit, subjects who are dissatisfied with therapy and receiving inadequate improvement with their treatment assignment can cross over to the other treatment arm, if desired. The following figure shows the flow of study design.

Figure 17. Study design



Clinical Inclusion and Exclusion Criteria

Key Inclusion Criteria

Enrollment in the DISTINCT study was limited to patients who met the specified inclusion criteria. Key inclusion criteria were:

- Age ≥18 years
- Patient has chronic (at least 6 months), refractory axial low back pain with a neuropathic component and is not a candidate for spine surgery
- Patient has back pain for ≥6 months inadequately responsive to supervised conservative care
- Patient has not had spine surgery for back or leg pain
- Low back pain ≥6 on Numerical Rating Scale
- Oswestry Disability Index score of ≥30%

Key Exclusion Criteria

Patients were not permitted to enroll in the DISTINCT study if they met any of the specified exclusion criteria. Key exclusion criteria were:

- Pathology seen on imaging tests obtained within the past 12 months that is clearly identified and is likely the cause of the chronic low back pain, that can be addressed with surgery
- Primary complaint of leg pain, or leg pain is greater than back pain
- Back pain is due to any of the following:
 - spinal instability defined as >2 mm translation on radiographic imaging
 - visceral causes (for example, endometriosis or fibroids)
 - vascular causes (for example, aortic aneurysm)
 - spinal infection (for example, osteomyelitis)
 - inflammation or damage to the spinal cord (for example, arachnoiditis or syringomyelia)

- tumor or spinal metastases
- Widespread pain (such as fibromyalgia) or pain in other area(s) not intended to be treated in this study (such as neck pain, shoulder pain)
- Patient has seronegative spondyloarthropathy (such as rheumatoid, lupus, psoriatic)
- Neurological deficit (such as foot drop)
- Prior lumbar spine surgery or sacroiliac joint fusion
- Patient has used a morphine equivalent daily dose of more than 50 MME in the last 30 days
- Patient is bed bound
- Imaging (MRI, CT, X-ray) findings within the last 12 months that contraindicates lead placement
- Severe scoliotic deformity (>11 degrees in thoracic or lumbar spine)
- BMI >40
- Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements of the clinical investigation results

Clinical Endpoints

Primary Endpoint

The primary effectiveness endpoint is the difference in proportion of responders between the two treatment groups at 6 months. A subject is considered a responder for the primary endpoint if an improvement in back pain intensity from baseline was reported, defined as a $\geq 50\%$ decrease on Numerical Rating Scale (NRS).

Secondary Endpoints

Seven secondary endpoints, as listed below, are compared between the two treatment groups and tested in the following order:

Table 56. Secondary endpoints

Secondary Endpoint	Responder Definition at 6 months, if applicable
1. Proportion (%) of Composite responder on NRS or ODI	50% reduction on NRS 13 point reduction on ODI or score <20, demonstrating a meaningful, clinical improvement in disability (MCID)
2. Percent (%) of NRS change from baseline to 6 months	N/A
3. Oswestry Disability Index (ODI) score change from baseline to 6 months	N/A
4. Proportion (%) of Pain Catastrophizing Scale (PCS) responder	Proportion of subjects that are either clinically catastrophizing on PCS at baseline (PCS score >30) and report a score of <30 at follow-up, or report 40% decrease in score at follow-up compared to baseline.
5. Proportion (%) of Patient Global Impression of Change (PGIC) responder	"Better and a definite improvement that has made a real and worthwhile difference" or "Great deal better and considerable improvement that has made all the difference" on PGIC questionnaire
6. Percent (%) of Patient-Reported Outcomes Measurement Information System (PROMIS-29) Pain Interference, change from baseline to 6 months	N/A
7. Percent (%) of Patient-Reported Outcomes Measurement Information System (PROMIS-29)	N/A

Table 56. Secondary endpoints

Secondary Endpoint	Responder Definition at 6 months, if applicable
Physical Function change from baseline to 6 months	

Descriptive Endpoints

The following endpoints shown in this summary are through 6 months and have been evaluated using descriptive statistics appropriate to the specific endpoints but not formally tested.

Change from baseline at each timepoint on the following, among others:

- Numerical Rating Scale (NRS) (page 82)
- Oswestry Disability Index (ODI) (page 82)
- PROMIS-29 questionnaire (page 83)
- Pain Catastrophizing Scale (PCS) (page 84)
- Patient satisfaction (page 85)
- Exercise frequency (page 85)

Proportion of patients who elect to cross over after the primary endpoint

Sample Size Design and Statistical Analysis

Up to 270 subjects were randomized in the DISTINCT study in two phases. Phase I included the first 20 randomized subjects which were used in this analysis. Phase II is the continued access phase which added a further 70 randomized subjects. SCS and CMM subjects were randomized in a 3:2 ratio. Testing was performed with a Z-test with unequal variance. Assuming a responder rate of 45% in SCS and 20% in CMM, and a 25% attrition rate in both groups by the 6 month timepoint, there was at least 90% power with a Type I error rate of 5% in the 200-subject cohort.

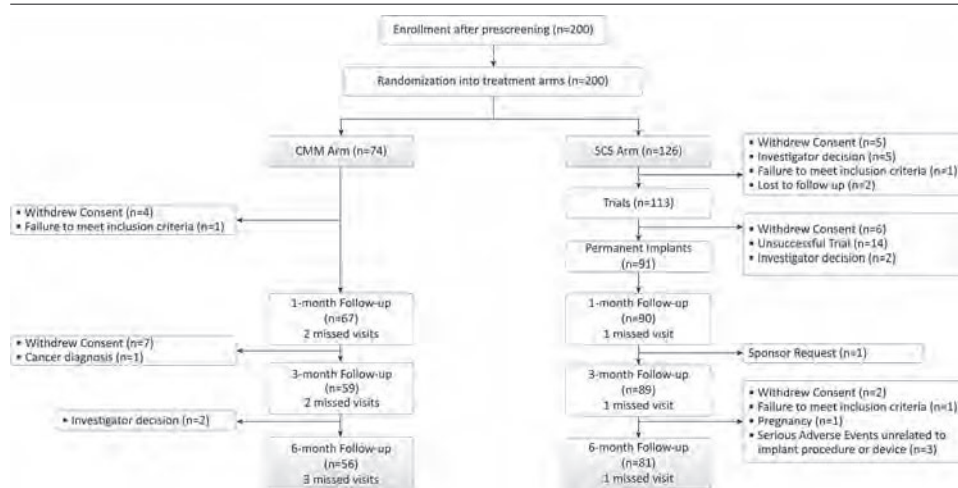
The analysis populations include:

- **Intention-to-Treat (ITT) Population:** includes all randomized subjects. Subjects are analyzed according to the treatment group they were randomized to. The ITT population is used as the primary analysis population for the primary endpoint.
- **Modified Intention-to-Treat (mITT) Population:** includes all randomized CMM subjects and SCS subjects that had a successful trial and received a permanent implant. Subjects are analyzed according to the treatment group they were randomized to.
- **Per-Treatment Evaluable (PTE) Population:** includes all subjects in the mITT population who either receive permanent implant or receive CMM. Subjects are analyzed according to the actual treatment received. The PTE population is used as the analysis population for the study except the primary endpoint analysis.

Accountability of 200-Subject Cohort

A total of 270 subjects were successfully enrolled from September 04, 2020, to September 16, 2021 at 29 investigational sites across the United States. Phase 1 enrollment completed on June 24, 2021. This report includes the data collected through April 29, 2022, accounting for the Phase 1 200-subject cohort at 6 months, as summarized in the following figure. The study is ongoing and all 270 subjects are planned for follow-up through 2 years.

Figure 18. 200-Subject Cohort used for analysis



A total of 58 subjects across both treatment arms were exited early from the study before the 6 month follow-up timepoint could be met. Therefore, a total of 137 subjects across both treatment arms were included in the primary and secondary endpoints analysis at the 6 month timepoint.

A total of fifteen (15) subjects exited the CMM arm by the 6 month timepoint. The largest group (n=11) no longer wished to participate and withdrew consent. The other group (n=4) of subjects was terminated due to no longer meeting inclusion/exclusion criteria, investigator termination, and other medical diagnosis.

A total of forty three (43) subjects exited the SCS arm by the 6 month timepoint. Thirteen (13) were terminated prior to the trial phase of the study. Once the trial phase began, the majority (14) were terminated due to an unsuccessful trial; that is, NRS for back pain did not decrease by at least 50%, while 6 withdrew consent and no longer wished to participate, and 2 were terminated by investigator. After the permanent implant, a total of 8 subjects were terminated, of which 3 subjects were lost to serious adverse events (deaths), unrelated to implant procedure or device/therapy.

Study Results

Demographics and Baseline Assessments

The following table summarizes the demographics and baseline assessments for the 200 subjects. Data is typical of a chronic pain study population.

The average age of subjects was 59 years. Fifty eight percent (58%) of the subjects were female. Most subjects were Caucasian (83.5%). Fifty percent (50%) reported chronic pain for over 10 years (average of 13.03 ± 12.21 years). The underlying etiologies of this non-surgical population are also listed in the following table.

Table 57. Demographics and baseline characteristics

Variable	CMM (N=74)	SCS (N=126)
Age (years)	(N=71)	(N=126)
Mean ±SD	61.8±13.2	58.8±13.5
Gender, n (%)	(N=71)	(N=126)
Female	53.5% (38/71)	57.1% (72/126)
Male	46.5% (33/71)	42.9% (54/126)
Race, n (%)	(N=71)	(N=126)
White	85.9% (61/71)	81.0% (102/126)

Table 57. Demographics and baseline characteristics

Variable	CMM (N=74)	SCS (N=126)
Black or African American	4.2% (3/71)	8.7% (11/126)
Asian	8.5% (6/71)	7.1% (9/126)
American Indian or Alaska Native	2.8%(0/71)	0.8% (1/126)
Declined or unable to disclose due to local regulation	0.0% (0/71)	1.6% (2/126)
Native Hawaiian or Other Pacific Islander	0.0% (71)	0.8% (1/126)
Weight (kg)	(N=71)	(N=126)
Mean ±SD	85.32 ±18.81	87.42 ±17.31
Height (cm)	(N=71)	(N=126)
Mean ±SD	171.10 ±9.97	169.87 ±10.77
BMI	(N=71)	(N=126)
Mean ±SD	29.8 ±5.33	30.24 ±5.01
Pain Numeric Rating Scale (NRS)		
Lower back	(N=74)	(N=126)
Mean ±SD	7.9 ±1.1	7.8 ±1.3
Right leg	(N=66)	(N=109)
Mean ±SD	2.9 ±2.8	2.8 ±2.6
Left leg	(N=67)	(N=112)
Mean ±SD	2.9 ±2.8	3.0 ±2.8
Pain distribution	(N=74)	(N=126)
Back pain only	32.4% (24/74)	29.4% (37/126)
Back with unilateral leg pain	20.3% (15/74)	34.1% (43/126)
Back with bilateral leg pain	47.3% (35/74)	36.5% (46/126)
Patient-reported impact of pain on subject's life	(N=71)	(N=126)
None	0.0% (0/71)	0.0% (0/126)
Very Mild	0.0% (0/71)	0.0% (0/126)
Mild	1.4% (1/71)	1.6% (2/126)
Moderate	22.5% (16/71)	19.8% (25/126)
Severe	59.2% (42/71)	59.5% (75/126)
Very Severe	16.9% (12/71)	19.0% (24/126)
Frequency of subject's exercise	(N=71)	(N=126)
None	33.8% (24/71)	35.7% (45/126)
<1 day/week	14.1% (10/71)	12.7% (16/126)
1-2 days/week	14.1% (10/71)	13.5% (17/126)
3-5 days/week	19.7% (14/71)	24.6% (31/126)

Table 57. Demographics and baseline characteristics

Variable	CMM (N=74)	SCS (N=126)
>5 days/week	18.3% (13/71)	13.5% (17/126)
Duration of subject's pain on subject's life (year)	(N=71)	(N=126)
Mean $\pm$ SD	13.98 $\pm$ 13.09	12.11 $\pm$ 11.40
Pain diagnosis*, n (%)	(N=71)	(N=126)
Chronic, non-specific, low back pain	59.2% (42/71)	57.9% (73/126)
Discogenic pain	7.0% (5/71)	6.3% (8/126)
Degenerative disc disease	42.3% (30/71)	28.6% (36/126)
Lumbar disc herniation	4.2% (3/71)	4.0% (5/126)
Lumbar facet arthropathy	31.0% (22/71)	23.0% (29/126)
Lumbar radiculopathy	49.3% (35/71)	35.7% (45/126)
Lumbar spinal stenosis	31.0% (22/71)	23.0% (29/126)
Lumbar spondylosis	60.6% (43/71)	53.2% (67/126)
Mechanical low back pain	2.8% (2/71)	6.3% (8/126)
Spondylolisthesis	4.2% (3/71)	4.8% (6/126)
Scoliosis	4.2% (3/71)	4.0% (5/126)
Other	21.1% (15/71)	8.7% (11/126)
Treatment for current condition*	(N=68)	(N=118)
Physical therapy	98.5% (67/68)	94.9% (112/118)
Occupational therapy	22.1% (15/68)	13.6% (16/118)
Massage therapy	38.2% (26/68)	40.7% (48/118)
Chiropractic therapy	52.9% (36/68)	55.1% (65/118)
Acupuncture	19.1% (13/68)	36.4% (43/118)
Subject undergone any injections or interventions to treat their low back pain*	(N=65)	(N=121)
Injection	90.8% (59/65)	96.7% (117/121)
Radiofrequency ablation/rhizotomy	49.2% (32/65)	44.6% (54/121)
Other	13.8% (9/65)	19.8% (24/121)
Current work status	(N=71)	(N=126)
Full Time	23.9% (17/71)	26.2% (33/126)
Part Time	7.0% (5/71)	4.0% (5/126)
Not Working	16.9% (12/71)	14.3% (18/126)
Unemployed	7.0% (5/71)	6.3% (8/126)
Disabled	5.6% (4/71)	14.3% (18/126)

Table 57. Demographics and baseline characteristics

Variable	CMM (N=74)	SCS (N=126)
Retired	39.4% (28/71)	34.9% (44/126)
Subject not working as direct result of low back pain	(N=71)	(N=126)
N/A	43.7% (31/71)	41.3% (52/126)
Yes	23.9% (17/71)	20.6% (26/126)
No	29.6% (21/71)	35.7% (45/126)
Reduced or modified duty	2.8% (2/71)	2.4% (3/126)
If working, days missed last month due to pain	(N=37)	(N=60)
Mean $\pm$ SD	4.2 $\pm$ 9.3	2.4 $\pm$ 7.1

*Subjects may be counted in more than one category.

Procedural Results

Summary data for trial and implant procedures are shown for subjects randomized to the SCS treatment arm. A minimum of 4 days was recommended for the trial period. Only percutaneous leads were used for SCS trials per protocol. Fourteen (14) of the 113 subjects did not move to permanent procedure due to inadequate pain relief (that is, 50% back pain relief as measured by NRS) in 13 subjects and 1 subject could not complete the trial due to an adverse event. This resulted in a trial success rate of 87.6%. Two subjects (2/113) were terminated due to investigator decision. Subjects (20/113) that did not move forward with the permanent implant are classified and described in the following table along with length of trial period and distribution of systems used for trialing purposes.

Table 58. Trialing Characteristics of SCS subjects in trial period

Length of trial (days)		
	Mean $\pm$ SD (n)	6.7 $\pm$ 1.2 (n=113)
System Used n (%)		
	Percutaneous lead	100%
	External pulse generator	100%
Reason, if not moving to permanent procedure, n (%)		
	Inadequate pain relief	65.0% (13/20)
	Subject aversion to procedure	5.0% (1/20)
	Adverse event preventing permanent procedure	5.0% (1/20)
	Other reason	25.0% (5/20)

Subjects that successfully completed the trial and chose to move forward were implanted with a permanent system. All permanent implant procedures initiated were completed successfully. The characteristics of implanted systems are summarized in the following table.

Table 59. Characteristics of Permanent Implants in SCS arm subjects

IPG Model		
	3660	98.9% (90/91)
	3772	1.1% (1/91)
Lead Model		
	3186	50.5% (46/91)
	3228	49.5% (45/91)
Implanted Lead Level		
	T5	1.1% (1/91)
	T6	2.2% (2/91)
	T7	45.1% (41/91)
	T8	50.5% (46/91)
	T9	12.1% (11/91)

SCS systems were programmed by trained personnel either during post-operative recovery or at an in-office visit in accordance with Abbott Medical routine procedures. After programming, the subject receives a patient controller and is instructed on how to use the system to relieve their pain. Subjects can adjust the stimulation to ensure the best results. Tonic programming is typically used to paresthesia map painful body areas. Of the implanted subjects, 99% (90/91) received BurstDR™ stimulation programming parameters at implant. At 6 months, all subjects were using BurstDR™ stimulation therapy.

Primary Effectiveness

The primary endpoint of the study was designed to show a superior responder rate in the SCS group compared to CMM. The endpoint was met, and analysis results are shown in the following table.

Table 60. Primary Endpoint and Sensitivity analysis – Difference in Response Rates at 6 Months

	CMM	SCS	Difference [95% CI]³	P-Value⁴	Conclusion⁵
Primary Endpoint Response Rate, ITT Analysis Population [95% Confidence Interval] ¹	7.1% (4/56) [2.0%, 17.3%]	72.6% (69/95) ² [62.5%, 81.3%]	65.5% [54.3%, 76.7%]	<0.0001	Endpoint met
ITT Analysis Population, Multiple imputation [95% Confidence Interval] ³	6.7% [0.2%, 13.2%]	82.6% [74.5%, 90.8%]	75.9% [65.7%, 86.1%]	<0.0001	Endpoint met
mITT Analysis Population [95% Confidence Interval] ¹	7.1% (4/56) [2.0%, 17.3%]	85.2% (69/81) [75.6%, 92.1%]	78.0% [67.8%, 88.3%]	<0.0001	Endpoint met
PTE Analysis Population [95% Confidence Interval] ¹	7.1% (4/56) [2.0%, 17.3%]	85.2% (69/81) [75.6%, 92.1%]	78.0% [67.8%, 88.3%]	<0.0001	Endpoint met

¹Exact Clopper-Pearson

²Trial failures are imputed as non-responders.

³By normal approximation

⁴Two-sided Z-Test with unpooled variance

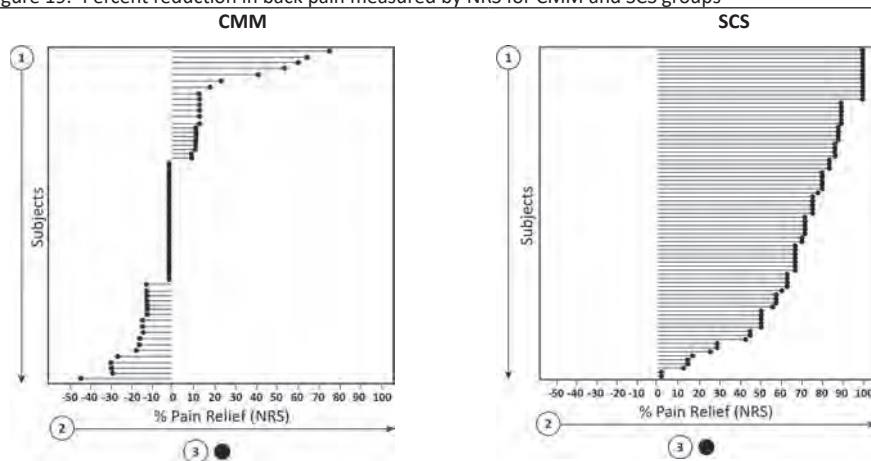
⁵P-value <0.05 indicates endpoint is met.

The primary analysis included any subjects that failed the SCS trial phase as non-responders (n=14) as the ITT population. Of those treated with SCS, 72.6% reported at least 50% pain relief; 65.5% more than those receiving CMM (p <0.0001).

Multiple imputation was used to determine responder status for any subjects with missing data at 6 months in either treatment arm. The results of the ITT analysis with missing data imputed showed that 82.6% of SCS subjects responded compared to 6.7% of CMM subjects. This analysis was consistent with the primary endpoint results in demonstrating the superiority of SCS over CMM at 6 months. All subjects with data at 6 months received the treatment assigned at randomization resulting in identical populations for mITT and PTE; 85.2% of SCS subjects responded compared to 7.1% of CMM subjects. Additionally, no difference was observed in treatment effect by site, by gender, and age in SCS and CMM arms by poolability and subgroup analyses.

The following figure shows pain relief for 200-subject cohort at 6 months for SCS and CMM groups. Back pain increased relative to baseline on the 0 through 10 numeric scale in 17 subjects treated with CMM compared to zero receiving SCS. Of the responders in the SCS group, 51% (35/69) reported ≥80% relief. No CMM subjects reported greater than 80% relief; 13 SCS subjects reported 100% pain relief. SCS subjects 60% (49/81) reported a NRS score ≤2. CMM subjects 3.5% (2/56) reported a score below or equal to 2 at 6 months.

Figure 19. Percent reduction in back pain measured by NRS for CMM and SCS groups



Secondary Effectiveness

Seven statistically powered and pre-defined secondary endpoints were tested on the per-treatment evaluable (PTE) population. The PTE analysis is the same as the modified intent to treat analysis as all subjects received the treatment assigned at randomization. Statistical testing was executed in a pre-defined order and only carried out if the previous endpoint reached significance. All secondary endpoints were successfully met for the SCS arm with a statistically significant difference compared to the CMM arm, as shown in the following table. Together, this supports superior improvements in pain (NRS), back pain-related function (ODI), emotional suffering (PCS), patient satisfaction (PGIC), pain interference and physical function (PROMIS-29 domains), achieved by SCS when compared with CMM.

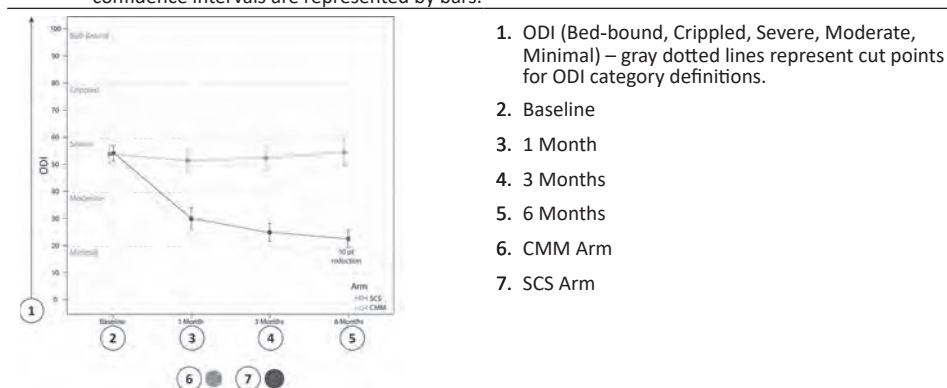
Table 61. Summary of Secondary Endpoints at 6 months

Secondary Endpoints	CMM	SCS	Difference [95% CI] ²	P-Value	Conclusion ⁵
Composite Responder Rate [95% Confidence Interval] ¹	19.6% (11/56) [10.2%, 32.4%]	91.4% (74/81) [83.0%, 96.5%]	71.7% [59.6%, 83.8%]	<0.0001 ³	Endpoint met
NRS Relative change from Baseline to 6 Months Mean ±SD (n) [95% Confidence Interval] ²	3.6 ±22.7 (56) [-2.5, 9.7]	69.7 ±25.0 (81) [64.2, 75.2]	66.1 [57.9, 74.2]	<0.0001 ⁴	Endpoint met
ODI Change from Baseline to 6 Months Mean ±SD (n) [95% Confidence Interval] ²	0.7 ±14.4 (56) [-3.1, 4.6]	30.6 ±19.8 [26.2, 35.1]	29.9 [24.1, 35.8]	<0.0001 ⁴	Endpoint met
PCS Responder Rate [95% Confidence Interval] ¹	21.4% (12/56) [11.6%, 34.4%]	86.4% (70/81) [77.0%, 93.0%]	65.0% [51.9%, 78.1%]	<0.0001 ³	Endpoint met
PGIC Responder Rate [95% Confidence Interval] ¹	3.6% (2/56) [0.4%, 12.3%]	77.8% (63/81) [67.2%, 86.3%]	74.2% [63.9%, 84.5%]	<0.0001 ³	Endpoint met
PROMIS-29 Pain Interference Relative change from Baseline to 6 Months Mean ±SD (n) [95% Confidence Interval] ²	1.1 ±10.6 (56) [-1.8, 3.9]	18.1 ±11.4 (81) [15.6, 20.6]	17.0 [13.3, 20.8]	<0.0001 ⁴	Endpoint met
PROMIS-29 Physical function Relative change from Baseline to 6 Months Mean ±SD (n) [95% Confidence Interval] ²	1.3 ±13.1 (56) [-2.2, 4.8]	28.0 ±25.1 (81) [22.5, 33.6]	26.7 [20.2, 33.2]	<0.0001 ⁴	Endpoint met

¹ Exact Clopper-Pearson² By normal approximation³ Two-sided Z-Test with unpooled variance⁴ Two-sample T-test⁵ P-value <0.05 indicates endpoint is met.

Baseline ODI scores in SCS (53.3 ±14.5) and CMM (55.4 ±13.6) arms were similar, and the average score in both groups reflected severe disability. The average score in the SCS group is reduced to moderate disability (22.7 ±14.2) at 6 months. This represents an average score reduction of 30 points, more than twice the Minimally Clinically Important Change (MCID, >13 point reduction from baseline). An average of less than 1-point change is reported by the CMM group (54.7 ±18.9). See the following figure.

Figure 20. Average ODI score at 1, 3, and 6-month timepoints (open circles). The upper and lower 95% confidence intervals are represented by bars.



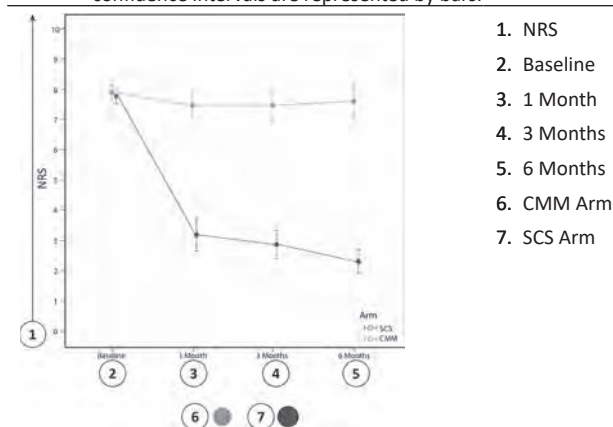
Descriptive Endpoints and Additional Analysis

The following analysis for the 200-subject cohort at 6 months consists of descriptive endpoints (not formally tested) that were predetermined and evaluated per the clinical study protocol, as well as additional data that was analyzed post hoc.

NRS

At 6 months, the average NRS score in the SCS group decreased by an average of 69.7% compared to 3.4% in CMM group. NRS score decreased from 7.8 ± 1.3 at baseline to 2.3 ± 1.9 at 6 months; 5.1 more points compared to the CMM group. See the following figure.

Figure 21. Average NRS score at 1, 3, and 6-month timepoints (open circles). The upper and lower 95% confidence intervals are represented by bars.

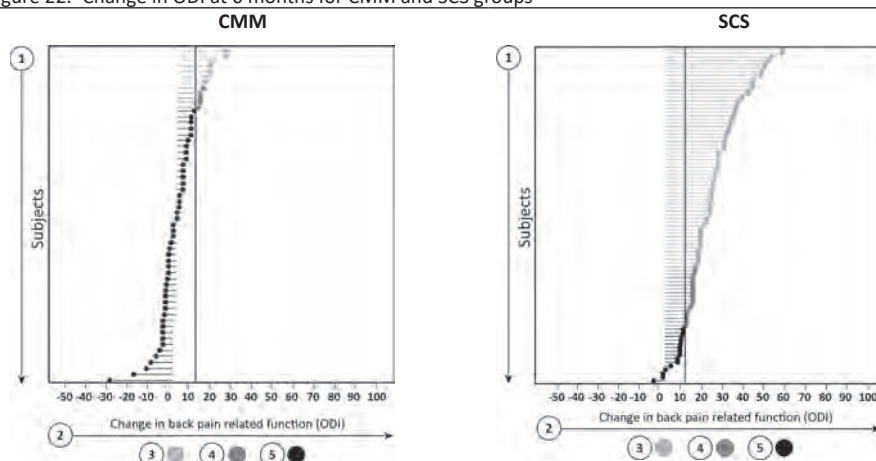


ODI

The change in back pain-related function, measured by ODI, for each group is shown in the following figure. Of the SCS subjects, 65% (51/78) reported a substantial (≥ 20 point reduction from baseline) improvement on ODI at 6 months compared to 10.7% in the CMM group (6/56). Of the SCS subjects, 83.3% (65/78) reported a Minimally Clinically Important Change (MCID, >13 point reduction from baseline) improvement on ODI at

6 months compared to 19.6% in the CMM group (11/56). Overall, 89.5% of SCS subjects moved from severe pain-related disability to mild compared to 15% in CMM subjects.

Figure 22. Change in ODI at 6 months for CMM and SCS groups



1. Subjects
2. Change in back pain-related function (ODI)
3. Substantial
4. MCID
5. Non-responder

PROMIS-29

At 6 months, a greater improvement was observed in SCS subjects compared to CMM subjects for all domains of PROMIS-29, such as physical function, anxiety, depression, pain interference, fatigue, sleep disturbance, and social participation as shown by the change in T-score in the following table.

Table 62. Change at 6-month follow-up in PROMIS-29 domains T-score

PROMIS-29 Domain	CMM		SCS	
	Baseline Score	Change in T-score from Baseline at 6 months	Baseline Score	Change in T-score from Baseline at 6 months
Physical Function	N=71	N=56	N=91	N=81
Mean $\pm$ SD	33.2 $\pm$ 4.3	0.2 $\pm$ 4.2	33.7 $\pm$ 4.9	8.9 $\pm$ 6.9
[95% Confidence Interval] ¹	[32.2, 34.2]	[-0.9, 1.4]	[32.7, 34.8]	[7.4, 10.4]
Anxiety	N=71	N=56	N=90	N=80
Mean $\pm$ SD	55.7 $\pm$ 11.5	0.9 $\pm$ 9.3	55.6 $\pm$ 11.6	8.4 $\pm$ 11.3
[95% Confidence Interval] ¹	[53.0, 58.5]	[-1.6, 3.4]	[53.1, 58.0]	[5.9, 10.9]
Depression	N=71	N=56	N=91	N=81
Mean $\pm$ SD	53.3 $\pm$ 10.0	-0.2 $\pm$ 7.3	52.9 $\pm$ 10.0	6.6 $\pm$ 8.9
[95% Confidence Interval] ¹	[50.9, 55.7]	[-2.2, 1.7]	[50.8, 54.9]	[4.6, 8.6]
Pain interference	N=71	N=56	N=91	N=81

Table 62. Change at 6-month follow-up in PROMIS-29 domains T-score

PROMIS-29 Domain	CMM		SCS	
	Baseline Score	Change in T-score from Baseline at 6 months	Baseline Score	Change in T-score from Baseline at 6 months
Mean $\pm$ SD [95% Confidence Interval] ¹	68.3 $\pm$ 5.5 [67.0, 69.6]	1.0 $\pm$ 7.2 [-0.9, 3.0]	68.4 $\pm$ 5.0 [67.3, 69.4]	12.6 $\pm$ 8.3 [10.8, 14.4]
Fatigue	N=71	N=56	N=91	N=81
Mean $\pm$ SD [95% Confidence Interval] ¹	59.0 $\pm$ 8.4 [57.0, 61.0]	-1.4 $\pm$ 7.6 [-3.4, 0.7]	58.9 $\pm$ 8.7 [57.1, 60.7]	10.2 $\pm$ 0.0 [8.0, 12.5]
Sleep disturbance	N=71	N=56	N=91	N=81
Mean $\pm$ SD [95% Confidence Interval] ¹	58.3 $\pm$ 8.4 [56.3, 60.3]	-1.6 $\pm$ 7.4 [-3.6, 0.3]	56.7 $\pm$ 9.0 [54.8, 58.6]	7.4 $\pm$ 10.2 [5.1, 9.6]
Social Participation	N=71	N=56	N=91	N=81
Mean $\pm$ SD [95% Confidence Interval] ¹	38.4 $\pm$ 7.1 [36.7, 40.0]	-0.2 $\pm$ 8.5 [-2.5, 2.1]	38.0 $\pm$ 7.6 [36.4, 39.6]	12.2 $\pm$ 9.7 [10.1, 14.4]

¹By normal approximation

PCS

The average PCS score for subjects treated with SCS decreased at 6-month follow-up to below that expected of a normal, non-chronic pain population. The average score for CMM subjects remained comparable to baseline through 6 months, decreasing by only 0.3 to 2.1 points at most. Additionally, all patients clinically catastrophizing at baseline were no longer catastrophizing (report a score of <30) at 6 months after receiving BurstDR™ stimulation therapy compared to 15% of CMM patients.

Table 63. Change at 6-month follow-up in PCS score

PCS Domain	CMM		SCS	
	Baseline Score	Change in PCS score from baseline at 6 months	Baseline Score	Change in PCS score from baseline at 6 months
Rumination	N=71	N=56	N=91	N=81
Mean $\pm$ SD [95% Confidence Interval] ¹	9.8 $\pm$ 4.7 [8.7, 10.9]	0.3 $\pm$ 4.0 [-0.8, 1.4]	10.3 $\pm$ 4.7 [9.3, 11.2]	7.6 $\pm$ 5.3 [6.4, 8.7]
Magnification	N=71	N=56	N=91	N=81
Mean $\pm$ SD [95% Confidence Interval] ¹	5.3 $\pm$ 3.7 [4.4, 6.1]	0.5 $\pm$ 2.5 [-0.1, 1.2]	5.0 $\pm$ 3.6 [4.2, 5.7]	3.7 $\pm$ 3.9 [2.8, 4.5]
Helplessness	N=71	N=56	N=91	N=81
Mean $\pm$ SD [95% Confidence Interval] ¹	12.2 $\pm$ 5.6 [10.8, 13.5]	1.3 $\pm$ 4.4 [0.1, 2.5]	12.3 $\pm$ 6.6 [11.0, 13.7]	9.6 $\pm$ 6.9 [8.1, 11.1]
Total Score	N=71	N=56	N=91	N=81

Table 63. Change at 6-month follow-up in PCS score

PCS Domain	CMM		SCS	
	Baseline Score	Change in PCS score from baseline at 6 months	Baseline Score	Change in PCS score from baseline at 6 months
Mean $\pm$ SD [95% Confidence Interval] ¹	27.2 $\pm$ 12.9 [24.1, 30.2]	2.1 $\pm$ 8.7 (56) [-0.2, 4.5]	27.6 $\pm$ 13.6 [24.7, 30.4]	20.8 $\pm$ 14.7 [17.6, 24.0]

¹By normal approximation

Patient Satisfaction

Subjects were asked to rate their satisfaction with the level of pain relief provided by the current therapy (SCS or CMM). At 6 months, 87.6% SCS subjects report satisfaction. Comparatively, only 16% CMM subjects are satisfied with their therapy.

Exercise Frequency

At 6 months, 74% of SCS subjects reported exercising at least 1 day a week, which was an increase from baseline of 56% of SCS subjects. Fewer CMM subjects reported exercising at least 1 day a week at 6 months, decreasing from 52% at baseline to 48% at 6 months.

Crossover

Subjects had the option to cross over once the 6-month follow-up visit was completed, and any time up to when the 12-month follow-up visit was due. At the time of primary endpoint analysis for the 200-subject cohort, 87.5% of the 56 CMM subjects with a 6 month visit elected to cross over and undergo an SCS trial.

Lead Type Analysis

Primary and secondary endpoints at the 6-month follow-up timepoint were analyzed by implanted lead type as shown in the following table. Point estimates for both lead types are within the 95% confidence intervals associated with the analysis of the complete 6 month data set for the 200-subject cohort.

Table 64. Primary and secondary endpoints by lead type for SCS within 200-subject cohort

	Paddle (N=45)	Percutaneous (N=46)	SCS (N=91)
Primary Endpoint mITT Analysis Population [95% Confidence Interval] ¹	90.7% (39/43) [77.9%, 97.4%]	78.9% (30/38) [62.7%, 90.4%]	85.2% (69/81) [75.6%, 92.1%]
Secondary Endpoints Composite Responder Rate [95% Confidence Interval] ¹	95.3% (41/43) [84.2%, 99.4%]	86.8% (33/38) [71.9%, 95.6%]	91.4% (74/81) [83.0%, 96.5%]
NRS Relative change from Baseline to 6 Months Mean $\pm$ SD (n) [95% Confidence Interval] ²	71.5 $\pm$ 21.3 (43) [64.9, 78.1]	67.7 $\pm$ 28.8 (38) [58.2, 77.1]	69.7 $\pm$ 25.0 (81) [64.2, 75.2]
ODI Change from Baseline to 6 Months Mean $\pm$ SD (n)	35.0 $\pm$ 21.0 (42) [28.4, 41.5]	25.6 $\pm$ 17.2 (36) [19.8, 31.4]	30.6 $\pm$ 19.8 (78) [26.2, 35.1]

Table 64. Primary and secondary endpoints by lead type for SCS within 200-subject cohort

	Paddle (N=45)	Percutaneous (N=46)	SCS (N=91)
[95% Confidence Interval] ²			
PCS Responder Rate [95% Confidence Interval] ¹	88.4% (38/43) [74.9%, 96.1%]	84.2% (32/38) [68.7%, 94.0%]	86.4% (70/81) [77.0%, 93.0%]
PGIC Responder Rate [95% Confidence Interval] ¹	79.1% (34/43) [64.0%, 90.0%]	76.3% (29/38) [59.8%, 88.6%]	77.8% (63/81) [67.2%, 86.3%]
PROMIS-29 Pain Interference Relative change from Baseline to 6 Months Mean ±SD (n) [95% Confidence Interval] ²	17.5 ±11.4 (43) [14.0, 21.0]	18.7 ±11.5 (38) [14.9, 22.5]	18.1 ±11.4 (81) [15.6, 20.6]
PROMIS-29 Physical function Relative change from Baseline to 6 Months Mean ±SD (n) [95% Confidence Interval] ²	31.7 ±28.8 (43) [22.8, 40.6]	23.9 ±19.6 (38) [17.4, 30.3]	28.0 ±25.1 (81) [22.5, 33.6]

¹Exact Clopper-Pearson²By normal approximation

Additional Analysis

Three outcomes that measure different domains of chronic pain (pain intensity (NRS), back pain-related disability (ODI), and emotional suffering (PCS)) were posthoc analyzed for the number of subjects that responded on 1, 2, or all 3 measures. Of the SCS subjects, 99% (80/81) responded on at least 1 measure; 88.4% (70/81) responded on 2 measures; 74% (60/81) responded on both ODI and NRS; 70% (54/81) responded on all 3 measures.

Adverse Events

A total of 14 adverse events were reported for the 200-subject cohort in the first 6 months up to the primary endpoint timepoint during the study. There were 3 serious device-related adverse effects (SADEs), 3 non-device-related serious adverse events (SAEs), and 8 adverse device effects (ADEs). The following table summarizes adverse events.

Table 65. Adverse events for 200 subject cohort through 6 month follow-up timepoint

Event Type	CMM (N=74)		SCS (N=126)	
	Number of Events	Subjects with Events n/N (%)	Number of Events	Subjects with Events n/N (%)
SAE	0	0/74 (0.0%)	3	3/126 (2.4%)
SADE	N/A	N/A	3	3/126 (2.4%)
ADE	N/A	N/A	8	8/126 (6.3%)

Table 65. Adverse events for 200 subject cohort through 6 month follow-up timepoint

Event Type	CMM (N=74)		SCS (N=126)	
	Number of Events	Subjects with Events n/N (%)	Number of Events	Subjects with Events n/N (%)
Total	0	0/74 (0.0%)	14	14/126 (11.1%)

SADE = Serious Adverse Device Effects - Device/Procedure Related

SAE = Serious Adverse Events (SAEs) - Not Device/Procedure Related

ADE = Non-Serious Adverse Device Effects - Device/Procedure Related

N/A = not applicable

Three non-device related SAE (2 cardiovascular-related death and 1 non-cardiovascular death) occurred in 3 of the 126 subjects randomized to the SCS arm. The cause of death in 1 subject was flash pulmonary edema. The cause of death in the second subject was development of digitalis toxicity after treatment for atrial fibrillation and diastolic congestive heart failure. The cause of death in the third subject was bladder rupture post exploratory laparotomy leading to septic shock, renal failure, and acute respiratory failure. All 3 events were determined to be unrelated to device/procedure for SCS treatment.

Three device- or procedure-related serious adverse events were reported in the SCS treatment arm subjects. There was 1 infection and 1 post-surgical pain due to permanent implant procedure, and 1 event of numbness due to trial implant procedure, as shown in the following table. All SADEs were resolved with sequelae.

Table 66. Summary of serious adverse device effects (SADEs)

Event Description	Related to	Subjects with Events n/N (%)	Number of Events
Infection	Permanent implant procedure (1)	1/126 (0.8%)	1
Numbness below the level of implant	Trial implant procedure (1)	1/126 (0.8%)	1
Post-Surgical Pain	Permanent implant procedure (1)	1/126 (0.8%)	1

Eight (8) non-serious adverse device effects were reported at the time of data cut-off for this report for the 200-subject cohort, as shown in the following table. Note that a single adverse event can have more than one causal relationship and subjects can experience multiple adverse events.

Table 67. Summary of adverse device effects (ADEs)

Event Description	Related to	Subjects with Events n (%)	Number of Events
Changes In Stimulation Or Reduced Pain Relief Due To Lead Migration	Lead and lead anchor (1), lead (1)	2/126 (1.6%)	2
Dermatitis And Desquamation	Trial implant procedure (1)	1/126 (0.8%)	1
Implant Migration	IPG and lead (1)	1/126 (0.8%)	1
Infection	IPG and permanent implant procedure (1)	1/126 (0.8%)	1
Movement or Vibration of the IPG or Leads	Lead and trial implant procedure (1)	1/126 (0.8%)	1

Table 67. Summary of adverse device effects (ADEs)

Event Description	Related to	Subjects with Events n (%)	Number of Events
Persistent pain at the lead site	IPG (1)	1/126 (0.8%)	1
Skin Reaction	Trial implant procedure (1)	1/126 (0.8%)	1

The adverse events reported in this study were anticipated for the study population and are considered acceptable.

Conclusions Drawn from the Study

Effectiveness

The primary endpoint successfully demonstrated greater effectiveness in those treated with SCS compared to CMM; 72.6% of SCS subjects reported 50% pain relief or greater compared to 7.1% in the CMM arm in an ITT analysis population. The Per Treatment Analysis (PTE) reported 85.2% responders in the SCS arm. Hierarchical testing of the 7 secondary endpoints was initiated and was completed for all 7 as each reported statistically significant greater effectiveness in the SCS group. These endpoints support greater improvements in back pain (NRS), back pain-related disability (ODI), pain-related emotional suffering (PCS), patient satisfaction (PGIC), pain interference on day-to-day living, and physical function (PROMIS-29).

Safety

Three deaths, unrelated to treatment, were reported during the study. No stimulation-related SAEs or any events categorized as unanticipated adverse device effects (UADEs) were reported during the study. A total of 14 adverse events were reported in 14 subjects of the 200-subject cohort through the 6-month follow-up timepoint. Of these, 3 were device- or procedure-related SAEs while 8 were device- or procedure-related adverse events in the SCS treatment arm; these rates of observations were within expectations and considered acceptable.

Study Limitations

The open-label crossover design did not blind investigators or subjects as to whether they were receiving SCS or CMM treatment. The nature of the treatment groups precludes the ability to blind investigators and participants to the randomized status. Subjects randomized to the SCS arm undergo a trial period using an external pulse generator, and if successful pain relief is reported they are then eligible to receive an implanted system. In addition to the necessary procedures, external components are required for the system to function (clinician and patient controllers). To minimize potential sources of bias, the investigators, participants, and sponsor statistical team remained blinded to all data until primary endpoint data was complete and only informed of recommendations made from a pre-planned interim analysis.

Treatments available to CMM subjects are a continuation of pre-enrollment care. Regular follow-up visits with further CMM optimization (including injections and ablation procedures) sets the expectation that subjects in this arm can improve on the outcomes collected. The study design also includes the option to cross over after 6 months.

Benefit-Risk Conclusions

The DISTINCT (Dorsal spinal cord STimulation vs mediCal management for the Treatment of non-surgical low back pain) clinical study established superior effectiveness of Spinal Cord Stimulation delivered by devices capable of BurstDR™ stimulation therapy for the treatment of chronic non-surgical, intractable back pain and back pain-related disability and impaired physical function, emotional suffering, and interference on day-to-day living compared with Conventional Medical Management treatment. An acceptable rate of events consistent with the safety profile of SCS systems was observed in the DISTINCT study.

Overall Conclusions

The use of spinal cord stimulation (SCS) delivered by devices capable of BurstDR™ stimulation therapy is an effective treatment option for chronic and intractable non-surgical back pain patients.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-05
ARTEN600283815 B



Implantable Pulse Generator

Prodigy™ IPG

Prodigy MRI™ IPG

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Indications for Use.	1
Contraindications.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	2
Adverse Effects.	3
Product Description.	4
Package Contents.	4
Identifying the IPG.	4
Directions for Use.	5
Creating an IPG Pocket.	5
Tunneling to the Pocket.	5
Connecting a Lead or Extension to the IPG.	6
Implanting the IPG.	8
Replacing the IPG.	9
Disposing of Explanted Components.	9
Maintaining the IPG Battery.	9
Recharging the IPG Battery.	10
Preserving the IPG When Not in Use.	10
Technical Support.	10
Appendix A: Product Specifications.	10
IPG Specifications.	10
Appendix B: Regulatory Statements.	11
Statement of FCC Compliance (FCC ID:PX 2001).	11
Disposal Guidelines for Battery-Powered Devices.	11
Appendix C: Symbols and Definitions.	12

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This rechargeable neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

Abbott Medical spinal cord stimulation (SCS) systems are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Additional Prescription Information

Refer to the clinician's system manual for additional instructions and other important information, including indications for use, contraindications, warnings, precautions, and adverse effects related to the complete neurostimulation system.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to these components.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may forcefully dislodge implanted components, damage the device electronics, and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation system. Contact between an active electrode and an implanted IPG, lead, or extension can

cause severe injury to the patient. If use of electrocautery is necessary, first turn off the neurostimulation system.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Case damage. Do not handle the IPG if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

IPG disposal. Return all explanted IPGs to Abbott Medical for safe disposal. IPGs contain lithium ion batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

Product materials. Neurostimulation systems have materials that come in contact or may come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.

Precautions

The following precautions apply to these components.

General Precautions

Physician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of two systems. If two systems are implanted, ensure that at least 20 cm (8 in.) separates the implanted IPGs to minimize the possibility of interference during programming.

Implant heating. While recharging an IPG, patients may perceive an increase in temperature. In patients who have areas of increased sensitivity to heat, consider placing the implant where the patient has normal sensation.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their

perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

Mobile phones. The effect of mobile phones on neurostimulation systems is unknown; patients should avoid placing mobile phones directly over the system.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use the system if the use-by date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

External defibrillators. The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead.

Home and Occupational Environments

Electromagnetic interference (EMI). Certain commercial electrical equipment (for example, arc welders, induction furnaces, and resistance welders), communication equipment (for example, microwave transmitters, linear power amplifiers, and high power amateur transmitters), and high voltage power lines may generate sufficient EMI to interfere with the operation of the neurostimulation system if approached too closely.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with implanting or using this IPG:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation immediately.)
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)

- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the IPG site
- Seroma (mass or swelling) at the IPG site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect.

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Product Description

This IPG is a rechargeable, electronic device designed to be connected to one or more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The IPG can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas (called MultiStim™ programs). New features can be introduced to the system via software updates allowing for upgraded technology to be used. An Abbott Medical external programmer may be needed for certain types of software updates to this product.

NOTE:

- Patients may experience a sensation of tingling, “pins and needles,” prickling, or even burning called paresthesia. Paresthesia may be brief or it may last a long time. Current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia.
- For more information about this neurostimulation system, see the programming and reference clinician's system manual.

Package Contents

In addition to the product documentation, the Prodigy MRI™ IPG kit (Model 3772) and Prodigy™ IPG kit (Model 3799) contain the following items:

- 1 IPG
- 1 pocket sizer
- 1 torque wrench (Model 1101)
- 2 port plugs (Model 1111)
- 1 tunneling tool (Model 1112)

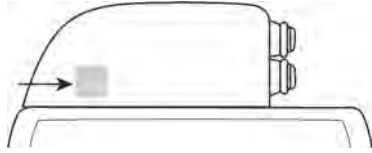
Identifying the IPG

Using standard X-ray procedures, you can view the code that identifies the manufacturer and model number of the IPG in the header of the IPG.

- For the Prodigy MRI™ IPG (Model 3772), the code is SJM Nnn.
- For the Prodigy™ IPG (Model 3799), the code is SJM Ynn.

'SJM' represents Abbott Medical as the manufacturer; 'N' or 'Y' represents Model 3772 or 3799 respectively; and 'nn' represents the last two digits of the year of manufacture. For example, SJM N15 identifies a Prodigy MRI IPG (Model 3772) manufactured in 2015.

Figure 1. Location of the IPG code



Directions for Use

Read this section carefully for suggested directions for use related to the IPG. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

NOTE: Well in advance of the surgical procedure, authorize the programmer to the IPG while the IPG is in its sterile packaging to ensure that it is functional.

Creating an IPG Pocket

To create an IPG pocket:

1. Determine the site for the IPG, ensuring that the lead is long enough to reach the pocket and provide a strain relief loop.

NOTE: The IPG should be located in an area that the patient can easily reach with the programming wand. Common sites for implantation are: along the midaxillary line, in the upper buttock along the posterior axillary line (taking care to avoid the belt line), and in the area over the abdomen just below the lowermost rib. To ensure a flat area is selected, you can mark a flat area prior to the surgical procedure while the patient is in a sitting position.

CAUTION: Do not place the IPG deeper than 2.25 cm (0.9 in.) because the patient programmer and charger may not communicate efficiently with the IPG and the charger may not charge efficiently.

2. Create the pocket so that the IPG is parallel to the skin surface and no deeper than 2.25 cm (0.9 in.) below the skin surface.
3. Insert and remove the pocket sizer to ensure that the pocket is large enough to accommodate the IPG, allowing enough extra room for a strain relief loop for each lead or extension.

Tunneling to the Pocket

Tunneling is usually done from the lead anchor site directly to the IPG pocket. However, when an extension is used or the IPG pocket is in the abdominal region, tunneling is done from the lead anchor site to a midpoint (where an incision and appropriate dissection have been performed) and then continued to the IPG pocket site.

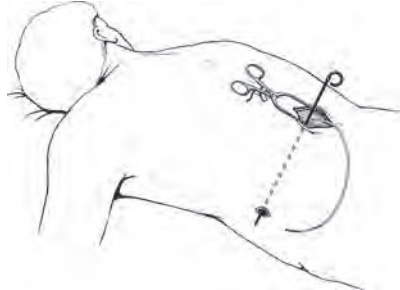
To tunnel from the lead anchor site to the IPG pocket:

CAUTION: Use extreme care so as not to damage a lead with the sharp point of the tunneling tool.

NOTE: The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.

1. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the IPG pocket.

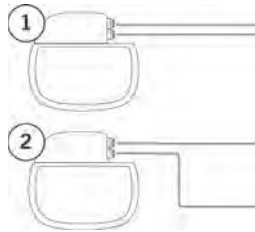
Figure 2. Suggested tunnel to the IPG pocket



2. Withdraw the tunneling tool from the cannula sleeve, leaving the cannula sleeve in the subcutaneous tunnel.

CAUTION: Multiple leads must be routed adjacent to one another. Patients with nonadjacent leads may experience changes in perceived stimulation from theft detectors and metal screening devices.

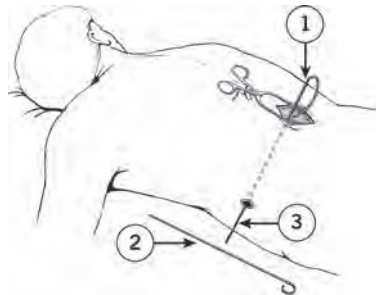
Figure 3. Correct way to route multiple leads



1. Correct
2. Incorrect

3. Carefully pass the end of the lead or leads through the cannula sleeve from the anchor site to the IPG pocket; or, if a two-step tunneling procedure is used, pass the lead or leads from the anchor site to the midway incision site and then to the IPG pocket. Multiple leads may be placed in the same tunnel.

Figure 4. Sequence of tunneling steps



1. Leave cannula sleeve in place
2. Remove tunneling tool
3. Pull lead through cannula sleeve to IPG pocket

4. Withdraw the cannula sleeve from the subcutaneous tunnel by passing it over the lead or leads, taking care not to cause traction on them.

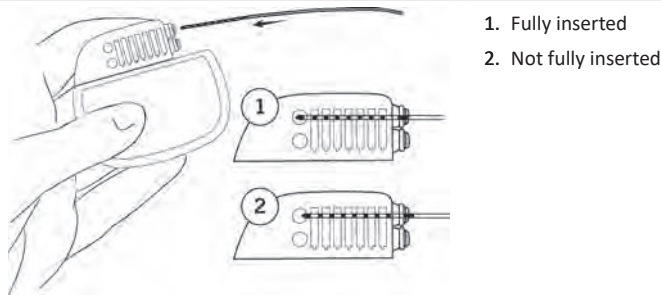
Connecting a Lead or Extension to the IPG

To connect a lead or extension to the IPG:

CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

1. If any of the lead or extension contacts came in contact with body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.
CAUTION: Observe these cautions when performing the following step:
 - Do not bend the lead sharply or it may be damaged.
 - Do not loosen the setscrew in the connector more than a quarter turn at a time while trying to insert the lead. Retracting the setscrew too far can cause the setscrew to come loose and make the connector assembly unusable.
2. Using clean gloves, carefully slide the lead or extension into the IPG header until all of the contact bands are fully inside the connector assembly and hidden from view.

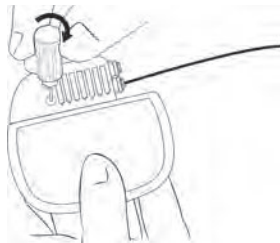
Figure 5. Insert the lead fully into the IPG header



CAUTION: Use only the torque wrench that is compatible with the IPG or the device may be damaged and rendered unusable.

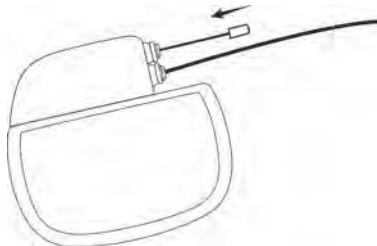
3. Insert the torque wrench through the septum and tighten the setscrew, turning it clockwise until the wrench clicks.

Figure 6. Tighten the setscrew clockwise



4. Remove the torque wrench and check the septum to ensure that it closed. If the septum did not close, gently reseat the septum flaps.
5. If implanting two leads, repeat the previous steps. If implanting a single lead only, insert the header port plug into the unused port, and use the torque wrench to tighten the setscrew until it clicks.

Figure 7. Insert the port plug



Implanting the IPG

To implant the IPG:

CAUTION: Observe these cautions when performing the following step:

- Do not implant the IPG face down. Implant it with the label facing toward the skin, or it may not communicate or recharge.
 - If using more than one IPG, implant them at least 20 cm (8 in.) apart. Putting them too close together may interfere with the patient programmer's ability to communicate with each IPG separately.
1. Place the IPG into the IPG pocket, at a depth not to exceed 2.25 cm (0.9 in.), with the label facing the skin surface.

Figure 8. Place the IPG in the pocket

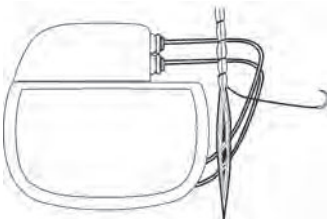


2. Carefully coil any excess lead or extension behind the IPG in loops no smaller than 2.5 cm (1 in.) in diameter to provide strain relief for the lead or extension and IPG connection.
CAUTION: Do not bring the suture needle in contact with an IPG, lead, or extension, or the component may be damaged.
3. To stabilize the IPG within the pocket, pass a suture through the hole at the top of the IPG header and secure it to connective tissue.
4. Check the entire system by fluoroscopy prior to closing to ensure proper positioning of the lead or leads and that it is straight, with no sharp bends or kinks.
5. Connect the communication wand to the patient programmer, place the wand in a sterile bag, and position the wand over the IPG site.
6. Ensure that the patient programmer achieves effective communication with the IPG and that the system is operational.

NOTE: IPG output may not be identical to that of the trial stimulator at the same settings.

7. Ensure that the IPG is away from the pocket incision suture line, close the pocket incision, and apply the appropriate dressings.

Figure 9. Close the pocket incision



Replacing the IPG

To replace an IPG:

1. Turn off the IPG or verify that it is turned off.

CAUTION: Exercise care when using sharp instruments or electrocautery around leads or extensions, or they may be damaged.

2. Open the IPG implant site per normal surgical procedure.
3. Insert the torque wrench through the septum of the IPG header and loosen the setscrew by turning it counterclockwise.

CAUTION: When performing the following step, do not bend the lead or extension sharply; or it may be damaged.

4. Gently remove the lead or extension from the IPG header; then clean and dry all connections, ensuring they are free of fluid and tissue.
5. To complete the IPG replacement procedure, see the following sections: “Connecting a Lead or Extension to the IPG” (page 6) and “Implanting the IPG” (page 8).

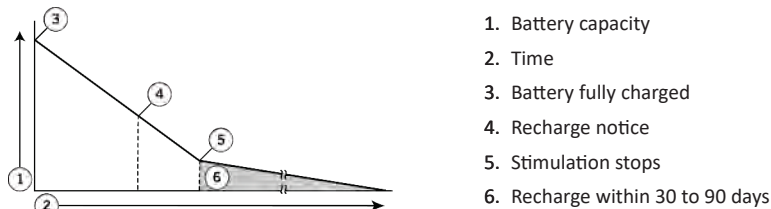
Disposing of Explanted Components

Explanted Abbott Medical components should be returned to Abbott Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your Abbott Medical representative or Technical Support.

Maintaining the IPG Battery

The IPG contains a lithium ion battery. The time it takes to recharge a battery depends on these factors: age of the battery, daily usage time, stimulation settings, and length of time since the last recharge. The following graph shows how the rechargeable battery depletes over time.

Figure 10. IPG battery depletion over time



If the patient does not recharge the battery, stimulation will eventually stop, and the patient then must recharge the battery to prevent battery damage. After stimulation stops, a new battery can last up to 90 days before it must be recharged, while a ten-year-old battery should be recharged within 30 days.

When the IPG is used at high stimulation parameters for tonic programs or at nominal stimulation parameters for BurstDR™ stimulation programs, battery usage studies demonstrate that the battery should allow at least ten years of practical recharging. In other words, a ten-year-old device will maintain at least 24 hours of continuous therapy between recharges.

Depending on the patient's stimulation parameters, the device will continue to operate for months to years. Patients may experience a significantly longer device life before recharging is determined to be impractical if they use lower stimulation parameters, a frequent recharging protocol, or both. Frequent recharging can reduce charging session times and maximize the IPG's life.

NOTE: The model used to predict device longevity was generated by fitting a mathematical model to three years of real-time cycling data, which was then used to extrapolate device battery capacity at the end of ten years.

Recharging the IPG Battery

For information about the charging system and how to recharge the IPG battery, see the user's guide for the charging system.

WARNING: Do not let an IPG battery remain depleted for an extended period of time. If a depleted battery is not recharged within 30 to 90 days of its full discharge, the charger may not be able to recharge it; and it will have to be surgically replaced to resume therapy.

Preserving the IPG When Not in Use

To preserve the IPG when discontinuing stimulation for an extended period of time:

1. Recharge the battery to its maximum capacity before turning off the IPG.
2. Recharge the battery to its maximum capacity every 3 months while it is not in use.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

IPG Specifications

The Prodigy MRI™ IPG (Model 3772) and Prodigy™ IPG (Model 3799) have the following physical specifications.

Table 1. IPG specifications

Model	3772	3799
MRI status	MR Conditional	MR Unsafe
Height	4.8 cm (1.89 in.)	
Length	5.3 cm (2.09 in.)	
Thickness	0.95 to 1.1 cm (0.37 to 0.43 in.)	
Weight	29.0 g (1.0 oz)	
Volume	17.7 cm ³ (1.08 in. ³)	
Power source	Rechargeable lithium ion cell	
Storage temperature	-10°C-55°C (14°F-131°F)	
Storage humidity	10%-90% (noncondensing)	
Storage pressure	70-150 kPa (10.2-21.8 psi)	
Connector strength	Exceeds EN45502-1 requirements	

The IPG has the following operating parameters.

Table 2. Operating parameters for the IPG

Parameter	Tonic Range	Tonic Steps	Burst Range*	Burst Steps*
Pulse width	50-500 µs	Alternating 12 and 13 µs (starting with 12 µs)	50-1000 µs	50 µs

Table 2. Operating parameters for the IPG

Parameter	Tonic Range	Tonic Steps	Burst Range*	Burst Steps*
Frequency	2–200 Hz	2 Hz	–	–
	200-500 Hz	10 Hz	–	–
	500-1,200 Hz	20 Hz	–	–
Burst rate frequency	–	–	10-60 Hz	10 Hz
Intraburst frequency	–	–	250-500 Hz	10 Hz
			500-1000 Hz	20 Hz
Amplitude	0-25.5 mA (max 12 V)	0.1-1.0 mA	0-12.75 mA	0.05-0.50 mA

NOTE:

- Columns with * represent operating parameters for BurstDR™ stimulation programs on IPGs capable of BurstDR stimulation mode.
- The number of stim sets in use for a tonic program governs the maximum frequency (1,200/number of stim sets).
- The maximum current depends on the impedance, frequency, and pulse width settings.

Appendix B: Regulatory Statements

This section contains regulatory statements about your product.

Statement of FCC Compliance (FCC ID:PX 2001)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.

Appendix C: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 3. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Do not re-use
	Do not re-sterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged

Table 3. Symbols and definitions

Symbol	Definition
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Implantable device
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	Sterilized using ethylene oxide

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-05
ARTEN600283816 B



Prodigy™ Patient Programmer

User's Guide



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

About This Guide.	1
Symbols and Definitions.	1
Terms Used in This Document.	3
Prescription and Safety Information.	3
Intended Use.	3
Indications for Use.	3
Contraindications.	3
MRI Safety Information.	3
Warnings.	4
Precautions.	5
Adverse Effects.	6
About Your System.	7
About Your Programmer.	8
Package Contents.	8
Your Personal Identification Card.	8
Parts of the Patient Programmer.	9
Setting Up the Patient Programmer.	10
Turning the Programmer On and Off.	10
About the Operational Display Screen.	12
Changing Programmer Settings.	12
Displaying IPG and Programmer Information.	13
Replacing the Programmer Batteries.	14
Using the Programmer.	15
Selecting a Program.	15
Starting Stimulation.	16
Stopping Stimulation.	16
Using the Stim Set Balance Feature.	18
About the Stimulation Modes.	19
Using the MRI Mode Feature.	20
Learning If You Have an MR Conditional System.	20
Preparing for an MRI Scan.	21
Setting the IPG to MRI Mode.	21
Disabling the MRI Mode.	22
Recharging Your IPG.	22
Checking the Remaining IPG Battery Capacity.	23
Caring for and Maintaining Your Programmer.	23
Troubleshooting.	24
Troubleshooting a Diagnostic Message.	24
Troubleshooting Messages for MRI Mode.	25
Saving an X Program.	26
Troubleshooting Other Potential Problems.	27
Service and Ordering Information.	29
Technical Support.	29
Ordering Information.	29
Appendix A: Regulatory Statements.	30
Statement of FCC Compliance.	30
Disposal Guidelines for Battery-Powered Devices.	30
Wireless Technology Information.	30
Appendix B: Electromagnetic Compatibility Guidelines.	31

About This Guide

This guide explains how to use the Prodigy™ patient programmer (Model 3856) with your Prodigy™ or Protégé™ neurostimulation system. If you have any questions about your system, contact Technical Support.

Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 1. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website
	Type BF Applied Part
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Keep dry; keep away from rain
	Use-by date
	Date of manufacture
	Manufacturing facility
	Temperature limit

Table 1. Symbols and definitions

Symbol	Definition
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Programmer
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
	This device is listed by the Canadian Standards Association (CSA) International as certified

Terms Used in This Document

This section contains definitions of some of the terms used in this document.

Amplitude. A measure of the strength of the stimulation.

BurstDR™ stimulation program. A program where the stimulation frequency consists of a group of pulses in rapid succession followed by a period without pulses before repeating the pulse group.

Magnetic Resonance (MR) Conditional system. An group of implanted parts that allows a patient to receive a magnetic resonance imaging (MRI) scan safely if all the requirements for the implanted parts and for scanning are met.

Program. A combination of one or more subprograms (stim sets).

Stimulation parameter. A setting that is part of a complete subprogram (stim set).

Stimulation set (stim set). A combination of stimulation parameters intended to deliver stimulation to an area of the body.

Tonic program. A program where the stimulation frequency consists of a single, repeating pulse.

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This rechargeable neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

Abbott Medical spinal cord stimulation (SCS) systems are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

You may be implanted with the parts that make up a Magnetic Resonance (MR) Conditional system, which allows you to receive a magnetic resonance imaging (MRI) scan if all the requirements for the implanted parts and for scanning are met. Contact your physician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks. Additionally, before receiving an MRI scan, inform the healthcare professional that you are implanted with a neurostimulation system. If you do not have an MR Conditional system, you cannot receive an MRI.

Do not bring your programmer into the scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is considered MR Unsafe.

Warnings

The following warnings apply to this neurostimulation system.

Diathermy therapy. You cannot have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on your body if you have any part of a neurostimulation system implanted. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. You are advised to inform your healthcare professional that you cannot be exposed to diathermy treatment.

Operation of machines, equipment, and vehicles. If you are using a therapy that generates paresthesia, you should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract you from properly operating them. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. If you do not feel paresthesia, sudden stimulation changes are less likely to occur and distract you while operating motorized vehicles, machinery, or equipment.

Lead movement. Avoid bending, twisting, stretching, or lifting objects over 2 kg (5 lb) for six to eight weeks postimplantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

Explosive or flammable gases. Do not use the patient programmer in an environment where explosive or flammable gas fumes or vapors are present, including hyperbaric chambers. Operating the device could cause it to ignite, causing severe burns, injury, or death.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Patients with diabetes. Patients with diabetes may be more likely to experience complications with surgery. Seek medical attention if you experience signs of infection (fever, redness, fluid discharge at the incision), problems with surgical site healing, headache after surgery, disorientation, chest pain, or shortness of breath.

Changes in blood glucose levels. If you have diabetes, you should monitor your blood glucose closely after surgery. Patients with diabetes may experience unstable blood glucose levels following any surgical procedure.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Cardioverter defibrillators. Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Precautions

The following precautions apply to this neurostimulation system.

Keep the programmer dry. Your programmer is not waterproof. Keep it dry to avoid damage. Do not use the programmer when engaging in activities that might cause it to get wet, such as swimming or bathing.

Handle the programmer with care. The programmer is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Battery care. Batteries can explode, leak, or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

Disconnecting the wand. Do not pull directly on the cord to disconnect the wand from the programmer. Doing so can damage the cord and make the wand inoperable. To disconnect the wand, grasp the connector at the contoured finger grips and gently pull downward.

Medical tests and procedures. Before undergoing medical tests or procedures, contact your physician to determine if the procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotriptors, therapeutic X-rays, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system.

Electromagnetic interference (EMI). Certain commercial electrical equipment (for example, arc welders, induction furnaces, resistance welders), communication equipment (for example, microwave programmers, linear power amplifiers, high-power amateur transmitters), and high-voltage power lines may generate sufficient EMI to interfere with neurostimulation system operation if approached too closely. Use caution when approaching such devices, and turn your IPG off if you feel any unusual sensations. Do not turn the IPG on again until you are away from the area of EMI.

Postural changes. Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Turn your IPG off or lower the amplitude before stretching, lifting your arms over your head, or exercising. If unpleasant sensations occur, turn off the IPG.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Use caution when approaching such a device and request assistance to bypass the device. If you must proceed through the device, turn off the stimulator and proceed with caution, ensuring to move through the detector quickly.

Control of your programmer. Keep your programmer out of the hands of children to avoid potential damage or unauthorized change in stimulation parameters.

Physician instructions. Always follow the programs and therapy instructions established for you by your physician. If you do not, the therapy may be less effective in providing pain relief.

Unauthorized programming changes. Do not make unauthorized changes to physician-established stimulation parameters. If you find yourself in an unfamiliar screen display, press the Previous Screen key.

Device components. The use of components not approved for use by Abbott Medical may result in damage to the system and increased risk of injury.

Magnet usage. The magnet provided with the system is a high-powered magnet intended for use solely with the system. Keep it away from watches, credit cards, computer disks, and other magnetically sensitive items to avoid damaging them. Always place the keeper bar on the magnet when not in use.

Mobile phones. The effect of mobile phones on implantable neurostimulation systems is unknown; patients should avoid placing mobile phones directly over the device.

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted device.

External defibrillators. The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with implanting or using this neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off your IPG immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage

- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or IPG site
- Seroma (mass or swelling) at the IPG site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect.

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control.

About Your System

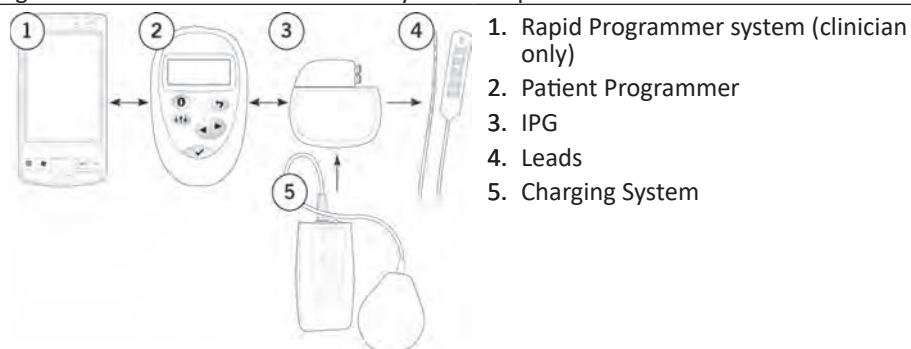
This rechargeable neurostimulation system is designed to deliver low-intensity electrical pulses to nerve structures. The neurostimulation system includes the following main components:

- Implantable pulse generator (IPG)
- Leads
- Patient programmer
- Rapid Programmer™ system
- Charging system

The IPG delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation. The Rapid Programmer system and the patient programmer allow clinicians to create and modify programs. Patients use the programmer to control these prescribed programs, and they use the charging system to recharge the IPG's battery.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction between main system components



NOTE: This manual provides instructions for using the patient programmer. For instructions about the charging system, see the charging system's user guide.

About Your Programmer

The patient programmer allows you to view, select, and control the programs, which your physician has prescribed. The programmer communicates with the IPG through a communication wand using radiofrequency (RF) signals.

Package Contents

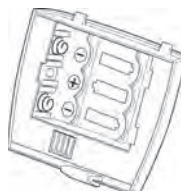
The Prodigy™ patient programmer package (Model 3856) includes the following items:



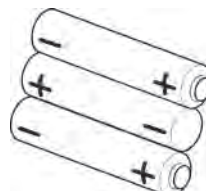
Patient programmer



Communication wand



Battery pack



AAA batteries (3)



Patient magnet



Programmer case



Patient binder

Your Personal Identification Card

A personal medical identification card is included in the package of your programmer. This card does the following things:

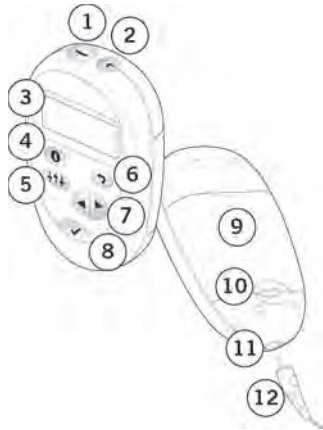
- Identifies you as having an implanted medical device
- Identifies the model numbers and locations of your implanted system parts to help determine if you can safely receive an MRI scan
- Helps you pass through security systems like those in airports
- Provides information that allows your physician to be contacted in an emergency

If you have questions about your card, contact Technical Support.

Parts of the Patient Programmer

The following image shows the different parts of the patient programmer.

Figure 2. Parts of the Patient Programmer



1. Amplitude Decrease key
2. Amplitude Increase key
3. Display screen
4. Power key
5. Balance key
6. Previous Screen key
7. Scroll keys (left and right)
8. Select key
9. Battery pack
10. Battery release latch
11. Wand port
12. Communication wand connector

The following table provides a description of the functions of the programmer keys.

Table 2. Functions of the programmer keys

Key	Description	Function
	Amplitude Decrease key	Decreases the amplitude of the program that is running.
	Amplitude Increase key	Increases the amplitude of the program that is running.
	Power key	Turns on the power to the programmer and turns off the IPG. (After one minute of inactivity, the programmer automatically shuts off.)
	Balance key	Opens a feature that allows you to adjust the amplitude of individual stim sets.
	Select key	Selects and activates menu and program changes. Confirms on-screen messages.
	Previous Screen key	Returns the display to the previous screen or cancels an action.
	Scroll keys	Scroll through programs and through mode and menu options.

Setting Up the Patient Programmer

This section provides information about getting the patient programmer ready to control programs, changing the programmer settings, and viewing system information.

NOTE: Each time before using the system, inspect the device and its accessories for damage. Avoid using a damaged device or accessory. Return it to Abbott Medical for evaluation.

Turning the Programmer On and Off

To turn the programmer on, press the Power key.

To turn the programmer off, do not press any keys for one minute. The programmer automatically turns off after one minute of inactivity.

Communicating With the IPG

To establish communication with the IPG:

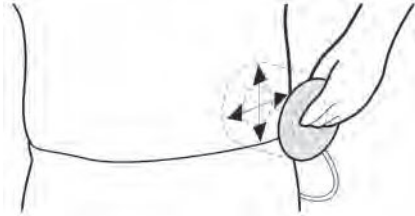
1. Ensure that the programmer is off. (It turns itself off after one minute of non-use.)
2. Plug the communication wand into the wand port on the bottom of the programmer.

Figure 3. Plug the wand into the programmer



3. Press the Power key to turn on the programmer. The Diagnostic Test screen appears.
4. Place the flat, circular end of the wand over the IPG site.

Figure 4. Place the wand over the IPG site



5. Wait for the LOCATING IPG screen to appear, and hold the wand in place. The programmer beeps while it is trying to locate the IPG.

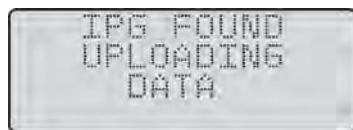
Figure 5. LOCATING IPG screen



NOTE:

- The programmer will try to locate the IPG for about 5 seconds before a screen appears to retry communication. If the programmer does not establish communication, move the wand slowly over the IPG site in small circular movements until you achieve communication.
 - After you have established communication with the IPG, keep the wand in place. If you move the wand from over the IPG site, you may lose communication with the IPG.
6. Check the programmer's screen to verify that the programmer has established communication with the IPG. When the programmer finds the IPG, the beeping stops and the following screen appears.

Figure 6. IPG FOUND screen

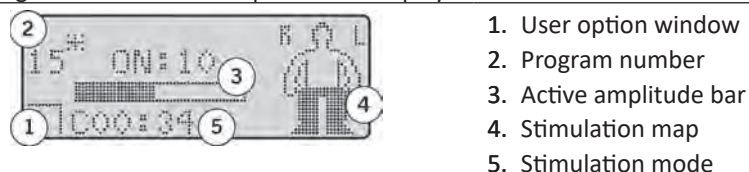


The next screen that appears shows information about the IPG, and then the Operational Display screen appears. See "About the Operational Display Screen" (page 12) for more information.

About the Operational Display Screen

The Operational Display screen is the home screen of the patient programmer. From this screen, you can view and control programs in the standard operating mode. The following image shows the main parts of the Operational Display screen.

Figure 7. Parts of the Operational Display screen



User option window. Shows an icon that allows you to select different programmer modes. During standard operating mode, this area of the screen is blank. To allow you to enter other modes, it displays one of the following icons:

- The Program icon (P) indicates program selection mode.
- The Menu icon (M) indicates the menu mode.
- The Battery icon (B) indicates IPG battery capacity mode.
- The MRI Mode icon (MR) indicates MRI mode (available only with models that support MRI mode).

Program number. Shows the current program number that is downloaded to the IPG. If the program number shows a star (*) beside it, it means that the program is a BurstDR™ stimulation program.

Active amplitude bar. Shows the active amplitude level when the IPG is on. When the IPG is on, the word “ON” is displayed above the graphic with the numeric amplitude level. When the IPG is off, the word “OFF” is displayed above the graphic.

Stimulation map. Shows shaded areas, which indicate where a program is intended to provide stimulation. R and L designate right and left sides of the body.

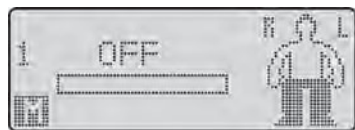
Stimulation mode. Provides information about a program’s stimulation mode. For more information, see “About the Stimulation Modes” (page 19).

Changing Programmer Settings

To change the programmer display and volume settings from the Menu screen:

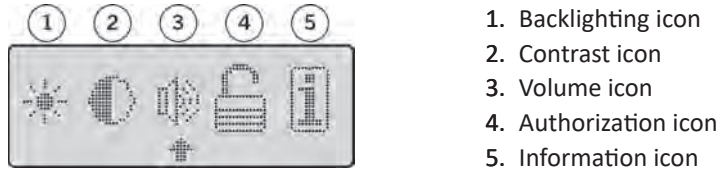
1. From the Operational Display screen, press either Scroll key until the Menu icon (M) appears in the user option window.

Figure 8. Scroll to the Menu icon (M)



2. Press the Select key. The Menu screen appears.

Figure 9. The Menu screen



1. Backlighting icon
2. Contrast icon
3. Volume icon
4. Authorization icon
5. Information icon

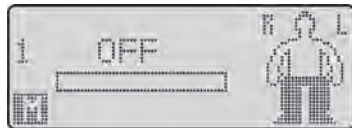
3. Press either Scroll key until the arrow is under the icon of the setting that you want to change: backlighting, contrast, or volume.
4. Press the Select key. The programmer displays the screen of the setting you selected.
5. Press the Scroll keys to adjust the selected setting.
6. To save your changes, press the Select key. The Operational Display screen appears.

Displaying IPG and Programmer Information

To view information about the IPG and the programmer from the Menu screen:

1. From the Operational Display screen, press either Scroll key until the Menu icon (M) appears in the user option window.

Figure 10. Scroll to the Menu icon (M)



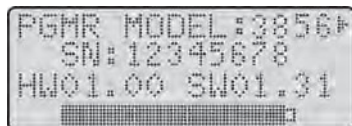
2. Press the Select key. The Menu screen appears.
3. Press either Scroll key until the arrow is under the Information icon.

Figure 11. Select the information icon



4. Press the Select key. A screen appears showing information about the programmer and its remaining battery power.

Figure 12. Programmer information screen



5. To view the screen showing IPG information, press the Scroll key on the right. To view the screen showing the programmer information again, press the Scroll key on the left.
6. When you are finished viewing the information screens, press the Select key.

Replacing the Programmer Batteries

The programmer is powered by three disposable AAA alkaline batteries contained in a battery pack. When the battery power is low, an alarm will sound and the following screen appears. If this occurs, you should replace your AAA batteries.

Figure 13. Programmer Battery Low screen

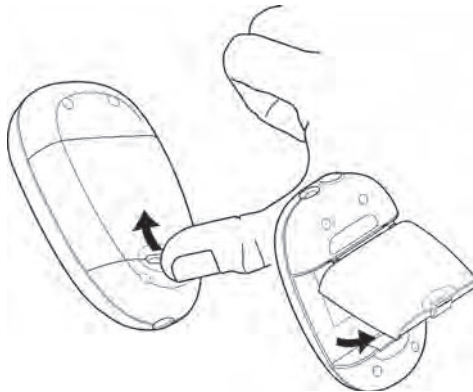


NOTE: Do not dispose of batteries as general waste. Follow local regulations about disposing of batteries safely.

To replace the batteries in the programmer:

1. Ensure the programmer power is off.
2. Push and hold the battery release latch on the bottom of the battery pack, and lift the battery pack from the battery compartment.

Figure 14. Remove the battery pack from the programmer



3. Remove the AAA batteries from the battery pack, and insert new AAA batteries into the battery pack, ensuring that the + and - signs on the batteries line up with the signs in the battery pack.
4. Place the battery pack into the battery compartment.

Using the Programmer

This section provides information for using the programmer to select and control programs. Before you start these instructions, you need to establish communication with the IPG. See “Communicating With the IPG” (page 10).

Selecting a Program

If more than one program is saved on the programmer, you can use the programmer to select the desired program and load it on the IPG.

NOTE:

- If the Program icon (P) does not appear, the programmer does not have any more programs to select.
- The amplitude keys are still active. If you press one during this procedure, the stimulation will change accordingly and the Operational Display screen will appear.

To select a program:

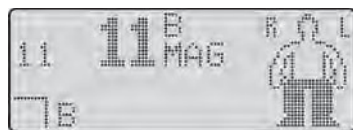
1. From the Operational Display screen, press either Scroll key until the Program icon (P) appears in the user option window. The number for the current program appears on the left of the screen.

Figure 15. Scroll to the Program icon (P)



2. Press the Select key. The Program Selection screen appears showing the currently selected program in the center of the screen.

Figure 16. Access the Program Selection screen



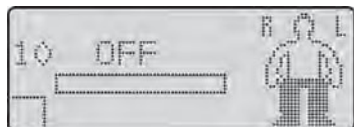
3. Press either Scroll key until the program you want appears in the center of the screen.

Figure 17. Scroll to other programs



4. Press the Select key. Stimulation stops, and the Operational Display screen appears showing the number of the newly selected program on the left side of the screen.

Figure 18. Operational Display screen showing a new program



Starting Stimulation

To start stimulation:

1. From the Operational Display screen, press or press and hold the Amplitude Increase key. The amplitude level shown on the active amplitude bar increases.
2. Press the Amplitude Increase key to increase stimulation or the Amplitude Decrease key to decrease stimulation to a comfortable level.

Figure 19. Active amplitude bar on the Operational Display screen



The amplitude for each program is divided incrementally into 26 levels. When you start stimulation for a tonic program, the amplitude slowly increases to the prescribed perception level for that program (level 6). When you start stimulation for a BurstDR™ stimulation program, the amplitude slowly increases to a prescribed target level. From here, you can increase stimulation up to level 26 or decrease stimulation to 1.

Stopping Stimulation

You can turn off the IPG and stop stimulation by using either the programmer or the magnet. With the magnet, you can stop stimulation immediately.

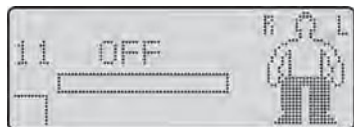
Stopping Stimulation Using the Programmer

To stop stimulation using the programmer, perform either of the following actions from the Operational Display screen:

- Press the Power key.
- Press or press and hold the Amplitude Decrease key until the level shown on the active amplitude bar reaches zero and OFF is displayed.

If you perform either action, the programmer turns off the IPG and stimulation stops. You should see the following screen.

Figure 20. Operational Display screen showing stimulation off



Stopping Stimulation Using the Magnet

The system comes with a magnet that can turn off the IPG or turn it on and off. How the IPG functions depends on the program settings. A program can be set with one of the following magnet modes:

- **Magnet off.** The magnet can turn off the IPG but cannot turn it on. In magnet off mode, if you use the magnet to turn off the IPG, you must use the programmer to turn it back on.
- **Magnet on/off.** The magnet can turn the IPG on or off. When selected, magnet on/off mode appears as MAG on the Program Selection screen.

Figure 21. Program in magnet on/off mode (MAG)



NOTE:

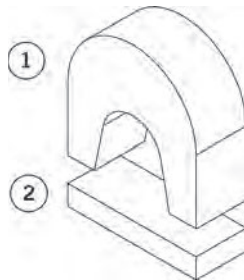
- In magnet on/off mode, if you hold the magnet over the IPG site for about 30 seconds, the IPG will turn off and you must use the programmer to turn it back on.
- The magnet is powerful and intended for use solely with IPGs. When the magnet is not in use, position the keeper bar on it properly.

CAUTION: Do not use the magnet provided with the system around magnetically sensitive items to avoid damaging them.

To stop stimulation using the magnet:

1. Take the keeper bar off the magnet.

Figure 22. Take the keeper bar off the magnet



1. Magnet
2. Keeper bar

2. Place the magnet directly over the IPG.
3. Hold the magnet in place for two seconds.
4. Remove the magnet, replace the keeper bar, and store the magnet.
5. If desired, confirm that stimulation is stopped by turning on the programmer and establishing communication with the IPG. In the Operational Display screen that appears, OFF is displayed above the active amplitude bar.

Using the Stim Set Balance Feature

Your physician may have prescribed a stimulation program that contains up to eight subprograms, called stim sets, that are intended to deliver stimulation to different areas of your body. Programs with more than one stim set are called MultiStim™ programs. Sometimes you may need more or less stimulation than your prescribed settings allow. The Stim Set Balance feature enables you to bypass your programmed settings and adjust each stim set individually.

NOTE: You may readjust stim sets as often as you like. When you restart your system or load a new program, all stim set values revert to the prescribed settings.

To use the Stim Set Balance feature:

1. Press the Amplitude Increase key to start stimulation.
2. Press the Balance key. The following screen appears.

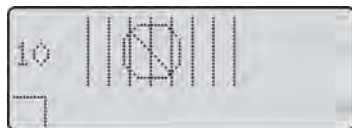
Figure 23. Stim Set Balance screen



NOTE:

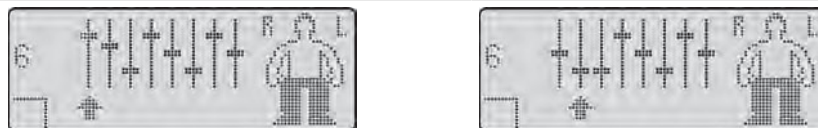
- The previous figure shows adjustment bars for eight stim sets. If a program has only one stim set, only one adjustment bar will display.
- If the amplitude is at zero, the following screen will display. To use the Stim Set Balance feature for a stimulation program, press the Amplitude Increase key to increase amplitude; then press the Balance key.

Figure 24. Amplitude at zero screen



3. Press one of the Scroll keys to move the arrow under the stim set that you want to adjust.
4. Adjust the amplitude of the indicated stim set by pressing the Amplitude Increase key or the Amplitude Decrease key.

Figure 25. Upward adjustment of selected stim set (left) and downward adjustment of selected stim set (right)



5. Repeat steps 3 and 4 for other stim sets, if desired.

- Press the Select key to activate the changes.

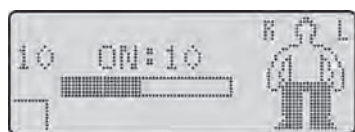
About the Stimulation Modes

Programs on your system can be in any of three stimulation modes: continuous, cycle, or bolus.

Continuous Mode

Continuous mode provides continuous stimulation to the patient. When the system is turned on, it delivers therapy until it is manually turned off. Continuous mode is the default mode and does not display a mode indicator on the Operational Display screen.

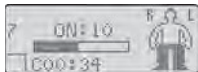
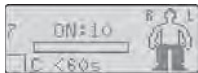
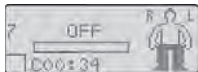
Figure 26. The Operational Display screen in continuous mode



Cycle Mode

Cycle mode allows the physician to set intervals for therapy that cycle between on and off. The cycling of the therapy enables battery conservation and stimulation refinement. When a program is set to cycle mode, the letter C is displayed on the Operational Display screen with information about the “on” or “off” time remaining.

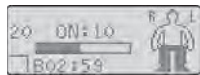
Table 3. Descriptions of the Operational Display screens in cycle mode

Operational Display Screen	Description
	Stimulation is cycled on and more than a minute of stimulation time remains (displayed in hours and minutes).
	Stimulation is cycled on with less than a minute remaining.
	Stimulation is cycled off and more than a minute remains in the off phase (displayed in hours and minutes).
	Stimulation is cycled off with less than a minute remaining in the off phase.

Bolus Mode

Bolus mode allows the physician to set a time period for therapy to be on and a time period for therapy to be off. After a stimulation period expires, a lockout phase begins during which no stimulation can be activated. After the lockout, the patient can manually restart stimulation for the set time period. When a program is set to bolus mode, the letter B is displayed on the Operational Display screen with information about the “on” or “off” time remaining.

Table 4. Description of the Operational Display screens in bolus mode

Operational Display Screen	Description
	Stimulation is on for the time displayed (in hours and minutes or in minutes and seconds).
	Stimulation is in a lockout phase, where stimulation is off and cannot be restarted until the displayed time expires (in hours and minutes or in minutes and seconds).
	Stimulation is off, the lockout phase is finished, and the bolus program can be restarted.
	NOTE: When the bolus lockout time expires, the patient must use the programmer to restart stimulation.

Using the MRI Mode Feature

You may be implanted with the parts that make up a Magnetic Resonance (MR) Conditional system, which allows you to receive an MRI scan if all the requirements for the implanted parts and for scanning are met. This section provides information and instructions about what you need to do before and after an MRI scan.

NOTE:

- Contact your physician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks.
- The features in this section are available only with models that support MRI mode. Before you follow the instructions in this section, you need to establish communication with your IPG. See “Communicating With the IPG” (page 10) for these steps.

Learning If You Have an MR Conditional System

When your system is implanted, you receive an identification card that lists the model numbers and locations of the implanted parts of your system. Ensure you have your identification card to share with your physician or MRI clinician to help them find out if you have the components of an MR Conditional system.

Your patient programmer also provides information about whether your IPG is part of an MR Conditional system. To see if you have an IPG that is approved as a part of an MR Conditional system:

1. View the IPG information screen. See “Displaying IPG and Programmer Information” (page 13) for instructions.
2. Look for the MR icon in the upper right corner of the IPG information screen (see the following image). If you do not see the MR icon, then you do not have an MR Conditional system.

Figure 27. MR icon on the IPG information screen



Preparing for an MRI Scan

If you do have the implanted parts of an MR Conditional system and you will receive an MRI scan, follow these guidelines:

- Fully charge your IPG before you arrive for your procedure to be able to set your IPG to MRI mode. For instructions on charging, see the user's guide.
- Set your IPG to MRI mode within a day before you arrive for your procedure. See "Setting the IPG to MRI Mode" (page 21) for instructions.
- Bring your identification card, patient programmer, and charger to the procedure.

CAUTION: Do not bring your programmer or charger into the scanner magnet room. Although you may be implanted with the parts of an MR Conditional system, your programmer and charger can still be affected by the MRI magnet, may present a projectile hazard, and are MR Unsafe.

Setting the IPG to MRI Mode

To set your IPG into MRI mode:

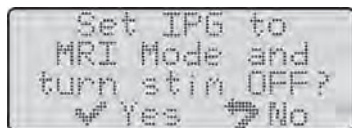
1. From the Operational Display screen, press either one of the Scroll keys until the MRI mode icon (MR) appears in the user option window.

Figure 28. Scroll to the MRI mode icon



2. Press the Select key on the programmer. The following screen appears.

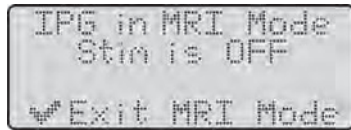
Figure 29. Enter MRI mode screen



3. Press the Select key. The programmer stops stimulation, checks the impedance on the lead electrodes, and checks the remaining battery capacity of the IPG. If the checks are successful, the following screen appears indicating that the IPG is in MRI mode.

NOTE: If you see a warning screen instead of the following MRI mode screen, refer to "Troubleshooting" (page 24) for guidelines.

Figure 30. MRI mode screen

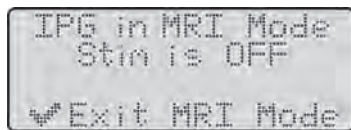


Disabling the MRI Mode

After your procedure, you need to disable the MRI mode to restart stimulation. To disable the MRI mode:

1. Establish communication with the IPG. You should see the following screen indicating that the IPG is in MRI mode.

Figure 31. MRI mode screen



2. Press the Select key. The following screen appears.

Figure 32. Exit MRI mode screen



3. Press the Select key. The programmer disables MRI mode, and a screen appears similar to the following Operational Display screen showing that stimulation is off.

Figure 33. Operational Display screen showing stimulation off



4. To start stimulation, press the Amplitude Increase key.

Recharging Your IPG

You may recharge your IPG on any schedule that is convenient for you and that maintains effective therapy. However, a daily recharge routine can reduce the time it takes to recharge the battery and can extend the life of your IPG.

For more information about when and how to recharge your IPG battery, see the user's guide for your charging system.

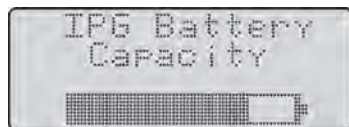
Checking the Remaining IPG Battery Capacity

To check the remaining battery capacity of the IPG:

NOTE: To get an accurate measurement, wait two minutes after charging the IPG before checking the IPG battery capacity.

1. Establish communication with the IPG. See “Communicating With the IPG” (page 10).
2. From the Operational Display screen, press a Scroll key until the Battery icon (B) appears in the user option window.
3. Press the Select key. The IPG Battery Capacity screen appears. The dark portion of the battery icon shows the amount of energy remaining in the IPG battery.

Figure 34. IPG Battery Capacity screen



Caring for and Maintaining Your Programmer

To keep your programmer running its best:

- Handle the programmer with care. Avoid actions that may damage your programmer, such as dropping it on the floor.
- Keep your programmer and wand dry and avoid activities that might cause them to get wet.
- Clean your programmer and wand as needed by wiping the outer surface using a damp cloth and a small amount of mild soap. Do not submerge the programmer or wand in liquids or use a cloth that is soaked. Do not use alcohol, cleaning solutions, or solvents to clean the programmer or wand.
- To disconnect the wand from the programmer, do not pull on the cable. Gently pull from the connector that plugs into the programmer port.
- Do not expose the programmer to prolonged, direct sunlight.
- Use your programmer within a safe range of storage and operating conditions as shown in the following table.
- The expected service life of your programmer is 5 years. To order replacement parts for your system, contact Technical Support.

Table 5. Storage and operating conditions

Temperature	Storage	-10°C-55°C (14°F-131°F)
	Operating	10°C-40°C (50°F-104°F)
Relative humidity (noncondensing)	Storage	10%-90%
	Operating	30%-75%

Table 5. Storage and operating conditions

Pressure	Storage	70-150 kPa (10.2-21.8 psi)
	Operating	70-106 kPa (10.2-15.4 psi)

Troubleshooting

This section provides troubleshooting procedures to help you identify and solve problems that may occur.

NOTE: If problems occur other than those described in this section, contact Technical Support.

Troubleshooting a Diagnostic Message

The programmer contains an automatic diagnostic program that continuously checks the system during operation. If a malfunction or abnormal condition is detected related to the programmer, IPG, or wand, a diagnostic message will appear. The following table describes how to troubleshoot the common diagnostic messages.

Table 6. Troubleshooting for Diagnostic Messages

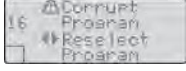
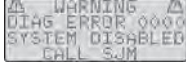
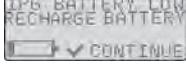
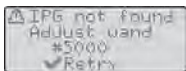
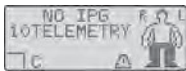
Programmer Message	Screen	Solution
Connect wand		Ensure the wand is properly connected to the programmer.
Comm to IPG interrupted (off)		Select another program.
Comm to IPG interrupted (reselect program)		Select the program again, or select another program.
Corrupt program (off)		Have your physician edit the current program.
Corrupt program (reselect program)		Select another program or have your physician edit the current program.
Diagnostic error		Call Technical Support.
IPG battery low (recharge battery)		Stimulation continues, but the IPG battery is low. Press the Select key and recharge your IPG battery at your earliest convenience (see the charging system user's guide).

Table 6. Troubleshooting for Diagnostic Messages

Programmer Message	Screen	Solution
IPG battery low (stim off)		Stimulation stops to preserve the low IPG battery. Press the Select key and recharge your IPG battery (see the charging system user's guide).
IPG comm error		Reposition the wand over the IPG and press the Select key.
IPG not found		Reposition the wand over the IPG and press the Select key.
No telemetry		IPG location was interrupted by pressing the Select key. No communication was established in this mode. Let the programmer turn off and recommunicate with the IPG.
Programmer battery low		Replace the batteries in the programmer.
Programmer authorized for S/N nnnnnnn		The programmer is authorized for a different IPG. Contact Technical Support.
System error		Contact Technical Support.
Wrong IPG type		Contact Technical Support.

Troubleshooting Messages for MRI Mode

The following table shows programmer screens that you may see while setting MRI mode before a scan. If you see any of these screens, follow the guidelines to help troubleshoot the issue.

Table 7. Troubleshooting screens for MRI mode

Screen	Description	Guideline
	The battery capacity of the IPG is too low.	Press the Previous Screen key, and fully recharge the IPG battery. See the charging system user's guide.

Table 7. Troubleshooting screens for MRI mode

Screen	Description	Guideline
	The check of the lead impedance failed, likely because no lead is inserted in port 1 of the IPG header.	Contact your physician to help determine if it is safe to enter MRI mode. Use your identification card as a reference for information about your implanted parts.
	The check of the lead impedance failed, likely because no lead is inserted in port 2 of the IPG header.	Contact your physician to help determine if it is safe to enter MRI mode. Use your identification card as a reference for information about your implanted parts.
	The check of the lead impedance failed, likely because one or both ports of the IPG header contain a 4-electrode lead, which is not MR Conditional. (The actual screen shows a number in place of the "X," ranging from 1 to 5.)	Contact Technical Support.
	The check of the lead impedance failed for another reason unrelated to the lead configuration.	Contact Technical Support.
	The check of the lead impedance did not complete.	Press the Previous Screen key, and try entering MRI mode again.
	The system check failed because of a problem with the IPG.	Contact Technical Support.

Saving an X Program

Your programmer is authorized to work specifically with your IPG. If your programmer is not available, your physician can use another programmer to adjust the stimulation parameters in your IPG. When this occurs, the Operational Display screen may show an X instead of a program number the next time you use your programmer to communicate with your IPG.

Figure 35. X program icon on the Operational Display screen



If this “X program” is effective, have your physician or representative save the program on your programmer. If you change programs before the X program is saved, then you will lose the X program.

Troubleshooting Other Potential Problems

Refer to the following table for possible causes and solutions to problems you may have.

Table 8. Possible causes and solutions to potential problems

Problem	Possible Cause	Possible Solution
Uncomfortable stimulation	Change in body position, or unintended programming change.	Decrease the amplitude. If you are unable to correct the problem, turn off the IPG and contact your physician.
No stimulation	Stimulation is off.	Start stimulation.
	Amplitude is set too low.	Increase the amplitude until you achieve comfortable stimulation.
	IPG is in the “off” phase in the cycle or bolus mode.	Check to see if the IPG is in the off phase in the cycle or bolus mode. Wait until the phase is completed.
	IPG is in MRI mode.	Turn off MRI mode.
	IPG battery needs recharging.	Recharge your IPG battery. (See the charging system’s user’s guide.)
	Unintended programming change.	Contact your physician.
	Program load error.	Try to select another program. If this does not work, contact your physician.

Table 8. Possible causes and solutions to potential problems

Problem	Possible Cause	Possible Solution
	Implanted components are not functioning.	Contact Technical Support.
Intermittent stimulation	Sensitive to body position.	Adjust the amplitude to a comfortable level. If you are unable to adjust stimulation satisfactorily, contact your physician.
	Implanted components are not functioning.	Contact Technical Support.
Ineffective stimulation	Change in body position.	Adjust the amplitude to a comfortable level. If you are unable to adjust stimulation satisfactorily, contact your physician.
	Programmer is damaged.	Contact Technical Support.
Changes in stimulation coverage	Change in body position.	Adjust the amplitude to a comfortable level. If you are unable to adjust stimulation satisfactorily, contact your physician.
No control of the IPG	Wand is positioned incorrectly.	Reposition the wand over the IPG.
	Wand is not inserted properly.	Reinsert the wand.
	IPG is recharging.	Remove the charger antenna from over the IPG site, and use the programmer to try to communicate with IPG.
	Electrical interference is interrupting communication between the programmer and the IPG.	Move to another area away from electrical equipment that can cause electrical interference, and try again.

Table 8. Possible causes and solutions to potential problems

Problem	Possible Cause	Possible Solution
No programmer power or display	Wand is damaged.	Contact Technical Support.
	Programmer is damaged.	Contact Technical Support.
	Programmer has not been used in over a minute and has automatically turned off.	Press the Power key.
	Batteries are depleted.	Replace the programmer batteries.
	Battery pack or batteries are not inserted properly.	Reinsert the battery pack or batteries.
	Programmer is damaged.	Contact Technical Support.

Service and Ordering Information

This section provides information for contacting Technical Support and for ordering replacement parts and accessories.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Ordering Information

To order parts, contact Technical Support. Refer to the following list for order numbers.

Table 9. Ordering information for the patient programmer

Model	Description
1210	Patient magnet
1232	Communication wand
1254	Battery pack
1272	Genesis programmer case*
3856	Prodigy patient programmer

* This accessory can be used with the Prodigy patient programmer (Model 3856)

Appendix A: Regulatory Statements

Please note the following regulatory statements related to the patient programmer.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.

Wireless Technology Information

The following table summarizes technical details of the wireless technology of the patient programmer.

Table 10. Wireless technology information for patient programmer

Operating frequency (inductively coupled device)	87.5 kHz $\pm$ 2.5 kHz

Table 10. Wireless technology information for patient programmer

Field strength (inductively coupled device)	32 dBμA/m at 3 m*
Effective range	0.5–2.5 cm
Quality of service (QoS)	QoS is ensured by a communication link between the implant and the patient programmer, which is assessed during initial linking of the devices and monitored throughout the system's use. If the devices cannot establish a sufficient link or if either device receives invalid data, the patient programmer will display an error message.
Wireless security measures	The wireless data that is sent between the implanted generator and the patient programmer is through short-range inductive coupling, which does not propagate through free space. The patient programmer uses a proprietary data format that is incompatible with other systems.

*H-field measurement per ETSI EN 302 195 (radio requirements for ultra-low-power active medical implants and peripherals)

Appendix B: Electromagnetic Compatibility Guidelines

The Prodigy™ patient programmer, hereafter the device, is medical equipment and should be used with the following guidance:

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device has no essential performance, as defined by IEC 60601-1/AMD1:2012 (Edition 3.1). Performance of the device was maintained during electromagnetic disturbance testing. The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION: The device complies with the limits for medical devices contained in IEC 60601-1-2:2014-04 and CISPR11:2015 (BS EN 55011:2016). However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.

CAUTION: To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by Abbott Medical with this system. Do not use Abbott Medical components with devices or systems that are not approved by Abbott Medical.

Table 11. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

NOTE: The RF output frequency of the device is 87.5 kHz. The field strength is 32 dBμA/m at 3 m (inductively coupled device).

Table 12. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	No guidance for battery-powered devices.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	No guidance for battery-powered devices.
Voltage dips, short interruptions IEC 61000-4-11	<5% U _T 40% U _T 70% U _T	Not applicable	No guidance for battery-powered 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM/Radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	6 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters)

Table 12. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			and the device as recommended below, according to the maximum output power of the communications equipment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d} \sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).

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

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

Table 13. Guidance and Manufacturer's Declaration – Proximity Fields

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance $d = 0.3 \text{ m}$
	450 MHz: 28 V/m @ FM modulation $\pm 5 \text{ kHz}$ tolerance	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

abbott.com

2023-04
ARTEN600283819 A



**Prodigy™ Neurostimulation System Programming and
Reference**
Models 3855, 3856

Clinician's System Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Indications for Use.	1
Contraindications.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	2
Adverse Effects.	4
Patient Selection.	4
Instructions to Patients.	5
Safety and Effectiveness Studies.	5
System Overview.	5
Product Description.	5
Package Contents.	6
Compatibility of Patient Programmer With IPGs.	6
Parts of the Patient Programmer.	6
Setting Up the Patient Programmer.	7
Turning the Programmer On and Off.	7
About the Operational Display Screen.	9
Changing Programmer Settings.	9
Authorizing the Programmer.	10
Displaying IPG and Programmer Information.	12
Replacing the Programmer Batteries.	13
Using the Programmer.	14
Selecting a Program.	14
Starting Stimulation.	15
Stopping Stimulation.	15
Checking the Remaining IPG Battery Capacity.	17
Browsing Programs.	17
Creating and Editing Programs.	18
Accessing Programming Mode.	18
Programming BurstDR™ Stimulation Programs.	19
Creating a New Program.	20
Working With Stim Sets.	20
Setting Frequency.	22
Setting Pulse Width.	23
Setting Electrode Polarities.	23
Setting Amplitude Levels.	24
Setting the Stimulation Mode.	26
Measuring Impedance.	29
Saving a Program.	29
Saving an X Program.	30
Deleting Programs.	31
Deleting All Programs.	31
Deleting a Single Program.	31
Maintaining the System.	31
Maintaining and Cleaning the Programmer.	31
Maintaining the IPG Battery.	32
Troubleshooting.	32
Troubleshooting Procedure.	32
Troubleshooting a Diagnostic Message.	33
IPG Heating During Charging.	34
Troubleshooting Chart for Intraoperative Testing.	34
Troubleshooting Chart for Postoperative Programming.	35
Technical Support.	37
Appendix A: Product Specifications.	37

Patient Programmer Specifications.	37
Default Settings for Programs.	38
Appendix B: Regulatory Statements.	38
Statement of FCC Compliance (FCC ID:PX 2001).	38
Disposal Guidelines for Battery-Powered Devices.	38
Wireless Technology Information.	39
Appendix C: Symbols and Definitions.	39
Appendix D: Electromagnetic Compatibility Guidelines.	41

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This rechargeable neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

Abbott Medical spinal cord stimulation (SCS) systems are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to this neurostimulation system.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may forcefully dislodge implanted components, damage the device electronics, and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation system. Contact between an active electrode and an implanted IPG, lead, or extension can cause severe injury to the patient. If use of electrocautery is necessary, first turn off the neurostimulation system.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac

system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Explosive or flammable gases. Do not use the patient programmer in an environment where explosive or flammable gas fumes or vapors are present, including hyperbaric chambers. The operation of the patient programmer could cause them to ignite, causing severe burns, injury, or death.

Operation of machines, equipment, and vehicles. Patients using therapy that generates paresthesia should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract them from properly operating it. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. For patients who do not feel paresthesia, sudden stimulation changes are less likely to occur and distract them while operating motorized vehicles, machinery, or equipment.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Case damage. Do not handle the IPG if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

Component disposal. Return all explanted IPGs to Abbott Medical for safe disposal. IPGs contain lithium ion batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

Product materials. Neurostimulation systems have materials that come in contact or may come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.

Precautions

The following precautions apply to this neurostimulation system.

General Precautions

Physician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of two systems. If two systems are implanted, ensure that at least 20 cm (8 in.) separates the implanted IPGs to minimize the possibility of interference during programming.

Implantation of multiple leads. If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads can possibly create a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.

Implant heating. While recharging an IPG, patients may perceive an increase in temperature. In patients who have areas of increased sensitivity to heat, consider placing the implant where the patient has normal sensation.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or may render the patient incapable of controlling the patient programmer. If unpleasant sensations occur, the device should be turned off immediately.

Postural changes. Changes in posture or abrupt movements may result in a decrease or increase in the perceived level of stimulation. Perception of higher levels of stimulation has been described by some patients as uncomfortable, painful, or jolting. Patients should be advised to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting their arms over their heads, or exercising. If unpleasant sensations occur, the IPG should be turned off immediately.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks after implantation of a neurostimulation system. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

Stimulation parameters. Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs unless ordered to do so by a physician.

Mobile phones. The effect of mobile phones on neurostimulation systems is unknown; patients should avoid placing mobile phones directly over the system.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use the system if the use-by date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Prior to connection, exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

External defibrillators. The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead.

Home and Occupational Environments

Electromagnetic interference (EMI). Certain commercial electrical equipment (for example, arc welders, induction furnaces, and resistance welders), communication equipment (for example, microwave transmitters, linear power amplifiers, and high power amateur transmitters), and high voltage power lines may generate sufficient EMI to interfere with the operation of the neurostimulation system if approached too closely.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with implanting or using this neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off your IPG immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or IPG site
- Seroma (mass or swelling) at the IPG site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect.

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in SCS clinical studies, refer to the clinical summaries manual for SCS systems.

Patient Selection

Before a system is implanted, patients should have undergone a successful trial screening period and should have demonstrated a willingness to participate in the treatment protocol. For best results, patients should be fully informed about the therapy risks and benefits, implantation procedure, follow-up requirements, and self-care responsibilities.

Neurostimulation with this device is appropriate for patients who

- Meet the indications for use

- Are able to operate the device
- Are suitable candidates for surgery and free of active general infections

Instructions to Patients

The patient should be given simple and practical instructions regarding the operation and care of the neurostimulation system. Also, the patient should be given guidelines about how posture and activity can affect stimulation as well as under what circumstances the physician should be contacted regarding device problems.

Safety and Effectiveness Studies

For information that supports the clinical use of this neurostimulation system, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems (available online at medical.abbott/manuals). This neurostimulation system is similar in technology and intended use to the systems reported in the literature and clinical studies. Therefore, the literature and clinical studies represent the safety and effectiveness of this neurostimulation system.

System Overview

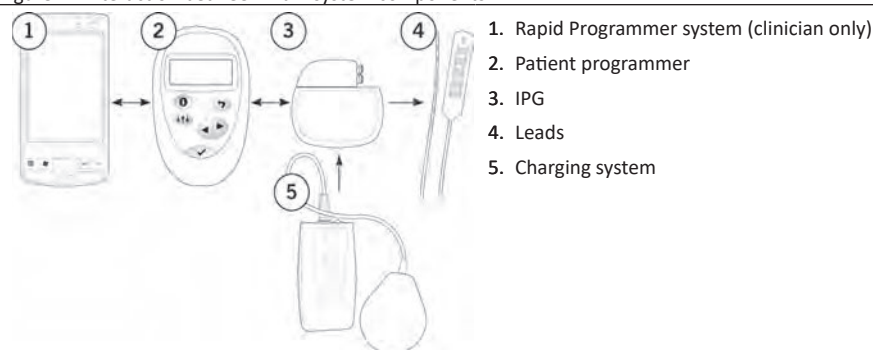
This rechargeable neurostimulation system is designed to deliver low-intensity electrical pulses to nerve structures. The neurostimulation system includes the following main components:

- Implantable pulse generator (IPG)
- Leads
- Patient programmer
- Rapid Programmer™ system
- Charging system

The IPG delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation. The Rapid Programmer system and the patient programmer allow clinicians to create and modify programs for a patient. Patients use the programmer to control these prescribed programs, and they use the charging system to recharge the IPG's battery.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction between main system components



NOTE: This manual provides instructions for using the patient programmer. For instructions about implantable components, such as leads and the IPG, see the applicable clinician's manual for that component.

Product Description

The patient programmer allows clinicians to create and modify programming parameters for the IPG. Powered by three disposable AAA batteries, the programmer communicates with the IPG using radiofrequency (RF)

signals from a communication wand. The patient programmer also allows patients to view, select, and control their prescribed programs, which are stored on the programmer.

Package Contents

In addition to the product documentation, the Prodigy™ patient programmer package (Model 3855 or 3856) contains the following items:

- 1 Prodigy patient programmer (Model 3855 or 3856)
- 3 AAA alkaline batteries
- 1 battery pack (Model 1254)
- 1 programmer case (Model 1272)
- 1 patient magnet (Model 1210)
- 1 communication wand (Model 1232)

NOTE: The patient programmer is supplied nonsterile.

Compatibility of Patient Programmer With IPGs

The following table shows the IPG models with which the different model patient programmers can program and control.

Table 1. Compatibility of Prodigy™ patient programmers with IPGs

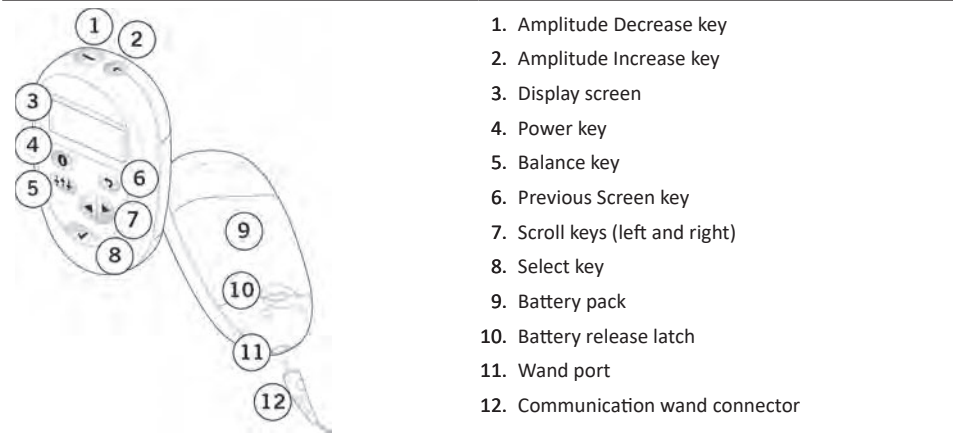
Patient Programmer Model	IPG Model
3855	3789* Prot g IPG
	3799 Prodigy IPG
3856	3771* Prot g MRI IPG
	3772 Prodigy MRI IPG
	3789* Prot g IPG
	3799 Prodigy IPG

*The patient programmer is compatible with this model IPG if BurstDR™ stimulation mode has been enabled

Parts of the Patient Programmer

The following image shows the different parts of the patient programmer.

Figure 2. Parts of the Patient Programmer



The following table provides a description of the functions of the programmer keys.

Table 2. Functions of the programmer keys

Key	Description	Function
	Amplitude Decrease key	Decreases the amplitude of the program that is running. In programming mode, it performs other special functions.
	Amplitude Increase key	Increases the amplitude of the program that is running. In programming mode, it performs other special functions.
	Power key	Turns on the power to the programmer and turns off the IPG. After one minute of inactivity, the programmer automatically shuts off.
	Balance key	Enables individual adjustments of amplitude to selected stim sets within a MultiStim™ stimulation program.
	Select key	Selects and activates menu and program changes. Confirms on-screen messages.
	Previous Screen key	Returns the display to the previous screen or cancels an action.
	Scroll keys	Scroll through programs and through mode and menu options.

Setting Up the Patient Programmer

This section provides information about the patient programmer and has definitions, overviews of screens, stimulation modes, and authorization modes. For more information about the programmer, see the user's guide for the patient programmer.

NOTE: Each time before using the system, inspect the device and its accessories for damage. Avoid using a damaged device or accessory. Return it to Abbott Medical for evaluation.

Turning the Programmer On and Off

To turn the programmer on, press the Power key.

To turn the programmer off, do not press any keys for one minute. The programmer automatically turns off after one minute of inactivity.

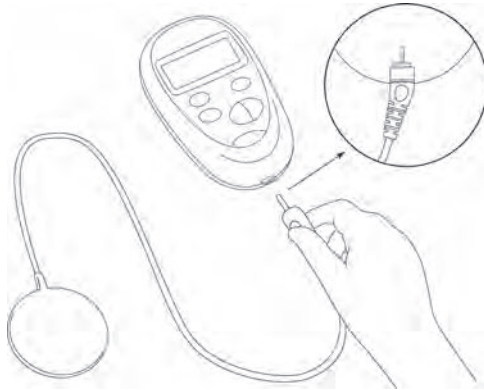
NOTE: The programmer will not turn off if it is in programming mode. Ensure you are not in programming mode to turn off the programmer.

Communicating With the IPG

To establish communication with the IPG:

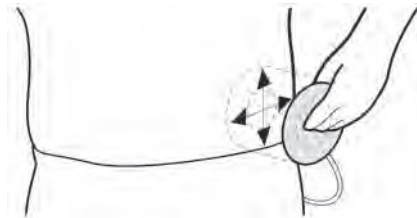
1. Ensure that the programmer is off. (It turns itself off after one minute of non-use.)
2. Plug the communication wand into the wand port on the bottom of the programmer.

Figure 3. Plug the wand into the programmer



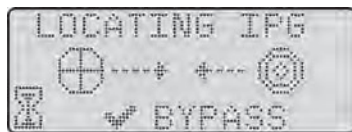
3. Press the Power key to turn on the programmer. The Diagnostic Test screen appears.
4. Place the flat, circular end of the wand over the IPG site.

Figure 4. Place the wand over the IPG site



5. Wait for the LOCATING IPG screen to appear, and hold the wand in place. The programmer beeps while it is trying to locate the IPG.

Figure 5. LOCATING IPG screen



NOTE:

- The programmer will try to locate the IPG for about 5 seconds before a screen appears to retry communication. If the programmer does not establish communication, move the wand slowly over the IPG site in small circular movements until you achieve communication.
 - After you have established communication with the IPG, keep the wand in place. If you move the wand from over the IPG site, you may lose communication with the IPG.
6. Check the programmer's screen to verify that the programmer has established communication with the IPG. When the programmer finds the IPG, the beeping stops and the following screen appears.

Figure 6. IPG FOUND screen

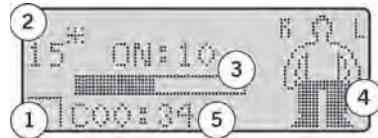


The next screen that appears shows information about the IPG, and then the Operational Display screen appears. See “About the Operational Display Screen” (page 9) for more information.

About the Operational Display Screen

The Operational Display screen is the home screen of the patient programmer. From this screen, you can view and control programs in the standard operating mode, and you can enter programming mode to create and edit programs. The following image shows the main parts of the Operational Display screen.

Figure 7. Parts of the Operational Display screen



1. User option window
2. Program number
3. Active amplitude bar
4. Stimulation map
5. Stimulation mode

User option window. Shows an icon that allows you to select different programmer modes. During standard operating mode, this area of the screen is blank. To allow you to enter other modes, it displays one of the following icons:

- The Program icon (P) indicates program selection mode.
- The Menu icon (M) indicates the menu mode (and programming mode).
- The Battery icon (B) indicates IPG battery capacity mode.
- The MRI Mode icon (MR) indicates MRI mode (available only with models that support MRI mode).

Program number. Shows the current program number that is downloaded to the IPG. If the program number shows a star (*) beside it, it means that the program is a BurstDR™ stimulation program. For more information on BurstDR stimulation programs, see “Programming BurstDR™ Stimulation Programs” (page 19).

Active amplitude bar. Shows the active amplitude level when the IPG is on. When the IPG is on, the word “ON” is displayed above the graphic with the numeric amplitude level. When the IPG is off, the word “OFF” is displayed above the graphic.

Stimulation map. Shows shaded areas, which indicate where a program is intended to provide stimulation. R and L designate right and left sides of the body.

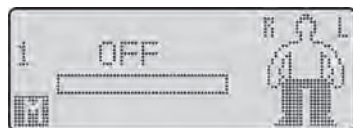
Stimulation mode. Provides information about a program’s stimulation mode. For more information, see “Setting the Stimulation Mode” (page 26).

Changing Programmer Settings

To change the programmer display and volume settings from the Menu screen:

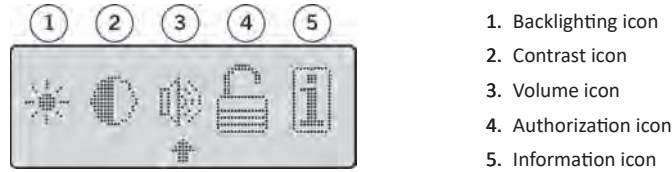
1. From the Operational Display screen, press either Scroll key until the Menu icon (M) appears in the user option window.

Figure 8. Scroll to the Menu icon (M)



2. Press the Select key. The Menu screen appears.

Figure 9. The Menu screen



3. Press either Scroll key until the arrow is under the icon of the setting that you want to change: backlighting, contrast, or volume.
4. Press the Select key. The programmer displays the screen of the setting you selected.
5. Press the Scroll keys to adjust the selected setting.
6. To save your changes, press the Select key. The Operational Display screen appears.

Authorizing the Programmer

After you establish communication with a new IPG, an X icon appears on the Operational Display screen. This icon means that the programmer is unauthorized with the IPG.

Figure 10. X icon on the Operational Display screen



The patient programmer has several authorization modes to ensure patient safety and programmer usability. The authorization modes are as follows:

- **Unauthorized.** The programmer has never been assigned to an IPG implant (or has been reinitialized).
- **Not authorized.** The IPG serial number does not match the serial number stored in the programmer.
- **Partially authorized.** The programmer serial number does not match the programmer serial number stored in the IPG.
- **Fully authorized.** Both the programmer and the IPG match the respective serial numbers for authorization.

Before you can use a programmer with an IPG to create and save a program, you must authorize the programmer to work with that particular IPG. To use a programmer with an IPG for the first time, see “Authorizing the Programmer With an IPG” (page 10). To use the programmer with a different IPG, see “Reauthorizing a Programmer With a Different IPG” (page 11).

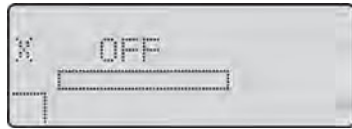
Authorizing the Programmer With an IPG

You can use any Model 3855 or 3856 Prodigy™ patient programmer to modify the program that is stored in a Prodigy™ IPG or Protégé™ IPG, and you can use any Model 3856 programmer to modify the program that is stored in a Prodigy MRI™ IPG or Protégé MRI™ IPG. However, before allowing the programmer to save a program or download other saved programs to the IPG, the programmer and IPG must be fully authorized.

To authorize the patient programmer to an IPG:

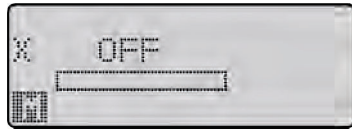
1. Establish communication with the IPG. See “Communicating With the IPG” (page 7). The Operational Display screen appears.

Figure 11. X icon on the Operational Display screen



2. Press a Scroll key until the Menu icon (M) appears in the user option window.

Figure 12. Scroll to the Menu icon (M)



3. Press the Select key. The Menu screen appears.
4. Press a Scroll key until the selection arrow is under the Authorization icon.

Figure 13. Select the Authorization icon



5. Press the Balance key; then press the Select key. The following screen appears.

Figure 14. Screen showing an unauthorized programmer



6. Press the Balance key; then press the Select key. The following screen appears.

Figure 15. Screen showing an authorized programmer



7. Press the Previous Screen key twice. The Operational Display screen appears and the programmer is authorized to the IPG.
8. Use the programmer to create and save a program for the IPG. The X icon will remain on the Operational Display screen until you save the program.

Reauthorizing a Programmer With a Different IPG

When a programmer is not authorized to work with an IPG, an X appears on the Operational Display screen.

To reauthorize a programmer:

NOTE: Performing the following steps deletes all the programs in the programmer and reauthorizes the IPG serial number.

1. Establish communication with the IPG. See “Communicating With the IPG” (page 7). The Operational Display screen appears.

Figure 16. X icon on the Operational Display screen



2. Press a Scroll key until the Menu icon (M) appears in the user option window.

Figure 17. Scroll to the Menu icon (M)



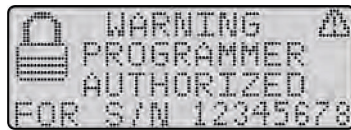
3. Press the Select key. The Menu screen appears.
4. Press a Scroll key until the selection arrow is under the Authorization icon (lock).

Figure 18. Select the Authorization icon



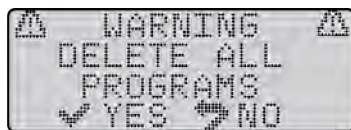
5. Press the Balance key; then press the Select key. The following screen appears.

Figure 19. Programmer authorized for a different IPG



6. Press the Balance key; then press the Select key. The following screen appears:

Figure 20. Warning to delete all programs



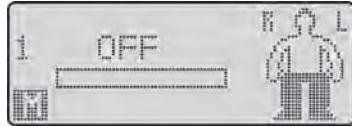
7. Press the Select key. The programmer deletes all programs, reinitiates communication with the IPG, and ensures that it is authorized with the IPG.
8. Use the programmer to create and save a program for the IPG. The X icon will remain on the Operational Display screen until you save the program.

Displaying IPG and Programmer Information

To view information about the IPG and the programmer from the Menu screen:

1. From the Operational Display screen, press either Scroll key until the Menu icon (M) appears in the user option window.

Figure 21. Scroll to the Menu icon (M)



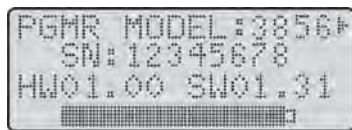
2. Press the Select key. The Menu screen appears.
3. Press either Scroll key until the arrow is under the Information icon.

Figure 22. Select the information icon



4. Press the Select key. A screen appears showing information about the programmer and its remaining battery power.

Figure 23. Programmer information screen



5. To view the screen showing IPG information, press the Scroll key on the right. To view the screen showing the programmer information again, press the Scroll key on the left.
6. When you are finished viewing the information screens, press the Select key.

Replacing the Programmer Batteries

The programmer is powered by three disposable AAA alkaline batteries contained in a battery pack. When the battery power is low, an alarm will sound and the following screen appears. If this occurs, you should replace your AAA batteries.

Figure 24. Programmer Battery Low screen

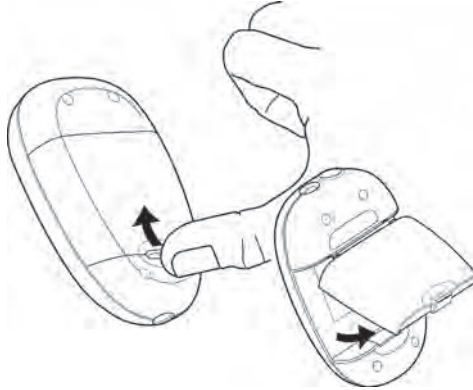


NOTE: Do not dispose of batteries as general waste. Follow local regulations about disposing of batteries safely.

To replace the batteries in the programmer:

1. Ensure the programmer power is off.
2. Push and hold the battery release latch on the bottom of the battery pack, and lift the battery pack from the battery compartment.

Figure 25. Remove the battery pack from the programmer



3. Remove the AAA batteries from the battery pack, and insert new AAA batteries into the battery pack, ensuring that the + and - signs on the batteries line up with the signs in the battery pack.
4. Place the battery pack into the battery compartment.

Using the Programmer

This section provides information for using the programmer to select and control programs while it is in its standard operating mode. It does not provide information about programming. For information about programming, see "Creating and Editing Programs" (page 18).

Except for "Browsing Programs" (page 17), you will need to establish communication with the IPG before you start these instructions. See "Communicating With the IPG" (page 7).

Selecting a Program

If more than one program is saved on the programmer, you can use the programmer to select the desired program and load it on the IPG.

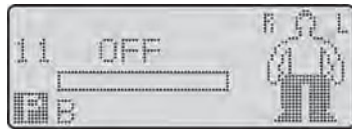
NOTE:

- If the Program icon (P) does not appear, the programmer does not have any more programs to select.
- The amplitude keys are still active. If you press one during this procedure, the stimulation will change accordingly and the Operational Display screen will appear.

To select a program:

1. From the Operational Display screen, press either Scroll key until the Program icon (P) appears in the user option window. The number for the current program appears on the left of the screen.

Figure 26. Scroll to the Program icon (P)



2. Press the Select key. The Program Selection screen appears showing the currently selected program in the center of the screen.

Figure 27. Access the Program Selection screen



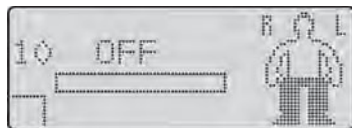
3. Press either Scroll key until the program you want appears in the center of the screen.

Figure 28. Scroll to other programs



4. Press the Select key. Stimulation stops, and the Operational Display screen appears showing the number of the newly selected program on the left side of the screen.

Figure 29. Operational Display screen showing a new program



Starting Stimulation

To start stimulation:

1. From the Operational Display screen, press or press and hold the Amplitude Increase key. The amplitude level shown on the active amplitude bar increases.
2. Press the Amplitude Increase key to increase stimulation or the Amplitude Decrease key to decrease stimulation to a comfortable level.

Figure 30. Active amplitude bar on the Operational Display screen



The amplitude for each program is divided incrementally into 26 levels. When you start stimulation for a tonic program, the amplitude slowly increases to the prescribed perception level for that program (level 6). When you start stimulation for a BurstDR™ stimulation program, the amplitude slowly increases to a prescribed target level. From here, you can increase stimulation up to level 26 or decrease stimulation to 1.

Stopping Stimulation

You can turn off the IPG and stop stimulation by using either the programmer or the magnet. With the magnet, you can stop stimulation immediately.

Stopping Stimulation Using the Programmer

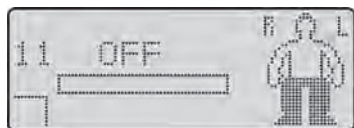
To stop stimulation using the programmer, perform either of the following actions from the Operational Display screen:

- Press the Power key.

- Press or press and hold the Amplitude Decrease key until the level shown on the active amplitude bar reaches zero and OFF is displayed.

If you perform either action, the programmer turns off the IPG and stimulation stops. You should see the following screen.

Figure 31. Operational Display screen showing stimulation off



Stopping Stimulation Using the Magnet

The system comes with a magnet that can turn off the IPG or turn it on and off. How the IPG functions depends on the program settings. A program can be set with one of the following magnet modes:

- **Magnet off.** The magnet can turn off the IPG but cannot turn it on. In magnet off mode, if you use the magnet to turn off the IPG, you must use the programmer to turn it back on.
- **Magnet on/off.** The magnet can turn the IPG on or off. When selected, magnet on/off mode appears as MAG on the Program Selection screen.

Figure 32. Program in magnet on/off mode (MAG)



NOTE:

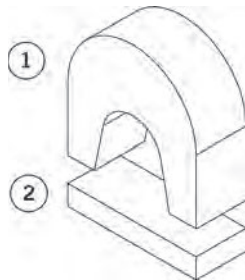
- In magnet on/off mode, if you hold the magnet over the IPG site for about 30 seconds, the IPG will turn off and you must use the programmer to turn it back on.
- The magnet is powerful and intended for use solely with IPGs. When the magnet is not in use, position the keeper bar on it properly.

CAUTION: Do not use the magnet provided with the system around magnetically sensitive items to avoid damaging them.

To stop stimulation using the magnet:

1. Take the keeper bar off the magnet.

Figure 33. Take the keeper bar off the magnet



1. Magnet
2. Keeper bar

2. Place the magnet directly over the IPG.
3. Hold the magnet in place for two seconds.
4. Remove the magnet, replace the keeper bar, and store the magnet.

5. If desired, confirm that stimulation is stopped by turning on the programmer and establishing communication with the IPG. In the Operational Display screen that appears, OFF is displayed above the active amplitude bar.

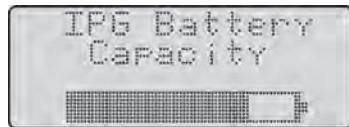
Checking the Remaining IPG Battery Capacity

To check the remaining battery capacity of the IPG:

NOTE: To get an accurate measurement, wait two minutes after charging the IPG before checking the IPG battery capacity.

1. From the Operational Display screen, press a Scroll key until the Battery icon (B) appears in the user option window.
2. Press the Select key. The IPG Battery Capacity screen appears. The dark portion of the battery icon shows the amount of energy remaining in the IPG battery.

Figure 34. IPG Battery Capacity screen

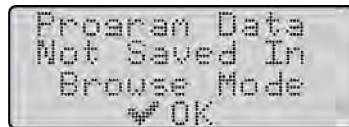


Browsing Programs

The browse mode is a demonstration mode that allows you to view the programs saved in the programmer while it is not communicating with an IPG.

NOTE: To prevent untested changes from causing unwanted stimulation, Browse mode does not allow you to save program changes. The following screen appears if you try to save.

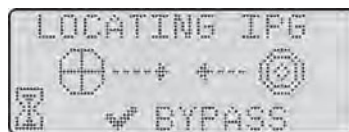
Figure 35. Program Data Not Saved screen



To access browse mode:

1. Connect the programming wand to the programmer.
2. Press the Power key to turn on the programmer. the Diagnostic Test screen appears for a few seconds; then the LOCATING IPG screen appears.

Figure 36. LOCATING IPG screen



3. Press the Select key. The NO IPG TELEMETRY screen appears. You can now use the keys on the programmer to view programs.

Figure 37. NO IPG TELEMETRY screen



Creating and Editing Programs

The patient programmer can run two types of stimulation programs: tonic programs and BurstDR™ stimulation programs.

- **Tonic program.** A program where the stimulation frequency consists of a single, repeating pulse.
- **BurstDRstimulation program.** A program where the stimulation frequency consists of a group of pulses in rapid succession followed by a period without pulses before repeating the pulse group.

Using a patient programmer, you can create and edit tonic programs only. You must use the Rapid Programmer™ system to create and edit BurstDR stimulation programs.

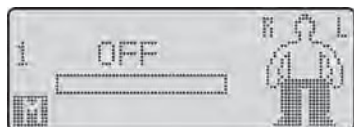
Accessing Programming Mode

To access programming mode:

NOTE: The current program (the one shown on the Operational Display screen) is the only one that you can modify or copy after accessing programming mode.

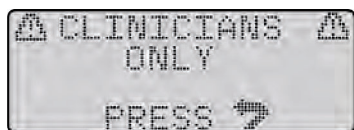
1. Select a program that you want to modify or copy from the Program Selection screen. See the steps in “Selecting a Program” (page 14).
2. From the Operational Display screen, press a Scroll key until the Menu icon (M) appears in the user option window.

Figure 38. Scroll to the Menu icon (M)



3. Press the Balance key; then press the Select key. The CLINICIANS ONLY warning screen appears.

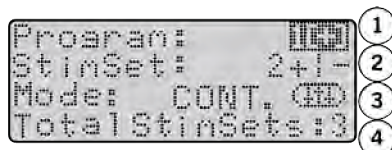
Figure 39. CLINICIANS ONLY screen



NOTE: To prevent inadvertent program changes, do not show the patient how to access the Program screen.

4. Press the Balance key; then press the Select key. When the programmer is in programming mode, the Program screen appears, showing introductory information about the program.

Figure 40. Parts of the Program screen



1. **Program field.** Shows the program number and a [+] to indicate whether there is room to add another program.
2. **StimSet field.** Shows the stim set number and a + or - to indicate whether there is another stim set.
3. **Mode field.** Shows the stimulation delivery mode.
4. **Total StimSets field.** Shows the total number of stim sets in the program.

NOTE: An X in the Program field indicates that this is the first program following the authorization process. Make and save changes to this program, and it will become program 1.

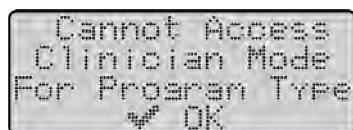
5. To add a program with the same parameters as the current program or to add one with default values, follow the steps in "Creating a New Program" (page 20). Otherwise, modify any parameters in the current program as desired.

Programming BurstDR™ Stimulation Programs

You can use the patient programmer to program tonic programs. However, you must use the Rapid Programmer™ system to program BurstDR™ stimulation programs. See the clinician's manual for the Rapid Programmer system for information and instructions on BurstDR stimulation programming.

If you try to enter programming mode with a BurstDR stimulation program, the following screen will appear.

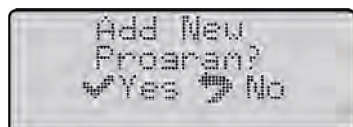
Figure 41. Cannot Access Clinician Mode screen



If you receive this screen:

1. Press the Select key. The following screen appears.

Figure 42. Add New Program screen



2. Perform one of the following actions:
 - To create a new default tonic program, press the Select key.
 - To program using an existing tonic program, press the Previous Screen key, select a tonic program from the Program Selection screen, and access programming mode again.

To program the selected BurstDR stimulation program, press the Previous Screen key and connect the patient programmer to the Rapid Programmer™ system (see the clinician's manual for the Rapid Programmer system).

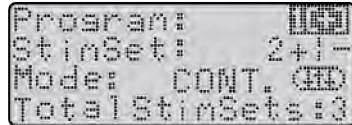
Creating a New Program

You can create a new program that has either the default values from the preloaded program or the values from the current program you selected in “Selecting a Program” (page 14).

To create a new program:

1. From the Program screen, press either Scroll key until it highlights the program number with the plus sign in brackets [+].

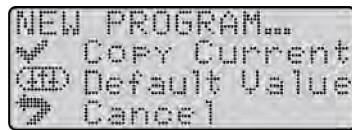
Figure 43. Highlight the Program field



NOTE: If the [+] does not appear, you cannot add a program because the maximum number of programs has already been reached.

2. Press the Amplitude Increase key. The NEW PROGRAM screen appears.

Figure 44. NEW PROGRAM screen



3. Perform one of the following actions:
 - To add a program with the same values as the current program, press the Select key.
 - To add a program with default values, press the Balance key.

The programmer creates the program and displays it on the Program screen with a new program number, making it the current program. You can now modify any parameters in the new program as desired.

Working With Stim Sets

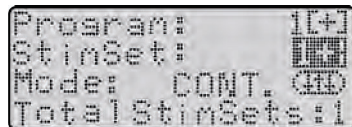
Each program can hold up to eight stim sets (or stimulation sets). The program that you select before accessing the Program screen contains at least one stim set. You can modify this stim set by following the steps in “Modifying a Stim Set in a Program” (page 20), or you can add a new stim set to the program by following the steps in “Adding a Stim Set to a Program” (page 21).

Modifying a Stim Set in a Program

To modify a stim set in a program:

1. From the Program screen, press the Balance key to highlight the StimSet field.

Figure 45. Highlight the StimSet field



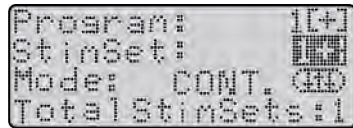
2. If the number of the stim set that you want to modify is not shown on the screen, press the Amplitude Increase key until it appears.
3. Select and modify the stimulation parameters.

Adding a Stim Set to a Program

To add a stim set in a program:

1. From the Program screen, press the Balance key to highlight the StimSet field.

Figure 46. Highlight the StimSet field



2. Press the Amplitude Increase key. The Add StimSet screen appears.

Figure 47. Add StimSet screen



3. Press the Select key. The Program screen appears with a new StimSet number and the Total StimSets number increased by one.

NOTE: If the Freq/PW Limit screen appears, the frequency settings are too high. Press the Select key to automatically reduce the frequency settings.

Figure 48. Freq/PW Limit Screen



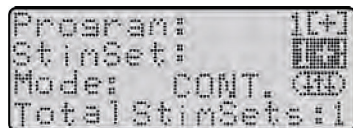
Deleting a Stim Set From a Program

To delete a stim set from a program:

NOTE: The last stim set in a program cannot be deleted.

1. From the Program screen, press the Balance key until it highlights the StimSet field.

Figure 49. Highlight the StimSet field



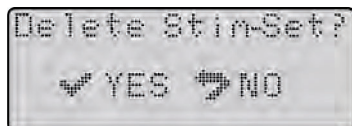
2. If the number of the stim set that you want to delete is not shown on the screen, press the Amplitude Increase key until it appears.
3. Press the Balance key to highlight the Pol field.

Figure 50. Highlight the Pol field



4. Press the Scroll keys to move to each polarity in the field, and press the Amplitude Increase key or the Amplitude Decrease key to change the polarity to zero.
5. After all polarities are set to zero, press the Select key. The Delete Stim-Set screen appears.

Figure 51. Delete Stim-Set screen



6. Press the Select key. The Save-Continue screen appears.
7. Press the Select key. The programmer deletes the stim set, and the Program screen appears showing the Total StimSets number decreased by one.

Setting Frequency

Frequency is the number of stimulation pulses that the system delivers each second and is measured in hertz (Hz). Frequency can be set between 2 and 1200 Hz.

NOTE:

- While high frequencies may assist with patient comfort, they deplete the battery at a faster rate and make it necessary to recharge more frequently.
- Frequencies for stim sets in a MultiStim™ stimulation program must be identical and cannot exceed 1200 Hz divided by the number of stim sets in the program.

Depending on the frequency setting, the following step-size adjustments are available.

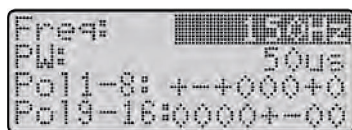
Table 3. Step size increments by frequency range

Frequency Range	Step Size
2–200 Hz	2 Hz
200–500 Hz	10 Hz
500–1200 Hz	20 Hz

To set the frequency for a stim set:

1. From the Program screen, press the Balance key until it highlights the Freq field.

Figure 52. Highlight the Freq field

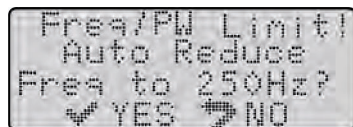


CAUTION: Rapid changes in frequency can cause uncomfortable sensations for the patient.

2. Press the Amplitude Increase key or Amplitude Decrease key until the screen shows the desired value.
3. To save the settings, press the Select key.
4. If the Save-Continue screen appears, press the appropriate key.

NOTE: If the Freq/PW Limit screen appears, the frequency settings are too high. Press the Select key to automatically reduce the frequency settings.

Figure 53. Freq/PW Limit screen



Setting Pulse Width

Pulse width is the duration of each electrical pulse (time stimulation is on) and is measured in microseconds (μ s). Pulse width adjustments can be made between 50 and 500 μ s and in alternating increments of 12 and 13 μ s, starting with 12 μ s.

NOTE: Wide pulse widths will deplete the battery at a faster rate and increase recharging frequency.

1. From the Program screen, press the Balance key until it highlights the PW parameter.

Figure 54. Highlight the PW field



CAUTION: An increase in pulse width without a previous decrease in amplitude can cause uncomfortable stimulation sensations. Always adjust amplitude accordingly when adjusting pulse width.

2. Press the Amplitude Increase (or Decrease) key until you reach the desired value.

NOTE: Changes to pulse width will reset any prior perception or maximum tolerable settings.

Setting Electrode Polarities

Electrode polarities control the formation of the electrical fields and where the patient feels stimulation. You can select a polarity symbol (+, -, or 0) for each electrode on a lead, and each electrode has a default setting of neutral (0). The system can also be set to function with the IPG (also called a “can”) as the anode (+).

When using a single quadripolar lead, the first four polarity symbols in Pol 1-8 represent electrodes 1-4. When using a dual quadripolar lead configuration, the first four polarity symbols in Pol 9-16 represent electrodes 5-8.

NOTE: Changes to polarities automatically set any active amplitude to zero and reset the perception and the maximum tolerable values.

Setting Polarities Using Only the Electrodes

These instructions present the method that is normally used to set electrode polarities. With this method, you set at least one electrode on the lead to function as an anode (+).

To set electrode polarities using only the electrodes:

1. From the Program screen, press the Balance key until it highlights the Pol field.

Figure 55. Highlight the Pol field



2. Press a Scroll key to highlight the electrode that you want to set.
3. Press the Amplitude Increase (or Decrease) key to select a polarity (-, +, or 0).
4. To change the polarity of another electrode, repeat steps 2 and 3.

Setting Polarities Using the IPG as an Anode

These instructions present a method that is not normally used to set electrode polarities. With this method, you set the IPG (can) to function as the anode (+). This may be the only solution when, for example, you cannot reach the targeted nerve fiber by programming a simple bipole (one - and one +) on the electrodes.

NOTE: Use these instructions only if you cannot provide adequate stimulation coverage by using only the electrodes. See “Setting Polarities Using Only the Electrodes” (page 23).

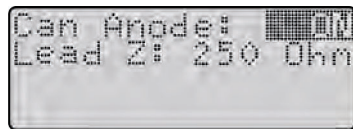
To set electrode polarities using the IPG can as the anode:

1. From the Program screen, press the Balance key until it highlights the Can Anode field.

NOTE: Any time the Can Anode field is set to ON, all electrode polarities are reset to 0 and cannot be set to function as anodes (+).

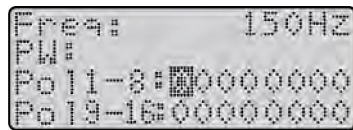
2. Press the Amplitude Increase key to select ON.

Figure 56. Highlight the Can Anode field



3. Press the Balance key until it highlights the Pol field.

Figure 57. Highlight the Pol field



4. Press a Scroll key to highlight an electrode that you want to select as a cathode (-).
5. Press the Amplitude Increase (or Decrease) key.
6. To change another electrode to a cathode (-), repeat steps 4 and 5.

Setting Amplitude Levels

Amplitude is controlled by the keys on top of the patient programmer. You can set the following four amplitude parameters:

- Step size
- Main amplitude
- Perception amplitude
- Maximum tolerable amplitude

NOTE: For some combinations of parameters, the programmer will display that the IPG cannot achieve the desired system output. When this occurs, you need to adjust the parameter to achieve an output of which the system is capable.

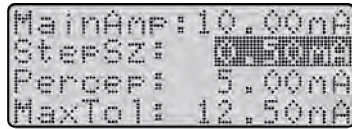
Setting Step Size (StepSz)

Step size controls the size of the incremental increase or decrease that the programmer uses when you are changing MainAmp values. Step sizes range from 0.1 to 1.0 mA. Larger step sizes enable you to reach values faster. Once reached, smaller increments can be used for safety and specificity.

To set step size:

1. From the Program screen, press the Balance key until it highlights the StepSz field.

Figure 58. Highlight the StepSz field



NOTE: When you do not know the patient's perception or maximum tolerable levels, use small step sizes to prevent overstimulating the patient.

2. Press the Amplitude Increase key or the Amplitude Decrease key until you reach the desired value.

Setting Main Amplitude (MainAmp)

Main amplitude controls the active amplitude. When you use this parameter, the programmer is actively controlling the stimulation that is being delivered. The MainAmp parameter enables you to test stimulation parameters during a programming session. You can use main amplitude to determine perception amplitude and maximum tolerable amplitude values before setting them.

To set main amplitude:

1. From the Program screen, press the Balance key until it highlights the MainAmp field.

Figure 59. Highlight the MainAmp field



CAUTION: Do not select an amplitude value that may be too high or the patient may receive unwanted stimulation.

2. Press the Amplitude Increase (or Decrease) key until you reach the desired value. The amplitude changes in increments according to the StepSz value.

NOTE: To immediately stop stimulation, press the Power key or use the magnet.

Setting Perception Amplitude (Percep)

Perception amplitude is the level at which the patient first perceives stimulation. The IPG automatically ramps up to this value when the patient turns on the programmer and pushes the Amplitude Increase key once.

To set perception amplitude:

1. Use MainAmp to establish a perception level.
2. Press the Balance key until it highlights the Percep field.

Figure 60. Highlight the Percep field



CAUTION: Do not set the perception amplitude value too high or the patient may receive unwanted stimulation.

3. Press the Amplitude Increase (or Decrease) key and set the value at the level at which the patient first perceives stimulation.

NOTE: The perception amplitude value cannot exceed the value of the maximum tolerable amplitude value.

Setting Maximum Tolerable Amplitude (MaxTol)

Maximum tolerable amplitude is the maximum level at which stimulation is tolerable and effective. Once you set the MaxTol parameter, the patient cannot increase the amplitude past this value without going through a manual bypass process. Maximum tolerable amplitude is an important safety feature that reduces the possibility of the patient being overstimulated. The programmer also uses this value to determine the usage range of the amplitude, and it must be properly set for each stim set.

To set maximum tolerable amplitude:

1. Use MainAmp to establish a maximum tolerable level.
2. Press the Balance key until it highlights the MaxTol field.

Figure 61. Highlight the MaxTol field



CAUTION: Do not set the maximum tolerable value too high or the patient may receive unwanted stimulation.

3. Press the Amplitude Increase (or Decrease) key and set the highest value at which the patient receives stimulation that is tolerable and effective.

Setting the Stimulation Mode

The stimulation mode governs how the IPG delivers the stimulation. Three modes are available: continuous, cycle, and bolus.

NOTE: If you do not set a mode, the system sets the continuous mode by default.

To Set Continuous Stimulation Mode

Continuous mode provides continuous stimulation to the patient. When the system is turned on, it delivers therapy until it is manually turned off. Continuous mode is the default mode and does not display a mode indicator on the Operational Display screen.

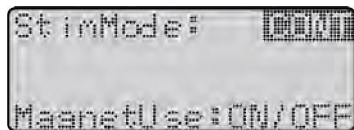
Figure 62. The Operational Display screen in continuous mode



To set the stimulation mode to continuous:

1. From the Program screen, press the Balance key until it highlights the StimMode field, and press the Balance key again. The StimMode screen appears.
2. Press the Amplitude Increase key until CONT appears in the StimMode field.

Figure 63. Select CONT in the StimMode field



3. Press the Balance key to highlight the MagnetUse field.
4. Press the Amplitude Decrease key to change the magnet mode.

To Set Cycle Stimulation Mode

Cycle mode allows the physician to set intervals for therapy that cycle between on and off. The cycling of the therapy enables battery conservation and stimulation refinement. When a program is set to cycle mode, the letter C is displayed on the Operational Display screen with information about the “on” or “off” time remaining.

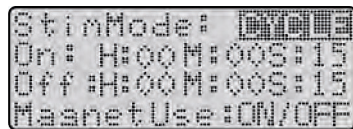
Table 4. Descriptions of the Operational Display screens in cycle mode

Operational Display Screen	Description
	Stimulation is cycled on and more than a minute of stimulation time remains (displayed in hours and minutes).
	Stimulation is cycled on with less than a minute remaining.
	Stimulation is cycled off and more than a minute remains in the off phase (displayed in hours and minutes).
	Stimulation is cycled off with less than a minute remaining in the off phase.

To set the stimulation mode to cycle:

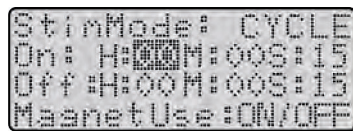
1. From the Program screen, press the Balance key until it highlights the StimMode field. The StimMode screen appears.
2. Press the Amplitude Increase key until CYCLE appears in the StimMode field.

Figure 64. Select CYCLE in the StimMode field



3. Press the Balance key to highlight the On field.

Figure 65. Highlight the On field



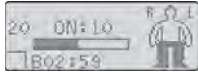
NOTE: Cycle mode can provide up to 24 hours of “on” time and 24 hours of “off” time.

4. Press a Scroll key to highlight the desired time field (H for hours, M for minutes, or S for seconds), and press the Amplitude Increase key or Amplitude Decrease key to increase or decrease the value.
5. After you finish setting all values for “on” time, press the Balance key to highlight the Off field.
6. Follow step 4 to set the value for the “off” time.
7. Press the Balance key to highlight the MagnetUse field.
8. Press the Amplitude Decrease key to change the magnet mode.

To Set Bolus Stimulation Mode

Bolus mode allows the physician to set a time period for therapy to be on and a time period for therapy to be off. After a stimulation period expires, a lockout phase begins during which no stimulation can be activated. After the lockout, the patient can manually restart stimulation for the set time period. When a program is set to bolus mode, the letter B is displayed on the Operational Display screen with information about the “on” or “off” time remaining.

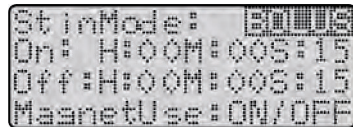
Table 5. Description of the Operational Display screens in bolus mode

Operational Display Screen	Description
	Stimulation is on for the time displayed (in hours and minutes or in minutes and seconds).
	Stimulation is in a lockout phase, where stimulation is off and cannot be restarted until the displayed time expires (in hours and minutes or in minutes and seconds).
	Stimulation is off, the lockout phase is finished, and the bolus program can be restarted. NOTE: When the bolus lockout time expires, the patient must use the programmer to restart stimulation.

To set the stimulation mode to bolus:

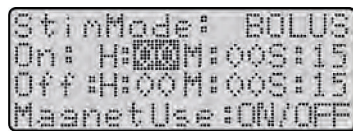
1. From the Program screen, press the Balance key until it highlights the StimMode field. The StimMode screen appears.
2. Press the Amplitude Increase key until BOLUS appears in the StimMode field.

Figure 66. Select BOLUS in the StimMode field



3. Press the Balance key to highlight the On field.

Figure 67. Highlight the On field



NOTE:

- Bolus mode can provide up to 18 hours of “on” time and 18 hours of “off” time.
 - Since the patient cannot start the bolus stimulation during the lockout phase, many clinicians enter a one-second “off” time so that the patient can restart stimulation when desired.
4. Press a Scroll key to highlight the desired time field (H for hours, M for minutes, or S for seconds), and press the Amplitude Increase key or Amplitude Decrease key to increase or decrease the value.
 5. After you finish setting all values for “on” time, press the Balance key to highlight the Off field.
 6. Follow step 4 to set the value for the “off” time.
 7. Press the Balance key to highlight the MagnetUse field.
 8. Press the Amplitude Decrease key to change the magnet mode.

Measuring Impedance

To measure the electrical impedance in the system:

NOTE: The programmer turns off the amplitude during this impedance test.

1. From the Program screen, press the Balance key until it highlights the Lead Z field.

Figure 68. Highlight the Lead Z field



2. Press the Amplitude Increase key and wait for the programmer to evaluate the impedance. The programmer displays the electrical impedance in the system.

Figure 69. Lead Z field displays the system impedance.



The readings and their meanings are as follows:

- **Low.** Below 200 ohms.
- **High.** Above 3,000 ohms. The systems may have an open (broken) circuit. Check all of the connections.
- **Invalid.** Programmer did not communicate with the IPG within 18 seconds. Try this step again.

Saving a Program

Once you have established settings for a patient, have tested them, and are satisfied with the program, save the program.

To save the stimulation settings as a program:

1. From any of the programming screens available in programming mode (for example, the Program screen), press the Select key. The following screen appears.

Figure 70. Save screen for programs



2. Perform one of the following actions:
 - To save the program and continue programming, press the Select key. The system saves the program in the next available program register.
 - To save the program and exit to the Operational Display screen, press the Balance key. The system saves the program in the next available program register.
 - To cancel any program changes that you made and exit to the Operational Display screen, press the Previous Screen key. The system does not save the program.

Saving an X Program

Sometimes, an X appears on the programmer's screen instead of a program number. The X appears on a programmer's screen for one of the following reasons:

- A programmer that is not authorized for an IPG establishes communication with the IPG.
- A programmer that is authorized for an IPG establishes communication with the IPG and finds that the IPG has a program in it that was modified or added by a different programmer.

The X program normally appears either when an IPG is new or when a clinician creates a program without using the patient's authorized programmer.

To save an X program:

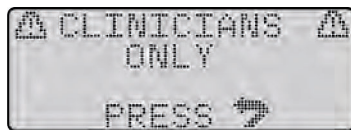
1. Establish communication with the IPG. See "Communicating With the IPG" (page 7).

Figure 71. X icon on the Operational Display screen



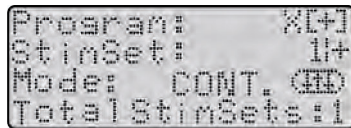
2. Press a Scroll key until the Menu icon (M) appears in the user option window.
3. Press the Balance key; then press the Select key. The CLINICIANS ONLY warning screen appears.

Figure 72. CLINICIANS ONLY screen



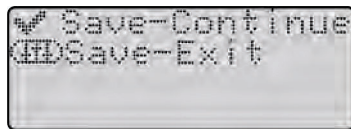
4. Press the Balance key; then press the Select key. The Program screen appears.

Figure 73. Program screen



5. Press the Balance key to highlight the Program field.
6. Press the Select key. The following screen appears.

Figure 74. Save screen for X programs



7. Perform either of the following actions:
 - To save the X program and continue programming, press the Select key.
 - To save the X program and quit programming, press the Balance key.The system saves the new program as the next available program number in the patient programmer.

Deleting Programs

This section provides information for deleting programs.

Deleting All Programs

To delete all of the programs from an authorized patient programmer and clear the programmer's memory:

1. From the Operational Display screen, press a Scroll key until the Menu icon (M) appears in the user option window.
2. Press the Select key. The Menu screen appears.
3. Press a Scroll key until the selection arrow is under the Authorization icon.

Figure 75. Select the Authorization icon



4. Press the Balance key; then press the Select key. The following screen appears.

Figure 76. PROGRAMMER AUTHORIZED screen



5. Press the Balance key; then press the Select key. The following screen appears.

Figure 77. DELETE ALL PROGRAMS warning screen



NOTE: Pressing the Select key in the next step permanently deletes all programs and authorization information from the programmer.

6. To delete all programs, press the Select key. (Otherwise, press the Previous Screen key.) The programmer deletes all programs, reinitiates communication with the IPG, and ensures its authorization with the IPG.

Deleting a Single Program

To delete an individual program from the patient programmer, connect a Rapid Programmer™ system to the patient programmer and follow the Rapid Programmer unit's menu instructions. If a Rapid Programmer system is not available, you cannot delete a program but must modify an unused program already stored on the patient programmer.

Maintaining the System

This section contains information about maintaining different parts of the neurostimulation system.

Maintaining and Cleaning the Programmer

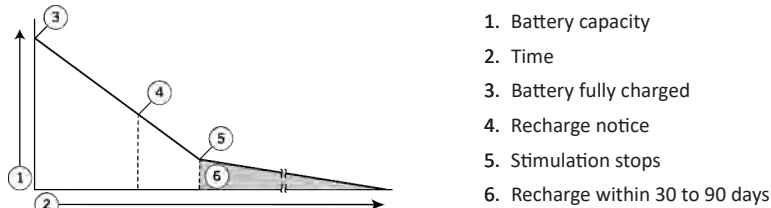
Occasionally clean your programmer, and inspect it for damage before using it. Other than these activities, the programmer does not need any other routine maintenance, testing, or service.

Clean the programmer as needed by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not submerge the programmer in liquids or use a cloth that is saturated. Do not use alcohol, cleaning solutions, or solvents to clean the programmer.

Maintaining the IPG Battery

The IPG contains a lithium ion battery. The time it takes to recharge a battery depends on these factors: age of the battery, daily usage time, stimulation settings, and length of time since the last recharge. The following graph shows how the rechargeable battery depletes over time.

Figure 78. IPG battery depletion over time



If the patient does not recharge the battery, stimulation will eventually stop, and the patient then must recharge the battery to prevent battery damage. After stimulation stops, a new battery can last up to 90 days before it must be recharged, while a ten-year-old battery should be recharged within 30 days.

When the IPG is used at high stimulation parameters for tonic programs or at nominal stimulation parameters for BurstDR™ stimulation programs, battery usage studies demonstrate that the battery should allow at least ten years of practical recharging. In other words, a ten-year-old device will maintain at least 24 hours of continuous therapy between recharges.

Depending on the patient's stimulation parameters, the device will continue to operate for months to years. Patients may experience a significantly longer device life before recharging is determined to be impractical if they use lower stimulation parameters, a frequent recharging protocol, or both. Frequent recharging can reduce charging session times and maximize the IPG's life.

NOTE: The model used to predict device longevity was generated by fitting a mathematical model to three years of real-time cycling data, which was then used to extrapolate device battery capacity at the end of ten years.

Troubleshooting

This section provides troubleshooting procedures to help you identify and solve problems that may occur.

NOTE: Keep functional backup items on hand. Especially keep the following items available during intraoperative testing: trial stimulator, trial cable, and fresh batteries.

Troubleshooting Procedure

If a patient programmer or IPG problem is suspected, follow these steps to help solve or isolate the problem:

NOTE: Always set the amplitude to zero before making adjustments; then slowly increase the amplitude to test the effect of the change.

1. Check the programmer screen for a diagnostic message. If there is one, continue with "Troubleshooting a Diagnostic Message" (page 33) and try the solution.
2. Verify that the IPG power is on.
3. Verify that the amplitude is at the correct level.
4. Wait for the programmer power to shut off (approximately one minute).
5. Turn on the programmer again.
6. Begin stimulation and adjust the amplitude to a comfortable level.
7. Try the suggested solution on the appropriate troubleshooting chart: "Troubleshooting Chart for Intraoperative Testing" (page 34) or "Troubleshooting Chart for Postoperative Programming" (page 35).
8. Call Technical Support.

Troubleshooting a Diagnostic Message

The programmer has a program that constantly checks the system while it is running. If a problem with the programmer, IPG, or wand occurs, the programmer will make a tone and a diagnostic message will appear. The following table describes how to troubleshoot the common diagnostic messages.

Table 6. Troubleshooting for Diagnostic Messages

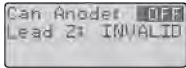
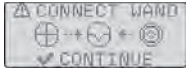
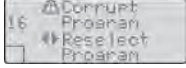
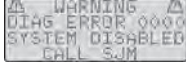
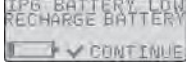
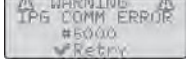
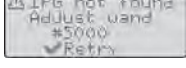
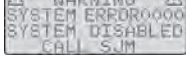
Programmer Message	Screen	Solution
Can Anode: OFF; Lead Z: INVALID		Ensure that all connections are tight. Repeat impedance check.
Connect wand		Ensure the wand is properly connected to the programmer.
Comm to IPG interrupted (off)		Select another program.
Comm to IPG interrupted (reselect program)		Select the program again, or select another program.
Corrupt program (off)		Edit the program.
Corrupt program (reselect program)		Edit the program or select another one.
Diagnostic error		Contact Technical Support.
IPG battery low (recharge battery)		IPG battery is low. Recharge it.
IPG battery low (stim off)		IPG battery is low and is not delivering stimulation. Recharge it.
IPG communication error		Reposition the wand over the IPG and press the Select key.
IPG not found		Reposition the wand over the IPG and press the Select key.
Programmer battery low		Replace the batteries in the programmer.
Programmer authorized for S/N nnnnnnn		Use the programmer that is authorized for the IPG or authorize the programmer for the IPG.
System error		Contact Technical Support.

Table 6. Troubleshooting for Diagnostic Messages

Programmer Message	Screen	Solution
Wrong IPG type		Contact Technical Support.

IPG Heating During Charging

During a charging session, it is normal if some patients perceive an increase in the temperature of the IPG. However, if the temperature of the IPG becomes uncomfortable for them, you should advise patients to try these troubleshooting tips:

- Stop charging until the discomfort subsides and then resume charging.
- Use the charger belt and antenna holder that is provided with the charging system to hold the antenna in place.
- Reposition the charger antenna over the IPG site.
- Consider recharging more frequently for less time.
- Avoid tightly inserting the charger antenna between the body and a surface that may trap heat, such as a bed or chair.

Troubleshooting Chart for Intraoperative Testing

The following table identifies solutions for problems that could occur during intraoperative testing using the programmer.

Table 7. Troubleshooting during intraoperative testing

Problem	Possible Cause	Possible Solution
Programmer has no power and does not show anything on the screen.	Programmer power is off or has timed out after one minute of inactivity.	Press the Power key.
	Batteries are depleted.	Replace the programmer batteries.
	Battery pack or batteries are not inserted properly.	Reinsert the battery pack or batteries.
	Programmer is damaged.	Replace the programmer.
Programmer is not communicating correctly with the IPG.	Programmer is in browse mode.	Allow the programmer to turn off. Turn on the programmer and establish communication with the IPG.
	Program did not load correctly.	Edit the program or select another one.
	Electrical interference is interrupting communication between the programmer and IPG.	Move to another area away from the electrical interference, and try again.
	IPG is implanted too deep in the pocket.	Reduce the implant depth of the IPG.
	Communication wand or programmer is damaged.	Check the programmer screen for a diagnostic message and try to correct the problem. If this action is not effective, replace the wand or programmer.

Table 7. Troubleshooting during intraoperative testing

Problem	Possible Cause	Possible Solution
Impedance measurement is high.	Lead is not connected properly.	Check that the lead is fully inserted in the IPG header, and measure the impedance again.

Troubleshooting Chart for Postoperative Programming

The following table identifies solutions for problems that could occur during postoperative programming.

Table 8. Troubleshooting during postoperative programming

Problem	Possible Cause	Possible Solution
No Programmer Power		
Programmer has no power and does not show anything on the screen.	Programmer power is off or has timed out after one minute of inactivity.	Press the Power key.
	Batteries are depleted.	Replace the programmer batteries.
	Battery pack or batteries are not inserted properly.	Reinsert the battery pack or batteries properly.
	Programmer is damaged.	Contact Technical Support.
No Stimulation		
Patient does not feel stimulation as amplitude is increased.	Programmer is in browse mode.	Allow the programmer to turn off. Turn on the programmer and establish communication with the IPG.
	Program did not load correctly.	Edit the program or select another one.
	Patient is using a BurstDR stimulation program.	Ensure that the selected program is a BurstDR stimulation program.
	Electrode polarity selection does not include at least 1 positive (+) and 1 negative (-) polarity.	Ensure that at least 1 positive (+) and 1 negative (-) polarity are selected for each stim set.
	Lead is damaged or malfunctioning.	Test the lead for an electrical circuit using the programmer.
	Amplitude is set too low.	Increase amplitude until comfortable stimulation is achieved.
	IPG is in the cycle or bolus off phase.	Check to see if the IPG is in cycle or bolus off phase. Wait until the phase is completed.
	IPG is in MRI mode.	Turn off MRI mode.
	IPG power is off.	Check to see that the IPG power is on.

Table 8. Troubleshooting during postoperative programming

Problem	Possible Cause	Possible Solution
	IPG battery is low and stimulation shut off.	Recharge the IPG.
	Patient has inadvertently changed the programming.	Reprogram the system; review operation and usage with the patient.
	Implant is damaged.	Contact Technical Support.
Less-Than-Optimal Stimulation		
Stimulation field does not overlap the pain pattern.	Active electrodes are not positioned over the target.	Set amplitude to zero and program different electrodes.
	Lead has migrated.	Evaluate with fluoroscopy. Attempt to reprogram the electrode selections prior to surgical intervention.
	Pain pattern has changed.	Reposition stimulation coverage by reprogramming electrode selection or surgically repositioning the lead.
Stimulation does not provide adequate pain relief but overlaps the pain pattern.	Stimulation program is ineffective.	Set amplitude to zero and select new stimulation values.
	MaxTol setting is too low.	Test the setting and reprogram if necessary.
	Patient adapted to stimulation.	Consider changing from continuous to MultiStim™ stimulation mode.
Intermittent Stimulation		
Amplitude settings remain constant but stimulation is intermittent.	Patient is sensitive to changes in body position that affect stimulation.	Adjust amplitude; reprogram the system if necessary.
	Patient has inadvertently changed the programming.	Reprogram the system; review operation and usage with the patient.
	Implantable system is damaged or malfunctioning.	Contact Technical Support.
Uncomfortable Stimulation		
Stimulation is uncomfortable.	Amplitude and/or pulse width settings are too high.	Adjust settings to a comfortable level, avoiding abrupt changes. NOTE: Amplitude should be decreased as pulse width is increased.

Table 8. Troubleshooting during postoperative programming

Problem	Possible Cause	Possible Solution
	Frequency is improperly set.	Adjust settings to a comfortable level, avoiding abrupt changes.
	Active electrodes are not positioned over the correct target.	Set amplitude to zero and program different electrodes.
	Patient has inadvertently changed the programming.	Reprogram the system; review operation and usage with the patient.
Painful Stimulation		
Patient feels a burning sensation.	Lead is fractured or current is leaking.	X-ray the entire system for lead fracture, breaks, or sharp angles.
	Patient has inadvertently changed the programming.	Reprogram the system; review operation and usage with the patient.
	Excessive scarring or fibrotic build-up is present around the electrodes.	Order a new X-ray and compare it with the original.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Patient Programmer Specifications

The Prodigy™ patient programmer (Model 3855 or 3856) has the following physical specifications.

Table 9. Patient programmer specifications

MRI status	MR Unsafe
Height	6.8 cm (2.7 in.)
Length	10.77 cm (4.2 in.)
Thickness (T)	2.6 cm (1.0 in.)
Weight	128 g (4.6 oz)
Expected service life	5 years
Storage temperature	-10°C–55°C (14°F–131°F)
Storage humidity	10%–90% (noncondensing)
Storage pressure	70–150 kPa (10.2–21.8 psi)
Operating temperature	10°C–40°C (50°F–104°F)

Table 9. Patient programmer specifications

Operating humidity	30%–75% (noncondensing)
Operating pressure	70–106 kPa (10.2–15.4 psi)

Default Settings for Programs

The following table shows the default values for tonic and BurstDR™ stimulation programs for this system.

Table 10. Default settings for programs

Program Parameter	Default Value for Tonic Programs	Default Value for Burst Programs
Pulse width	200 μ s	1000 μ s
Frequency	30 Hz	N/A
Burst rate frequency	N/A	40 Hz
Intraburst frequency	N/A	500 Hz
Amplitude	0 mA	0 mA
Polarities	Off	Off
Number of stim sets/burst pulses	1	5
Stimulation mode	Continuous	Continuous
Magnet use mode	On/Off	On/Off
Step size	0.1 mA	0.05 mA

Appendix B: Regulatory Statements

This section contains regulatory statements about your product.

Statement of FCC Compliance (FCC ID:PX 2001)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical

and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.

Wireless Technology Information

The following table summarizes technical details of the wireless technology of the patient programmer.

Table 11. Wireless technology information for patient programmer

Operating frequency (inductively coupled device)	87.5 kHz $\pm$ 2.5 kHz
Field strength (inductively coupled device)	32 dB μ A/m at 3 m*
Effective range	0.5–2.5 cm
Quality of service (QoS)	QoS is ensured by a communication link between the implant and the patient programmer, which is assessed during initial linking of the devices and monitored throughout the system's use. If the devices cannot establish a sufficient link or if either device receives invalid data, the patient programmer will display an error message.
Wireless security measures	The wireless data that is sent between the implanted generator and the patient programmer is through short-range inductive coupling, which does not propagate through free space. The patient programmer uses a proprietary data format that is incompatible with other systems.

*H-field measurement per ETSI EN 302 195 (radio requirements for ultra-low-power active medical implants and peripherals)

Appendix C: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 12. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website
	Type BF Applied Part
	Do not use if package is damaged
	MR Unsafe

Table 12. Symbols and definitions

Symbol	Definition
	NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Keep dry; keep away from rain
	Use-by date
	Date of manufacture
	Manufacturing facility
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Programmer
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health,

Table 12. Symbols and definitions

Symbol	Definition
	which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
	This device is listed by the Canadian Standards Association (CSA) International as certified

Appendix D: Electromagnetic Compatibility Guidelines

The Prodigy™ patient programmer, hereafter the device, is medical equipment and should be used with the following guidance:

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device has no essential performance, as defined by IEC 60601-1/AMD1:2012 (Edition 3.1). Performance of the device was maintained during electromagnetic disturbance testing. The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION: The device complies with the limits for medical devices contained in IEC 60601-1-2:2014-04 and CISPR11:2015 (BS EN 55011:2016). However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.

CAUTION: To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by Abbott Medical with this system. Do not use Abbott Medical components with devices or systems that are not approved by Abbott Medical.

Table 13. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

NOTE: The RF output frequency of the device is 87.5 kHz. The field strength is 32 dBμA/m at 3 m (inductively coupled device).

Table 14. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	No guidance for battery-powered devices.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	No guidance for battery-powered devices.

Table 14. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions IEC 61000-4-11	<5% U _T 40% U _T 70% U _T	Not applicable	No guidance for battery-powered 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM/Radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	6 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d} \sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).

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

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

Table 15. Guidance and Manufacturer's Declaration – Proximity Fields

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance d = 0.3 m
	450 MHz: 28 V/m @ FM modulation ±5 kHz tolerance	28 V/m	
	710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz pulse modulation	9 V/m	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-04
ARTEN600283818 A



Proclaim™ Implantable Pulse Generator

Models 3660, 3661, 3662, 3663, 3670, 3671, 3672, 3673

Clinician's System Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Indications for Use.	1
Contraindications.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	3
Adverse Effects.	5
Safety and Effectiveness Studies.	5
System Overview.	5
Product Description.	6
Package Contents.	6
Identifying the IPG.	7
Directions for Use.	7
Creating an IPG Pocket.	7
Connecting a Lead or Extension to the IPG.	7
Implanting the IPG.	9
Replacing the IPG.	10
Disposing of Explanted Components.	10
Checking the Status of the IPG Battery.	10
Technical Support.	10
Appendix A: Product Specifications.	10
Storage Specifications.	10
Product Materials.	10
IPG Specifications.	11
Compatibility Guidelines for IPGs with Compatible Headers.	12
Appendix B: System Components and Accessories.	13
IPGs.	13
Programmers and Controllers.	13
Leads and Extensions.	13
Adapters.	14
Trial System.	14
Appendix C: Battery Longevity Information.	15
Energy Factors for Tonic Stimulation Parameters.	15
Energy Factors for BurstDR™ Stimulation Parameters.	20
Battery Longevity Graphs.	33
Appendix D: Regulatory Statements	34
Disposal Guidelines for Battery-Powered Devices.	34
Statement of FCC Compliance.	34
Identification Information for Product Registration.	34
Wireless Technology Information.	34
Radio Transmitter, Cables, Transducers.	35
Quality of Service for Wireless Technology.	35
Appendix E: Symbols and Definitions.	36

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

Refer to the Indications for Use Data Sheet for Abbott Medical spinal cord stimulation systems.

Contraindications

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to this neurostimulation system.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an electrosurgery device, place the device in Surgery Mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure.

During implant procedures, if electrosurgery devices must be used, take the following actions:

- Use bipolar electrosurgery only.
- Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.

- Set the electrosurgery device to the lowest possible energy setting.
- Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Other active implanted devices. The neurostimulation system may interfere with the normal operation of another active implanted device, such as a pacemaker, defibrillator, or another type of neurostimulator. Conversely, the other active implanted device may interfere with the operation of the neurostimulation system.

Interference with other devices. Some of this system's electronic equipment, such as the programmer and controller, can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Operation of machines, equipment, and vehicles. Patients using therapy that generates paresthesia should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract them from properly operating it. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. For patients who do not feel paresthesia, sudden stimulation changes are less likely to occur and distract them while operating motorized vehicles, machinery, or equipment.

Explosive and flammable gases. Do not use a clinician programmer or patient controller in an environment where explosive or flammable gas fumes or vapors are present, including hyperbaric chambers. The operation of these devices could cause them to ignite, causing severe burns, injury, or death.

Keep the device dry. Programmer and controller devices are not waterproof. Keep them dry to avoid damage. Advise patients to not use their device when engaging in activities that might cause it to get wet, such as swimming or bathing.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Application modification. To prevent unintended stimulation, do not modify the operating system or application in any way. Do not use the application if the operating system is compromised (that is, jailbroken).

Case damage. Do not handle the IPG if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

IPG disposal. Return all explanted IPGs to Abbott Medical for safe disposal. IPGs contain batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

Product materials. Neurostimulation systems have materials that come in contact or may come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.

Precautions

The following precautions apply to this neurostimulation system.

General Precautions

Clinician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of two systems. If two systems are implanted, ensure that at least 20 cm (8 in.) separates the implanted IPGs to minimize unintended interaction with other system components.

Implantation of multiple leads. If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads can possibly create a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the stimulator. If unpleasant sensations occur, the device should be turned off immediately.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks after implantation of a neurostimulation system. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

Patient training. Instruct patients to use their neurostimulation system only after an authorized clinician has programmed the device and has trained the patient how to control stimulation and safely use the system.

Programmer use. Allow only authorized use of the clinician programmer to avoid any programming changes that may injure a patient.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use the system if the use-by date has expired.

Handle the device with care. The clinician programmer and patient controller are sensitive electronic devices that can be damaged by rough handling, such as dropping them on the ground.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Prior to connection, exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

System testing. To ensure correct operation, always test the system during the implant procedure, before closing the neurostimulator pocket, and before the patient leaves the surgery suite.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

External defibrillators. The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead. Damage to the system may not be immediately detectable.

Home and Occupational Environments

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Patients should cautiously approach such devices and should request help to bypass them. If they must go through a gate or doorway containing this type of device, patients should turn off their IPG and proceed with caution, being sure to move through the device quickly.

Scuba diving or hyperbaric chambers. Patients should not dive below 30 m (100 ft) of water or enter hyperbaric chambers above 4.0 atmospheres absolute (ATA). Pressures below 30 m (100 ft) of water (or above 4.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the device and generator; however, it will not change the prescribed programmed parameters. Patients should be advised to keep their mobile phones and smart watches at least 15 cm (6 in.) away from the generator and avoid placing any smart device in a pocket near the generator. If a patient is concerned about a smart device interacting with their neurostimulation system, consider disabling magnet mode. For more information about setting the magnet mode, refer to the clinician programmer manual or contact Technical Support.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with using this neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or IPG site
- Seroma (mass or swelling) at the IPG site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Safety and Effectiveness Studies

For information that supports the clinical use of this neurostimulation system, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems (available online at medical.abbott/manuals). This neurostimulation system is similar in technology and intended use to the systems reported in the literature and clinical studies. Therefore, the literature and clinical studies represent the safety and effectiveness of this neurostimulation system.

System Overview

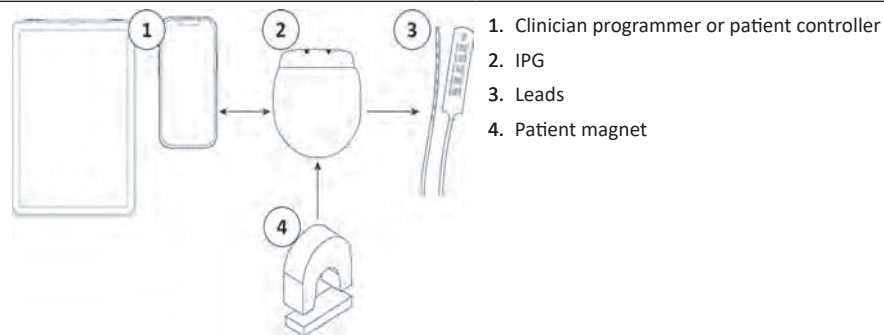
This neurostimulation system is designed to deliver electrical stimulation to nerve structures. The neurostimulation system includes the following main components:

- Implantable pulse generator (IPG)
- Leads
- Clinician programmer
- Patient controller
- Patient magnet

The IPG delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation. The patient magnet can turn the IPG on and off if the physician enabled this functionality. Physicians use the clinician programmer to create and modify programs for a patient. Patients use the patient controller to control their prescribed programs.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction among main system components



NOTE: This manual provides instructions for implanting the IPG. For instructions for using other components, see the applicable manuals for those components.

Product Description

This implantable pulse generator (IPG) is an electronic device designed to be connected to one or more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The IPG can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The IPG communicates wirelessly with system programmers and controllers, and IPGs are available in small and large sizes to accommodate different power needs.

Some models support additional functions:

- **Upgradeability.** Models can receive software upgrades after implantation to provide patients with additional features as approved by the respective regulatory agencies. To upgrade features on the IPG, a system programmer is needed.
- **Compatible header.** Models with a compatible header are designed to allow the IPG to connect to leads or extensions from another manufacturer that meet the compatibility guidelines (referred to as “IPGs with compatible headers”).

For more information about which models provide these additional functions, as well as other IPG specifications, see the appropriate appendix in this manual.

NOTE:

- For more information about the neurostimulation system, see the clinician’s programming manual for this system.
- In this document, the term “clinician programmer” refers to the NeuroSphere™ Clinician Programmer device, “patient controller” refers to the NeuroSphere™ Patient Controller device, “clinician programmer app” refers to the NeuroSphere™ Clinician Programmer software application (app), and “patient controller app” refers to the NeuroSphere™ Patient Controller app.

Package Contents

In addition to the product documentation, the IPG kit contains the following items:

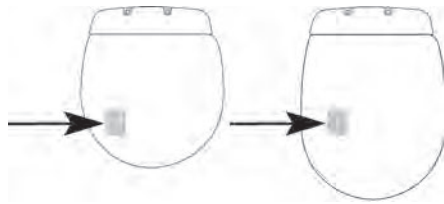
- 1 IPG (see the appendix in this manual for model numbers)
- 1 pocket sizer
- 1 torque wrench (Model 1101)
- 2 port plugs (Model 1111)

Identifying the IPG

Before implanting the IPG, you can view the model number engraved on the IPG. After implantation, you can identify the IPG using a radiopaque identification tag that you can view with standard X-ray procedures. The tag, which is located in the lower left corner of the IPG when the logo side of the IPG is facing toward you, contains a code in the following format: SJMLN. 'SJM' designates Abbott Medical as the manufacturer; 'LN' is a letter and a number combination that identifies the model family (see the following figure).

For the Proclaim™ IPG, the code is SJM A1. To determine the exact model IPG that is implanted, use the clinician programmer app to communicate with the IPG and view IPG information. See the clinician's manual for the clinician programmer for instructions.

Figure 2. Location of the IPG code on a small IPG (left) and large IPG (right)



Directions for Use

Read this section carefully for suggested directions for use related to the IPG. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

NOTE: Before the surgical procedure, set up communication between the clinician programmer and the IPG while the IPG is in its sterile packaging to ensure that it is functional. If the IPG has never established communication with a programmer, you must first activate the IPG for communication ("wake up" the IPG) by holding a magnet over the IPG for 10 seconds.

Creating an IPG Pocket

The following steps outline the suggested procedure to create an IPG pocket:

1. Determine the site for the IPG, ensuring that the lead is long enough to reach the pocket and provide a strain relief loop.

CAUTION: Do not place the IPG deeper than 4.0 cm (1.57 in.) because the clinician programmer may not communicate effectively with the IPG.

NOTE: Common sites for IPG implantation are along the midaxillary line, in the upper buttock along the posterior axillary line (taking care to avoid the belt line), and in the area over the abdomen just below the lowermost rib. To ensure a flat area is selected, you can mark a flat area prior to the surgical procedure while the patient is in a sitting position.

2. Create the pocket so that the IPG is parallel to the skin surface and no deeper than 4.0 cm (1.57 in.) below the skin surface.
3. Insert and remove the pocket sizer to ensure that the pocket is large enough to accommodate the IPG, allowing enough extra room for a strain relief loop for each lead or extension.

Connecting a Lead or Extension to the IPG

The following steps outline the suggested guidelines to connect a lead or extension to the IPG:

WARNING: To avoid harming the patient or damaging the neurostimulation system, ensure that any electrosurgery procedures are completed before connecting the leads or extensions to the IPG.

CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

1. If any of the lead or extension contacts came in contact with body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.

2. To help ensure that the lead or extension can be fully inserted into the IPG header, insert the torque wrench through the septum on the IPG header, turn the torque wrench clockwise to tighten the setscrew until the torque wrench clicks, and then loosen the setscrew again by turning the wrench counterclockwise about 2.5 times.

CAUTION:

- Use only the torque wrench included in the extension, IPG, or torque wrench kit. If you need to loosen the setscrew, turn the setscrew (in quarter turns counterclockwise) just enough to insert or remove the lead or extension from the IPG header. Retracting the setscrew too far may cause it to come loose and fail to secure the lead or extension to the IPG.
 - To avoid sharply bending and damaging the lead or extension when performing the following step, insert the lead or extension parallel with the header port. Additionally, try grasping the lead or extension about 5 mm at a time from the opening of the header port while inserting.
3. Using clean gloves, carefully slide the proximal end of the lead or extension into the IPG header until it stops. Confirm that the lead or extension is correctly inserted by following these visual indicators and referring to the corresponding figures that follow:
 - For IPGs that connect to Abbott Medical leads or extensions, the first contact band (at the tip) of the lead or extension extends slightly past the first header contact and is visible, the windows between each of the header contacts are clear, and the ninth contact band of the lead or extension is not visible.
 - For IPGs with compatible headers, the windows between each of the header contacts are clear and none of the contact bands are visible.

Figure 3. Correct versus incorrect insertion of the lead or extension (IPGs with Abbott Medical leads or extensions)

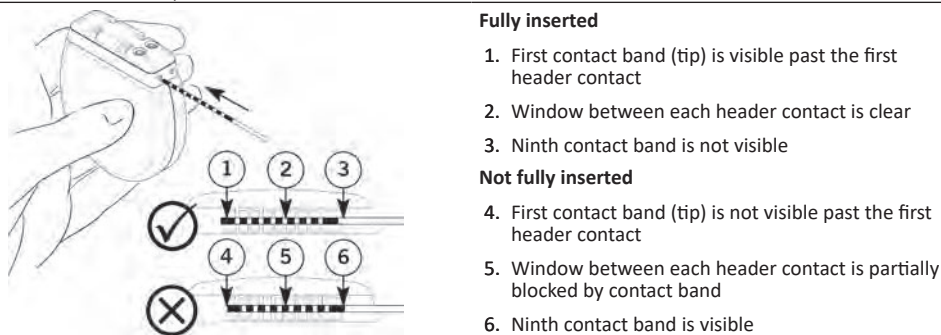
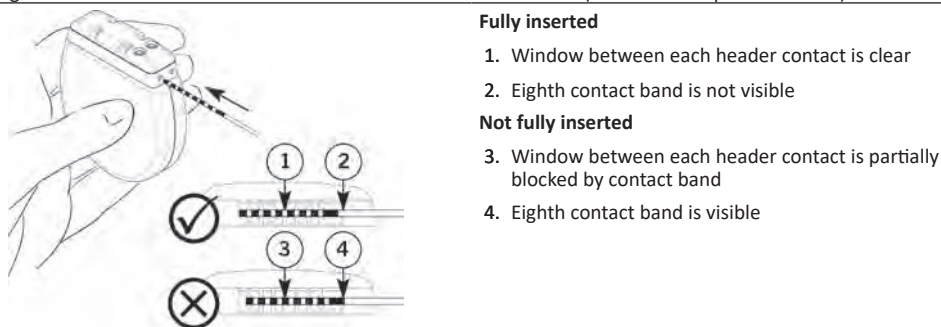


Figure 4. Correct versus incorrect insertion of the lead or extension (IPGs with compatible header)



4. Use the clinician programmer app to communicate with the IPG, and test the impedance to ensure that the lead or extension is fully inserted. See the clinician's manual for the clinician programmer app for instructions.

5. Insert the torque wrench through the septum and tighten the setscrew, turning it clockwise until the torque wrench clicks.

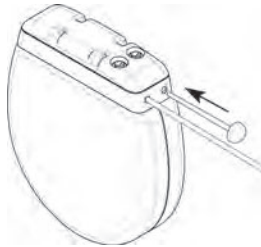
NOTE: After removing the torque wrench, check the septum to ensure it has closed. If the septum did not close, gently reseal the septum flaps.

Figure 5. Tighten the setscrew clockwise



6. If implanting two leads, repeat the previous steps. If implanting a single lead only, insert the header port plug into the unused port, and use the torque wrench to tighten the setscrew until the torque wrench clicks.

Figure 6. Insert the port plug



Implanting the IPG

The following steps outline the suggested procedure to implant the IPG:

1. Place the IPG into the IPG pocket with the logo side facing the skin surface and at a depth not to exceed 4.0 cm (1.57 in.).

NOTE: By implanting the IPG with the logo side facing the skin surface, you enhance the IPG's ability to detect a magnet.

2. Carefully coil any excess lead or extension behind the IPG in loops no smaller than 2.5 cm (1 in.) in diameter to provide strain relief for the lead or extension and IPG connection.

CAUTION: Do not bring the suture needle in contact with an IPG, lead, or extension, or the component may be damaged.

3. To stabilize the IPG within the pocket, pass suture through the holes at the top of the IPG header and secure it to connective tissue.
4. Check the entire system by fluoroscopy before closing to ensure proper positioning of the lead or leads and that it is straight, with no sharp bends or kinks.
5. Use the clinician programmer app to communicate with the IPG and perform intraoperative testing to confirm that the system is operational. See the clinician's manual of the clinician programmer app for instructions.

NOTE: IPG output may not be identical to that of the trial stimulator at the same settings.

6. Ensure that the IPG is away from the pocket incision suture line, close the pocket incision, and apply the appropriate dressings.

Replacing the IPG

The following steps outline the suggested procedure to replace an IPG:

1. Turn off stimulation or verify that it is turned off.
CAUTION: Exercise care when using sharp instruments or electrocautery around leads or extensions, or they may be damaged.
2. Open the IPG implant site per normal surgical procedure.
3. Insert the torque wrench through the septum of the IPG header and loosen the setscrew by turning it counterclockwise.
CAUTION: When performing the following step, do not bend the lead or extension sharply; or it may be damaged.
4. Gently remove the lead or extension from the IPG header; then clean and dry all connections, ensuring they are free of fluid and tissue.
5. To complete the IPG replacement procedure, see the following sections: “Connecting a Lead or Extension to the IPG” (page 7) and “Implanting the IPG” (page 9).

Disposing of Explanted Components

Explanted Abbott Medical components should be returned to Abbott Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your Abbott Medical representative or Technical Support.

Checking the Status of the IPG Battery

The IPG contains a nonrechargeable battery. The amount of time that the battery will provide active stimulation depends on the patient’s stimulation settings and daily usage time. To check the status of the IPG battery, use the clinician programmer app or patient controller app. For more information about this function, refer to the clinician’s programming manual and the user’s guide for the patient controller app. For information about estimating longevity of the IPG battery, see the appropriate appendix in this manual.

NOTE: IPG battery status is available one day after first using the clinician programmer app to program the IPG.

The following list provides general information about the battery status:

- A low-battery warning will appear on the clinician programmer app or patient controller app when the battery is approaching its end of service.
- Stimulation will automatically stop when the battery cannot support stimulation.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components in this kit according to the following conditions.

Table 1. Storage conditions for components

Temperature	-20°C–60°C (-4°F–140°F)

Product Materials

The following components are intended to come into contact with tissue.

Table 2. Product materials for IPG kit

Component	Material
IPG	Titanium, silicone rubber
Pocket sizer	Polybutylene terephthalate
Port plug	Polysulfone
NOTE: These components are not made with natural rubber latex.	

IPG Specifications

The Proclaim™ IPGs have the following physical specifications.

Table 3. IPG specifications

			MRI Status	Upgradeable Features, Burst Capable	FlexBurst360™ Capable	Compatible Header
Model	3660	3662	MR Conditional	Yes	No	No
	3661	3663	MR Unsafe	Yes	No	Yes
	3670	3672	MR Conditional	Yes	Yes	No
	3671	3673	MR Unsafe	Yes	Yes	Yes
Height	5.55 cm (2.19 in.)	6.68 cm (2.63 in.)				
Length	4.95 cm (1.95 in.)	5.02 cm (1.98 in.)				
Thickness	1.34 cm (0.53 in.)	1.35 cm (0.53 in.)				
Weight	48.9 g (1.7 oz)	58.3 g (2.1 oz)				
Volume	30.4 cm ³ (1.9 in. ³)	38.6 cm ³ (2.4 in. ³)				
Power source	Carbon monofluoride/silver vanadium oxide cell					
Connector strength	10 N (Models 3660, 3662, 3670, 3672)					
	5 N (Models 3661, 3663, 3671, 3673)					
Program storage capacity	15 programs					

The IPG has the following operating parameters.

Table 4. Operating parameters for the IPG

Parameter	Tonic Range	Tonic Steps	Burst Range*	Burst Steps*
Pulse width	20–1000 μ s	10 μ s (20–500 μ s range) 50 μ s (500–1000 μ s range)	50–1000 μ s	50 μ s
Frequency	2–200 Hz	2 Hz	—	—
	200–500 Hz	10 Hz	—	—
	500–1200 Hz	20 Hz	—	—
Burst rate frequency	—	—	10–60 Hz	10 Hz
Intraburst frequency	—	—	250–500 Hz	10 Hz
			500–1000 Hz	20 Hz
Amplitude	0–25.5 mA	0.1–1.0 mA	0–12.75 mA	0.05–0.50 mA
	0–12.75 mA	0.05–0.50 mA		

NOTE:

- Columns with * represent operating parameters for BurstDR™ stimulation programs on IPGs capable of BurstDR stimulation mode.
- For each tonic program, you have the option to select the amplitude range. For information on setting the amplitude range, see the clinician's programming manual for this system.
- The number of areas in use for a tonic program governs the maximum frequency (1200/number of areas). The number of areas in use for a burst program governs the maximum burst rate frequency (60/number of areas).
- The maximum current depends on the impedance, frequency, and pulse width settings.

Compatibility Guidelines for IPGs with Compatible Headers

IPGs with compatible headers are compatible with the following Medtronic† leads and extensions available before May 5, 2015.

Table 5. Compatible Medtronic leads and extensions

Device	Model
Permanent lead	3776-45, 3776-60, 3776-75, 3876-45, 3876-60, 3876-75, 3777-45, 3777-60, 3777-75, 3877-45, 3877-60, 3877-75, 3778-45, 3778-60, 3778-75, 3878-45, 3878-60, 3878-75, 39286-30, 39286-65, 39565-30, 39565-65
Extension	3708120, 3708140, 3708160, 3708220, 3708240, 3708260, 3708320, 3708340, 3708360, 3876, 3877, 3878

WARNING: The use of Medtronic leads or extensions other than those specified in this table may increase risk to the patient, including the potential for tissue damage.

Appendix B: System Components and Accessories

The Proclaim™ neurostimulation system includes the following components.

NOTE:

- Not all models are available in all countries. Contact your local representative for more information.
- Model 3661, 3663, 3671, and 3673 IPGs are compatible only with the leads and extensions listed in “Compatibility Guidelines for IPGs with Compatible Headers” (page 12). They are not compatible with Abbott Medical leads and extensions.

IPGs

3660 Proclaim™ XR 5 implantable pulse generator
3661 Proclaim™ 5 implantable pulse generator
3662 Proclaim™ XR 7 implantable pulse generator
3663 Proclaim™ 7 implantable pulse generator
3670 Proclaim™ Plus 5 implantable pulse generator
3671 Proclaim™ Plus 5 implantable pulse generator
3672 Proclaim™ Plus 7 implantable pulse generator
3673 Proclaim™ Plus 7 implantable pulse generator

IPG Accessories

1101 Torque wrench
1111 Port plug

Programmers and Controllers

3874 NeuroSphere™ Clinician Programmer App
3875 NeuroSphere™ Patient Controller App

Programmer and Controller Accessories

1210 Patient magnet
3884 SCS patient manual and magnet

Leads and Extensions

3100-series percutaneous leads
3200-series paddle leads
3300-series extensions

Lead and Extension Accessories

1100-series stylets
1102 Guide wire for percutaneous leads
1103 Introduce-AK™ lead introducer
1105 Lead anchor, butterfly
1106 Lead anchor, long
1109 Strain relief
1112 Tunneling tool, 12 in.
1114 Epidural needle, 14 gauge, 4 in. (10 cm)
1116 Epidural needle, 14 gauge, 6 in. (15 cm)
1120 Tunneling tool, 20 in.
1192 Swift-Lock™ anchor
1194 Cinch™ anchor

1701 SCS accessory kit
1803 Lead and extension insertion tool

Adapters

2311 8-channel adapter, M, 10 cm
2316 8-channel adapter, M, 60 cm

Trial System

3599 Abbott Medical External Pulse Generator

Trial System Accessories

1203 Cleaning cloths
1212 Coin cell batteries
1213 Pouch with adhesive (5)
1214 Pouch without adhesive and belt (5)
1216 EPG header cap
1218 Carrying case
1917 Battery door
3013 Multilead trial cable
3032 External pulse generator, 2-port header

Appendix C: Battery Longevity Information

The longevity of the IPG battery depends on the following factors:

- Programmed settings for each area
- Program impedance
- Hours of stimulation per day
- Shelf life of the device between the dates of manufacture and implant
- Duration of communication sessions between the IPG and the patient controller or clinician programmer

NOTE: An “Area” refers to a combination of selected stimulation parameters. For tonic stimulation, stimulation parameters for each area include electrode configuration, amplitude, frequency and pulse width. For BurstDR™ stimulation, stimulation parameters for each area include electrode configuration, amplitude, pulse width, burst frequency, intra-burst rate and number of pulses.

To estimate battery longevity manually, perform the following steps. For additional help with estimating battery longevity, contact Technical Support.

1. Locate the energy factor for the desired stimulation parameters according to the lead impedance in the tables in one of the following sections:
 - For IPGs using tonic stimulation parameters, see “Energy Factors for Tonic Stimulation Parameters” (page 15).
 - For IPGs using BurstDR™ stimulation parameters, see “Energy Factors for BurstDR™ Stimulation Parameters” (page 20).

NOTE: If the desired parameters do not appear in the tables, estimate the energy factor by choosing a value between the listed energy factors for the closest parameters.

2. For IPGs using multiple areas, perform one of the following options:
 - For tonic stimulation programs, determine the energy factor for each area from the previous step, and add each of these values together.
 - For BurstDR stimulation programs with equivalent parameters for each area, find the tables with the equivalent number of areas and burst frequency and determine the energy factor.
 - For BurstDR stimulation programs with different parameters for each area, find the tables with the equivalent number of areas and burst frequency. Then, determine the energy factor for each area’s parameters and average the energy factor values.
3. Use the figures in “Battery Longevity Graphs” (page 33) to determine the estimated battery longevity by finding the energy factor from the previous steps on the curve for the appropriate model IPG.

Energy Factors for Tonic Stimulation Parameters

The following tables show energy factors according to various stimulation parameters for tonic programs.

NOTE: Energy factors are for IPGs that provide 12 hours of daily stimulation. For an IPG that is providing 24 hours of daily stimulation, double the energy factor shown in the table.

Table 6. Energy factors for various tonic stimulation parameters (350-ohm impedance)

Amplitude (mA)	Frequency (Hz)	Pulse Width (μs)			
		100	200	300	500
1	30	13	14	14	15
	60	18	19	20	23
	90	22	24	26	29
2	30	15	17	20	24
	60	21	26	30	40
	90	27	34	41	54

Table 6. Energy factors for various tonic stimulation parameters (350-ohm impedance)

Amplitude (mA)	Frequency (Hz)	Pulse Width (μ s)			
		100	200	300	500
3	30	16	19	23	30
	60	24	30	37	51
	90	30	41	51	71
4	30	17	22	26	47
	60	26	35	44	85
	90	34	47	61	122
5	30	21	30	38	55
	60	34	51	68	102
	90	46	71	97	148
6	30	23	33	43	81
	60	37	58	78	152
	90	51	81	112	223
7	30	29	44	60	92
	60	49	80	112	175
	90	68	115	162	257
8	30	31	49	67	125
	60	53	89	125	242
	90	74	129	183	359
9	30	33	64	89	139
	60	58	118	169	271
	90	81	173	249	401
10	30	41	69	97	182
	60	73	130	186	355
	90	105	190	274	528

Table 7. Energy factors for various tonic stimulation parameters (500-ohm impedance)

Amplitude (mA)	Frequency (Hz)	Pulse Width (μ s)			
		100	200	300	500
1	30	13	14	14	15
	60	18	19	20	23
	90	22	24	26	29
2	30	15	17	20	24
	60	21	26	30	40
	90	27	34	41	54
3	30	16	19	23	38
	60	24	30	37	68
	90	30	41	51	97
4	30	19	26	33	47
	60	31	44	58	85
	90	41	61	82	122
5	30	24	35	47	69
	60	40	62	85	130
	90	54	88	122	190
6	30	26	40	54	81
	60	44	71	98	152
	90	61	102	142	274
7	30	33	52	72	111
	60	57	96	135	214
	90	80	139	198	317
8	30	35	58	94	148
	60	62	107	180	288
	90	88	156	264	426
9	30	43	74	104	190
	60	78	139	200	372
	90	112	203	294	554
10	30	53	92	131	210
	60	96	175	254	412
	90	140	258	376	613

Table 8. Energy factors for various tonic stimulation parameters (700-ohm impedance)

Amplitude (mA)	Frequency (Hz)	Pulse Width (μ s)			
		100	200	300	500
1	30	13	14	16	18
	60	18	19	24	28
	90	22	24	31	38
2	30	15	17	20	24
	60	21	26	30	40
	90	27	34	41	54
3	30	18	23	28	38
	60	27	37	48	68
	90	36	51	66	97
4	30	22	31	40	58
	60	35	53	71	107
	90	47	75	102	156
5	30	24	41	55	83
	60	40	73	102	158
	90	54	105	148	232
6	30	30	47	63	114
	60	51	85	119	220
	90	71	122	173	325
7	30	37	60	84	151
	60	65	112	159	294
	90	92	163	234	436
8	30	45	76	108	197
	60	81	144	207	382
	90	116	211	305	566
9	30	58	98	139	220
	60	103	184	265	427
	90	147	269	390	710
10	30	62	119	169	271
	60	112	225	326	529
	90	160	330	482	871

Table 9. Energy factors for various tonic stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Frequency (Hz)	Pulse Width (μ s)			
		100	200	300	500
1	30	14	15	16	18
	60	19	21	24	28
	90	24	27	31	38
2	30	16	20	23	30
	60	24	31	37	51
	90	31	41	51	72
3	30	20	26	33	47
	60	31	44	58	85
	90	41	61	81	122
4	30	24	35	47	69
	60	40	62	85	130
	90	54	88	122	190
5	30	30	47	64	98
	60	51	85	119	186
	90	72	122	173	275
6	30	37	60	84	131
	60	65	112	160	292
	90	92	163	234	431
7	30	49	80	112	195
	60	85	148	211	377
	90	120	215	345	558
8	30	58	98	139	243
	60	103	184	293	473
	90	148	269	432	702
9	30	68	119	185	297
	60	124	225	358	580
	90	178	362	529	939
10	30	80	153	221	356
	60	147	293	429	699
	90	213	433	635	1126

Energy Factors for BurstDR™ Stimulation Parameters

The following tables show energy factors according to various stimulation parameters for BurstDR™ stimulation programs. There are unique sets of tables for various numbers of BurstDR™ stimulation areas and frequency combination.

NOTE:

- Energy factors represent IPGs that provide 24 hours of daily stimulation using default values for the number of pulses, Intra-burst Rate, and Pulse Width settings.
- In neurostimulation therapy, “dose” refers to the delivery of a quantity of energy to tissue. A difference in “dose” in this context does not imply differences in expected effectiveness response as it would with a drug. There is no demonstrated difference in safety or effectiveness among these doses.

One BurstDR™ Stimulation Area with Frequency of 40 Hz

Table 10. Energy factors for one BurstDR stimulation area at 40 Hz for various BurstDR stimulation parameters (350-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	47	31	25	23	16	13	7	77
0.4	71	43	34	28	20	17	10	89
0.6	93	53	41	34	24	20	12	104
0.8	117	65	49	40	29	25	13	118
1.0	146	76	56	46	34	28	16	134
1.2	175	106	84	73	50	42	24	240
1.4	202	121	95	82	56	48	26	270
1.6	230	135	106	91	63	55	29	301
1.8	247	151	120	100	70	60	33	330
2.0	279	163	133	110	76	65	35	361

Table 11. Energy factors for one BurstDR stimulation area at 40 Hz for various BurstDR stimulation parameters (500-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	46	32	25	23	15	13	7	76
0.4	71	44	34	29	19	18	9	91
0.6	95	56	41	34	24	20	12	105
0.8	121	67	49	41	28	25	14	120
1.0	151	93	73	64	43	37	21	211
1.2	174	108	84	73	50	43	23	240
1.4	203	122	96	82	57	48	26	271
1.6	225	137	106	93	64	55	29	301
1.8	264	160	129	111	70	59	32	330
2.0	297	196	168	146	97	83	45	512

Table 12. Energy factors for one BurstDR stimulation area at 40 Hz for various BurstDR stimulation parameters (700-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	49	32	26	23	15	13	8	73
0.4	72	43	34	29	20	17	10	90
0.6	94	53	41	35	24	21	12	101
0.8	125	79	62	54	37	31	17	180
1.0	153	95	74	64	43	37	20	208
1.2	177	108	85	73	50	42	23	239
1.4	209	129	103	90	57	48	27	273
1.6	239	159	132	115	80	68	36	417
1.8	271	179	149	132	88	75	41	465
2.0	299	195	164	146	97	83	44	509

Table 13. Energy factors for one BurstDR stimulation area at 40 Hz for various BurstDR stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	48	32	26	23	15	13	7	77
0.4	71	43	34	29	20	17	10	93
0.6	100	64	51	45	30	26	15	152
0.8	126	78	62	56	37	31	17	182
1.0	151	96	73	64	44	37	20	212
1.2	184	127	106	94	62	53	29	333
1.4	215	145	119	107	72	61	33	378
1.6	241	163	134	120	80	68	37	422
1.8	281	208	183	160	106	92	49	556
2.0	312	228	197	182	117	100	54	607

Two BurstDR™ Stimulation Areas each with Frequency of 20 Hz

Table 14. Energy factors for two BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (350-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	58	41	31	25	20	18	10	79
0.4	92	62	43	34	30	25	14	—
0.6	128	83	56	42	38	33	17	—
0.8	162	105	69	50	47	40	21	—
1.0	197	127	83	59	55	47	25	—
1.2	232	158	110	86	75	64	34	—
1.4	267	179	125	97	85	73	39	—
1.6	304	202	142	109	95	82	44	—
1.8	338	226	156	120	106	91	49	—
2.0	371	249	172	132	116	100	54	363

Table 15. Energy factors for two BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (500-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	58	40	31	26	21	18	10	79
0.4	93	62	44	34	29	26	13	—
0.6	127	83	57	42	38	33	17	—
0.8	161	105	69	51	46	40	21	—
1.0	196	136	95	74	64	56	29	—
1.2	232	157	110	86	75	65	34	—
1.4	268	180	125	98	85	73	39	—
1.6	303	203	140	109	95	83	44	—
1.8	338	227	156	121	106	91	49	—
2.0	370	263	197	163	133	115	61	511

Table 16. Energy factors for two BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (700-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	57	41	30	25	21	18	9	79
0.4	93	62	44	34	29	26	14	—
0.6	128	83	57	42	38	33	18	—
0.8	162	111	79	63	53	46	25	—
1.0	196	134	95	75	64	55	29	—
1.2	231	156	110	86	74	64	34	—
1.4	267	181	125	98	85	73	39	—
1.6	302	215	162	134	110	94	51	—
1.8	337	240	180	149	122	105	56	—
2.0	373	266	198	163	134	115	62	512

Table 17. Energy factors for two BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	57	40	30	25	21	18	10	78
0.4	94	63	43	34	29	25	14	—
0.6	127	88	64	51	43	37	20	—
0.8	161	111	79	63	54	47	25	—
1.0	196	134	95	75	63	56	30	—
1.2	233	166	126	104	85	73	39	—
1.4	268	191	144	120	97	84	45	—
1.6	301	216	162	135	109	94	50	—
1.8	338	252	203	177	137	117	63	—
2.0	371	278	222	194	150	130	69	661

Two BurstDR™ Stimulation Areas each with Frequency of 30 Hz

Table 18. Energy factors for two BurstDR stimulation areas each at 30 Hz for various BurstDR stimulation parameters (350-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	78	45	38	32	25	21	12	107
0.4	126	68	51	42	34	30	16	—
0.6	177	90	64	53	44	38	20	—
0.8	226	112	78	62	53	45	25	—
1.0	275	134	93	72	63	54	29	—
1.2	326	177	134	111	90	77	42	—
1.4	378	202	153	127	103	88	48	—
1.6	428	229	172	141	116	100	53	—
1.8	477	254	190	157	128	111	59	—
2.0	480	280	209	172	141	121	65	533

Table 19. Energy factors for two BurstDR stimulation areas each at 30 Hz for various BurstDR stimulation parameters (500-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	78	47	37	32	26	23	12	107
0.4	117	69	50	42	35	31	16	—
0.6	176	91	65	51	44	38	20	—
0.8	226	113	78	61	53	46	25	—
1.0	277	153	116	97	78	68	36	—
1.2	327	178	134	112	90	79	42	—
1.4	377	203	154	126	103	89	47	—
1.6	428	231	171	142	115	100	53	—
1.8	440	289	231	203	155	134	72	—
2.0	531	318	254	223	171	148	79	757

Table 20. Energy factors for two BurstDR stimulation areas each at 30 Hz for various BurstDR stimulation parameters (700-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	78	47	37	32	24	22	11	107
0.4	128	69	52	41	34	30	16	—
0.6	161	90	64	52	43	37	20	—
0.8	229	128	99	82	65	57	30	—
1.0	253	151	116	96	78	68	36	—
1.2	326	179	134	112	91	79	42	—
1.4	379	232	185	163	125	108	58	—
1.6	430	260	209	183	140	121	65	—
1.8	481	289	232	203	156	135	72	—
2.0	531	328	270	243	185	157	83	867

Table 21. Energy factors for two BurstDR stimulation areas each at 30 Hz for various BurstDR stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	73	47	37	32	25	22	11	107
0.4	117	69	51	42	34	30	16	—
0.6	179	102	78	67	53	46	24	—
0.8	209	127	97	82	66	56	30	—
1.0	278	151	116	97	78	68	36	—
1.2	304	200	163	143	109	95	50	—
1.4	381	231	185	163	125	108	57	—
1.6	405	290	245	223	165	143	75	—
1.8	484	322	273	249	184	159	85	—
2.0	536	354	301	274	203	175	93	981

Three BurstDR™ Stimulation Areas each with Frequency of 20 Hz

Table 22. Energy factors for three BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (350-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	81	58	43	35	29	25	13	107
0.4	134	89	61	47	42	36	19	—
0.6	188	122	82	60	54	47	25	—
0.8	239	155	101	72	68	58	31	—
1.0	290	186	120	85	81	70	37	—
1.2	344	232	162	125	109	94	51	—
1.4	394	267	185	143	125	108	57	—
1.6	447	302	208	160	141	121	65	—
1.8	503	337	231	178	157	135	72	—
2.0	553	370	254	195	171	148	79	533

Table 23. Energy factors for three BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (500-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	82	57	42	35	30	26	13	107
0.4	133	90	62	48	42	36	19	—
0.6	187	122	81	60	55	47	25	—
0.8	237	154	101	72	69	59	31	—
1.0	291	199	138	108	94	81	43	—
1.2	342	234	162	126	110	94	51	—
1.4	393	267	185	143	126	108	58	—
1.6	448	302	208	160	140	122	65	—
1.8	501	356	266	220	180	155	83	—
2.0	551	393	293	242	197	169	91	757

Table 24. Energy factors for three BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (700-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	81	57	43	34	29	25	13	107
0.4	135	90	62	47	42	37	19	—
0.6	187	122	81	59	55	47	25	—
0.8	239	163	115	91	79	68	36	—
1.0	292	198	139	109	93	81	43	—
1.2	342	232	163	126	110	94	50	—
1.4	393	283	210	176	143	124	66	—
1.6	446	321	240	198	161	139	74	—
1.8	498	358	266	221	180	155	83	—
2.0	554	396	302	263	203	174	94	866

Table 25. Energy factors for three BurstDR stimulation areas each at 20 Hz for various BurstDR stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	81	58	42	35	28	25	13	107
0.4	135	89	62	47	41	36	19	—
0.6	187	129	93	74	63	53	29	—
0.8	237	163	117	91	78	67	36	—
1.0	289	197	139	109	94	81	43	—
1.2	344	246	185	154	125	107	58	—
1.4	396	283	212	176	142	123	66	—
1.6	447	338	269	235	181	156	83	—
1.8	500	376	300	262	202	173	93	—
2.0	550	414	332	289	223	192	103	981

Four BurstDR™ Stimulation Areas each with Frequency of 10 Hz

Table 26. Energy factors for four BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (350-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	59	52	42	31	28	24	13	79
0.4	92	83	66	45	44	38	21	—
0.6	128	115	89	59	59	51	28	—
0.8	162	148	113	72	76	65	36	—
1.0	197	177	135	86	92	79	43	—
1.2	233	212	165	114	112	96	52	—
1.4	267	243	190	130	128	111	60	—
1.6	304	274	215	147	145	125	68	—
1.8	338	308	239	163	162	139	75	—
2.0	371	336	264	179	178	153	82	363

Table 27. Energy factors for four BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (500-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	58	51	42	31	28	25	13	79
0.4	93	83	65	44	44	38	21	—
0.6	128	115	89	58	59	51	28	—
0.8	163	147	113	72	75	66	36	—
1.0	197	179	141	98	95	81	44	—
1.2	234	210	166	115	112	96	51	—
1.4	267	243	190	130	128	110	60	—
1.6	303	274	215	147	145	126	67	—
1.8	338	307	239	163	162	139	75	—
2.0	371	337	275	203	184	159	85	512

Table 28. Energy factors for four BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (700-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	58	52	42	31	28	24	13	79
0.4	93	83	65	45	44	38	20	—
0.6	128	115	89	59	60	51	28	—
0.8	162	146	116	82	78	68	36	—
1.0	197	179	141	98	95	82	44	—
1.2	231	211	166	114	112	95	52	—
1.4	267	243	191	130	128	110	60	—
1.6	302	276	223	166	151	130	70	—
1.8	339	309	249	184	168	145	78	—
2.0	371	339	274	202	185	159	86	514

Table 29. Energy factors for four BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	57	51	41	31	28	24	13	79
0.4	93	83	65	45	44	38	20	—
0.6	128	116	91	65	62	54	29	—
0.8	163	146	116	82	79	68	36	—
1.0	196	180	141	98	95	82	44	—
1.2	232	211	172	128	116	100	54	—
1.4	266	242	197	147	134	115	62	—
1.6	303	275	224	166	151	130	70	—
1.8	338	305	257	205	174	150	81	—
2.0	373	339	284	226	192	165	89	661

Six BurstDR™ Stimulation Areas each with Frequency of 10 Hz

Table 30. Energy factors for six BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (350-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	82	73	59	43	40	34	18	108
0.4	134	120	95	63	63	55	30	—
0.6	189	168	130	85	87	75	40	—
0.8	240	216	165	106	112	95	52	—
1.0	291	263	200	126	136	116	63	—
1.2	344	312	244	168	165	142	76	—
1.4	397	357	282	192	189	163	88	—
1.6	451	406	319	217	216	185	99	—
1.8	504	454	355	242	240	208	112	—
2.0	551	500	393	265	264	227	123	534

Table 31. Energy factors for six BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (500-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	82	72	60	43	39	34	18	108
0.4	134	122	94	64	65	55	30	—
0.6	189	170	129	85	88	75	41	—
0.8	240	215	165	105	112	96	52	—
1.0	292	264	208	144	140	120	65	—
1.2	346	311	245	168	165	142	77	—
1.4	399	359	282	192	191	164	88	—
1.6	450	408	319	217	215	185	100	—
1.8	503	454	370	273	249	215	115	—
2.0	552	505	408	301	275	236	127	758

Table 32. Energy factors for six BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (700-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	83	73	59	43	39	34	18	107
0.4	135	120	95	64	65	55	29	—
0.6	188	169	129	85	88	76	41	—
0.8	241	216	171	119	115	99	54	—
1.0	291	265	208	145	140	121	65	—
1.2	343	312	245	168	165	143	77	—
1.4	395	362	292	217	198	171	91	—
1.6	453	408	332	246	224	192	104	—
1.8	504	453	370	274	250	214	115	—
2.0	552	502	410	305	277	238	127	831

Table 33. Energy factors for six BurstDR stimulation areas each at 10 Hz for various BurstDR stimulation parameters (1000-ohm impedance)

Amplitude (mA)	Intermittent Dosage (On Time/Off Time)							Continuous Dosage
	5 s/ 15 s	15 s/ 45 s	30 s/ 90 s	60 s/ 180 s	30 s/ 150 s	30 s/ 180 s	30 s/ 360 s	
0.2	82	73	59	43	40	34	18	108
0.4	133	120	94	64	63	55	30	—
0.6	187	168	134	95	90	78	42	—
0.8	240	218	172	120	115	100	54	—
1.0	292	264	208	144	140	121	65	—
1.2	343	312	255	189	172	147	79	—
1.4	397	360	293	218	197	170	92	—
1.6	449	409	344	274	232	200	107	—
1.8	503	455	384	305	258	223	119	—
2.0	552	503	424	336	284	246	132	982

Battery Longevity Graphs

The first figure shows the estimated battery longevity of a newly implanted IPG. The second figure shows the estimated longevity of an IPG battery after the low-battery warning, also called an elective replacement indicator (ERI). The ERI first appears on the clinician programmer app or patient controller app when the battery is approaching its end of service.

NOTE: The following figures show estimated battery longevity, and several factors may affect the actual longevity. This neurostimulation system allows you to monitor IPG battery status and usually first displays the ERI at least 3 months before the IPG needs to be replaced. The ERI may first appear when less than 3 months remain of the battery's life if a patient's system uses high settings.

Figure 7. Estimated battery longevity by energy factor for Proclaim™ IPGs (from time of implant)

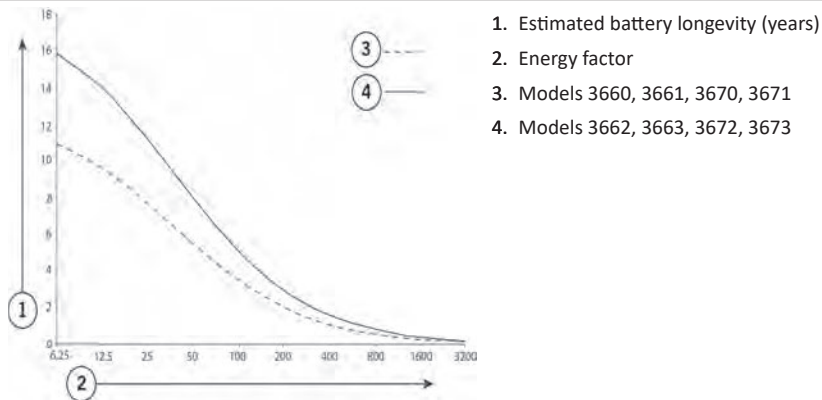
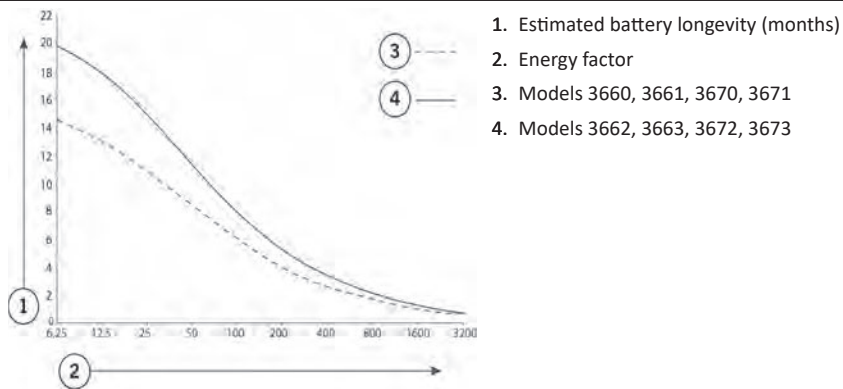


Figure 8. Estimated battery longevity by energy factor for Proclaim IPGs (from time of ERI)



Appendix D: Regulatory Statements

This section contains regulatory statements about your product.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 34. Registration identification information

Identifier Type	Registration Identifier
FCC registration number	RIASJMRFC

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® Low Energy (LE) wireless technology as it is implemented in the device.

Table 35. Bluetooth Low Energy (LE) wireless technology information

Antenna type	Embedded patch antenna in header
Antenna dimensions	8.1 mm x 5.1 mm x 4.9 mm
Modulation	GFSK
Magnetic field strength (at 2 m distance)	16.3 μ A/m
Electric field strength (at 2 m distance)	6.1 mV/m

Table 35. Bluetooth Low Energy (LE) wireless technology information

Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
Range	1–2 m typical
Center frequency	2.44 GHz
Channel	40 logical channels
Bandwidth	2 MHz per channel
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology

*EIRP = Equivalent isotropically radiated power

Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15 dB): 2.398 to 2.4855 GHz
- Channel: 40 logical channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- Magnetic field strength (at 2 m distance): 16.3 μ A/m
- Duty cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator and the clinician programmer or patient controller. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol is grayed out.

The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (that is, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, please refer to “Troubleshooting for Wireless and Coexistence Issues” (page 36).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator will encrypt its wireless communication.
- Only one patient controller or clinician programmer may communicate with the generator at the same time.
- A unique key for each unit that is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth® Low Energy (LE) wireless technology, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator.

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the generator and the clinician programmer or patient controller, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the clinician programmer or patient controller app, and turn the clinician programmer or patient controller off and on.
- Wait a few minutes and try connecting again.
- Do not operate other wireless devices (such as laptop, tablet, mobile phone, or cordless phone) at the same time.

NOTE: Wireless communication equipment (such as wireless home network devices, mobile and cordless telephones, and tablets) can affect the device.

Appendix E: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 36. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe

Table 36. Symbols and definitions

Symbol	Definition
	NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Non-ionizing electromagnetic radiation
	Do not re-use
	Do not resterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Implantable device
	Accessories
	Serial number

Table 36. Symbols and definitions

Symbol	Definition
	Batch code
	Unique Device Identifier
	Prescription use only
	Sterilized using ethylene oxide
	Authorized representative in the European Community
	European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-04
ARTEN600283835 A



NeuroSphere™ Patient Controller

Spinal Cord Stimulation Systems
Model 3875

User's Guide



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

About This Guide.	1
Symbols and Definitions.	1
Terms Used in This Document.	6
Prescription and Safety Information.	6
Intended Use.	6
Indications for Use.	7
Contraindications.	7
MRI Safety Information.	7
Warnings.	8
Precautions.	13
Adverse Effects.	18
Product Description.	20
About Your System.	20
Overview of the Patient Controller.	22
Items You Will Receive.	23
Your Personal Identification Card.	24
Directions for Use.	25
Connecting to Your Generator.	25
Overview of the Therapy Screen.	29
Starting and Stopping Stimulation.	31
Mode.	33
Using the Surgery Mode Feature.	35
Using the MRI Mode Feature.	37
Viewing and Selecting a Program.	41
Adjusting Program Strength.	44
Adjusting Areas Strength.	47
System Information.	50
Additional Patient Controller Information.	51
Maintaining the Generator and Patient Controller.	52
Checking the Generator Battery Status.	52
Checking the Patient Controller Battery Status.	53
Caring for the Generator.	54
Caring for the Patient Controller.	55
Cybersecurity.	55
Protecting Access to the Patient Controller.	55
Wireless Security Measures.	56

Guidelines for Secure Use.	57
Legal and Privacy Notice.	58
Troubleshooting.	59
Technical Support.	68
Appendix A: Downloading the Patient Controller App.	68
Appendix B: Pairing the Patient Controller to the Generator.	70
Appendix C: Regulatory Statements.	72
Statement of FCC Compliance.	72
Identification Information for Product Registration.	73
Product Classification Statement (CISPR 11, Class B).	74
Wireless Technology Information.	74
Radio Transmitter, Cables, Transducers.	76
Quality of Service for Wireless Technology.	77
Appendix D: Electromagnetic Compatibility Guidelines.	78
Radio Frequency Information.	84

About This Guide

This guide explains how to use the NeuroSphere™ Patient Controller application (Model 3875) with your neurostimulation system. If you have any questions about your system, contact Technical Support.

Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

NOTE: For symbols and definitions for the patient controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app; or, on the patient controller Home screen, tap **Settings** > **General** > **Legal & Regulatory**.

Table 1. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use

Table 1. Symbols and definitions

Symbol	Definition
 medical.abbott/manuals	Follow instructions for use on this website
	Type BF Applied Part
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Non-ionizing electromagnetic radiation

Table 1. Symbols and definitions

Symbol	Definition
	Keep dry; keep away from rain
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Use-by date
	Date of manufacture
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturing facility
	Temperature limit
	Humidity limitation

Table 1. Symbols and definitions

Symbol	Definition
	Atmospheric pressure limitation
	Manufacturer
	Do not use if package is damaged
	Packaging unit
	Programmer
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	This product shall not be treated as household waste. Instead it is the user's

Table 1. Symbols and definitions

Symbol	Definition
	responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
	Authorized representative in the European Community
	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)

Table 1. Symbols and definitions

Symbol	Definition
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Terms Used in This Document

This section contains definitions of some of the terms used in this document.

Magnetic Resonance (MR) Conditional system. A group of implanted parts that allows a patient to receive a magnetic resonance imaging (MRI) scan safely if all the requirements for the implanted parts and for scanning are met.

Program. A combination of one or more subprograms (areas).

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The NeuroSphere™ Patient Controller app is intended to be used with the generator to help the patient manage prescribed stimulation programs.

Indications for Use

Abbott Medical spinal cord stimulation (SCS) systems are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Contraindications

This neurostimulation system is contraindicated for patients who are unable to use the system. Additionally, the permanent system is contraindicated for patients who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

If you are using a trial system, you should not be subjected to an MRI. The electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could cause a jolting or shocking sensation.

If you are using a permanent system, you may be implanted with the parts that make up a Magnetic Resonance (MR) Conditional system, which allows you to receive an MRI scan if all the requirements for the implanted parts and for scanning are met. Scanning under different conditions may cause device malfunction, severe injury, or death. Contact your

physician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks. Additionally, before receiving an MRI scan, inform the healthcare professional that you are implanted with a neurostimulation system. If you do not have an MR Conditional system, you cannot receive an MRI.

Do not bring your patient controller into the scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is MR Unsafe.

For more information about what you need to do to prepare for an MRI scan, refer to “Using the MRI Mode Feature” (page 37) in this guide.

Warnings

The following warnings apply to these components.

NOTE: For nontherapy-related warnings for the NeuroSphere™ Patient Controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.

System Warnings

Diathermy therapy. You cannot have any short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on your body if you have any part of a neurostimulation system implanted. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. You are advised to inform your healthcare professional that you cannot be exposed to diathermy treatment.

Operation of machines, equipment, and vehicles. If you are using a therapy that generates paresthesia, you should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract you from properly operating them. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. If you do not feel paresthesia, sudden stimulation changes are less likely to occur and distract you while operating motorized vehicles, machinery, or equipment.

Implanted cardiac system. Be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the

functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the functions of the implantable cardiac system.

Electrosurgery devices. Electrosurgery devices may harm you or damage your neurostimulation system. If you need to receive a procedure using an electrosurgery device, place your IPG in Surgery Mode. Your physician may only use bipolar electrosurgery devices and they should keep the device as far away from your neurostimulation system as possible. Additionally, they must confirm the neurostimulation system is functioning correctly after your procedure.

Lead movement. Avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for at least six weeks after implantation. These activities may cause lead movement, resulting in understimulation or overstimulation. Excessive lead migration may require reoperation to replace the leads.

Emergency procedures. Designate a representative (family member or close friend) to notify any emergency medical personnel of your implanted neurostimulation system if emergency care is required. You will receive an identification card to carry that will inform emergency medical personnel of your implanted system. Use caution when undergoing any procedure that could include radiofrequency (RF) or microwave ablation, defibrillation, or cardioversion.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy, nursing, the unborn fetus, or delivery have not been established.

Patients with diabetes. Patients with diabetes may be more likely to experience complications with surgery. Seek medical attention if you experience signs of infection (fever, redness, fluid discharge at the incision), problems with surgical site healing, headache after surgery, disorientation, chest pain, or shortness of breath.

Changes in blood glucose levels. If you have diabetes, you should monitor your blood glucose closely after surgery. Patients with diabetes may experience unstable blood glucose levels following any surgical procedure.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Additional Warnings Only Applicable to the Trial System

Routine medical procedures. If you are using a trial system, inform your healthcare providers and avoid elective medical procedures.

Additional Warnings Only Applicable to the Permanent System

Cardioverter defibrillators. Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Device Warnings

Explosive or flammable gases. Do not use the device in an environment where explosive or flammable gas fumes or vapors are present, including hyperbaric chambers. Operating the device could cause it to ignite, causing severe burns, injury, or death.

Interference with other devices. This equipment can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Application modification. To prevent unintended stimulation, do not modify the operating system or application in any way.

Strangulation. The cords in this system pose a strangulation risk. To avoid strangulation, be careful when using cords and keep cords out of the reach of children.

Precautions

The following precautions apply to these components.

NOTE: For nontherapy-related precautions for the NeuroSphere™ Patient Controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.

System Precautions

Medical tests and procedures. Before undergoing medical tests or procedures (such as therapeutic radiation or electrolysis), contact your physician to determine if the procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotriptors, therapeutic X-rays, computerized tomography (CT) scans, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system. If using a trial system and radiation therapy is required, disconnect the trial generator from the leads or extensions. Damage to the system may not be immediately detectable.

Component manipulation. Do not rub or press on implanted components through the skin. This may cause the leads to move leading to stimulation at the implant site, IPG inversion leading to the inability to communicate with the device, or skin erosion that can lead to another surgical procedure or possible infection.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances,

or render you incapable of controlling the stimulator. If unpleasant sensations occur, turn off the device immediately.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Postural changes. Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Turn stimulation off or lower the stimulation strength before stretching, lifting your arms over your head, or exercising. If unpleasant sensations occur, turn off stimulation.

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are

implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Use caution when approaching such a device and request assistance to bypass the device. If you must proceed through a gate or doorway containing this type of device, turn off stimulation and proceed with caution, being sure to move through the device quickly.

Scuba diving or hyperbaric chambers. Avoid scuba diving below 30 m (100 ft) of water or entering hyperbaric chambers above 4.0 atmospheres absolute (ATA). Pressures below 30 m (100 ft) of water (or above 4.0 ATA) could damage your neurostimulation system. Before diving or using a hyperbaric chamber, contact your physician to discuss the effects of high pressure.

Physician instructions. Always follow the programs and therapy instructions established for you by your physician. If you do not, the therapy may be less effective in providing pain relief.

Patient training. Do not use your neurostimulation system until an authorized clinician has trained you how to control stimulation and safely use the system.

Device components. The use of components not approved for use by Abbott Medical may result in damage to the system and increased risk of injury.

Magnet usage. The magnet provided with the system is a high-powered magnet intended for use solely with the system. Keep it away from watches, credit cards, computer disks, and other magnetically sensitive items to

avoid damaging them. Always place the keeper bar on the magnet when not in use.

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted device. If lithotripsy must be used, do not focus the energy near the device.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted device.

Home use. This product is intended for home use per physician instruction. To avoid damage and other potential hazards, keep this product away from children and pets.

Infection. Follow proper infection control procedures and avoid showering and touching the bandages.

Household appliances. Household appliances that contain magnets (such as refrigerators, freezers, inductive cooktops, stereo speakers, mobile telephones, cordless telephones, standard wired telephones, AM/FM radios, and some power tools) may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the device and generator.

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the patient controller and generator; however, it will not change the prescribed programmed parameters.

To prevent accidental interference, keep your smart device at least 15 cm (6 in.) away from the generator, and do not carry any smart device in a pocket near the generator. Contact Technical Support or your physician to discuss modifying the magnet mode setting on your neurostimulation system or if you have any other questions.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

Additional Precautions Only Applicable to the Permanent System

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation, confirm the neurostimulation system is still working.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area

over the implanted IPG should be shielded with lead. Damage to the system may not be immediately detectable.

Overcommunicating with the IPG. Use your patient controller to communicate with your IPG only when needed because excessive communication with the IPG can shorten the remaining battery life.

Device Precautions

Keep the device dry. Your device is not waterproof. Keep it dry to avoid damage. Do not use the device when engaging in activities that might cause it to get wet, such as swimming or bathing.

Handle the device with care. The device is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Battery precaution. This device contains a lithium ion battery as well as other potentially hazardous materials. Do not crush, puncture, or burn the device because explosion or fire may result. Return it to Abbott Medical for proper disposal.

Control of your device. Keep your device out of the hands of children to avoid potential damage or unauthorized change in stimulation parameters.

Adverse Effects

The use of a neurostimulation system involves risks. In addition to those risks commonly associated with surgery,

the following risks are also associated with use of a neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or IPG site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to device or implant materials
- Implant migration or skin erosion around the implant
- Battery failure

- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control.

Product Description

The NeuroSphere™ Patient Controller application (Model 3875) allows you to view, select, and control the programs that your physician has prescribed. The NeuroSphere™ Patient Controller communicates wirelessly with the generator.

NOTE: In this document, the term “patient controller” refers to the NeuroSphere™ Patient Controller device and “patient controller app” refers to the NeuroSphere™ Patient Controller application (app).

About Your System

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The neurostimulation system includes the following primary components:

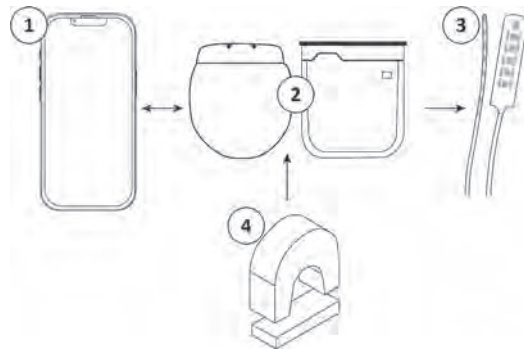
- External pulse generator (EPG) or Implantable pulse generator (IPG)
- Extensions

- Leads
- Patient magnet (provided by Abbott Medical)
- Patient controller (a device provided by Abbott Medical or a compatible personal Apple® iOS® device)

NOTE: For more information on compatible devices, see “Appendix A: Downloading the Patient Controller App” (page 68).

The EPG or IPG delivers electrical pulses through the leads to electrodes near selected nerve fibers to provide therapeutic stimulation. The patient magnet can turn the EPG or IPG on and off if the physician enabled this functionality. Physicians use the clinician programmer to create and modify a program for a patient. Patients use the patient controller to control their prescribed program. The following image shows how the major system components are intended to interact.

Figure 1. Interaction between major system components



1. Patient controller
2. EPG or IPG
3. Leads
4. Patient magnet

Overview of the Patient Controller

Your patient controller may be a device provided by Abbott Medical or a compatible personal Apple® iOS® device.

Before you begin, be sure you are familiar with how to perform basic operational functions on your patient controller:

- Turning the patient controller on and off
- Placing the patient controller in sleep mode
- Waking the patient controller from sleep mode
- Locking and unlocking the patient controller

- Using touchscreen functions such as tap and screen swipe actions
- Returning to the Home screen

NOTE: For nontherapy-related information on how to use the patient controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.

The patient controller app is available from the Apple App Store and can be downloaded to your device using your Apple ID.

NOTE: If you are programmed with FlexBurst360™ stimulation technology, you should use the latest version of the patient controller app that is available on the Apple App Store. This feature is not available with every IPG. Talk to your clinician for more information.

See “Appendix A: Downloading the Patient Controller App” (page 68) for more information on compatible devices and for instructions on downloading the patient controller app.

Items You Will Receive

If you are using a patient controller provided by Abbott Medical, you will receive the following items to use with your system:

- Patient controller and charging cord
- Protective case for the patient controller
- Patient magnet

- Product documentation

If you are using a compatible personal Apple® iOS® device, you will receive the following items:

- Patient magnet
- Product documentation

NOTE: For more information on compatible devices, see “Appendix A: Downloading the Patient Controller App” (page 68).

Your Personal Identification Card

A temporary medical identification card is included with the product documentation. Your physician will complete the card and give it to you. Once you or your physician submit a patient registration form, Abbott Medical will mail you a permanent identification card. The registration card does the following things:

- Identifies you as having an implanted medical device
- Identifies the model numbers and locations of your implanted system parts to help determine if you can safely receive an MRI scan
- Helps you pass through security systems like those in airports
- Provides information that allows your physician to be contacted in an emergency

If you have questions about your card or need to request a replacement card, contact Customer Service at 1-800-727-7846 and follow the prompt.

Directions for Use

Read this section for instructions on how to use the patient controller app.

Connecting to Your Generator

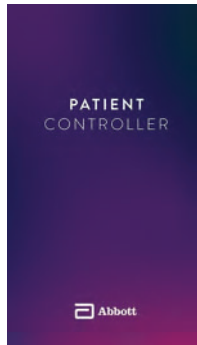
When you turn on your patient controller, the patient controller app should be available on the Home screen. If you do not see the patient controller app, see “Appendix A: Downloading the Patient Controller App” (page 68) for instructions.

Figure 2. Patient controller app icon



-
1. Tap the patient controller app icon. The Start-up screen appears.

Figure 3. Start-up screen



If you have not previously launched the patient controller app after installation or update and accepted the Terms of Use and the Privacy Policy, screens will display requiring your agreement before you can use the app.

2. Tap **Accept** on the Terms of Use screen.
3. Tap **Acknowledge** on the Privacy Policy screen.

NOTE: To view this information again, tap the Information icon and then **Terms of Use** or **Privacy Policy** on the Information screen.

After your app launches, the Generators screen appears.

Figure 4. Generators screen*



* The generator icon in this screen is a representation. The actual screen displays an icon of the implanted generator.

NOTE: If the “No Generators Found” message displays, see “Appendix B: Pairing the Patient Controller to the Generator” (page 70) for instructions.

4. Select your generator. If you have multiple generators, select the generator you want to use from the list.

After selecting your generator, the patient controller app connects with the generator.

NOTE:

- After 3 minutes of inactivity, the patient controller app will disconnect from your generator.

- In some cases, use of Bluetooth® wireless media devices (such as headphones or speakers) may prevent the patient controller from connecting to your generator. Abbott Medical recommends disconnecting these accessories before you attempt to adjust your therapy.
- To avoid interruption while adjusting your therapy, Abbott Medical recommends enabling Do Not Disturb mode on your patient controller before connecting to your generator. Refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.
- If a passcode is not set for the device, the *Consider adding a passcode to this device* message will display. Open the device's settings to add a passcode to secure the device.

Overview of the Therapy Screen

After the patient controller app connects with the generator, the Therapy screen appears.

Figure 5. Therapy screen

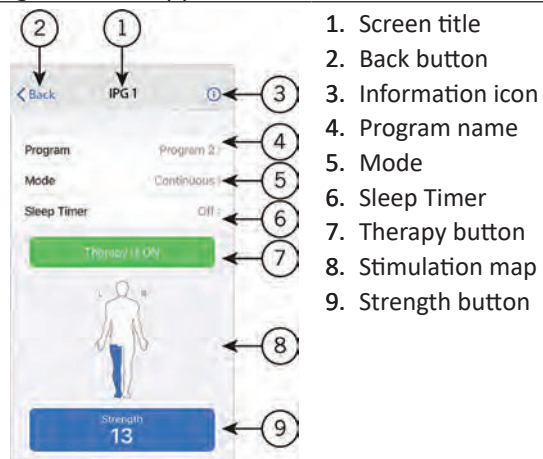


Table 2. Therapy screen descriptions

Screen Section or Button Name	Description
Screen title	Displays the name of the screen you are viewing.
Back button	Tap to display the Generators screen and end the session with the current generator.
Information icon	Tap the Information icon to display the system information screen. See “System Information” (page 50) for more information.
Program name	Displays the name of the active program. Tap to display the Programs screen. See “Viewing and Selecting a Program” (page 41) for more information.
Mode	Displays the active dosage (Continuous, Intermittent, or Sleep). Tap to display the Mode screen and enable Airplane Ready mode, Surgery Mode, or MRI Mode. See “Mode” (page 33) for more information.

Table 2. Therapy screen descriptions

Screen Section or Button Name	Description
Sleep Timer	Displays the amount of time until therapy turns off. Tap to display the Sleep Timer screen. See “Mode” (page 33) for more information.
Therapy button	Displays whether therapy is on or off. Tap to turn therapy on or off.
Stimulation map	Displays the body area currently receiving stimulation.
Strength button	Displays the active program stimulation strength level. Tap to display the Strength screen. See “Adjusting Program Strength” (page 44) for more information.

Starting and Stopping Stimulation

You may start and stop stimulation using the patient controller app or the included magnet if your physician has enabled magnet use.

Starting and Stopping Stimulation Using the Patient Controller

To start or stop stimulation using the patient controller app, do one of the following:

- Tap the Therapy is ON or Therapy is OFF button on the Therapy screen to turn stimulation on and off.
- Adjust stimulation strength all the way down on the Strength screen.

NOTE: When you turn stimulation on, stimulation strength will gradually return to a strength prescribed by your clinician or the last used strength level, whichever is lower.

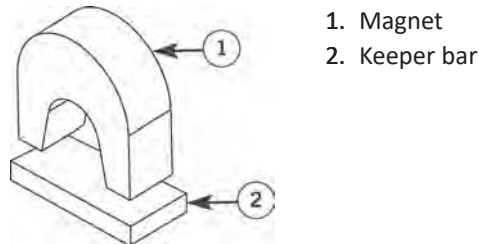
Starting and Stopping Stimulation Using the Magnet

If your physician has enabled magnet use, you may start and stop stimulation with a magnet.

To start or stop stimulation using the magnet:

1. Take the keeper bar off the magnet.

Figure 6. Magnet and keeper bar



2. Hold the magnet perpendicular to and centered directly over the generator site.
3. Hold the magnet in place for 2 seconds.
4. Remove the magnet, replace the keeper bar, and store the magnet.

Stimulation will either start (using the most recently used program) or stop.

CAUTION: Do not use the magnet provided with the system around magnetically sensitive items to avoid damaging them.

Mode

Depending on the programmed dosage, Continuous, Intermittent, or Sleep is displayed on the Therapy screen.

- **Continuous:** provides nonstop stimulation
- **Intermittent:** automatically alternates stimulation on and off for the preset periods in the selected program; displays the remaining time in the current on or off period
- **Sleep:** stimulation is on for a programmed amount of time, after which stimulation turns off and stays off until it is manually turned on (trial system only)

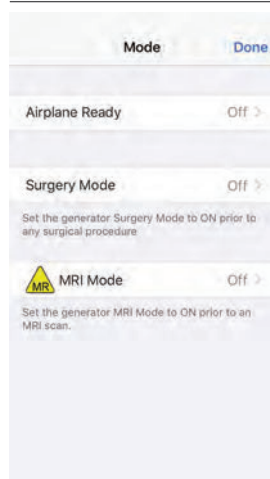
The Sleep Timer, which is only available with the permanent system, displays the remaining stimulation time or Off if the Sleep Timer is off.

- Tap **Sleep Timer** on the Therapy screen to open the Sleep Timer screen, then tap the desired amount of time until stimulation turns off.

Tap **Mode** to open the Mode screen. From this screen you may place your system in Airplane Ready mode, enable Surgery Mode, or enable MRI Mode (when applicable).

- To enable Airplane Ready mode, tap **Airplane Ready** to view the Airplane Ready screen. Follow the instructions on the screen to turn Airplane Ready on or off. For instructions about turning Bluetooth wireless technology on, see “Troubleshooting” (page 59).
- For more information about Surgery Mode, see “Using the Surgery Mode Feature” (page 35).
- For more information about MRI Mode, see “Using the MRI Mode Feature” (page 37).

Figure 7. Mode screen



Using the Surgery Mode Feature

This section provides information and instructions about what you need to do before and after a surgical procedure. Using this feature turns therapy off while you undergo your procedure.

NOTE: If you feel uncomfortable completing the following steps, contact Abbott Medical before your procedure. Contact your clinician before your procedure to learn more about any risks.

Preparing for a Surgical Procedure

If you are going to undergo a surgical procedure, follow these guidelines:

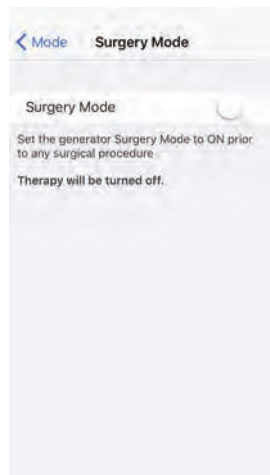
- Set your IPG to Surgery Mode before your procedure. See “Setting the IPG to Surgery Mode” (page 35) for instructions.
- Charge your patient controller before the procedure.
- Bring your identification card and patient controller to the procedure.

Setting the IPG to Surgery Mode

To set your IPG into Surgery Mode:

1. From the Therapy screen, tap **Mode** to display the Mode screen.
2. Tap **Surgery Mode** to view the Surgery Mode screen.

Figure 8. Surgery Mode screen



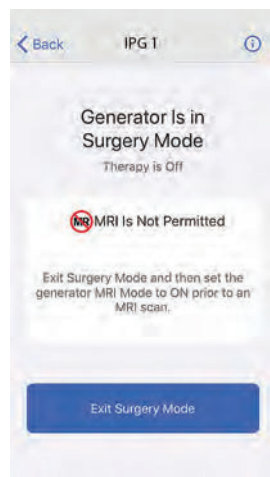
3. Tap the **Surgery Mode** toggle button.
Stimulation stops and you may undergo your surgical procedure.

Disabling the Surgery Mode

After your procedure, you need to disable Surgery Mode to restart stimulation. To disable Surgery Mode:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the IPG is in Surgery Mode.

Figure 9. Generator is in Surgery Mode screen



2. Tap **Exit Surgery Mode**. The patient controller app disables Surgery mode. The Therapy screen appears, showing that stimulation therapy is off.
3. To start stimulation, tap **Therapy is OFF**.

Using the MRI Mode Feature

You may be implanted with the parts that make up a Magnetic Resonance (MR) Conditional system, which allows you to receive an MRI scan if all the requirements for the implanted parts and scanning are met. This section provides information and instructions about what you need to do before and after an MRI scan.

NOTE: Contact your clinician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks.

You have two ways to learn if the implanted parts of your system are MR Conditional:

- Your personal identification card, which your clinician or MRI technologist will use
- Your patient controller app
 - Tap ⓘ to display the system information. The top of the screen displays the message “System is MR Conditional” if implanted parts of your system are approved MR Conditional models.
 - Tap **Mode** on the Therapy screen to display the Mode screen. The MRI Mode option is available if implanted parts of your system are approved MR Conditional models.

Preparing for an MRI Scan

If you have an MR Conditional system and will receive an MRI scan, follow these guidelines:

- Set your IPG to MRI mode within a day before you arrive for your procedure. See “Setting the IPG to MRI Mode” (page 39) for instructions.
- Charge your patient controller before the procedure.

- Bring your identification card and patient controller to the procedure.

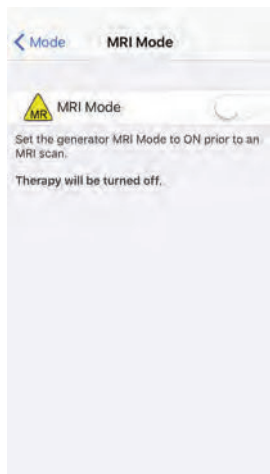
CAUTION: Do not bring your patient controller into the scanner magnet room since it may be affected by the MRI magnet, may present a projectile hazard, and is MR Unsafe.

Setting the IPG to MRI Mode

To set your IPG into MRI mode:

1. From the Therapy screen, tap **Mode** to display the Mode screen.
2. Tap **MRI Mode** to view the MRI Mode screen.

Figure 10. MRI Mode screen



3. Tap the **MRI Mode** toggle button.
4. When the “Set Generator to MRI Mode” message appears, tap **Continue**. Stimulation stops, and the patient controller app checks the system for any issues. If the checks are successful, the “Proceed with MRI” message appears and the MRI mode is on.

NOTE: If a warning screen appears instead of the “Proceed with MRI” message, you cannot set the IPG to MRI mode and cannot receive an MRI scan. Refer to “Troubleshooting” (page 59) for more information.

5. Tap **OK**.

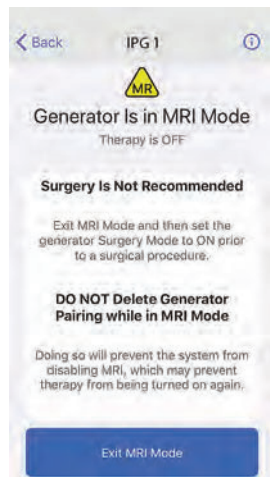
CAUTION: Do not delete the paired Bluetooth wireless connection between the IPG and the patient controller and do not delete the IPG from the Generators list while the system is in MRI mode. Doing so will prevent the system from disabling MRI mode, which may prevent therapy from being turned on again.

Disabling the MRI Mode

After your procedure, you need to disable the MRI mode to restart stimulation. To disable the MRI mode:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the IPG is in MRI mode.

Figure 11. MRI Mode screen



2. Tap **Exit MRI Mode**. The patient controller app disables MRI mode. The Therapy screen appears, showing that stimulation therapy is off.
3. To start stimulation, tap **Therapy is OFF**.

Viewing and Selecting a Program

Tap the program name on the Therapy screen to open the Programs screen. On the Programs screen you can view and select any of the saved programs.

To navigate between the saved programs, either:

- Swipe the screen right or left in the area containing the program information

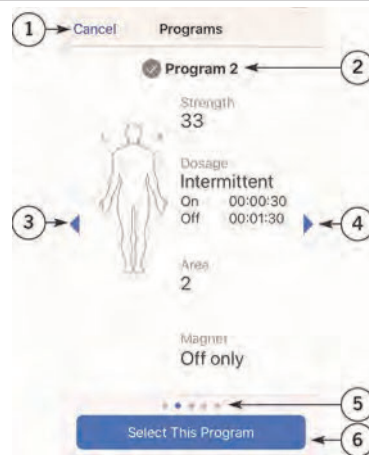
- Tap the right or left arrows

To select a program:

- When you locate the program you want to activate, tap **Select This Program**.

NOTE: When you select a new program, stimulation strength will gradually increase to the perception strength level set for the selected program.

Figure 12. Programs screen



1. Cancel button
2. Program name
3. Left arrow
4. Right arrow
5. Program indicator
6. Select This Program button

Table 3. Programs screen descriptions

Screen Section or Button Name	Description
Cancel button	Tap Cancel to return to the Therapy screen. No program changes will be made.
Program name	Displays the program name of the current Programs screen. A check mark next to the program name indicates the currently selected program.
Left and right arrows	Tap the left and right arrows to scroll through your saved programs.
Program indicator	Displays the number of programs available and indicates which program is on the screen.
Select This Program button	Tap Select This Program to select the currently displayed program as your active program.

Adjusting Program Strength

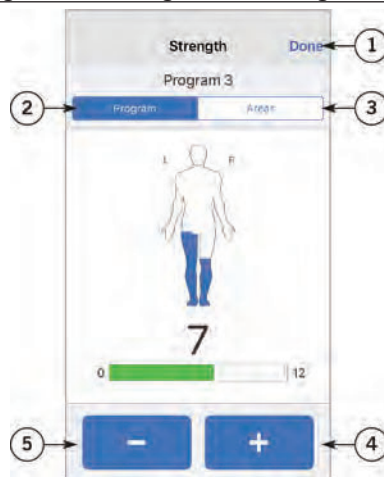
Tap **Strength** on the Therapy screen to open the Strength screen. On the Strength screen you can modify the active program strength or the strength of an individual area.

For instructions on modifying the strength of an Area, see “Adjusting Areas Strength” (page 47).

- Tap the + or – buttons to increase or decrease strength.

The number and green bar above the buttons will increase or decrease as you increase or decrease strength.

Figure 13. Strength screen Program tab – Multiple Areas



1. Done button
2. Program tab
3. Areas tab
4. Increase button
5. Decrease button

If the active program has only one programmed area, you will see the following screen.

Figure 14. Strength screen – One Area



Table 4. Strength screen descriptions

Screen Section or Button Name	Description
Done button	Tap Done to save changes and return to the Therapy screen.
Program tab	Selected by default. If the program only has one Area, the Program tab will not appear on the screen.

Table 4. Strength screen descriptions

Screen Section or Button Name	Description
Areas tab	Tap the Areas tab to open the Areas screen. If the program only has one Area, the Area tab will not appear on the screen. See “Adjusting Areas Strength” (page 47) for more information.
Increase button	Tap to increase the strength for the selected Program.
Decrease button	Tap to decrease the strength for the selected Program.

Adjusting Areas Strength

Tap **Strength** on the Therapy screen to open the Strength screen, and then tap the **Areas** tab to open the Areas portion of the Strength screen. On the Areas screen you can modify the stimulation strength for each Area in the active program (a program may contain multiple areas). Use this feature when you want to increase or decrease the strength for each Area independently of other areas.

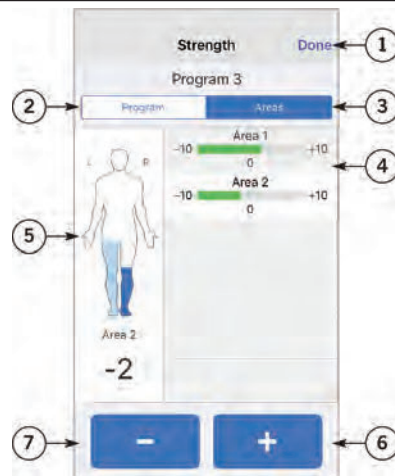
To modify the strength for an Area:

1. Tap the Area you want to modify.

The selected Area displays with a white background and the stimulation map displays the affected area in dark blue.

2. Tap the + or – buttons to increase or decrease strength for the selected Area.
The green bar below the Area name will increase or decrease as you increase or decrease strength.
You will see the Adjusting Strength message while the system is adjusting.
3. Modify other Areas as needed by following the steps above.
4. When you are finished adjusting the Area strength, tap **Done** to return to the Therapy screen.

Figure 15. Strength screen Areas tab



1. Done button
2. Program tab

3. Areas tab
4. Selected Area
5. Stimulation map
6. Increase button
7. Decrease button

Table 5. Areas screen descriptions

Screen Section or Button Name	Description
Done button	Tap Done to save changes and return to the Therapy screen.
Program tab	Tap the Program tab to open the Program screen. See “Adjusting Program Strength” (page 44) for more information.
Areas tab	Modify the strength of each Area in the active program on this screen.
Area name	Tap to select the Area you want to modify. The stimulation map displays the affected area.
Increase button	Tap to increase the strength for the selected Area.
Decrease button	Tap to decrease the strength for the selected Area.

System Information

Tap ⓘ on the Therapy screen to display the system information. From these screens you can view the information for your generator, leads and extensions, and patient controller app by tapping the corresponding buttons.

Figure 16. System information Generator screen



1. Done button
2. Manuals button
3. Generator button
4. Leads/Extensions button
5. Patient Controller button

Table 6. System information descriptions

Screen Section or Button Name	Description
Done button	Tap Done to save changes and return to the Therapy screen.
Manuals button	Tap to view information about how to download the MRI Procedure Information manual.
Generator button	Tap to view information about your generator, such as the generator model number.
Leads/Extensions button	Tap to view information about your leads and extensions, such as the model numbers.
Patient Controller button	Tap to view information about your patient controller, such as the patient controller app model number.

Additional Patient Controller Information

Tap ⓘ at the bottom of the Generators screen to view additional patient controller information, view the Instructions for Use (IFU), and export the patient controller log.

NOTE: When exporting the patient controller log, you must select whether to Remove or Include Personally

Identifiable Information (PII). It is recommended to select Remove unless directed by your physician or Technical Support.

Maintaining the Generator and Patient Controller

This section provides tips and other information about maintaining and caring for your generator and patient controller.

Checking the Generator Battery Status

Refer to the IPG and EPG information below for instructions on viewing your generator battery status. How long the battery lasts depends on the programmed stimulation settings, how often stimulation is used, and how often you communicate with the generator, so communicate with your generator only when necessary.

NOTE: You may also receive low battery warnings regarding the patient controller, so make sure to read the warning before dismissing.

To view the IPG battery status:

The generator battery indicator on the Generator information screen shows the battery status for the IPG battery. When the IPG battery status is good,  is displayed; and when the battery is approaching the end of service,  is displayed.

NOTE: When the IPG battery is approaching the end of service a warning pops up on your patient controller app.

To view the EPG battery status:

As the battery is used, the generator battery indicator on the System screen shows the remaining life (the figure below shows the EPG battery indicator progression).

NOTE: When using a trial system, contact your physician for replacement batteries if your battery indicator shows 2 or less as shown in the figure below. Do not attempt to replace the batteries.

Figure 17. EPG battery indicator progression



NOTE:

- When the remaining EPG battery charge reaches 2 or 1 a warning pops up on your patient controller app.
- When the EPG battery is too low to support stimulation (0), generator stimulation automatically turns off.

Checking the Patient Controller Battery Status

Be sure to monitor the patient controller battery status (indicated in the top right corner of the screen). As the battery is used, the battery indicator shows the remaining

charge. Recharge the patient controller using only the Apple® charging cord and wall outlet plug provided with your device.

When using the trial system, Abbott Medical does not recommend charging the provided patient controller with a computer since personal information may be transferred to the patient controller, which will be returned to Abbott Medical.

NOTE: Keep the patient controller charged or have a power supply nearby. Familiarize yourself with the patient controller's battery life so you can anticipate its recharging needs. For more information, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.

Caring for the Generator

Read the following tips for information on how to care for your trial system:

- Do not disturb the protective bandages or generator pouch.
- Do not expose the generator to prolonged direct sunlight.
- Avoid exposing your generator to sand, dust, and other environmental hazards.
- Avoid getting the generator wet. If the generator does get wet, do not use it. Contact Technical Support for help.

Caring for the Patient Controller

If you are using a patient controller provided by Abbott Medical, clean the protective case by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not use a cloth that is saturated. Do not use alcohol, ammonia-based cleaning agents, cleaning solutions, or solvents to clean the case.

NOTE: For more information on how to care for the patient controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your patient device.

Protecting Access to the Patient Controller

To prevent unauthorized access to your Apple® device, set up a passcode or other supported method of biometric security (such as Touch ID® or Face ID®). For

instructions, refer to the user guide available at support.apple.com/manuals. Under the browse manual by product section, tap the Apple device you are using to run the patient controller app, and then scroll and tap the User Guide for your device's iOS® version.

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator will encrypt its wireless communication.
- Only one patient controller may communicate with the generator at the same time.
- A unique key for each unit that is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth® Low Energy (LE) wireless technology, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator.

Guidelines for Secure Use

Users should adhere to the following guidelines when using the system:

- Do not use the application if the operating system is compromised (for example, jailbroken).
- Do not share your Apple® ID login information or device passcode.
- Do not leave the device unattended where it could be lost or stolen.
- Do not allow other users to access the mobile device unless you also give them permission to access the patient controller app, which lets them control your therapy.
- Do not install untrusted apps on the device you are using to run the patient controller app.
- Secure your home network with a Wi-Fi® password, and only connect to trusted secured networks when not at home.
- If the Apple device is lost or stolen, use the instructions provided by Apple at support.apple.com to disable or erase your device. Tap the drop-down menu or scroll down to locate the Search Support box. Tap in the Search Support box, type “lost” or “stolen,” and then select the quick link or tap “Go” and scroll to the instructions.
- If you receive a “Device Not Secure” notification in the App, contact Abbott Medical.

- Regularly check and upgrade to the latest available version of the Patient Controller App from the App Store.

NOTE: If you are programmed with FlexBurst360™ stimulation technology, you should use the latest version of the patient controller app that is available on the Apple App Store.

- Install iOS® software upgrades on your device as they are made available by Apple®, after verifying iOS software version compatibility with the Patient Controller App via www.NMmobiledevicesync.com/cp.

Legal and Privacy Notice

The terms of use and privacy policy are displayed the first time the patient controller app is launched after installing or updating the app. To view this information again, tap ⓘ on the Generators screen or view online at <https://www.virtualclinic.abbott/policies>.

Abbott Medical is committed to protecting the privacy of our customers and patients. This privacy statement summarizes how we protect, gather, and use personal information of users. For more information, view our US or Global Privacy Policies online at www.abbott.com/privacy-policy.html.

We may amend these terms of use, privacy statements, and privacy policies from time to time, so please check for updates.

Troubleshooting

This section provides troubleshooting procedures to help you identify and solve problems that may occur.

NOTE:

- If you encounter problems other than those described in this section, contact Technical Support.
- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Patient Controller App		
Cannot locate patient controller app.	Patient controller app is not on patient controller Home screen.	Swipe through screens from the patient controller Home screen to locate app. Search for the app using the iOS® search function. Ensure you have the app installed and see this icon:  If you do not see the above icon on any patient controller screen, then download the app again.
Patient controller app version is out of date.	Patient controller app must be updated to work with the newer generator software.	Open the App Store from the device and update the patient controller app to the latest version. See

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		"Appendix A: Downloading the Patient Controller App" (page 68) for more information. If you continue to encounter this problem, contact Technical Support.
Patient Controller Device		
Patient Controller is not accessible.	Patient controller is lost or damaged.	Contact Technical Support. If you receive a replacement patient controller, see "Appendix B: Pairing the Patient Controller to the Generator" (page 70).
Patient controller has no power or has lost power.	Patient controller's battery is drained.	Charge the patient controller.
	Patient controller is damaged or malfunctioning.	Replace the patient controller. Contact Technical Support.
Patient controller will not charge.	Patient controller charging cable is loose or not securely connected.	Connect the charging cable to the patient controller.
	Plug adapter or charging cable is defective.	Replace the plug adapter or charging cable.
	Correct plug adapter (voltage converter) is not connected to the charger.	Connect the appropriate plug adapter (voltage converter) to the charger.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Nothing is displayed on the screen.	Charger is defective.	Replace the charger.
	Patient controller is damaged or malfunctioning.	Replace the patient controller. Contact Technical Support.
	Patient controller is off or is in Sleep mode.	Turn on the patient controller.
	Patient controller's battery is drained.	Charge the patient controller.
Patient controller will not respond to input.	Screen is damaged or malfunctioning.	If the patient controller appears to be powered on but without display, the screen may be defective. Contact Technical Support.
	Patient controller has locked up.	Perform a soft reset by turning the patient controller off and back on.
Patient controller is not communicating with the generator.	Touchscreen interface is damaged or malfunctioning.	If the patient controller appears to be powered on but will not respond to input, the screen may be defective. Contact Technical Support.
	Patient controller is off or has timed out and is in standby mode.	Wake up the patient controller, see "Using a Provided Device".
	The patient controller is unable to pair to the generator because the generator is not sensing the magnet.	Position the magnet perpendicular to and centered directly over the generator site. See "Starting and Stopping

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Stimulation Using the Magnet” (page 32).
	Patient controller battery is drained.	Charge the patient controller battery.
	Bluetooth® wireless connection is not strong or turned off.	Decrease the distance between the devices. Move the devices away from other devices that may be causing interference.
		Move the devices so they share line of sight.
		Do not operate other wireless devices at the same time.
		Disconnect any Bluetooth® wireless media accessories (such as headphones or speakers).
		Wait a few minutes and try connecting again.
		Turn on Bluetooth® wireless technology using the instructions in the “Troubleshooting messages” table.
	Patient controller is damaged or malfunctioning.	Replace the patient controller.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Cannot find or connect to the generator.	The device is not supported.	Download the patient controller app for your system. Use the device provided by Abbott Medical or a compatible personal Apple® iOS® device. NOTE: For more information on compatible devices, see "Appendix A: Downloading the Patient Controller App" (page 68).
Generator		
Generator Unavailable message appears.	The generator is not in range.	Decrease the distance between the generator and patient controller.
Low Generator Battery message appears.	The EPG battery needs to be replaced soon.	Contact your clinician to schedule a replacement.
Generator Battery Depleted message appears.	The EPG battery level is too low to provide therapy.	Contact your clinician to schedule a replacement.
Replace Generator Soon message appears.	The IPG is approaching its end of service and will need to be replaced soon.	Contact your clinician to schedule a replacement.
Replace Generator message appears.	The IPG has reached the end of its service.	Contact your clinician to schedule a replacement.
Therapy		

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
A program is invalid or not available.	The program is missing information.	Talk to your clinician about reprogramming your therapy.
No stimulation	Stimulation is off, possibly due to a generator reset or magnet application.	Turn on stimulation using the patient controller app or magnet (if enabled).
Stimulation turns off unexpectedly.	The system impedance is measuring impedance and has stopped stimulation temporarily.	Stimulation will resume when the impedance measurement is completed.
	A magnet was used to turn off stimulation.	Turn on stimulation to resume therapy.
	The generator performed a reset.	Select a program and turn on stimulation to resume therapy.
	The generator entered Surgery mode.	If Surgery mode was triggered in error, follow the on-screen notification to exit Surgery mode.
	The generator entered MRI mode.	If MRI mode was triggered in error, follow the on-screen notification to exit MRI mode.
Program strength is off.	The generator could not deliver the desired program strength.	Try adjusting the program strength. If the problem persists, contact your clinician.
Increasing Strength is Not	The program may need to be modified.	Contact your clinician.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Recommended message appears.		
Bluetooth® Wireless Communication or Connection		
Patient controller cannot establish Bluetooth wireless connection with the generator or the connection was lost.	Interference in the environment (for example, from microwave ovens and Wi-Fi routers).	Move to a different area or room away from the interference.
	Patient controller is off or has timed out and is in standby mode.	Wake up the patient controller.
	Patient controller battery is drained.	Charge the patient controller battery.
	Bluetooth wireless technology is not connected.	Remove and re-enable the Bluetooth wireless technology pairing.
		In the device settings, select Bluetooth. Tap the toggle button to enable Bluetooth wireless technology.
	The user's hand is blocking the Bluetooth wireless antenna.	Try holding the patient controller differently.
	Bluetooth wireless connection is not strong.	Decrease the distance between the patient controller and the generator. Ensure the patient controller is in Bluetooth wireless range

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		of the generator (within 3 ft or 0.9 m).
		Turn on Bluetooth wireless technology on your patient controller if communication is disabled.
		1. Return to the patient controller Home screen and tap Settings .
		2. Tap Bluetooth , then tap the Bluetooth toggle button.
		NOTE: If you turn Bluetooth wireless technology off and on or reset the app, it will take longer to reconnect to your generator.
		Move to another location so the patient controller and generator are away from other devices that may be causing interference.
		Move the patient controller and generator so they have a line of sight and maintain an uninterrupted path for the Bluetooth wireless signal.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Do not operate other wireless devices at the same time.
		Disconnect any Bluetooth wireless media accessories (such as headphones or speakers, AirPlay [†] , AirDrop [†] , CarPlay [†] , or Hotspot [†]).
Surgery Mode		
Cannot put the generator in Surgery mode.	The generator is not connected to the patient controller.	Try connecting to the generator again. If the problem persists, contact Technical Support.
	The generator is in MRI mode.	Exit MRI mode to set Surgery mode.
MRI Mode		
MRI is Not Permitted is displayed instead of the MRI Mode option on the Mode screen.	A part of the system is not MR Conditional.	Contact your clinician for help identifying the models of your system. If you have any implanted parts that are not MR Conditional, you cannot receive an MRI scan.
MRI is Not Advised message appears.	The generator battery voltage is too low.	Contact your clinician.
	There may be a problem with the implanted lead or leads.	Contact your clinician. Your clinician may be able to perform an additional check to see if MRI Mode can be set.

Table 7. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Cannot put the generator in MRI mode.	The generator is not connected to the patient controller.	Try connecting to the generator again. If the problem persists, contact Technical Support.
	The generator is in Surgery mode.	Exit Surgery mode to set MRI mode.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Downloading the Patient Controller App

You must download the patient controller app to your patient controller (either a device provided by Abbott Medical or a compatible personal Apple® iOS® device) to use the patient controller with your generator. The patient controller app is compatible with Apple iOS mobile digital devices as specified on the Abbott Medical Neuromodulation patient resources page at www.NMmobiledevicesync.com/cp. Be sure your patient

controller is running an Apple-released iOS version before downloading the patient controller app.

If you do not have an Apple ID you can create one while setting up the device or before installing the app. For instructions, refer to the Apple ID support page at support.apple.com. Tap the drop-down menu or scroll down to locate the Search Support box. Tap in the Search Support box, type “Apple ID,” and then select the quick link or tap “Go” and scroll to the instructions for creating a new Apple ID.

If you have already set up your patient controller, see the following steps for downloading the app.

To create a new Apple ID:

1. Make sure the patient controller is connected to a Wi-Fi network.
2. Follow the onscreen prompts.

NOTE: Use an existing e-mail address or set up a free iCloud e-mail address. Note your password since you will need it to verify your account and update your app.

3. Click **Verify now** in the e-mail sent to your e-mail address.
4. Follow the onscreen prompts to finish creating your Apple ID.

To download the app:

1. Make sure the patient controller is connected to a Wi-Fi network.
2. Tap the App Store icon on the patient controller Home screen.

3. Enter **Abbott Patient Controller** in the Search field.
4. Once you locate the correct app, follow the onscreen prompts.

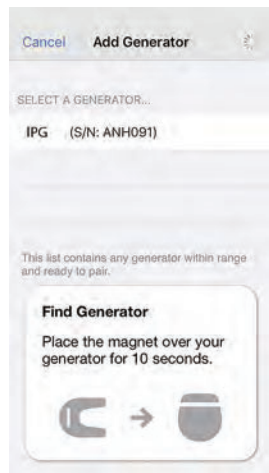
NOTE: If you encounter problems downloading the app, contact Technical Support.

Appendix B: Pairing the Patient Controller to the Generator

To pair the patient controller to the generator:

1. Place the magnet perpendicular to the generator for 10 seconds, and then move the magnet away from the generator.
2. Tap the patient controller app icon.
The patient controller app launches.
3. Tap **+**.
The Add Generator screen opens.

Figure 18. Add Generator screen



4. Tap an available generator in the “Select a Generator...” list.
If the “No Generators Found” message displays, repeat step 1 and then tap  to search for available generators again and refresh the generator list.
5. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
6. Tap **Pair** to pair the patient controller and generator.
The “Connecting to Generator...” message displays while the patient controller is connecting to the generator.

Appendix C: Regulatory Statements

These statements are applicable to the generator. For Regulatory Statements regarding the patient controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app; or, on the patient controller Home screen, tap **Settings** > **General** > **Legal & Regulatory**.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 8. EPG Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2SJMX599EPG

Table 9. Proclaim™ IPG Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	RIASJMRFC

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® Low Energy (LE) wireless technology as it is implemented in the device.

Table 10. Bluetooth Low Energy (LE) wireless technology information

EPG Antenna type	Embedded ceramic antenna
IPG Antenna type	Embedded patch antenna in header
EPG Antenna dimensions	4 mm x 3 mm x 1.1 mm
IPG Antenna dimensions	8.1 mm x 5.1 mm x 4.9 mm
Modulation	GFSK
EPG Magnetic Field Strength (at 10 m distance)	0.000145 A/m maximum

Table 10. Bluetooth Low Energy (LE) wireless technology information

IPG Magnetic Field Strength (at 2 m distance)	16.3 $\mu\text{A/m}$
EPG Electric Field Strength	0.055 V/m maximum
IPG Electric Field Strength (at 2 m distance)	6.1 mV/m
Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
EPG Range	2 meters typical
IPG Range	1–2 m typical
Center frequency	2.44 GHz
Channel	40 logical channels
Bandwidth	2 MHz per channel
Data-rate	1 Mbit/s
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology

*EIRP = Equivalent isotropically radiated power

Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15 dB): 2.398 to 2.4855 GHz
- Channel: 40 logical channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- EPG Magnetic field strength: 0.000145 A/m
- IPG Magnetic field strength (at 2 m distance): 16.3 μ A/m
- Duty cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator and the patient controller. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the patient controller is paired with a generator, the Bluetooth wireless technology symbol is visible on the patient controller in the upper right-hand corner of the screen. When the Bluetooth wireless connection is not active, the symbol is grayed out.

The standard Bluetooth LE wireless technology data rate is 1 Mbit/s. The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (that is, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, see “Troubleshooting for Wireless and Coexistence Issues” (page 78).

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the generator and the patient controller, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the patient controller app and turn the patient controller off and on.
- Wait a few minutes and try connecting again.
- Do not operate other wireless devices (such as laptop, tablet, mobile phone, or cordless phone) at the same time.

NOTE: Wireless communication equipment (such as wireless home network devices, mobile and cordless telephones, and tablets) can affect the device.

Appendix D: Electromagnetic Compatibility Guidelines

The EPG, hereafter the device, is medical equipment and should be used with the following guidance.

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used

in accordance with the information provided in this manual.

The device was tested for basic safety and essential performance, as defined by IEC 60601-1/AMD1:2012 (Edition 3.1). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION:

- **The device complies with the limits for medical devices contained in IEC 60601-1-2:2014-04, CISPR11:2015 (BS EN 55011:2016), and ETSI EN 300 328 V2.1.1 (2016-11). However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.**
- **To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by Abbott Medical with this system. Do not use Abbott Medical components with devices or systems that are not approved by Abbott Medical.**

Table 11. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions as a result of its internal and system interface functions. Its RF emissions

Table 11. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
		are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 12. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 15%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	No guidance for battery-powered devices.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	No guidance for battery-powered devices.

Table 12. Guidance and Manufacturer's Declaration –
Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions IEC 61000-4-11	<5% U_T 40% U_T 70% U_T	Not applicable	No guidance for battery-powered 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.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms (ISM/ Radio bands between 150 kHz to 80 MHz) 80% AM at 1 kHz	3 Vrms 6 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

Table 12. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d} \sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 13. Guidance and Manufacturer's Declaration – Proximity Fields

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance $d = 0.3 \text{ m}$
	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	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	

Table 13. Guidance and Manufacturer's Declaration – Proximity Fields

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Radio Frequency Information

The effective radiated power is below the limits as specified in:

- USA: FCC 47 CFR Part 15:2012

NOTE: Maintain a reasonable distance between other electronic equipment and the device.

CAUTION: The ISM band used by this device has been approved by the Federal Communications Commission for unlicensed use. However, there is no guarantee that this device will not receive

**interference or that any particular transmission
from this device will be free from interference.**

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

abbott.com

2023-04
ARTEN600283821 A



Eterna™ Implantable Pulse Generator
Model 32400

Clinician's System Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Indication for Use.	1
Contraindications.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	3
Adverse Effects.	5
Safety and Effectiveness Studies.	6
System Overview.	6
Product Description.	6
Package Contents.	7
Identifying the Generator.	7
Directions for Use.	7
Creating a Generator Pocket.	8
Connecting a Lead or Extension to the Generator.	8
Implanting the Generator.	10
Replacing the Generator.	10
Disposing of Explanted Components.	10
Checking the Status of the Generator Battery.	11
Technical Support.	11
Appendix A: Product Specifications.	12
Storage and Excursion Temperature Specifications.	12
Product Materials.	12
Generator Specifications.	12
Adapters and Extensions for Compatibility with Non-Abbott Leads.	13
Appendix B: System Components and Accessories.	14
Generator.	14
Generator Accessories.	14
Charging System.	14
Charging System Accessories.	14
Programmeters and Controllers.	14
Programmer and Controller Accessories.	14
Leads and Extensions.	14
Leads and Extensions Accessories.	15
Adapters and Extensions.	15
Appendix C: Generator Battery Information.	16
Appendix D: Regulatory Statements	16
Disposal Guidelines for Battery-Powered Devices.	16
Statement of FCC Compliance.	16
Identification Information for Product Registration.	17
Wireless Technology Information.	17
Quality of Service for Wireless Technology.	18
Appendix E: Electromagnetic Compatibility Guidelines.	19
Appendix F: Symbols and Definitions.	21

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The Eterna™ Spinal Cord Stimulation (SCS) System is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indication for Use

Refer to the Indications for Use Data Sheet for Abbott Medical spinal cord stimulation systems.

Contraindications

The Eterna™ SCS System is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to this neurostimulation system.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical candidates. Neurostimulation should not be used for patients with comorbidities that could prevent successful implant or effective therapy.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. If use of electrocautery is necessary, place the neurostimulator in Surgery mode using the clinician programmer app or the patient controller app before using an electrosurgery device.

During the implant procedure, if an electrosurgery device must be used, take the following actions:

- Use bipolar electrosurgery only.
- Place the neurostimulator in Surgery mode before using an electrosurgery device.

- Set the electrosurgery device to the lowest possible energy setting. Output power below 80 W is recommended for all activations.
- Complete any electrosurgery before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Exit Surgery mode during intraoperative testing and after the procedure is completed.

NOTE: During intraoperative testing, Surgery mode must be turned off for the neurostimulation system to function correctly.

- Confirm that the neurostimulation system is functioning correctly during the implant procedure, before closing the neurostimulator pocket, and after the implant procedure.

After any surgery, check the neurostimulation system for the following:

- Check the neurostimulator to ensure Surgery mode has been turned off, even if Surgery mode was not turned on at the beginning or during the procedure.
- Confirm the neurostimulation system is functioning.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems (minimum separation distance of approximately 8 cm (3 in.) between lead ends is recommended); (2) verify that the neurostimulation system is not interfering with the function of the implanted cardiac system; and (3) consider bipolar programming of both devices and use neurostimulation system settings that do not interfere with the function of the implantable cardiac system.

Other active implanted devices. The neurostimulation system may interfere with the normal operation of another active implanted device, such as a pacemaker, defibrillator, or another type of neurostimulator. Conversely, the other active implanted device may interfere with the operation of the neurostimulation system.

Interference with other devices. Some of this system's electronic equipment, such as the programmer and controller, can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Operation of machines, equipment, and vehicles. Patients using therapy that generates paresthesia should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract them from properly operating it. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. For patients who do not feel paresthesia, sudden stimulation changes are less likely to occur and distract them while operating motorized vehicles, machinery, or equipment.

Explosive and flammable gases. Do not use a clinician programmer or patient controller around explosive or flammable gas fumes or vapors. This includes oxygen-enriched environments such as hyperbaric chambers. Operating the device near gas fumes or vapors could cause them to catch fire. If gas fumes or vapors catch fire, it could cause severe burns, injury, or death.

Keep dry to avoid damage. Clinician programmers, patient controllers, and chargers are not waterproof. Keep them dry to avoid damage. Advise patients to not use their devices when engaging in activities that might cause them to get wet, such as swimming or bathing.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).

- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Device modification. This equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Application modification. To prevent unintended stimulation, do not modify the generator software in any way. Only apply software updates that are published directly by Abbott Medical.

Case damage. Do not handle the generator if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

Generator disposal. Return all explanted generators to Abbott Medical for safe disposal. Generators contain batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the generator because explosion or fire may result.

Product materials. Neurostimulation systems have materials that come in contact or may come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.

Precautions

The following precautions apply to this neurostimulation system.

General Precautions

Clinician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Patients should avoid charging their generator over an incision that has not completely healed. Infections related to system implantation might require that the device be explanted.

Implantation of two systems. If two systems are implanted, ensure that at least 20 cm (8 in.) separates the implanted generators to minimize unintended interaction with other system components.

Implantation of multiple leads. If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads can possibly create a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.

Implant heating. While charging the generator, patients may perceive an increase in temperature at the generator site. In patients who have areas of increased sensitivity to heat, consider placing the implant where the patient has normal sensation.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances or render the patient incapable of controlling the generator. If unpleasant sensations occur, turn off stimulation immediately.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the

neurostimulation system to turn on or turn off or affect communication between the device and generator; however, it will not change the prescribed programmed parameters. Patients should be advised to keep their mobile phones and smart watches at least 15 cm (6 in.) away from the generator and avoid placing any smart device in a pocket near the generator. If a patient is concerned about a smart device interacting with their neurostimulation system, consider disabling magnet mode. For more information about setting the magnet mode, refer to the clinician programmer manual or contact Technical Support.

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks after implantation of a neurostimulation system. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in overstimulation or ineffective stimulation.

Patient training. Instruct patients to use their neurostimulation system only after an authorized clinician has programmed the generator and has trained the patient on how to safely control stimulation and to charge the system.

Programmer use. Allow only authorized use of the clinician programmer to avoid any programming changes that may injure a patient.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use the system if the use-by date has expired.

Recharge-by date. A recharge-by date is printed on the packaging. If this date has been reached or has been exceeded before the date of implantation, the generator should be charged prior to implantation.

Handle devices with care. The clinician programmer and patient controller are sensitive electronic devices that can be damaged by rough handling, such as dropping them on the ground.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package, the device, or any device components show signs of damage, tampering, or if the sterile seal is ruptured, or contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline prior to connection can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

System testing. To ensure correct operation, always test the system during the implant procedure, before closing the neurostimulator pocket, and before the patient leaves the surgery suite.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may damage the electronic circuitry of an implanted generator. If lithotripsy must be used, do not focus the energy near the generator.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation, confirm the neurostimulation system is still working.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects

is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted generator should be shielded with lead. Damage to the system may not be immediately detectable.

Home and Occupational Environments

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Patients should cautiously approach such devices and should request help to bypass them. If they must go through a gate or doorway containing this type of device, patients should turn off their generator and proceed with caution, being sure to move through the device quickly.

Scuba diving or hyperbaric chambers. Before diving or using a hyperbaric chamber, patients should contact their physician to discuss the effects of high pressure on their implanted system. Implanted systems with non-Abbott Medical leads have not been evaluated for safety while scuba diving or in hyperbaric chambers. Patients with implanted Abbott Medical leads should avoid scuba diving in more than 30 m (100 ft) of water or entering hyperbaric chambers above 4.0 atmospheres absolute (ATA) for any length of time, as this may damage the neurostimulation system. For less than 30 m (100 ft) of water or pressures below 4.0 ATA, durations of less than 60 minutes are recommended.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with using this neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off your generator immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or generator site
- Seroma (mass or swelling) at the generator site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Safety and Effectiveness Studies

For information that supports the clinical use of this neurostimulation system, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems. This neurostimulation system is similar in technology and intended use to the systems reported in the literature and clinical studies. Therefore, the literature and clinical studies represent the safety and effectiveness of this neurostimulation system.

System Overview

This neurostimulation system is designed to deliver electrical stimulation to nerve structures. The neurostimulation system includes the following main components:

- Generator and accessories
- Charger and accessories
- Leads
- Clinician programmer application on clinician programmer device
- Patient controller application on patient controller device
- Patient magnet

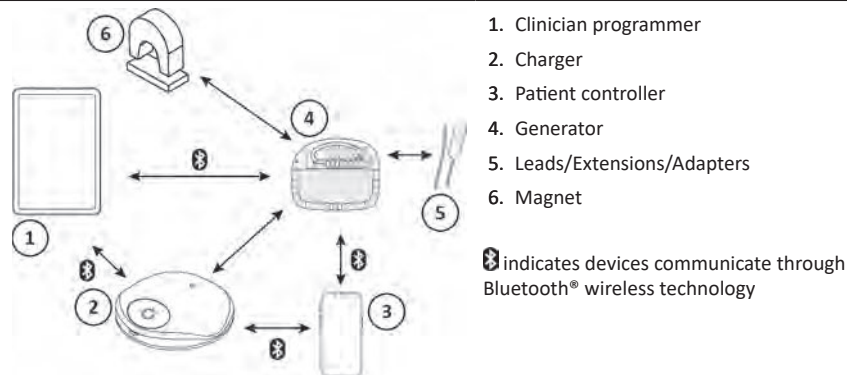
The implantable pulse generator (also referred to as an IPG or neurostimulator) delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation. The patient magnet can turn the generator on and off if the physician enables this functionality.

Physicians use the clinician programmer to create and modify programs for a patient, view and email program log files, and view generator and charger information. Patients use the patient controller to control their prescribed programs, monitor generator battery status to maintain stimulation, monitor charging status, and modify charger settings. Patients use the charger to charge their generator.

NOTE: In this document, the term “clinician programmer” refers to the Abbott Medical Clinician Programmer device, “patient controller” refers to the Abbott Medical Patient Controller device, “clinician programmer” app refers to the Abbott Medical Clinician Programmer app, and “patient controller app” refers to the Abbott Medical Patient Controller app.

The following image shows how the major system components are intended to interact.

Figure 1. System components



NOTE: This manual provides instructions for implanting the generator. For instructions for using other components or more information about the neurostimulation system, see the applicable manuals for those components.

Product Description

This implantable pulse generator is a rechargeable electronic device designed to be connected to one or more extensions or leads with up to 16 electrodes total. It is powered by a hermetically sealed rechargeable battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The generator can deliver stimulation with a single program or with multiple programs. Each program can

provide stimulation to a single anatomical area or to multiple areas. The generator communicates wirelessly with the clinician programmer and the patient controller and receives radio frequency energy from an external charger to charge the generator battery.

Additional functions supported:

- **Upgradeability.** Software upgrades after implantation provide patients with additional features as approved by the respective regulatory agencies. To upgrade features on the generator, a clinician programmer or patient controller is needed.
- **Compatibility.** The generator header is designed to allow the generator to connect to an Abbott adapter so compatible leads or extensions from another manufacturer can be used with the Eterna™ SCS system. Refer to the compatibility guidelines in this manual (see “Adapters and Extensions for Compatibility with Non-Abbott Leads” (page 13)).

Package Contents

In addition to the product documentation, the generator kit contains the following items:

- 1 generator (Model 32400)
- 1 pocket sizer (Model 12720)
- 1 torque wrench (Model 1101)
- 2 port plugs (Model 12710)

Identifying the Generator

You can identify the generator in the following ways:

- The model number and barcode are engraved on the generator.
- The generator has a radiopaque identification tag in the lower right corner that can be viewed with standard X-ray procedures. On the tag, ABT identifies Abbott Medical as the manufacturer, and the letter and a number combination A2 identifies the model family. Additionally, the header port plug is radiopaque and, if used, is visible with standard X-ray procedures (see the following figure).
- The clinician programmer app when connected to the generator indicates the model number and allows you to view other generator information. See the clinician programmer manual for instructions.

Figure 2. Location of the generator code on the Eterna™ implantable pulse generator



Directions for Use

Read this section carefully for suggested directions for use related to the Eterna™ implantable pulse generator. For directions for use for other system components such as the clinician programmer, see the clinician’s manual for the clinician programmer.

NOTE:

- Before the surgical procedure, set up communication between the clinician programmer and the generator while the generator is in its sterile packaging to ensure that it is functional and fully charged. If the generator has never established communication with a programmer, you must first activate the generator for communication by holding the magnet over the generator for 8 to 25 seconds.
- Ensure the generator is fully charged before implantation. The generator can be charged through its sterile packaging.

Creating a Generator Pocket

The following steps outline the suggested procedure to create a generator pocket:

1. Determine the site for the generator, ensuring that the lead is long enough to reach the pocket and provide a strain relief loop.

NOTE: Common sites for generator implantation are along the midaxillary line, in the upper buttock along the posterior axillary line (taking care to avoid the belt line), and in the area over the abdomen just below the lowermost rib. To ensure a flat area is selected, you can mark a flat area prior to the surgical procedure while the patient is in a sitting position.

CAUTION:

- **Do not place the generator deeper than 2.5 cm (0.98 in.) because the clinician programmer, generator charger, and patient magnet may not communicate effectively with the generator.**
 - **Ensure the generator is set to Surgery mode using the clinician programmer.**
2. Create the pocket so that the generator is parallel to the skin surface. Ensure the pocket is at least 0.5 cm (0.20 in.) below the surface of the skin but does not exceed a depth of 2.5 cm (0.98 in.).
 3. Insert and remove the pocket sizer to ensure that the pocket is large enough to accommodate the generator, allowing enough extra room for a strain relief loop for each lead or extension.

Connecting a Lead or Extension to the Generator

The following steps outline the suggested guidelines to connect a lead or extension to the generator:

WARNING: To avoid harming the patient or damaging the neurostimulation system, ensure that any electrosurgery procedures are completed before connecting the leads or extensions to the generator.

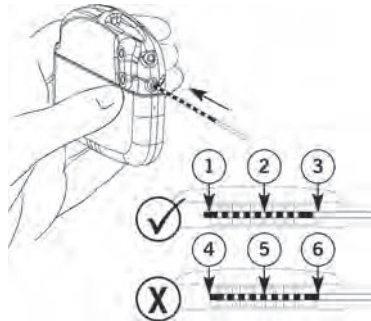
CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

1. If any of the lead or extension contacts are exposed to body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.
2. To help ensure that the lead or extension can be fully inserted into the generator header, insert the torque wrench through the septum on the generator header, turn the torque wrench clockwise to tighten the setscrew until the torque wrench clicks, and then loosen the setscrew again by turning the wrench counterclockwise about 2.5 times.

CAUTION:

- **Use only the torque wrench included in the extension, generator, or torque wrench kit. If you need to loosen the setscrew, turn the setscrew (in quarter turns counterclockwise) just enough to insert or remove the lead or extension from the generator header. Retracting the setscrew too far may cause it to come loose and fail to secure the lead or extension to the generator.**
 - **To avoid sharply bending and damaging the lead or extension when performing the following step, insert the lead or extension parallel with the header port. Additionally, try grasping the lead or extension about 5 mm at a time from the opening of the header port while inserting.**
3. Using clean gloves, carefully slide the proximal end of the lead or extension into the generator header until it stops. Confirm that the lead or extension is correctly inserted by following these visual indicators and referring to the following figure:
 - The first contact band (at the tip) of the lead or extension extends slightly past the first header contact and is visible, the windows between each of the header contacts are clear, and the ninth contact band of the lead or extension is not visible.

Figure 3. Correct versus incorrect insertion of the lead or extension



Fully inserted

1. First contact band (tip) is visible past the first header contact
2. Window between each header contact is clear
3. Ninth contact band is not visible

Not fully inserted

4. First contact band (tip) is not visible past the first header contact
5. Window between each header contact is partially blocked by contact band
6. Ninth contact band is visible

4. Use the clinician programmer app to communicate with the generator and test the impedance to ensure that the lead or extension is fully inserted. See the clinician's manual for the clinician programmer app for instructions.

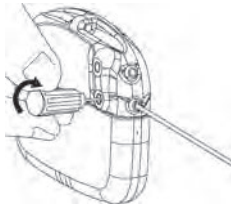
NOTE:

- To test the system integrity turn off Surgery mode. After system integrity has been verified, set the generator back into Surgery mode before closing the pocket.
- If the system integrity check fails, disconnect the lead or extension and reconnect to the generator. Repeat the system integrity check.

5. Insert the torque wrench through the septum and tighten the setscrew, turning it clockwise until the torque wrench clicks.

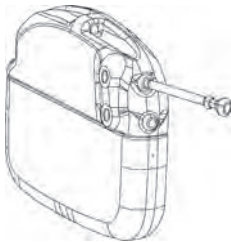
NOTE: After removing the torque wrench, check the septum to ensure it has closed. If the septum did not close, gently reseal the septum flaps.

Figure 4. Tighten the setscrew clockwise



6. If implanting two leads, repeat the previous steps. If implanting a single lead only, insert the header port plug into the unused port, and use the torque wrench to tighten the setscrew until the torque wrench clicks.

Figure 5. Insert the port plug



Implanting the Generator

The following steps outline the suggested procedure to implant the generator:

CAUTION: Do not implant the IPG face down. Implant it with the label facing toward the skin, or it may not communicate or recharge.

1. Place the generator into the generator pocket. The depth of the generator pocket from the surface of the generator to the surface of the skin should be at least 0.5 cm (0.20 in.) and not exceeding 2.5 cm (0.98 in.).
2. Carefully coil any excess lead or extension behind the generator in loops no smaller than 2.5 cm (0.98 in.) in diameter to provide strain relief for the lead or extension and generator connection.

CAUTION: Do not bring the suture needle in contact with a generator, lead, or extension, or the component may be damaged.

3. To stabilize the generator within the pocket, pass suture through the hole at the top of the generator header and through the hole on the side of the generator header, and secure these to connective tissue.
4. Check the entire system by fluoroscopy before closing to ensure proper positioning of the lead or leads and that the lead or leads are straight, with no sharp bends or kinks.
5. Use the clinician programmer app to communicate with the generator and perform intraoperative testing to confirm that the system is operational. See the clinician's manual of the clinician programmer app for instructions.

NOTE:

- Generator output may not be identical to that of the trial stimulator at the same settings.
- Ensure the generator is set to Surgery mode.

6. Ensure that the generator is away from the pocket incision suture line, close the pocket incision, and apply the appropriate dressings.

NOTE: When the surgical procedure is completed, ensure Surgery mode has been turned off.

Replacing the Generator

The following steps outline the suggested procedure to replace a generator:

1. Turn off stimulation or verify that it is turned off.

CAUTION: Exercise care when using sharp instruments or electrocautery around leads or extensions, or they may be damaged.

2. Open the generator implant site per normal surgical procedure.
3. Insert the torque wrench through the septum of the generator header and loosen the setscrew by turning it counterclockwise.

CAUTION: When performing the following step, do not bend the lead or extension sharply; or it may be damaged.

4. Gently remove the lead or extension from the generator header; then clean and dry all connections, ensuring they are free of fluid and tissue.
5. To complete the generator replacement procedure, see the following sections: "Connecting a Lead or Extension to the Generator" (page 8) and "Implanting the Generator" (page 10).

Disposing of Explanted Components

Explanted Abbott Medical components should be returned to Abbott Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your Abbott Medical representative or Technical Support.

Checking the Status of the Generator Battery

The generator contains a rechargeable battery. The amount of time that the battery will provide active stimulation depends on the patient's stimulation settings and daily usage time. To check the status of the generator battery, use the clinician programmer app or patient controller app.

NOTE: Generator battery status is available upon initial connection to the clinician programmer app and the patient controller app.

The following list provides additional information about the battery status:

- Stimulation will automatically stop when the battery cannot support stimulation.
- Alert messages will appear on the clinician programmer app and the patient controller app when the generator battery is low or depleted and when charging is required to maintain uninterrupted stimulation therapy.
- An elective replacement indicator (ERI) message will appear on the clinician programmer app and patient controller app stating the generator may need to be replaced due to the generator battery approaching its end of service.

NOTE: With rechargeable batteries, intervals between charging may become more frequent with use over time.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

Storage and Excursion Temperature Specifications

Store the components in this kit according to the following recommended conditions.

Table 1. Recommended storage and excursion conditions for components

Long Term Storage Temperature	Store at 23°C or 73°F
Temperature Excursions	Excursions below 15°C (59°F) or above 30°C (86°F) should be <24 hours in duration
Excursion Temperature Limits	-20°C (-4°F) to 60°C to (140°F)

Product Materials

The following materials are intended to come into contact with tissue.

Table 2. Product materials for generator kit

Component	Material
Generator	Titanium, silicone rubber, epoxy resin
Pocket sizer	Polybutylene terephthalate
Port plug	Polyether ether ketone (PEEK) with barium sulfate

NOTE: These components are not made with natural rubber latex.

Generator Specifications

The Eterna™ implantable pulse generator has the following physical specifications.

Table 3. Generator specifications

Specifications	Model 32400
MR Conditional	Yes
Upgradeable features	Yes
BurstDR™ stimulation capable	Yes
Height	3.87 cm (1.52 in.)
Length	4.81 cm (1.89 in.)
Thickness	0.90 cm (0.36 in.)
Weight	26.4 g (0.93 oz)
Volume	13.79 cm ³ (0.84 in. ³)
Power source	Rechargeable lithium ion cell battery
Connector specifications	Two 8-channel connectors In-line, 2.54 mm (0.1 in.) spacing Connector strength: 5N
Program storage capacity	16 programs with 8 stim sets each

The generator has the following operating parameters.

Table 4. Operating parameters for the generator

Parameter	Tonic Range	Tonic Steps	Burst Range*	Burst Steps*
Pulse width	20–1000 μ s	10 μ s (20–500 μ s range) 50 μ s (500–1000 μ s range)	50–1000 μ s	50 μ s
Frequency	2–200 Hz	2 Hz	—	—
	200–500 Hz	10 Hz	—	—
	500–1200 Hz	20 Hz	—	—
Burst frequency	—	—	10–60 Hz	10 Hz
Intra-burst rate	—	—	250–500 Hz	10 Hz
			500–1000 Hz	20 Hz
Amplitude	0–25.5 mA	0.1–1.0 mA	0–12.75 mA	0.05–0.50 mA
	0–12.75 mA	0.05–0.50 mA		

NOTE:

- Columns with * represent operating parameters for BurstDR™ stimulation programs on generators capable of BurstDR stimulation mode.
- For each tonic program, you have the option to select the amplitude range. For information on setting the amplitude range, see the clinician's programming manual for this system.
- The number of stim sets in use for a tonic program governs the maximum frequency (1200/number of stim sets).
- The maximum current depends on the impedance, frequency, and pulse width settings.

Adapters and Extensions for Compatibility with Non-Abbott Leads

The Eterna™ implantable pulse generator is compatible with select Medtronic leads and extensions. However, a compatible adapter or extension must be used to connect the Eterna™ implantable pulse generator to Medtronic leads. Compatible adapter and extension models are listed in the following table. Refer to the clinician manuals of the A127™ extension and the 8-channel adapter for the list of compatible Medtronic leads and extensions.

Table 5. Compatible Abbott Adapters

Device	Model
A127™ Extension	2341, 2342, 2343, 2346
8-Channel Adapter	2311, 2316

WARNING: Always use a compatible adapter to connect the Eterna™ implantable pulse generator to compatible Medtronic leads and extensions. Do not insert a Medtronic lead or extension directly into the Eterna generator header as this may damage the header.

Appendix B: System Components and Accessories

The Eterna™ SCS system includes the following components.

NOTE:

- Not all models are available in all countries. Contact your local representative for more information.
- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

Generator

Model	Description
32400	Eterna™ implantable pulse generator

Generator Accessories

Model	Description
1101	Torque wrench
12710	Port plug

Charging System

Model	Description
16000	Charger

Charging System Accessories

Model	Description
16730	Travel case
16740	Charging cable and power adapter kit
16750	Charging apparel kit – lumbar
16760	Charging apparel kit – pectoral
36000	Charger kit – lumbar

Programmeters and Controllers

Model	Description
55500	Patient controller app
55600	Clinician programmer app

Programmer and Controller Accessories

Model	Description
1210	Magnet kit
35500	SCS patient controller kit

Leads and Extensions

Model	Description
3100-series	Percutaneous leads

Model	Description
3200-series	Paddle leads
3300-series	Extensions

Leads and Extensions Accessories

Model	Description
1100-series	Stylets
1102	Guidewire for percutaneous leads
1103	Introduce-AK™ lead introducer
1105	Lead anchor, butterfly
1106	Lead anchor, long
1109	Strain relief
1112	Tunneling tool, 12 in.
1114	Epidural needle, 14 gauge, 4 in. (10 cm)
1116	Epidural needle, 14 gauge, 6 in. (15 cm)
1120	Tunneling tool, 20 in.
1192	Swift-Lock™ anchor
1194	Cinch™ anchor
1701	SCS accessory kit

Adapters and Extensions

Model	Description
2311	8-channel adapter, M, 10 cm
2316	8-channel adapter, M, 60 cm
2341	A127™ extension, 15 cm
2342	A127™ extension, 40 cm
2343	A127™ extension, 60 cm
2346	A127™ extension, 90 cm

Appendix C: Generator Battery Information

The Eterna™ implantable pulse generator contains a rechargeable lithium ion battery. This battery should provide at least 10 years of service before replacement is recommended. If the patient does not charge the generator battery, stimulation will eventually stop. At nominal stimulation settings, 1 hour of charging should be sufficient to support 3 weeks or more of stimulation therapy.

When a program requires a patient to charge more than once a day, an elective replacement indicator (ERI) message may display in the patient controller indicating that the generator is approaching its end of service and to consult the physician to determine if generator replacement is needed.

Battery longevity and the time it takes to recharge a battery depend on multiple factors, including but not limited to the following:

- Program stimulation settings, such as frequency, pulse width, amplitude, and number of active electrodes
- Program dosage
- Program impedance
- Daily usage time
- Age of the generator battery
- Length of time since the last charge
- Shelf life of the device between the dates of manufacture and implant
- Duration of communication sessions between the generator and the patient controller or clinician programmer
- If the generator was stored outside of recommended storage temperatures

Nominal stimulation settings for BurstDR™ programs are as follows:

- 2 leads
- 1 area
- BurstDR™ stimulation
- 5 pulses per Burst
- Amplitude: 0.6 mA
- Pulse width: 1000 μ s
- Burst frequency: 40 Hz
- Intra-burst rate: 500 Hz
- Intermittent dosage with 30 seconds On Time and 90 seconds Off Time
- Therapy on 24 hours a day
- Program impedance: 525 Ω

Appendix D: Regulatory Statements

This section contains regulatory statements about your product.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to Abbott Medical at the end of its operating life.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If

this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 6. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMIPG1

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® wireless technology as it is implemented in the device.

Table 7. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Modified monopole
Antenna dimensions	10.7 mm x 4.3 mm x 3.0 mm
Modulation	GFSK
Output power (EIRP*)	2 mW (+3 dBm) typical
Duty cycle	14.1% or less over 6 min period
Range	Up to 2 m typical
Center frequency	2.44 GHz
Channel frequency range	2.402 GHz to 2.480 GHz
Channel	40 logical channels using AFH**
Bandwidth per channel	2 MHz
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology
Semi-duplex capability	Yes

*EIRP = Equivalent isotropically radiated power (not duty cycle adjusted)

**AFH = Adaptive frequency hopping

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator or charger and the clinician programmer or patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator or charger, the Bluetooth wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol appears dimmed.

The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (for example, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 18).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator encrypts its wireless communication with the programming device using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the generator at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.
- Proprietary authentication for the patient controller or clinician programmer applications in addition to the pairing procedure specified in Bluetooth LE, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized application from communicating with the generator.
- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the generator to a legitimate patient controller or clinician programmer.

Troubleshooting for Wireless, Coexistence, or Interference Issues

If you experience issues with interactions within the neurostimulation system, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the clinician programmer or patient controller app; then turn the clinician programmer or patient controller off and on.
- Wait a few minutes and try connecting again.
- Avoid operating other consumer electronic devices, such as a laptop, tablet, mobile phone, or cordless phone at the same time.

NOTE:

- Equipment such as the following can interfere with the neurostimulation system: radiation-based imaging devices, electrosurgery devices, medical monitoring devices, radiofrequency identification devices (RFID), diathermy devices, wireless home network devices, and consumer electronic devices.
- For more information, refer to the clinician programmer manual to troubleshoot potential issues for wireless communication.

Appendix E: Electromagnetic Compatibility Guidelines

The implantable pulse generator (Model 32400), hereafter the device, is part of the Eterna™ SCS system and should be used with the following guidance:

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device has essential performance when operating as a system, as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). The device complies with the limits for medical devices contained in IEC 60601-1-2:2014+AMD1:2020 (Ed 4.1) and CISPR11:2015+AMD1:2016+AMD2:2019 (BS EN 55011:2016+A2:2021). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

NOTE: The non-Abbott Medical accessories supporting the clinician programmer, such as charging cords, adapters, should not be used while running the clinician programmer app. The effect of use of such accessories while running the app has not been evaluated.

Table 8. Guidance and Manufacturer's Declaration — Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device, when operating as a system, produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device, when operating as a system, is 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.
Harmonic emissions IEC 61000-3-2	Class A*	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class 5 Full Compliance*	

*Only applicable to Power Adapter (Model 16720) when operating with the charging system.

Table 9. Guidance and Manufacturer's Declaration — Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2**	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 10%.
Electrical fast transient/burst IEC 61000-4-4*	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or home environment for non-implantable parts of the system. Mains power is N/A to the device which operates on internal battery.
Surge IEC 61000-4-5*	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial, hospital, or home environment for non-implantable parts of the system. Mains power is N/A to the device which operates on internal battery.
Voltage dips, short interruptions IEC 61000-4-11*	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 s	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 s	Mains power quality should be that of a typical commercial, hospital, or home environment for non-implantable parts of the system. Mains power is N/A to the device which operates on internal battery.
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

Table 9. Guidance and Manufacturer's Declaration — Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			commercial, hospital, or home environment.
Conducted RF IEC 61000-4-6*	3 Vrms 150 kHz to 80 MHz	3 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Recommended minimum separation distance for higher immunity test levels
	6 Vrms ISM/Radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	$E = \frac{6}{d} \sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).

*Only applicable to Power Adapter (Model 16720) when operating with the charging system.

**Applicable to the Charging system (Model 16000,16740), Patient Controller (Model 55500), and Clinician Programmer (Model 55600) while operating with the IPG.

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 10. Guidance and Manufacturer's Declaration—Proximity Fields from RF Wireless Communication Equipment

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance d = 0.3 m
	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	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Table 11. Guidance and Manufacturer's Declaration—Enclosure Port Immunity to RF Wireless Communication Equipment

Immunity Test	Band (MHz)	Maximum Power (W)	Immunity Test Level (V/m)
IEC 61000-4-3	380 to 390	1.8	27
	430 to 470	2	28
	704 to 787	0.2	9
	800 to 960	2	28
	1700 to 1900	2	28
	2400 to 2570	2	28
	5100 to 5800	0.2	9

Table 12. Guidance and Manufacturer's Declaration—Enclosure Port Immunity to Proximity Magnetic Fields

Immunity Test	Test Frequency	Modulation	Immunity Test Level (A/m)
IEC 61000-4-39	30.0 kHz	Continuous wave	8
	134.2 kHz	Pulse modulation 2.1 kHz	65
	13.56 MHz	Pulse modulation 50 kHz	7.5

Appendix F: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 13. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Non-ionizing electromagnetic radiation
	Do not re-use

Table 13. Symbols and definitions

Symbol	Definition
	Do not resterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Long term storage temperature
	Temperature limit
	Excursions permitted within this range
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Medical Device
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Implantable device
	Accessories
	Serial number

Table 13. Symbols and definitions

Symbol	Definition
	Batch code
	Unique Device Identifier
	Prescription use only
	Sterilized using ethylene oxide
	Authorized representative in the European Community
	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797) and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directive. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-05
ARTEN600283836 B



NeuroSphere™ Patient Controller

Eterna™ Spinal Cord Stimulation System
Model 55500

User's Guide



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

About This Guide.	1
Terms Used in This Document.	1
Prescription and Safety Information.	1
Intended Use.	1
Indications for Use.	1
Contraindications.	1
MRI Safety Information.	1
Warnings.	2
Precautions.	4
Adverse Effects.	6
Product Description.	7
About Your System.	7
Overview of the Patient Controller.	9
Items You Will Receive.	9
Your Personal Identification Card.	9
Getting Started.	10
Managing Your Therapy.	11
Managing Your Generator	12
Starting and Stopping Therapy	13
Managing Therapy Programs	14
Setting Your Generator to MRI Mode	19
Preparing for an MRI Scan.	19
Disabling MRI Mode.	20
Setting Your Generator to Surgery Mode	21
Preparing for a Surgical Procedure.	21
Disabling Surgery Mode.	22
Setting Your Generator to Airplane Ready Mode	23
Setting Sleep Mode	24
Viewing Generator, Charger, and Patient Controller Battery Status	25
Viewing Generator Battery and Charging Status.	26
Viewing Generator Charging Sessions	27
Viewing the Charger Battery Status	28
Viewing Charger Charging Sessions	29
Managing Other Charger Settings	29
Viewing the Patient Controller Battery Status.	30
Viewing, Updating, and Exporting Device Information.	30
Updating Generator Software.	31
Updating Charger Software.	32
Updating Patient Controller App Software.	33
Exporting the Patient Controller Log	33
Caring for the Patient Controller.	34
Cybersecurity.	34
Protecting Access to the Patient Controller.	34
Wireless Security Measures.	34
Guidelines for Secure Use.	35
Legal and Privacy Notice.	35
Troubleshooting Chart.	36
Technical Support.	44
Appendix A: Downloading the Patient Controller App.	44
Appendix B: Pairing the Patient Controller with the Generator	45
Removing a Pairing Between a Generator and an Unused Patient Controller.	45
Appendix C: Pairing the Patient Controller With the Charger.	46
Appendix D: Regulatory Statements	47
Statement of FCC Compliance.	47

Identification Information for Product Registration.	47
Product Classification Statement (CISPR 11, Class B).	47
Wireless Technology Information.	48
Quality of Service for Wireless Technology.	48
Appendix E: Radio Frequency Information.	49
Appendix F: Electromagnetic Compatibility Guidelines.	50
Appendix G: Symbols and Definitions.	50

About This Guide

This guide explains how to use the NeuroSphere™ Patient Controller application (model 55500) with your Eterna™ Spinal Cord Stimulation (SCS) System. If you have any questions about your system, contact Technical Support.

Terms Used in This Document

This section contains definitions of some of the terms used in this document.

Magnetic Resonance (MR) Conditional system. A group of implanted parts that allows a patient to receive a magnetic resonance imaging (MRI) scan safely if all the requirements for the implanted parts and for scanning are met.

Perception. Perception strength is the value at which stimulation is first felt.

Program. A combination of one or more subprograms (areas).

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The clinician programmer and the patient controller applications are intended to communicate with pulse generators to manage stimulation programs. The applications allow clinicians to create customized therapy and help patients manage their prescribed stimulation programs.

Indications for Use

Abbott Medical spinal cord stimulation (SCS) systems are indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, non-surgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Contraindications

The Eterna™ SCS System is contraindicated for patients who are unable to operate the system. Additionally, the system is contraindicated for patients who have failed to receive effective pain relief during trial stimulation.

MRI Safety Information

You may be implanted with the parts that make up a Magnetic Resonance (MR) Conditional system, which allows you to receive an MRI scan if all the requirements for the implanted parts and for scanning are met. Scanning under different conditions may cause device malfunction, severe injury, or death. Contact your physician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks. Additionally, before receiving an MRI scan, inform the healthcare professional that you are implanted with a neurostimulation system. If you do not have an MR Conditional system, you cannot receive an MRI.

Do not bring your patient controller into the scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is MR Unsafe.

For more information about what you need to do to prepare for an MRI scan, refer to “Setting Your Generator to MRI Mode” (page 19) in this guide.

Warnings

The following warnings apply to these components.

NOTE: For nontherapy-related warnings regarding the patient controller, refer to the user guide available at support.apple.com/guide. for the Apple® iOS® device you are using to run the patient controller app.

System Warnings

Diathermy therapy. You cannot have any diathermy (a type of medical treatment that generates heat) if you have any part of a neurostimulation system implanted. This includes short-wave, microwave, or therapeutic ultrasound diathermy. Diathermy can cause injury near your implanted electrodes, resulting in severe injury or death. Diathermy may also damage your neurostimulation system, resulting in loss of therapy and the need for replacement surgery. Inform your healthcare professional that you cannot have diathermy treatment.

Operation of machines, equipment, and vehicles. Neurostimulation systems can cause tingling sensations throughout parts of your body. If you feel tingling sensations, turn off stimulation before operating motorized vehicles or potentially dangerous machinery and equipment. Sudden changes in your stimulation settings or physical position may make tingling worse and distract you from properly operating machines and equipment. Current data show that most patients using BurstDR™ stimulation therapy do not experience tingling sensation.

Implanted cardiac systems. Be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems (minimum separation distance of approximately 8 cm (3 in.) between lead ends is recommended); (2) verify that the neurostimulation system is not interfering with the function of the implanted cardiac system; and (3) consider bipolar programming of both devices and use neurostimulation system settings that do not interfere with the function of the implantable cardiac system.

Electrosurgery devices. Electrosurgery devices may harm you or damage your neurostimulation system. Inform your healthcare professional that only bipolar electrosurgery devices should be used and electrosurgery devices should be kept as far away as possible from your neurostimulation system. Additionally, your healthcare professional must confirm the neurostimulation system is functioning correctly after your procedure.

Lead movement. Avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks after implantation. These activities may cause lead movement,

resulting in understimulation or overstimulation. Excessive lead migration may require reoperation to replace the leads.

Emergency procedures. Designate a representative (family member or close friend) to notify any emergency medical personnel of your implanted neurostimulation system if emergency care is required. You will receive an identification card to carry that will inform emergency medical personnel of your implanted system. Use caution when undergoing any procedure that could include radiofrequency (RF) or microwave ablation, defibrillation, or cardioversion.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Patients with diabetes. Patients with diabetes may be more likely to experience complications with surgery. Seek medical attention if you experience signs of infection (fever, redness, fluid discharge at the incision), problems with surgical site healing, headache after surgery, disorientation, chest pain, or shortness of breath.

Changes in blood glucose levels. If you have diabetes, you should monitor your blood glucose closely after surgery. Patients with diabetes may experience unstable blood glucose levels following any surgical procedure.

Cardioverter defibrillators. Neurostimulation systems may adversely affect the programming of implanted cardioverter defibrillators.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Device Warnings

Explosive or flammable gases. Do not use your patient controller around explosive or flammable gas fumes or vapors. This includes oxygen-enriched environments such as hyperbaric chambers. Operating the device near gas fumes or vapors could cause them to catch fire. If gas fumes or vapors catch fire, it could cause severe burns, injury, or death.

Interference with other devices. This equipment can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Device modification. This patient controller is not serviceable by the customer. To prevent injury or damage to the system, do not modify the patient controller.

Application modification. To prevent unintended stimulation, do not modify the operating system or application in any way.

Strangulation. The cords in this system pose a strangulation risk. Keep cords out of the reach of children.

Keep dry to avoid damage. Your patient controller is not waterproof. Keep it dry to avoid damage. Do not use the patient controller when engaging in activities that might cause it to get wet, such as swimming or bathing.

Precautions

The following precautions apply to these components.

NOTE: For nontherapy-related precautions for the patient controller, refer to the user guide available at support.apple.com/guide for the Apple® iOS® device you are using to run the patient controller app.

System Precautions

Medical tests and procedures. Before undergoing medical tests or procedures (such as therapeutic radiation or electrolysis), contact your physician to determine if the procedure will cause you injury or damage your neurostimulation system. Specifically, you should be aware that medical devices such as electrohydraulic lithotriptors, therapeutic X-rays, computerized tomography (CT) scans, cobalt machines, and linear accelerators may cause damage to the electronic circuitry of an implanted neurostimulation system. Damage to the system may not be immediately detectable.

Component manipulation. Do not rub or press on implanted components through the skin. This may cause the leads to move, inducing stimulation at the implant site; generator inversion can occur, leading to the inability to communicate with the generator or skin erosion that can lead to another surgical procedure or possible infection.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations, motor disturbances, or make it difficult to control the generator using the patient controller. If unpleasant sensations occur, turn off stimulation immediately.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Postural changes. Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Turn stimulation off or lower the stimulation strength before stretching, lifting your arms over your head, or exercising. If unpleasant sensations occur, turn off stimulation.

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Use caution when approaching such a device and request assistance to bypass the device. If

you must proceed through a gate or doorway containing this type of device, turn off stimulation and proceed with caution, being sure to move through the device quickly.

Scuba diving or hyperbaric chambers. Before diving or using a hyperbaric chamber, you should contact your physician to discuss the effects of high pressure on your implanted system. Implanted systems with non-Abbott Medical leads have not been evaluated for safety while scuba diving or in hyperbaric chambers. Patients with implanted Abbott Medical leads should avoid scuba diving in more than 30 m (100 ft) of water or entering hyperbaric chambers above 4.0 atmospheres absolute (ATA) for any length of time, as this may damage the neurostimulation system. For less than 30 m (100 ft) of water or pressures below 4.0 ATA, durations of less than 60 minutes are recommended.

Physician instructions. Always follow the programs and therapy instructions established for you by your physician. If you do not, the therapy may be less effective in providing pain relief.

Patient training. Patients should use their neurostimulation system only after an authorized clinician has programmed their generator and has trained them on how to safely control stimulation and to charge the system.

Device components. The use of components not approved for use by Abbott Medical may result in damage to the system and increased risk of injury.

Magnet usage. The magnet provided with the system is a high-powered magnet intended for use solely with the system. Keep it away from watches, credit cards, computer disks, and other magnetically sensitive items to avoid damaging them. Always place the keeper bar on the magnet when not in use.

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the patient controller and generator; however, it will not change the prescribed programmed parameters. To prevent accidental interference, keep your smart device at least 15 cm (6 in.) away from the generator, and do not carry any smart device in a pocket near the generator. Contact Technical Support or your physician to discuss modifying the magnet mode setting on your neurostimulation system or if you have any other questions.

High-output ultrasonics and lithotripsy. The use of high-output therapeutic treatments, such as ultrasound and lithotripsy, may damage the generator. Inform your healthcare professional if lithotripsy treatment must be used.

Ultrasonic scanning equipment. The use of ultrasound may cause damage to a neurostimulation system if used directly over the generator. Inform your healthcare professional if ultrasound must be used.

Home use. This product is intended for home use per physician instruction. To avoid damage and other potential hazards, keep this product away from children and pets.

Infection. Follow proper infection control procedures. Also avoid showering and touching the bandages while your incisions are healing. If you need to charge your generator before your incisions have healed completely, take care not to disturb the bandages and follow your physician's guidance on charging.

Household appliances. Household appliances that contain magnets (such as refrigerators, freezers, inductive cooktops, stereo speakers, mobile telephones, cordless telephones, standard wired telephones, AM/FM radios, and some power tools) may

unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the patient controller and generator.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this patient controller, please ask for authorization to use it before turning it on.

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established. External defibrillation can cause induced currents in the lead-extension portion of the neurostimulation system. After defibrillation, confirm the neurostimulation system is still working.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted generator should be shielded with lead. Damage to the system may not be immediately detectable.

Overcommunicating with the generator. Use your patient controller to communicate with your generator only when needed because excessive communication with the generator can shorten the battery life.

Device Precautions

Keep the patient controller away from extreme temperatures. The patient controller may not function when the patient controller is very hot or very cold.

Handle the device with care. The patient controller is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Battery precaution. This patient controller contains a lithium ion battery and other potentially hazardous materials. Do not crush, puncture, or burn the patient controller because explosion or fire may result.

Component disposal. Do not dispose of the patient controller or charging system in fire. Dispose of the patient controller and charging system components according to local regulations. Do not incinerate or cremate the generator. The generator should be explanted and returned to Abbott Medical.

Control of your patient controller. Keep your patient controller out of the hands of children to avoid potential damage or unauthorized change in stimulation parameters.

Adverse Effects

The use of a neurostimulation system involves risks. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation immediately.)

- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or generator site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to device or implant materials
- Implant migration or skin erosion around the implant
- Battery failure
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control.

Product Description

The NeuroSphere™ Patient Controller communicates wirelessly through Bluetooth wireless technology with the Eterna™ implantable pulse generator (also called a generator or IPG) and charger. The NeuroSphere™ Patient Controller application (app) (model 55500) allows you to view, select, and control the programs that your physician has prescribed. The patient controller app also allows you to monitor charging sessions for your generator and charger and modify charger settings.

NOTE: In this document, the term “patient controller” refers to the NeuroSphere™ Patient Controller device and “patient controller app” refers to the NeuroSphere™ Patient Controller application (app).

About Your System

The Eterna™ SCS System is designed to deliver low-intensity electrical pulses to nerve structures. This neurostimulation system includes the following components:

- **Implantable pulse generator (IPG).** The generator delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation.
- **Leads.** Thin wires that deliver pulses from the generator to nerves along the spinal cord.
- **Patient magnet.** The patient magnet can be used to turn your generator on and off if your physician enables this functionality.

- **Charger and accessories.** The rechargeable charger is used to charge your generator wirelessly.
- **Patient controller (a device provided by Abbott Medical or a compatible personal Apple® iOS® device) and patient controller app.** The patient controller, with the patient controller app, is used to view, select, and control the programs that your physician has prescribed. The patient controller app also allows you to monitor charging sessions for your generator and charger and modify charger settings.

NOTE: For more information on compatible devices, see “Appendix A: Downloading the Patient Controller App” (page 44).

Your physician uses the clinician programmer to create and modify your stimulation programs.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction between major system components

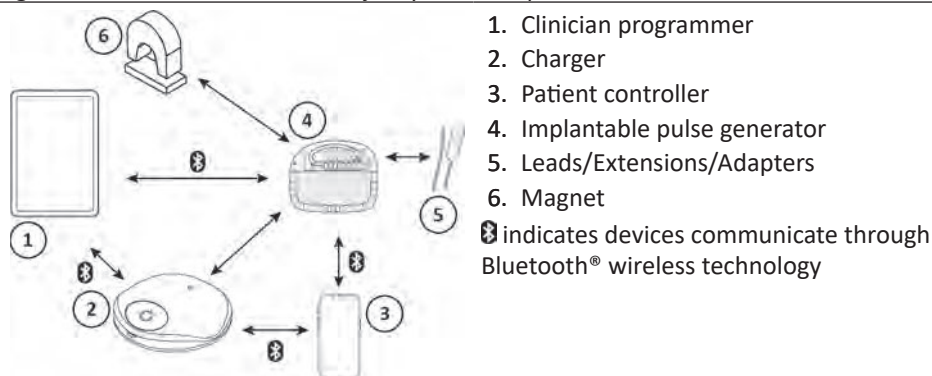
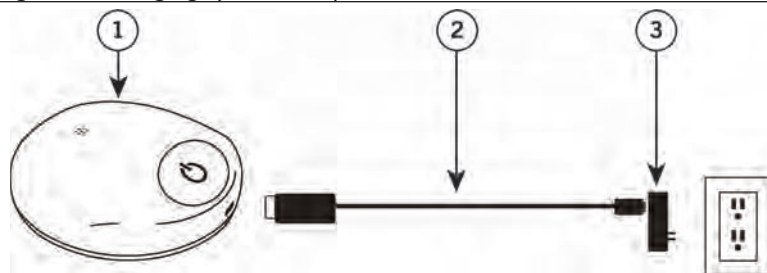


Figure 2. Charging system components



Overview of the Patient Controller

Your patient controller may be a device provided by Abbott Medical or a compatible personal Apple® iOS® device.

Before you begin, be sure you are familiar with how to perform basic operational functions on your patient controller.

- Turning the patient controller on and off
- Putting the patient controller to sleep
- Waking the patient controller
- Locking and unlocking the patient controller
- Using touchscreen functions such as tap and screen swipe actions
- Returning to the Home screen

NOTE:

- If a passcode is not set for the device, a message will appear advising you to consider adding a passcode. Open the device's settings to add a passcode to secure the device.
- For nontherapy-related information on how to use the patient controller, refer to the user guide available at support.apple.com/manuals for the Apple® iOS® device you are using to run the patient controller app.

The patient controller app is available from the Apple App Store and can be downloaded to your device using your Apple ID. See “Appendix A: Downloading the Patient Controller App” (page 44) for more information on compatible devices and for instructions on downloading the patient controller app.

Items You Will Receive

If you are using a patient controller provided by Abbott Medical, you will receive the following items to use with your system:

- Patient controller and charging cord
- Protective case for the patient controller
- Patient magnet
- Product documentation

If you are using a compatible personal device, you will receive the following items:

- Patient magnet
- Product documentation

Your Personal Identification Card

A temporary medical identification card is included with the product documentation. Your physician will complete the card and give it to you. Once you or your physician submit a patient registration form, Abbott Medical will mail you a permanent identification card. The registration card does the following things:

- Identifies you as having an implanted medical device

- Identifies the model numbers and locations of your implanted system parts to help determine if you can safely receive an MRI scan
- Helps you pass through security systems like those in airports
- Provides information that allows your physician to be contacted in an emergency

If you have questions about your card or need to request a replacement card, contact Customer Service at 1-800-727-7846 and follow the prompt.

Getting Started

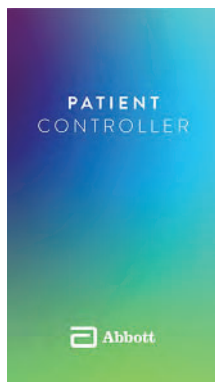
If using a device provided by Abbott Medical, the patient controller app should be available on the Home screen when you turn on your patient controller. If you do not see the app, refer to “Appendix A: Downloading the Patient Controller App” (page 44). If using your own device, you will need to download the patient controller app. Refer to “Appendix A: Downloading the Patient Controller App” (page 44).

Figure 3. Patient controller app icon



1. Tap the patient controller app icon. The Startup screen appears.

Figure 4. Patient controller app startup screen



2. The first time you launch the patient controller app, the Terms of Use and Privacy Policy popovers open. Tap **Accept** to accept the terms of use and tap Acknowledge to acknowledge the privacy policy to use the app.

NOTE: Each time the terms of use or privacy policy is updated, you will receive a notification. The terms of use and privacy policy can be viewed at any time by tapping the Information icon.

Managing Your Therapy

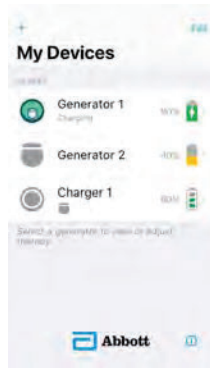
On the My Devices screen, you can view the devices, such as your generator (IPG) and charger, that have been paired with your patient controller and the battery status of each device.

NOTE: If you do not see your generator in the My Devices list, you will need to pair your patient controller and generator, see “Appendix B: Pairing the Patient Controller With the Generator” (page 45) for instructions.

For the connected devices, you can do the following:

- To view and edit therapy programs for your generator, tap the generator name or icon.
- To view and edit charger settings, tap the charger name.
- To view system information, tap ⓘ.

Figure 5. My Devices screen



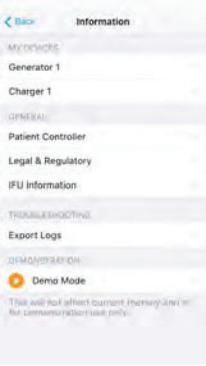
NOTE:

- Before the app can establish communication with the generator a prompt may display requesting the user to allow Bluetooth® wireless technology access. Tap **OK** to allow Bluetooth® wireless technology access. Otherwise, the app will be unable to communicate with the generator.
- In some cases, use of Bluetooth® wireless technology media devices (such as headphones or speakers) may prevent the patient controller from connecting to your generator. Abbott Medical recommends disconnecting these accessories before you attempt to adjust your therapy.

To view information about your system, tap ⓘ. The Information screen appears.

From the Information screen, you can view general information, such as software and device information and the terms of use and privacy statements. You can also export logs for troubleshooting and access a demonstration mode.

Figure 6. Information screen



Managing Your Generator

When you tap a generator in My Devices, the Therapy screen appears for that generator. The Therapy screen provides information about whether stimulation is on or off, the generator battery level, the remaining stimulation time based on generator battery (if enabled by your clinician), and the area and strength of stimulation.

Figure 7. Therapy screen

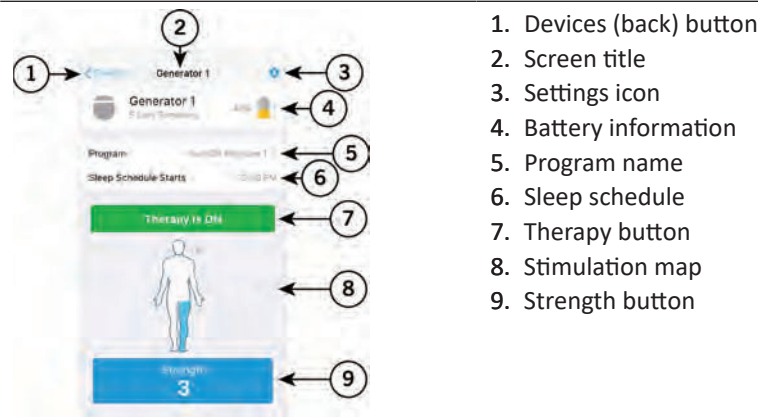


Table 1. Therapy screen descriptions

Screen Section or Button Name	Description
Devices (back) button	Tap the Devices button to return to the My Devices screen.
Screen title	Displays the name of the device you are viewing.
Settings icon	Tap the Settings icon to display the Mode screen.

Table 1. Therapy screen descriptions

Screen Section or Button Name	Description
Battery information	Displays the percentage of charge in the generator and how much stimulation time that percentage of charge can provide.
Program name	Displays the name of the active program. Tap to display the Programs screen for that program.
Sleep schedule	Displays whether sleep schedule is turned on or off. Sleep schedule is visible from the Therapy screen if a sleep schedule has been configured. Tap to turn sleep schedule on or off.
Therapy button	Displays whether therapy is on or off. Tap to turn therapy on or off.
Stimulation map	Displays the body area currently receiving stimulation.
Strength button	Displays the active program stimulation strength level. Tap to display the Strength screen.

Starting and Stopping Therapy

You may start and stop stimulation using the patient controller app or using the magnet if your physician has enabled magnet use.

Starting and Stopping Therapy Using the Patient Controller

To start or stop stimulation using the patient controller app, do the following:

- Tap the Therapy is ON button to turn off stimulation.
- Tap the Therapy is OFF button to turn on stimulation.

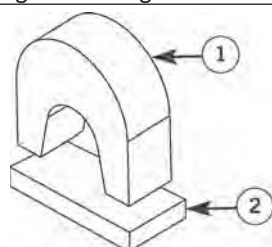
Starting and Stopping Therapy Using the Magnet

If your physician has enabled magnet use, you may use it to start and stop stimulation.

To start or stop stimulation using the magnet, follow these steps:

1. Take the keeper bar off the magnet.

Figure 8. Magnet and keeper bar

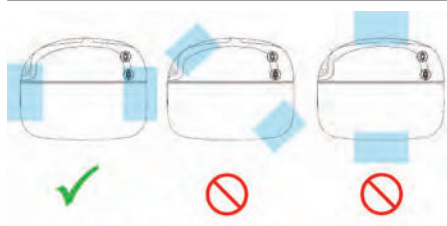


1. Magnet
2. Keeper bar

2. Hold the magnet centered directly over the generator for 1-2 seconds and then remove it.

NOTE: Ensure the two ends of the magnet are horizontal and level with the generator.

Figure 9. Correct versus incorrect magnet orientation



3. Place the magnet on the keeper bar and store the magnet. Stimulation will either start (using the most recently used program settings) or stop.

CAUTION: Do not use the magnet provided with the system around magnetically sensitive items to avoid damaging them.

Managing Therapy Programs

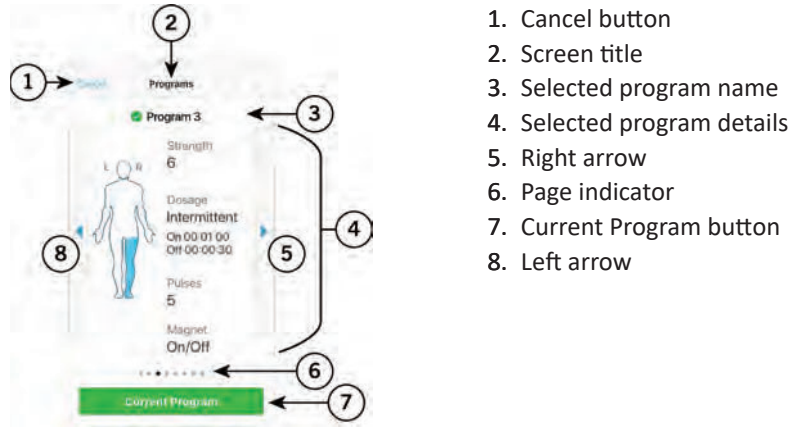
This section provides information and instructions for viewing, selecting, and adjusting your prescribed therapy programs.

NOTE: To avoid interruption while adjusting your therapy, Abbott Medical recommends enabling 'Do Not Disturb' mode on your patient controller prior to connecting to your generator. Instructions for doing so have been published by Apple, which can be found on their support website.

To view and select programs, follow these steps:

1. From **My Devices**, tap your generator. The Therapy screen appears.
2. Tap the program name. Your active program appears.

Figure 10. Current active program



NOTE: For Tonic programs, the number of areas is displayed. For Burst™ programs, the number of pulses is displayed.

3. Tap the right or left arrow to view or select other saved programs, if available.
4. If desired, tap **Select this Program**. Once selected, this becomes the active program. The Therapy screen updates and the strength will gradually increase to the perception strength level set for the selected program or to the last saved amplitude value.

Figure 11. Additional saved program

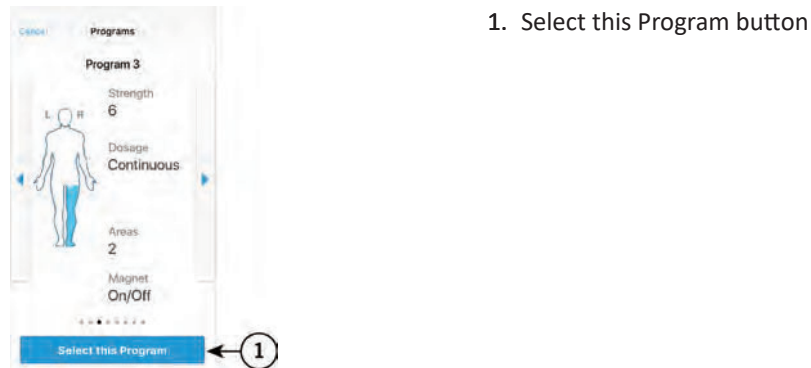


Table 2. Programs screen descriptions

Screen Section or Button Name	Description
Cancel button	Tap Cancel to return to the Therapy screen. No program changes will be made.

Table 2. Programs screen descriptions

Screen Section or Button Name	Description
Selected program name	Displays the program name of the current program. A check mark next to the program name indicates the active program.
Selected program details	Displays the information about the selected program.
▪ Strength	The current strength within a prescribed amplitude range. Amplitude is a measure of the strength of stimulation applied to the leads by the generator.
▪ Stimulation map	Displays the area the stimulation covers.
▪ Dosage	▪ Continuous – provides nonstop stimulation. ▪ Intermittent – automatically alternates stimulation on and off for the preset periods in the selected program; displays the remaining time in the current on or off period.
▪ Pulses	The number of pulses in a BurstDR™ program.
▪ Areas	The number of areas in a Tonic program.
▪ Magnet	Displays whether the magnet can turn the generator on and off if the clinician enabled this functionality.
Left arrow	Tap the left arrow to scroll through your saved programs (if you have more than one program).
Right arrow	Tap the right arrow to scroll through your saved programs (if you have more than one program).
Page indicator	Displays the number of programs available and indicates which program is on the screen.
Current Program button	Tap Current Program to return to the Therapy screen.

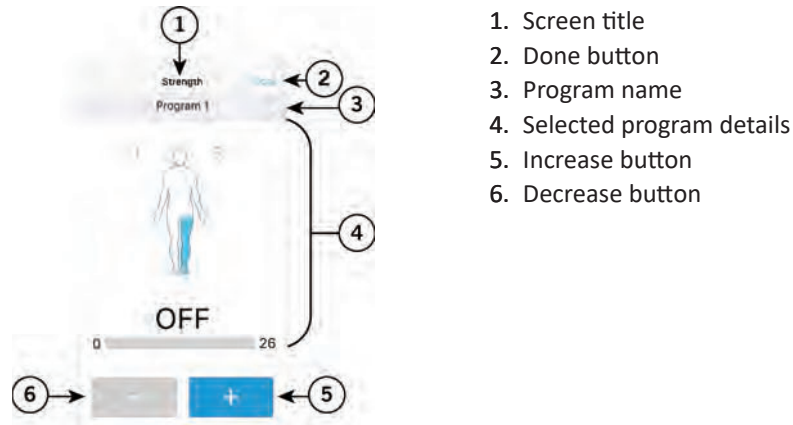
Adjusting Program Strength

To adjust the strength of a Tonic or Burst program, follow these steps:

1. Tap **Strength** on the Therapy screen. The Strength screen appears.
2. Tap the + or – buttons to increase or decrease the strength. The green bar will increase or decrease as you increase or decrease strength.

NOTE: If you tap + while stimulation is off, stimulation turns on. If you tap – when the strength is at **1**, stimulation turns off.

Figure 12. Strength screen – Tonic or Burst program



Adjusting Tonic Area Strength

If a Tonic program has multiple areas, you can modify the stimulation strength for each area. Use this feature when you want to increase or decrease the strength of an individual area.

To adjust the area strength of the active program, follow these steps:

1. On the Therapy screen, tap **Strength**. The Strength screen appears.
2. Tap **Areas**. The Areas portion of the Strength screen appears.

NOTE: If the program only has one area, the Areas tab will not appear on the screen.

3. Tap + or – to increase or decrease the strength for the selected area. The green bar will increase or decrease as you adjust strength.
4. Modify other areas as needed.
5. When you are finished adjusting the area strength, tap **Done** to return to the Therapy screen.

Figure 13. Strength screen Program tab – Tonic program with multiple areas

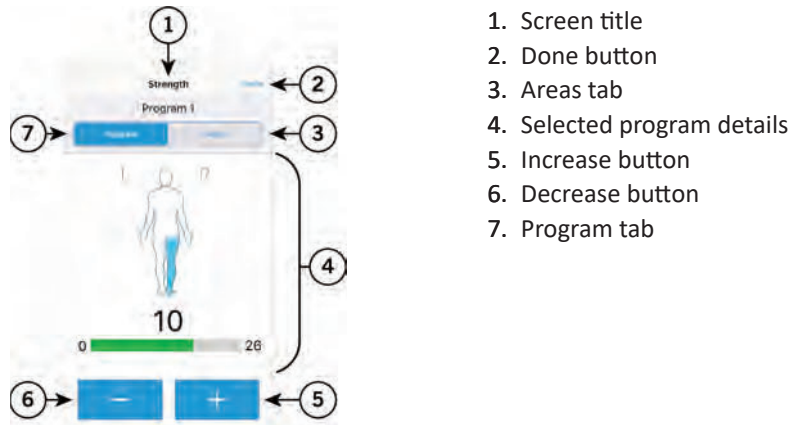


Figure 14. Strength screen Areas tab

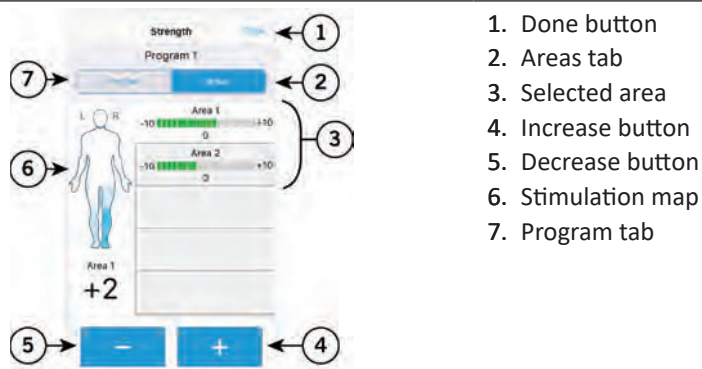


Table 3. Areas screen descriptions

Screen Section or Button Name	Description
Done button	Tap Done to save changes and return to the Therapy screen.
Program tab	Tap the Program tab to open the Strength screen for the program.
Areas tab	Modify the strength of each area in the active program on this screen.
Selected area	Tap to select the area you want to modify. The stimulation map displays the affected area.
Stimulation map	View the program areas.
Increase button	Tap to increase the strength for the selected area.

Table 3. Areas screen descriptions

Screen Section or Button Name	Description
Decrease button	Tap to decrease the strength for the selected area.

Setting Your Generator to MRI Mode

This section provides information and instructions about what you need to do before and after an MRI scan if you are implanted with a system that is Magnetic Resonance (MR) Conditional. An MR Conditional system allows you to receive an MRI scan if all the requirements for the implanted parts and scanning are met.

NOTE:

- Contact your clinician before receiving an MRI scan to find out if you can undergo the procedure and to learn more about any risks.
- Before scheduling an MRI appointment, it is recommended to place your system in MRI mode to confirm your system is MR Conditional and then exit to resume stimulation.

You have two ways to learn if the implanted parts of your system are MR Conditional:

- Your personal identification card, which your clinician or MRI technologist will use
- Your patient controller app
 - Tap ⓘ on the My Devices screen, and then tap the name of the generator you want to view to display the system information. The top of the screen displays a System is MR Conditional message if implanted parts of your system are approved MR Conditional models.
 - Tap ⚙ on the Therapy screen to display the Mode screen. The MRI Mode option is available if implanted parts of your system are approved MR Conditional models.

Preparing for an MRI Scan

If you have an MR Conditional system and will receive an MRI scan, follow these guidelines:

- Charge your generator and patient controller fully before you set your generator to MRI mode.
- Set your generator to MRI mode within one day of your MRI scan.

NOTE: If you have more than one generator implanted, each generator must be set to MRI mode. While a generator is in MRI mode, stimulation will be off.

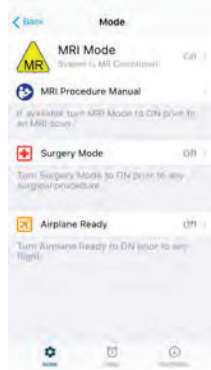
- Bring your identification card and patient controller to the MRI scan.

CAUTION: Do not bring your patient controller or charger into the scanner magnet room since they may be affected by the MRI magnet, may present a projectile hazard, and are MR Unsafe.

To set your generator to MRI mode, follow these steps:

1. In the Therapy screen, tap ⚙. The Mode screen appears.

Figure 15. Mode screen



2. Tap **MRI Mode** to view the MRI Mode screen.
3. Tap the **Turn MRI Mode On** button.
4. When a Set Generator to MRI Mode message appears, tap Continue. Stimulation turns off, and the patient controller app checks the system for any issues.

NOTE: If a warning message appears instead of a Proceed with MRI message, you cannot set the generator to MRI mode and cannot receive an MRI scan. Refer to “Troubleshooting Chart” for more information.

5. If the checks are successful, a Proceed with MRI message appears and the MRI mode is on. Tap **OK**.

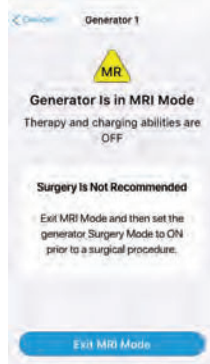
CAUTION: Do not remove the Bluetooth® wireless technology pairing between the generator and the patient controller and do not delete the generator from the Generators list while the system is in MRI mode. Doing so will require communication to be established again and may delay disabling MRI mode and resuming therapy.

Disabling MRI Mode

After your MRI scan, you need to disable MRI mode to restart stimulation. To disable MRI mode, follow these steps:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the generator is in MRI mode.

Figure 16. MRI Mode screen



2. Tap **Exit MRI Mode**. The patient controller app disables MRI mode. The Therapy screen appears, showing that stimulation therapy is off.
3. To start stimulation, tap **Therapy is OFF**.

Setting Your Generator to Surgery Mode

This section provides information and instructions about what you need to do before and after a surgical procedure.

NOTE:

- Using the Surgery Mode feature turns therapy off while you undergo your procedure.
- Contact your clinician before your procedure to learn more about any risks. If you feel uncomfortable completing the following steps, contact Technical Support before your procedure.

Preparing for a Surgical Procedure

If you are planning to undergo a surgical procedure, follow these guidelines:

- Charge your generator and patient controller fully before you set your generator to Surgery mode.
- Set your generator to Surgery mode before your procedure.

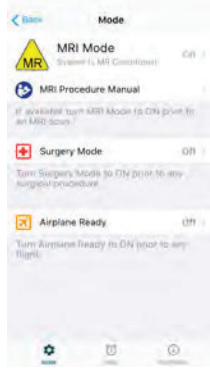
NOTE: If high current is detected, the generator turns on Surgery mode automatically.

- Bring your identification card and patient controller to the procedure.

To set your generator to Surgery mode, follow these steps:

1. In the Therapy screen, tap . The Mode screen appears.

Figure 17. Mode screen



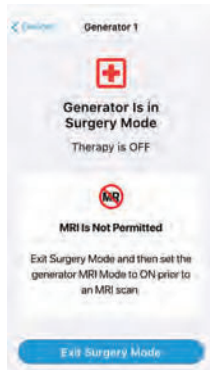
2. Tap **Surgery Mode** to display the Surgery Mode screen.
3. Tap **Turn Surgery Mode ON**. When the generator is placed in Surgery mode, the Surgery mode ON button turns green briefly and stimulation turns off.

Disabling Surgery Mode

After your procedure, you need to disable Surgery mode to restart stimulation. To disable Surgery mode, follow these steps:

1. Launch the patient controller app and connect with your generator. You should see the following screen, showing that the generator is in Surgery mode.

Figure 18. Generator is in Surgery Mode screen



2. Tap **Exit Surgery Mode**. The patient controller app disables Surgery mode. The Therapy screen appears, showing that stimulation therapy is off.

NOTE: If the generator detects high current, you will not be able to exit Surgery mode. When you leave the high current environment and high current is no longer detected, you will be able to exit Surgery mode.

3. To start stimulation, tap **Therapy is OFF**.

Setting Your Generator to Airplane Ready Mode

If traveling by airplane, you may be asked to place electronic devices in airplane mode. Follow all flight precautions regarding Bluetooth® wireless technology connections. You can place your patient controller in airplane mode by going to your patient controller iOS® settings and turning on airplane mode.

You can also place the generator in airplane mode, which disables Bluetooth® wireless technology between the generator and patient controller.

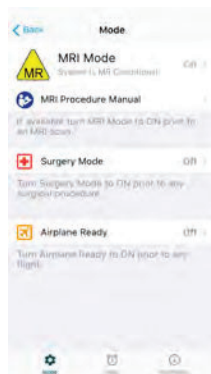
NOTE:

- Stimulation stays on even after disabling Bluetooth® wireless technology.
- Be sure to bring your magnet with you when you travel.

To place your generator in airplane mode, also known as Airplane Ready mode, follow these steps:

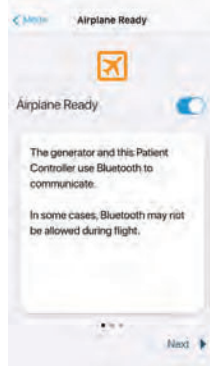
1. In the Therapy screen, tap . The Mode screen appears.

Figure 19. Mode screen



2. Tap Airplane Ready. The Airplane Ready screen appears.
3. Tap the Airplane Ready toggle button. The toggle button moves from left to right and turns blue.

Figure 20. Airplane Ready Mode screen



NOTE: The Airplane Ready screens contain additional information about what to do before and after your flight.

To adjust your system with your patient controller during flight, both airplane mode and Airplane Ready mode need to be deactivated using the magnet.

To deactivate Airplane Ready mode, follow these steps:

1. Hold your magnet over the generator for 5 seconds to enable Bluetooth® wireless technology connection.

NOTE: Ensure the two ends of the magnet are horizontal and level with the generator.

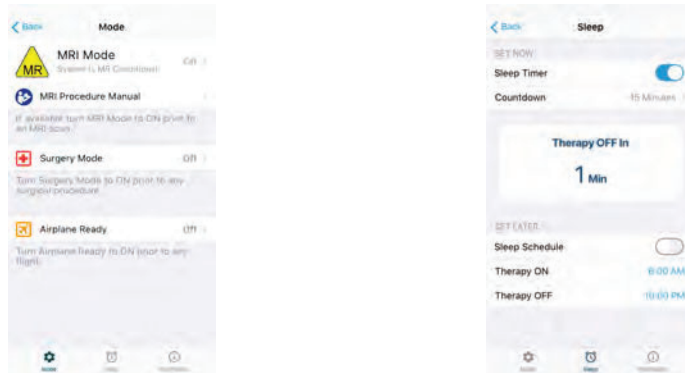
2. Remove the magnet and place it on the keeper bar.
3. In My Devices, tap your generator. The Therapy screen appears.
4. Tap . The Mode screen appears.
5. Tap Airplane Ready.
6. Tap the Airplane Ready toggle button. The button moves to the left and turns gray.

Setting Sleep Mode

This section provides information and instructions for using the optional Sleep mode features, which can be used separately or together. You can use the sleep timer to schedule stimulation to turn off at a set time for each program. If your clinician enables the sleep schedule feature, you can use the sleep schedule to turn stimulation on and off automatically at a set time for each program.

- Sleep Timer – allows you set stimulation to turn off in 15, 30, 45, or 60 minutes.
- Sleep Schedule – allows you to set a time for stimulation to automatically turn on or off each day.

Figure 21. Mode screen and Sleep screen



To turn on the sleep timer, follow these steps:

1. In the Therapy screen, tap . The Mode screen appears.
2. Tap . The Sleep screen appears.
3. Tap the **Sleep Timer** toggle button. The toggle button moves from left to right and turns blue.
4. To set the amount of time until therapy turns off, tap Countdown. The **Countdown** popover opens.
5. Select when you want stimulation to turn off.

NOTE: The Sleep screen displays the time remaining before stimulation turns off.

To set a sleep schedule, follow these steps:

1. In the Therapy screen, tap . The Mode screen appears.
2. Tap . The Sleep screen appears.
3. Choose one or both of the following options:
 - Tap **Therapy ON** to select the time you want stimulation to turn on.
 - Tap **Therapy OFF** to select the time you want stimulation to turn off.
4. Tap the **Sleep Schedule** toggle button. The toggle button moves from left to right and turns blue.

Viewing Generator, Charger, and Patient Controller Battery Status

Your generator, charger, and patient controller contain rechargeable batteries. You can view the charge level of your generator and charger batteries on the My Devices screen. The charge level of each device listed is displayed on the right with a percentage and battery icon. If a listed device is charging, you can view the charging status. The generator icon that appears under the charger name indicates how much charge the charger can provide the generator.

Figure 22. Device charge level and charging status



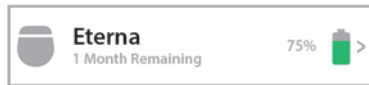
1. Generator 1 battery is charging and is 90% full
2. Generator 2 battery is 40% full
3. Charger 1 battery is 60% full and can charge a generator fully

Viewing Generator Battery and Charging Status

The patient controller app provides information about your generator's battery. Your clinician will also give you guidance to determine a charging schedule.

If your clinician has enabled this feature and the generator and patient controller are connected, you can view the estimated stimulation time remaining in the Therapy screen. The estimated stimulation time remaining appears below the name of the connected generator.

Figure 23. Estimated stimulation time and generator charge level on the Therapy screen



When your patient controller indicates your generator battery is low, you should charge the generator to maintain therapy.

The patient controller provides alert messages when the charge level of the generator is below 20% and you should charge your generator. It also displays an alert message when therapy is turned off due to a low generator battery, and the generator must be charged to resume therapy. When the generator battery is too low to provide therapy, or if therapy has turned off due to a low battery, the battery status on the patient controller displays as N/A.

NOTE: With rechargeable batteries, intervals between charging may become more frequent with use over time.

As the generator approaches its end of service, the patient controller app displays a Replace Implanted Generator message, indicating that you should contact your physician.

Viewing Generator Charging Sessions

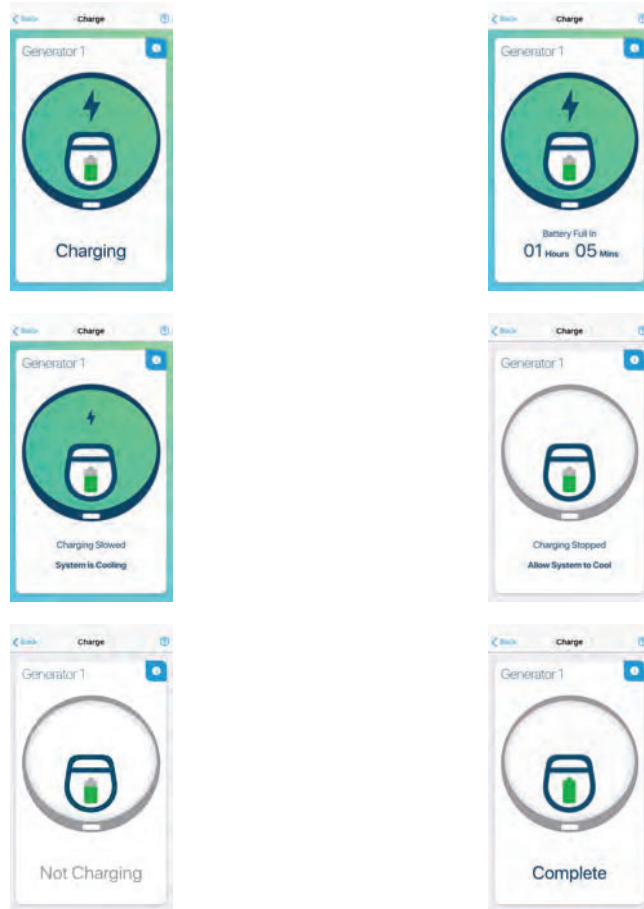
You can use your patient controller to monitor generator charging sessions. If enabled by your clinician, you can modify charging mode settings.

To view the charging status in detail, follow these steps:

1. From the My Devices screen, tap the name of the generator that is being charged.
The Therapy screen appears.
2. Tap the generator name or battery icon. The Charge screen appears.

The screen may show the generator is charging, the time remaining until the generator is fully charged (if enabled), and when generator charging is complete. It may also display when generator charging has slowed or stopped.

Figure 24. Generator charge screens



During generator charging sessions, it is normal to feel warming around the generator location. If the warming becomes uncomfortable, remove the charger and wait until the sensation is gone before charging again or set the charging mode to a lower setting.

You can also choose the charging setting that is most comfortable if your clinician has enabled the Charging mode feature. It is recommended to choose a setting based on the typical length of your charging session.

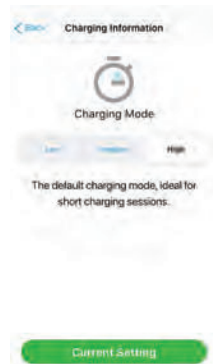
- Low is recommended for longer charging sessions.
- Medium is recommended for average-length charging sessions.
- High is recommended for short charging sessions.

NOTE: You can change your charging mode during charging sessions.

To change the charging mode, follow these steps:

1. From the My Devices screen, tap your generator. The Generator screen appears.
2. Tap **Generator Battery**. The Charge screen appears.
3. Tap ⓘ. The Charging Information screen appears.
4. Tap the desired mode.
5. Tap **Save This Setting**.

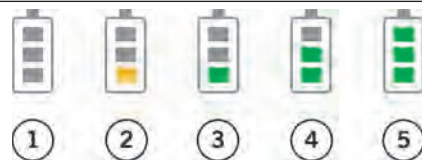
Figure 25. Charging mode settings



Viewing the Charger Battery Status

If your charger is in range of your patient controller or connected to it, you can view the battery status of your charger on the My Devices screen of your patient controller. The charger battery level is indicated by a battery icon with colored lights. See the following figure.

Figure 26. Charger battery status



1. Three gray bars: charger is off or is depleted
2. One yellow bar: charger will not fully charge a depleted generator
3. One green bar: charger may not be able to fully charge a depleted generator

4. Two green bars: charger can fully charge a depleted generator
5. Three green bars: charger can fully charge a depleted generator

NOTE: One yellow bar indicates you have 30 minutes or less remaining before the charger turns off due to low battery.

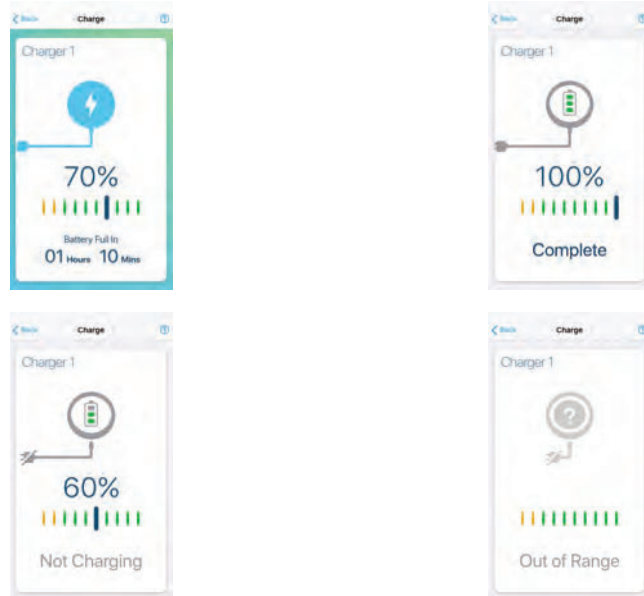
Viewing Charger Charging Sessions

To view the charging status in detail, follow these steps:

1. From the My Devices screen, tap the name of the charger that is being charged. The Charger screen appears.
2. Tap the charger name or battery icon. The Charge screen appears.

The screen may show the charger is charging, the time remaining until the charger is fully charged, and when charging is complete. It may also display when the charger is not charging or is out of range.

Figure 27. Charger charge screens



Managing Other Charger Settings

From the Charger screen, you can change the charger name and volume settings.

To edit the name of your charger, follow these steps:

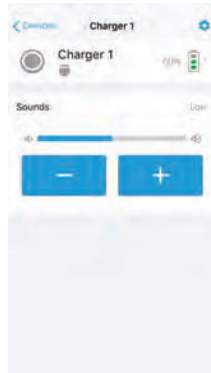
1. From My Devices, tap your charger. The Charger screen appears.
2. Tap . The Settings screen appears.
3. Tap the Charger Name field. The on-screen keypad appears.

4. Edit the charger name.

To edit the volume of your charger, do the following:

1. From My Devices, tap your charger. The Charger screen appears.
2. Tap + or – buttons to increase or decrease the charger volume. The blue bar will increase or decrease as you increase or decrease the volume.

Figure 28. Charger screen

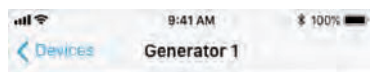


Viewing the Patient Controller Battery Status

Be sure to monitor the patient controller battery status (indicated in the top right corner of the screen). As the battery is used, the battery indicator shows the remaining charge. Recharge the patient controller using the charging cord and wall outlet plug provided with your device.

NOTE: Keep the patient controller charged or have a power supply nearby. Familiarize yourself with the patient controller's battery life so you can anticipate its charging needs. For more information, refer to the user guide available at support.apple.com/guide for the Apple® iOS® device you are using to run the patient controller app.

Figure 29. Patient controller battery status (varies by Apple® device version)

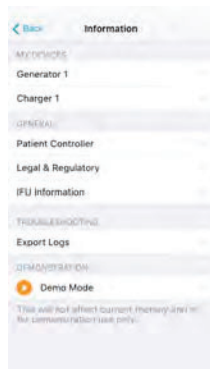


Viewing, Updating, and Exporting Device Information

From the Information screen, you can view information about your connected devices, such as model and software version; general information about the patient controller; and legal and regulatory information. From this screen, you can also update the patient controller app, generator, and charger software (when available) and export the patient controller logs.

To view general device and system information, tap ⓘ in the My Devices screen or in the Mode screen.

Figure 30. Information screen



Updating Generator Software

When a software update is available for your generator, you can perform the software update from the My Devices screen or from the Therapy screen. Follow these steps to update the software:

From the My Devices screen,

1. Tap the generator you want to view. If a software update is available, the Update Available popover opens.

CAUTION: Do not remove the Bluetooth® wireless technology pairing between the generator and the patient controller and do not delete the generator from the My Devices list while the software updates. Doing so may prevent the generator from establishing communication and prevent therapy from being turned on again.

2. Select **Dismiss** or **Update**. If Dismiss is selected, you will return to the Therapy screen. If Update is selected, the Update Software screen appears.

NOTE:

- The Update button is only visible when an update is available.
- During a software update, stimulation will be turned off temporarily.

3. Tap **Download Update**.

4. Place the magnet over the generator to confirm the software update.

NOTE:

- Ensure the two ends of the magnet are horizontal and level with the generator.
- Once the magnet confirms the update, the update cannot be canceled.
- If the magnet is not placed over the generator to confirm the update within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

From the Therapy screen,

1. Tap . The Mode screen appears.
2. Tap . A list of your paired devices appears.
3. Tap the connected generator you want to view.

4. Tap **Update**. The Update Software screen appears.
5. Tap **Download Update**.
6. Place the magnet over the generator to confirm the software update.

NOTE:

- Ensure the two ends of the magnet are horizontal and level with the generator.
- Once the magnet confirms the update, the update cannot be canceled.
- If the magnet is not placed over the generator to confirm the update within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

Updating Charger Software

When a software update is available for your charger, you can perform the software update from the My Devices screen or from the Charger screen. Follow these steps to update the software:

From the My Devices screen,

1. Tap the charger you want to view. If a software update is available, the Update Available popover opens.
2. Select **Dismiss** or **Update**. If Dismiss is selected, you will return to the charger screen. If Update is selected, the Update Software screen appears.

CAUTION: Do not remove the Bluetooth® wireless technology pairing between the charger and the patient controller and do not delete the charger from the My Devices list while the software updates. Doing so may prevent the charger from establishing communication.

3. Tap **Start Update**.

NOTE: The Update button is only visible when an update is available.

4. To confirm the software update, press the Power button on the charger.

NOTE:

- Once the Power button is pressed to confirm the update, the update cannot be canceled.
- If the Power button on the charger is not pressed within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

From the Charger screen,

1. Tap . The Mode screen appears.
2. Tap . A list of your paired devices appears.
3. Tap the connected charger you want to view.
4. Tap **Update**. The Update Software screen appears.
5. Tap **Start Update**.

NOTE: The Update button is only visible when an update is available.

6. To confirm the software update, press the Power button on the charger.

NOTE:

- Once the Power button is pressed to confirm the update, the update cannot be canceled.
- If the Power button on the charger is not pressed within 60 seconds, a Software Update Canceled message appears. If you receive this message, try updating the software again.

Updating Patient Controller App Software

When a software update is available for the patient controller app, follow these steps to update the software:

1. From the My Devices screen or the Mode screen, tap ⓘ. The Information screen appears.
2. Tap Patient Controller. The Patient Controller screen appears.
3. Tap **Update**. The Confirm Update popover opens.

NOTE: The Update button is only visible when an update is available.

4. Tap **Confirm Update**.
5. To confirm that the software was updated, see the app version on the patient controller device information screen.

Figure 31. Patient controller device information screen



Exporting the Patient Controller Log

Your generator performs a series of self-diagnostic tests to verify that the generator firmware and hardware are operating according to specifications. The generator saves the test results in a log file. If Technical Support asks you to obtain the troubleshooting logs, follow these steps:

1. From the My Devices screen or the Mode screen, tap ⓘ. The Information screen appears.

2. Under Troubleshooting, tap **Export Logs**. The Export Log screen appears.

NOTE:

- When exporting the patient controller log, you must select whether to Remove or Include Personally Identifiable Information (PII). It is recommended to select Remove unless directed by your clinician or Technical Support.
- If using the AirDrop feature of the patient controller, be aware that PII in the patient controller may be accessible.

3. Tap **Export**.

Caring for the Patient Controller

If you are using a patient controller provided by Abbott Medical, clean the protective case by wiping off the outer surface using a moist cloth and a small amount of mild soap. Do not use a cloth that is saturated. Do not use alcohol, ammonia-based cleaning agents, cleaning solutions, or solvents to clean the case.

NOTE: For more information on how to care for the patient controller, refer to the user guide available at support.apple.com/guide for the Apple® iOS® device you are using to run the patient controller app. If using a device from a different manufacturer, refer to the manufacturer's user guide for that device.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your patient device.

Protecting Access to the Patient Controller

To prevent unauthorized access to your Apple® device, set up a passcode or other supported method of biometric security (such as a Touch ID®). For instructions, refer to the user guide available at support.apple.com/guide for the Apple® iOS® device you are using to run the patient controller app.

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator and charger encrypt wireless communication with the patient controller using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the generator or charger at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.

- Proprietary authentication for patient controller app or clinician programmer app in addition to the pairing procedure specified in Bluetooth LE, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator or charger.
- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the generator or charger to a legitimate patient controller or clinician programmer.

Guidelines for Secure Use

Users should adhere to the following guidelines when using the system:

- Do not use the app if the operating system is compromised (for example, jailbroken).
- Do not share your Apple® ID login information or device passcode.
- Do not leave the device unattended or allow other users to access the patient controller.
- Do not install untrusted apps on the patient controller.
- Secure your home network with a Wi-Fi® password, and only connect to trusted secured networks when not at home.
- If your patient controller is lost or stolen before your generator has been paired, follow the instructions at support.apple.com/en-us/HT201472.
- If your patient controller is lost or stolen after your generator has been paired, use your replacement device to delete the previous patient controller and generator pairing. See “Removing a Pairing Between a Generator and an Unused Patient Controller” (page 45).
- If you receive a “Device Not Secure” notification in the patient controller app, contact Technical Support.
- When notified on the patient controller, upgrade to the latest available software version for the patient controller app.
- Install iOS® software upgrades on your device as they are made available by Apple®, after verifying iOS® software version compatibility with the patient controller app via www.NMmobiledevicesync.com/cp.

Legal and Privacy Notice

The terms of use and privacy policy are displayed the first time the patient controller app is launched after installing or updating the app. To view this information again, tap ⓘ on the patient controller app My Devices screen.

Abbott Medical is committed to protecting the privacy of our customers and patients. This privacy statement summarizes how we protect, gather, and use personal information of users. For more information, view our US or Global Privacy Policies online at www.abbott.com/privacy-policy.html.

We may amend these terms of use, privacy statements, and privacy policies from time to time, so please check for updates.

Troubleshooting Chart

This section provides troubleshooting procedures to help you identify and solve problems that may occur.

NOTE:

- If you encounter problems other than those described in this section, contact “Technical Support” (page 44).
- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Patient Controller Device		
Patient controller is not accessible.	Patient controller is lost or damaged.	Contact Technical Support. If you receive a replacement patient controller, delete all previous connections when prompted.
Patient controller is not communicating with the generator.	The generator is not sensing the magnet.	Position the magnet toward the top and close to the side of the generator. Ensure the two ends of the magnet are horizontal and level with the generator.
Patient controller has no power or has lost power.	Patient controller’s battery is drained.	Charge the patient controller.
	Patient controller is damaged or malfunctioning.	Contact Technical Support.
Patient controller will not charge.	Patient controller charging cable is loose or not well connected.	Connect the charging cable to the patient controller.
	Correct plug adapter (voltage converter) is not connected to the charging cable.	Connect the appropriate plug adapter (voltage converter) to the charging cable.
	Plug adapter or charging cable is defective.	Replace the plug adapter or charging cable.
	Patient controller is damaged or malfunctioning.	Contact Technical Support.
Nothing is displayed on the screen.	Patient controller is off or is in Sleep mode.	Turn on the patient controller.

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
	Patient controller's battery is drained.	Charge the patient controller.
	Screen is damaged or malfunctioning.	If the patient controller appears to be powered on but without display, the screen may be defective. Contact Technical Support.
Patient controller will not respond to input.	Patient controller has locked up.	Perform a soft reset by turning the patient controller off and back on.
	Touchscreen interface is damaged or malfunctioning.	If the patient controller appears to be powered on but will not respond to input, the screen may be defective. Contact Technical Support.
Cannot find or connect to the generator or charger.	The patient controller battery is low.	Charge the patient controller.
	Unsupported device.	Download and install the patient controller app for the Eterna™ SCS system. See "Appendix A: Downloading the Patient Controller App" (page 44). If you encounter problems installing the app, contact Technical Support.
	The patient controller pairing with the generator or charger was lost or removed.	1. Follow the alert message to remove the existing pairing from the patient controller iOS® settings. 2. Pair the patient controller with the generator or charger. See "Appendix B: Pairing the Patient Controller With the Generator" (page 45) or "Appendix C: Pairing the Patient Controller With the Charger" (page 46).

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Patient Controller App		
Cannot locate patient controller app.	Patient controller app is not on patient controller Home screen.	Swipe through screens from the patient controller Home screen to locate app.
		Search for the app using the iOS® search function.
		Ensure you have the patient controller app for the Eterna™ SCS system and see this icon: 
		Download and install the patient controller app for the Eterna™ SCS system. See “Appendix A: Downloading the Patient Controller App” (page 44). If you encounter problems installing the app, contact Technical Support.
		Enable notifications.
Bluetooth® Wireless Technology Communication or Connection		
Patient controller cannot establish Bluetooth connection with the generator or charger, or ▪ connection was lost or is intermittent. ▪ app returns to home screen. ▪ patient controller does not respond to input.	Interference in the environment, including temporary interference (for example, from microwave ovens and Wi-Fi® routers, or voltage surge produced by lightning).	Move to a different area or room away from the interference.
		Reconnect the patient controller with the generator or charger. Start new session.
	Patient controller is off or has timed out and is in standby mode.	Wake up the patient controller.
	Patient controller battery is drained.	Charge the patient controller battery.

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
	Generator battery is low or depleted.	Charge the generator battery.
	Bluetooth® wireless technology is not connected.	Remove and reenoble the Bluetooth® wireless technology pairing. In the device settings, select the patient controller app. Tap the toggle button to enable Bluetooth® wireless technology.
	The magnet was used and Bluetooth® wireless technology was disabled.	Hold your magnet over the generator for 5 seconds to enable Bluetooth® wireless technology.
	The user's hand is blocking the Bluetooth® wireless technology antenna.	Try holding the patient controller differently.
	Bluetooth® wireless technology connection is not strong.	Decrease the distance between the devices. Ensure the patient controller is in Bluetooth® wireless technology range of the generator within 0.9 m (3 ft) or charger within 2 m (6.5 ft). Turn on Bluetooth® wireless technology on your patient controller if communication is disabled. 1. Return to the patient controller Home screen and tap Settings . 2. Tap Bluetooth , then tap the Bluetooth toggle button. NOTE: If you turn Bluetooth® wireless technology off and on or reset the app, it will

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
		take longer to reconnect to your generator.
		Move to another location so the patient controller, generator, and charger are away from other devices that may be causing interference.
		Move the patient controller and generator or charger so they have line of sight and maintain an uninterrupted path for the Bluetooth® wireless technology signal.
		If the generator is being charged, stop charging and move the charger away from the generator.
		Disable Wi-Fi† in the iOS‡ settings.
		Do not operate other wireless devices at the same time.
Therapy		
A program is invalid or not available.	The program is missing information.	Talk to your physician about reprogramming your therapy.
No stimulation.	Stimulation is off, possibly due to a generator reset or magnet application.	Turn on stimulation using the patient controller app or magnet (if enabled).

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Stimulation turns off unexpectedly.	Stimulation has stopped according to the therapy schedule.	Check the therapy schedule.
	The system impedance is measuring impedance and has stopped stimulation temporarily.	Stimulation will resume when the impedance measurement is completed.
	A magnet was used to turn off stimulation.	Turn on stimulation to resume therapy.
	The generator performed a reset.	Select a program and turn on stimulation to resume therapy.
	The generator battery depleted.	Charge the generator.
	The generator entered Surgery mode.	If Surgery mode was triggered in error, follow the on-screen notification to exit Surgery mode. If the generator detected high current, move the source of the high current away from the generator or move the generator away from the source of the high current. When the generator no longer detects high current, follow the steps to exit Surgery mode.
Program strength is off.	The generator could not deliver the desired program strength.	Try adjusting the program strength. If the problem persists, contact your clinician.
Increasing Strength is Not Recommended message appears.	The program may need to be modified.	Contact your clinician.
MRI Mode		
MRI is Not Permitted is displayed instead of the MRI Mode option on the Mode screen.	A part of the system is not MR Conditional.	Contact your clinician for help identifying the models of your system. If you have any implanted parts that are

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
		not MR Conditional, you cannot receive an MRI scan.
	The generator battery is low and cannot enter MRI mode.	Check the generator battery status and charge the generator if the battery is low. Then try entering MRI mode again.
MRI is Not Advised message appears.	The generator battery voltage is too low.	Contact your clinician.
	There may be a problem with the implanted lead or leads.	Contact your clinician.
Cannot put the generator in MRI mode.	The generator is not connected to the patient controller.	Try connecting to the generator again. If the problem persists, contact Technical Support.
	The generator is in Surgery mode.	Exit Surgery mode to set MRI mode.
Cannot access the Mode screen.	The generator is not connected to the patient controller.	Try connecting to the generator again.
Surgery Mode		
Cannot put the generator in Surgery mode.	The generator is not connected to the patient controller.	Try connecting to the generator again. If the problem persists, contact Technical Support.
	The generator is in MRI mode.	Exit MRI mode to set Surgery mode.
Generator automatically enters Surgery mode and Surgery mode cannot be removed or turned off.	The generator has detected high current.	If possible, move the source of the high current away from the generator, or move the generator away from the source of the high current. When the generator no longer detects high current, follow the steps to exit Surgery mode.
Battery		

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Generator requires frequent charging.	The programs may need to be adjusted or the generator may be approaching its end of service.	Talk to your physician about reprogramming or replacing the generator.
Replace Implanted Generator or Charger Soon message appears.	The implanted generator or charger may be approaching its end of service.	Contact your physician.
Charger		
Charging is uncomfortable.	Charging mode may need to be adjusted.	Change the Charging mode (if enabled). See “Viewing Generator Charging Sessions” (page 27). Or talk to your physician about enabling Charging mode or adjusting settings. Stop charging until the discomfort subsides and then resume charging.
Software Update		
Generator or charger software update was not successful.	Generator or charger software update was interrupted.	Try installing the generator or charger software again. If unsuccessful, wait a while and try again. If you cannot locate the generator or charger on the patient controller app, contact Technical Support.
	Pairing was removed between the patient controller and the generator or charger.	Do not remove a pairing during a software update.
	Patient controller app must be updated to work with the newer generator software.	Perform the steps in “Appendix A: Downloading the Patient Controller App” (page 44) to update the app.
	Generator or charger battery is too low to update the software.	Charge the generator or charger.

Table 4. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Cannot locate programs after updating generator software.	After installing generator software, the previous program data was lost.	Contact your physician for reprogramming.
Software update is not available.	An update is not available at this time.	You should see a notification when a software update is available.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Downloading the Patient Controller App

If your patient controller does not have the patient controller app for the Eterna™ SCS system, you must download the app to your patient controller (either a device provided by Abbott Medical or a compatible personal Apple® iOS® device) in order to use the patient controller with your generator. The patient controller app is compatible with Apple® iOS® mobile digital devices as specified on the Abbott Neuromodulation patient resources page at www.NMmobiledevicesync.com/cp. Be sure your patient controller is running an Apple-released iOS version before downloading the patient controller app. If you do not have an Apple ID, you can create one while setting up the device or before installing the app. For instructions, refer to the Apple ID support page at support.apple.com/apple-id.

To download the patient controller app:

1. Make sure the device is turned on and connected to the internet.
2. Tap the App Store icon on the patient controller.
3. Tap **Search** and enter **Patient Controller RC - US** in the Search field.
4. Once you locate the correct app, tap **GET** and follow the onscreen prompts.

NOTE: If you encounter problems downloading the app, contact Technical Support for assistance.

Appendix B: Pairing the Patient Controller with the Generator

The following instructions outline the steps for pairing the patient controller to the generator.

1. Tap the patient controller app icon to open the app. The Startup screen appears.

NOTE: The first time you launch the patient controller app, the Terms of Use popover opens. Tap **Accept**. The Privacy Policy popover opens. Tap **Acknowledge** to use the app.
2. If no generator is listed, place the magnet over the generator for 10 to 15 seconds and then remove it.

NOTE: Ensure the two ends of the magnet are horizontal and level with the generator.
3. When the My Devices screen appears, Tap **+**.
4. Tap the appropriate generator in the Select Devices list.

NOTE: If no generators are found, you will see a No Generators Found message. Tap **🔍** to search for available generators again.
5. Enter the date of birth associated with the generator in the Patient field.
6. Tap **Register** to pair the patient controller and generator.

You may pair the patient controller with up to four different generators. If you reach the maximum number of paired devices, a message appears instructing you to delete a device.

The following instructions outline the steps for deleting a generator from a patient controller.

1. On the My Devices screen, tap **Edit**.
2. Tap **⊖** next to the generator you want to delete. The Delete button appears next to the generator.
3. Tap **Delete**. A confirmation message appears.
4. Tap **Delete** to remove the generator.

Removing a Pairing Between a Generator and an Unused Patient Controller

If you lost or are no longer using a patient controller or if you have exceeded the number of devices you can pair with your generator, you can remove a pairing.

To remove pairing information between a generator and an unused patient controller, do the following:

1. Connect the patient controller to your generator.
2. Tap **⚙️**. The Mode screen appears.
3. Tap **ℹ️**. The Information popover opens.
4. Tap **Delete Connections**. The Delete Connections screen appears.

5. Tap **Delete Others**. All patient controller pairing information is deleted from the generator except for the patient controller that is currently connected.

Appendix C: Pairing the Patient Controller With the Charger

To charge the generator, the charger does not need to be connected through Bluetooth wireless technology to the patient controller. However, a Bluetooth® wireless technology connection with the patient controller allows you to monitor charger charging sessions and perform charger software updates.

Before you can establish a Bluetooth® wireless technology connection between the patient controller and the charger, a one-time Bluetooth® wireless technology pairing must be performed. If the charger is paired to the patient controller, it will be listed in My Devices on the patient controller app.

If Bluetooth® wireless technology pairing is needed, follow these steps:

1. Launch the patient controller app.
2. Place the charger within Bluetooth® wireless technology range of the patient controller.
3. Turn on the charger by pressing the Power button. The charger emits a tone.
4. To begin pairing, press the Power button for approximately 5 seconds.
5. Confirm the charger is in a pairing state by observing the blinking light on the Power button and that it is in close proximity to the patient controller.

NOTE: Once the charger is in a pairing state and in close proximity to the patient controller, the charger light blinks, the charger beeps once, and pairing is completed automatically. The charger beeps again when charging is complete.

6. To confirm that pairing has been successful, locate the charger under My Devices on the patient controller app.
7. Power off the charger by pressing the Power button for approximately 5 seconds.

NOTE:

- If the pairing does not occur within 5 minutes, the charger exits pairing mode and then automatically turns off after 90 seconds of inactivity.
- If the charger is not paired with the patient controller, retry steps 1-3.

You may pair the patient controller with up to four different chargers. If you reach the maximum number of paired devices, a message appears instructing you to delete a device.

The following instructions outline the steps for deleting a charger from a patient controller.

1. On the My Devices screen, tap **Edit**.
2. Tap  next to the charger you want to delete. The Delete button appears next to the charger.
3. Tap **Delete**. A confirmation message appears.
4. Tap **Delete** to remove the charger.

Appendix D: Regulatory Statements

These statements are applicable to the generator. For Regulatory Statements regarding the patient controller, refer to the user guide available at support.apple.com/guide for the Apple® iOS® device you are using to run the patient controller app; or, on the patient controller Home screen, tap **Settings > General > Legal & Regulatory**.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 5. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMIPG1

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® wireless technology as it is implemented in the device.

Table 6. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Modified monopole
Antenna dimensions	10.7 mm x 4.3 mm x 3.0 mm
Modulation	GFSK
Output power (EIRP*)	2 mW (+3 dBm) typical
Duty cycle	14.1% or less over 6 min period
Range	Up to 2 m typical
Center frequency	2.44 GHz
Channel frequency range	2.402 GHz to 2.480 GHz
Channel	40 logical channels using AFH**
Bandwidth per channel	2 MHz
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology
Semi-duplex capability	Yes

*EIRP = Equivalent isotropically radiated power (not duty cycle adjusted)

**AFH = Adaptive frequency hopping

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator or charger and the clinician programmer or patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator or charger, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol appears dimmed.

The standard Bluetooth® wireless technology data rate is 1 Mbit/s. The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (for example, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, please refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 49).

Troubleshooting for Wireless, Coexistence, or Interference Issues

If you experience issues with interactions within the neurostimulation system, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the patient controller app; then turn the patient controller off and on.
- Wait a few minutes and try connecting again.
- Avoid operating other consumer electronic devices, such as a laptop, tablet, mobile phone, or cordless phone at the same time.

NOTE: Equipment such as the following can interfere with the neurostimulation system: wireless home network devices, mobile and cordless telephones, and consumer electronic devices.

Appendix E: Radio Frequency Information

The effective radiated power is below the limits as specified in:

- USA: FCC 47 CFR Part 15

NOTE: Maintain a reasonable distance between other electronic equipment and the device.

CAUTION: The ISM band used by this device has been approved by the Federal Communications Commission for unlicensed use. However, there is no guarantee that this device will not receive interference or that any particular transmission from this device will be free from interference.

Appendix F: Electromagnetic Compatibility Guidelines

The patient controller app (Model 55500) operates on an Apple® iOS® device as part of the Eterna™ SCS system. Refer to the precautions in this guide for information on sources of EMI, the effect of EMI on the patient and the Eterna™ SCS system, and instructions on how to reduce the risk of EMI (see “Precautions” (page 4)). Failure of the Apple® iOS® device will not result in an unacceptable risk to the user.

The Eterna™ SCS system has undergone electromagnetic disturbance testing to confirm essential performance of the associated medical equipment as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). Refer to the user's guide for the charging system for information regarding electromagnetic declaration and intended use environments.

NOTE:

- Apple® iOS® devices were included in the Eterna™ SCS system testing for electrostatic discharge (ESD), power frequency, radiated electric fields, and radiated magnetic fields.
- The non-Abbott accessories supporting the patient controller, such as charging cords, adapters, should not be used while running the patient controller app. The effect of use of such accessories while running the app has not been evaluated.

Appendix G: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

NOTE: For symbols and definitions for the patient controller, refer to the user guide available at support.apple.com/guide for the Apple® iOS® device you are using to run the patient controller app; or, on the patient controller Home screen, tap ⓘ > **Legal & Regulatory**.

Table 7. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website

Table 7. Symbols and definitions

Symbol	Definition
	Type BF Patient Applied Part
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Non-ionizing electromagnetic radiation
	Keep dry; keep away from rain
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Use-by date
	Date of manufacture
	Catalog number
	Manufacturing facility
	Temperature limit
	Humidity limitation

Table 7. Symbols and definitions

Symbol	Definition
	Atmospheric pressure limitation
	Manufacturer
	Do not use if package is damaged
	Packaging unit
	Programmer
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	This product shall not be treated as household waste. The product and its battery should be disposed of according to local laws and regulations. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.
	Authorized representative in the European Community
	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797) and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directive. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.

Table 7. Symbols and definitions

Symbol	Definition
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

abbott.com

2023-05
ARTEN600283837 B



Charging System

Eterna™ Spinal Cord Stimulation System
Model 16000

User's Guide



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2024 Abbott. All Rights Reserved.

Contents

About This Guide.	1
Prescription and Safety Information.	1
Intended Use.	1
Indications for Use.	1
Contraindications.	1
Additional Prescription Information.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	2
Adverse Effects.	3
Product Description.	3
Charger Indicators	5
Using Your Charger	7
Pairing the Charger with the Patient Controller	7
When to Charge Your Generator.	7
Charging Your Charger	8
Setting Up the Charging Apparel.	9
Charging Your Generator.	13
Caring for and Maintaining Your Charger and Charging Apparel	14
Traveling with Your Charging System	15
Troubleshooting.	15
Troubleshooting Charging Issues	16
Service and Ordering Information.	18
Appendix A: Regulatory Statements.	19
Disposal Guidelines for Battery-Powered Devices.	19
Statement of FCC Compliance.	19
Product Classification Statement (CISPR 11, Class B).	20
Identification Information for Product Registration	20
Wireless Technology Information.	20
Quality of Service for Wireless Technology.	21
Wireless Security Measures.	22
Troubleshooting for Wireless, Coexistence, or Interference Issues.	22
Appendix B: Product Specifications.	22
Appendix C: Technical Specifications	23
Appendix D: Electromagnetic Compatibility Guidelines.	24
Appendix E: Symbols and Definitions.	27

About This Guide

This guide explains how to use the charging system (model 16000 and charging system accessories). Follow the information in this guide to correctly use your charging system. If you have any questions about your system, contact Technical Support.

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The charging system is intended to be used to charge the Eterna™ implantable pulse generator (IPG), also referred to as a generator.

Indications for Use

The Eterna™ Spinal Cord Stimulation (SCS) System is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.

Contraindications

The Eterna™ SCS System is contraindicated for patients who are unable to operate the system. Additionally, the system is contraindicated for patients who have failed to receive effective pain relief during trial stimulation.

Additional Prescription Information

Refer to the user's guide for your patient controller for instructions for use and other important information, including indications for use, contraindications, warnings, precautions, adverse effects, and the personal identification card related to your neurostimulation system.

MRI Safety Information

Do not bring your charger into the scanner magnet room. It can be affected by the magnetic resonance imaging (MRI) magnet, may present a projectile hazard, and is considered MR Unsafe.

Warnings

The following warnings apply to this charging system.

Device inspection. Before using the charging system, check the charger, charging cable, and power adapter for visible damage or indication of prior disassembly. If any damage or prior disassembly is observed, do not use the charging system and contact Technical Support.

Device modification. This charger is not serviceable by the customer. To prevent injury to yourself or damage to the charging system, do not modify the charger. If needed, return the charger to Abbott Medical for service.

Battery warning. The charger contains a lithium-ion battery and other potentially hazardous materials. Do not crush, puncture, or burn the charger because explosion or fire may result.

Battery care. Batteries should not come in contact with metal or be exposed to high temperature or fire. Batteries can explode, leak, or melt if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire.

Power adapter and charging cable compatibility. Use only power adapters and charging cables that meet the ratings specified in the appendix for technical specifications. Use of accessories, transducers, and cables other than those specified or provided by Abbott Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity and result in improper operation of the system.

Power adapter handling. Do not position the power adapter in such a way that it is difficult to disconnect from an electrical outlet.

Explosive or flammable gases. Do not use your charger around explosive or flammable gas fumes or vapors. This includes oxygen-enriched environments such as hyperbaric chambers. Operating the device near gas fumes or vapors could cause them to catch fire. If gas fumes or vapors catch fire, it could cause severe burns, injury, or death.

Strangulation. The cords in this charging system pose a strangulation risk. Keep cords out of the reach of children.

Choking. Small parts in this charging system pose a choking risk. Keep small system parts out of the reach of children.

Keep dry to avoid damage. Your charger is not waterproof. Keep it dry to avoid damage. Never use the charger in or around water. If the charger becomes wet, allow it to dry completely before use.

Precautions

The following precautions apply to this charging system.

Device components. The charging system is for use with the Eterna™ implantable pulse generator only. You may use a commercially available power adapter and charging cable as long as it meets the technical specifications listed in the appendix.

Handle the device with care. The charger is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Review your user's guide. Before using your charger, review the system information in the applicable patient controller user's guide.

Infection. Follow proper infection control procedures. Also avoid showering and touching the bandages while your incisions are healing. If you need to charge your generator before your incisions have healed completely, take care not to disturb the bandages and follow your physician's guidance on charging.

Home use. This product is intended for home use per clinician instruction. To avoid damage and other potential hazards, keep this product away from children and pets.

Pain-relief patches. Avoid using pain-relief patches or topical anesthetics, such as pain-relieving creams or medicated balms, over your generator site before or during

charging. These pain-relief patches or topical anesthetics may reduce your ability to perceive discomfort due to charging.

Alcohol consumption. Avoid drinking alcoholic beverages before or during charging because they may reduce your ability to perceive discomfort due to charging.

Charging system immunity. Wireless communication equipment, such as wireless home network devices, mobile and cordless telephones, and walkie-talkies, can interfere with the charging system. To correct the effects of typical system interference, keep the charging system at least 0.5 m (1.6 ft) from these types of wireless communication equipment. If you continue to have problems with interference, further increase the distance between the equipment and your charging system.

Charge your charger. The charger should be fully charged after every generator charging session.

Unplug the cable carefully. To avoid damaging the charging cable, do not pull on cable when unplugging it from the charger or power adapter. Grasp the connector and pull carefully.

Patient training. Patients should use their neurostimulation system only after an authorized clinician has programmed their generator and has trained them on how to safely control stimulation and to charge the system.

Adverse Effects

The following adverse effects are associated with using this charging system. Refer to the patient controller user's guide for a complete list of adverse effects related to the use of the Eterna™ SCS system.

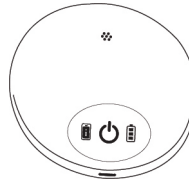
- Heating or discomfort at the pocket while charging. If you feel discomfort at the implant site while charging your generator, stop using the charger. Use your patient controller to change the charging mode or contact your physician.
- Heating or discomfort at surgical staples while charging. Charging should not be carried out while surgical staples are in place.
- Interference with another implanted medical device. This equipment generates, uses, and can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other implanted medical devices. To try to correct the effect of any interference with other devices, turn off the charging equipment or increase the distance between the charging equipment and the device being affected.

Product Description

The charging system consists of a charger, a charging cable, a power adapter, charging apparel, and a travel case for storing the charging system. The charger is used to charge the Eterna™ implantable pulse generator wirelessly. The charger interfaces with the patient controller application wirelessly through Bluetooth® wireless technology. The patient controller application allows you to modify charger settings, view the battery level of your charger and generator, and view the charging status of your charger and generator.

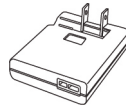
Charger

The charger is used to wirelessly charge your Eterna™ implantable pulse generator.



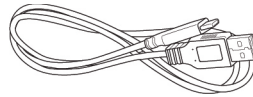
Power adapter

The power adapter connects with an electrical outlet and with the charging cable to charge the charger battery. The power adapter provided varies depending on country or region.



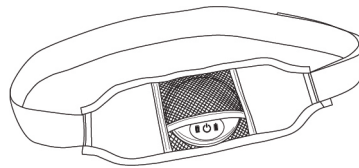
Charging cable

The charging cable connects with the power adapter and with the charger to charge the charger battery.



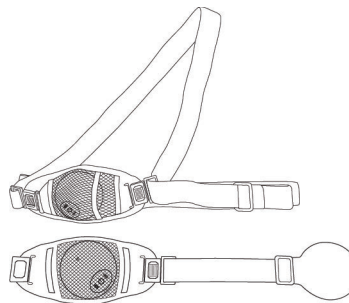
Charging apparel – lumbar

Charging apparel is used to position and stabilize the charger over your generator and charge the generator without having to manually hold the charger in place. The lumbar apparel is worn like a belt around your waist.



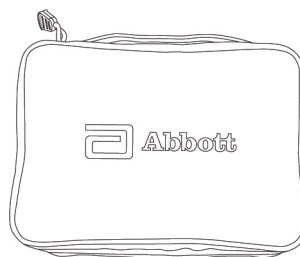
Charging apparel – pectoral

Charging apparel is used to position and stabilize the charger over your generator and charge the generator without having to manually hold the charger in place. The pectoral apparel can be worn in multiple configurations using the double strap or the counterweight.



Charger travel case

The travel case is used to store the parts of the charging system.



Charger Indicators

The charger has a power icon, a battery icon, and a patient controller alert icon as shown in the figure below. The charger provides indicator lights and sounds that show the charger status and the action being performed.

- **PC Alert icon.** The PC alert icon illuminates when the charger has encountered an error. You may view more information about the error on your patient controller.
- **Power icon.** The power icon illuminates when the charger is turned on. When the charger is charging the generator, the power icon blinks slowly. When the charger is in pairing mode, the power icon blinks quickly.
- **Battery icon.** The battery icon illuminates in segments to indicate the charger battery level. While the charger is being charged, a segment of the battery icon blinks.

NOTE: The indicator lights on the charger may be difficult to see if under direct sunlight.

Figure 1. Charger icons

1. PC Alert icon
2. Power icon
3. Battery icon

Table 1. Charger sounds

Event	Charger sound
Power on	1 beep
Volume on	1 beep
Power off	2 beeps
Error	3 beeps every 5 seconds
Low battery	3 beeps every 5 minutes
Generator found	Short, repeating beeps

Table 1. Charger sounds

Event	Charger sound
Generator charging started	2 beeps low tone then high tone
Generator charging stopped (not aligned)	2 beeps high tone then low tone
Generator charging complete (fully charged)	3 beeps low tone, high tone, then low tone

Using Your Charger

The instructions in this section explain how to use your charging system to charge your generator battery and charger battery, how to use the charging apparel, and how to care for and travel with your charging system.

NOTE: Each time before using the system, inspect the device and its accessories for damage. Avoid using a damaged device or accessory. If your device is damaged, contact Technical Support.

Pairing the Charger with the Patient Controller

Before you use your charger for the first time, you may want to pair the charger with your patient controller. Pairing refers to setting up communication between the charger and the patient controller. When these devices are paired, you can use your patient controller to monitor charging sessions, adjust charger settings, such as volume control, and perform charger software updates. Refer to your patient controller user guide for more information.

NOTE: Your charger and patient controller do not need to be paired or connected to Bluetooth® wireless technology in order to charge your generator.

To prepare the charger for pairing:

1. Ensure that your patient controller and charger are charged.
2. Place the patient controller near the charger.
3. Turn on the charger.
4. Press and hold the power icon on the charger for 5 seconds, and then release the button. The power icon and the battery icon blink once. Then the power icon blinks quickly, indicating the charger is in the pairing state.
5. On the patient controller, select the charger you are pairing. Refer to your patient controller manual for more information.

NOTE: If the pairing does not occur within 5 minutes, the charger exits pairing mode and then automatically turns off after 90 seconds of inactivity.

When to Charge Your Generator

Your clinician will help you plan a charging schedule that will work best for you to maintain effective therapy. For example, you may establish a charging routine of once per week.

The following are additional considerations to help you decide when to charge your generator:

- Prior to an MRI
- Prior to an upcoming surgery
- In anticipation of travel
- When the next charging opportunity is uncertain
- When the patient controller application displays a low battery notification for your generator

- When stimulation has stopped due to generator battery depletion

Your patient controller indicates the battery level of your generator. The level ranges from 0% charge to 100% charge. The patient controller also indicates the approximate stimulation time remaining based on the generator's current battery level and therapy settings.

When your implanted generator battery is low, your patient controller displays a low battery message. When this message appears, you should charge your generator at your earliest convenience. If you do not charge your generator after the low battery message appears, your stimulation will eventually stop. When stimulation stops, your controller will display an alert indicating therapy was turned off due to a low generator battery. You should charge your generator battery so that therapy can be restored.

NOTE:

- To maintain therapy without interruption and improve battery longevity, always charge your generator before it is depleted completely. If your generator is repeatedly allowed to deplete completely, its performance or longevity may be reduced over time.
- If your generator is depleted completely, it will take a few minutes for the generator to turn on again and communicate with your patient controller once you start charging.

Charging Your Charger

Like your generator, your charger contains a rechargeable battery that needs to be charged on a regular basis. The battery icon on the charger displays the charger battery level. The patient controller also displays the charger battery level. If the charger is in range of the patient controller or connected to it, the battery level is indicated by a battery icon with colored lights. See the following table.

Table 2. Charger battery status

Battery Icon	Bar Color	Charging Status
	Three gray bars	Charger is off or charger battery is depleted.
	One yellow bar	Charger will not fully charge a depleted generator.
	One green bar	Charger may not be able to fully charge a depleted generator.
	Two green bars	Charger can fully charge a depleted generator.
	Three green bars	Charger can fully charge a depleted generator.

NOTE:

- One yellow bar indicates you have 30 minutes or less remaining before the charger turns off due to low battery.
- When the charger battery is low, the charger beeps three times every 5 minutes until the battery is depleted.

To charge your charger:

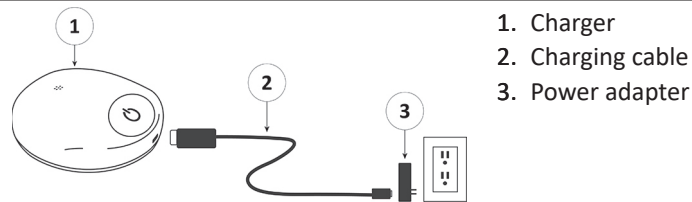
1. If the charger is in the charging apparel, remove the charger from the apparel before charging.

NOTE: The charging apparel is not intended to be used while charging the charger.

2. Plug the power adapter into an electrical outlet.
3. Connect the charging cable and power adapter.
4. Plug the charging cable into the charger. If the charger is connected successfully to the charging cable and power adapter, the charger beeps once and a segment of the battery icon blinks and then turns off. Once the charger is fully charged, all the segments of the battery icon illuminate for 60 seconds and then turn off.

NOTE: While the charger is charging, it should be placed on a stable surface, such as a table, counter, or floor.

Figure 2. Connecting components to charge the charger



NOTE:

- While the charger is charging, it cannot be used to charge the generator.
 - If your charger is not charging, you may be using an incorrect cable or power adapter. Refer to the appendix for technical specifications.
5. When you are ready to use the charger, unplug the charging cable from the charger. The power adapter connected to the charging cable can remain plugged into the electrical outlet.

While the charger is being charged, the charger is able to communicate with the patient controller. The patient controller indicates the charger battery level and when the charger is being charged.

Setting Up the Charging Apparel

Your charging system comes with reusable charging apparel that you can use, if desired, to help stabilize the charger over your generator during a charging session. Depending on the implant location of your generator, you will receive either pectoral charging apparel or lumbar charging apparel. The charging apparel can be configured to be worn in different ways, depending on your preference and implant location. For example, patients with generators implanted in the lower back may choose to use the lumbar

charging apparel like a belt. If you choose to use your charging apparel, you should adjust it for comfort and fit before charging your generator.

Your clinician will help you find the configuration that is most comfortable and suitable for your generator charging sessions.

NOTE: The charger and accessories are to be used with light clothing (<5 mm). If your clothing is very thick, the charger may not effectively charge your generator.

Placing Lumbar Charging Apparel

To set up your lumbar charging apparel, gather the charger and the charging apparel:

1. If the charger is connected to the charging cable, disconnect it.

NOTE: While the charger is charging, it cannot be used to charge the generator.

2. Press the power icon to turn on the charger. The three charger icons illuminate briefly and the charger beeps once if sound is enabled.
3. Insert the charger fully into the mesh pocket of the charging apparel with the icons facing the opening of the pocket.
4. Ensure the elastic edges of the pocket overlap, fully covering the charger.
5. Wrap the charging apparel around your waist so the charger is over your generator.
6. Adjust the velcro strap so the apparel is secure around your waist and the charger is on top of your generator.

NOTE:

- When the generator enters the charging zone, it beeps continuously until charging begins.
 - If the charger does not find the generator within 90 seconds, the charger turns off automatically. You can press the power icon through the mesh pocket to turn on the charger and align the charger over your generator.
7. Once you have adjusted the charging apparel to a comfortable fit around your waist, you can trim the excess strap length, if desired.

Placing Pectoral Charging Apparel

To set up your pectoral charging apparel, gather the charger and the charging apparel:

1. If the charger is connected to the charging cable, disconnect it.

NOTE: While the charger is charging, it cannot be used to charge the generator.

2. Press the power icon to turn on the charger. The three charger icons illuminate briefly and the charger beeps once if sound is enabled.
3. With the charger icons facing the opening of the pocket, insert the charger into the mesh pocket of the charging apparel by lifting one side of the opening and then pulling the other side over the charger.
4. Ensure the elastic edges of the pocket overlap, fully covering the charger.

NOTE:

- When the generator enters the charging zone, it beeps continuously until charging begins.

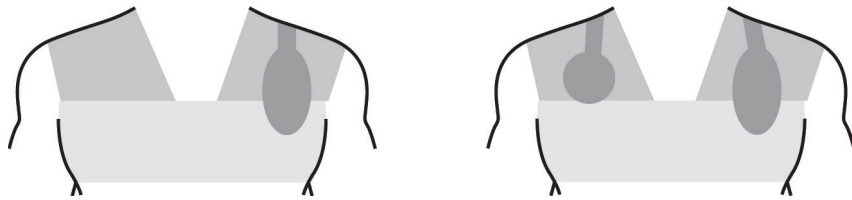
- If the charger does not find the generator within 90 seconds, the charger beeps two times and then turns off automatically. You can press the power icon through the mesh pocket to turn on the charger and align the charger over your generator.

Counterweight configurations

1. If connected, release the long strap from the charger pocket. The counterweight should remain buckled to the charger pocket.
2. Position the charger over your generator.
3. Place the counterweight over your shoulder so it rests on your back or around your neck so the counterweight rests on your opposite shoulder.

NOTE: You may need to adjust the length of the strap to fit properly.

Figure 3. Charger positioned over generator (left); counterweight positioned over opposite shoulder (right)



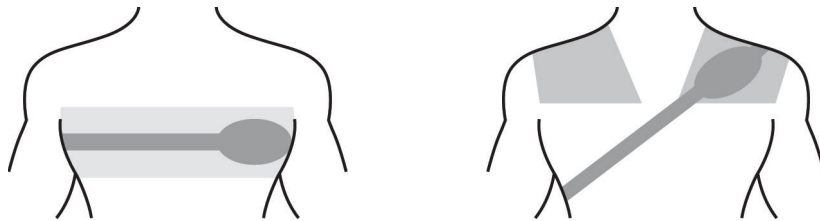
Single-strap configurations

1. Release the counterweight from the charger pocket.
2. Wrap the charging apparel around your chest or over your shoulder and fasten the buckle.

NOTE: If needed, use the excess strap near the buckle to tighten or loosen the apparel.

3. Adjust the strap until the charger is comfortably positioned over your generator.

Figure 4. Single-strap around chest (left); single-strap around one shoulder (right)



Double-strap configurations

Option 1 – Loop and charger on opposite sides

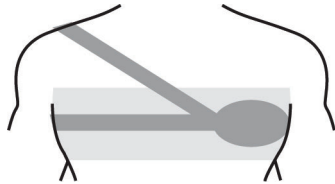
1. Release the counterweight from the charger pocket.

2. Grasp the plastic buckle so the charger pocket is hanging toward your feet.

NOTE: If your generator is located on the right side of your body, grasp the buckle with your right hand. If your generator is on your left side, grasp the buckle with your left hand.

3. Put the arm on the opposite side of your generator through the loop.

Figure 5. Arm through loop on opposite side of generator



4. Adjust the charging apparel so that a strap is comfortably over your shoulder and the other strap is under your armpit. The buckle should be in front of you.
5. Ensure that the charger is positioned over your generator.
6. Fasten the buckle.

NOTE: If needed, use the excess strap near the buckle to tighten or loosen the apparel.

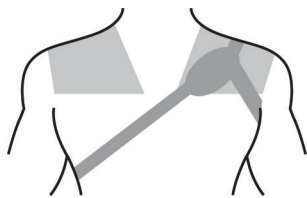
Option 2 – Loop and charger on same side

1. Release the counterweight from the charger pocket.
2. Grasp the charger pocket so the long strap is hanging toward your feet.

NOTE: If your generator is located on the right side of your body, hold the pocket with left hand. If your generator is on your left side, hold the pocket with your right hand.

3. Insert the opposite arm (the arm that is not holding the charger pocket) through the loop.

Figure 6. Arm through loop on same side as generator



4. Adjust the charging apparel so that a strap is comfortably over your shoulder and the other strap is under your armpit. The buckle should be in front of you.
5. Ensure that the charger is positioned over your generator.
6. Fasten the buckle.

NOTE: If needed, use the excess strap near the buckle to tighten or loosen the apparel.

Charging Your Generator

After you have charged your charger and have set up the charging apparel (if desired), you are ready to charge your generator. It is recommended to charge your generator frequently and to charge before stimulation turns off due to a low battery.

NOTE:

- You can receive stimulation while charging your generator. The patient controller can still communicate with the generator while charging. However, the charger software cannot be updated while the generator is charging.
- If you have more than one Eterna™ implantable pulse generator implanted, you can use the same charger to charge your generators.

WARNING: You may perceive an increase in temperature at the generator site while you charge. Ensure that the area around the charger is well ventilated and not covered by an insulating material such as a blanket. If you feel discomfort while recharging your generator, stop using the charger and refer to “Troubleshooting” (page 16). If the discomfort persists, contact your clinician. Only charge your generator while you are awake so that you can stop the charger if charging becomes uncomfortable.

To charge your generator:

1. Ensure the charger is not connected to an electrical outlet.

NOTE: If the charger is connected to an electrical outlet, it will not charge the generator.

2. Turn on the charger. The three icons on the charger illuminate and the charger beeps once if the sound is enabled in the patient controller.
3. Place the charger directly over the generator, using the charging apparel to hold the charger in place if desired. Charging begins automatically when the charger is positioned correctly over the generator. If charging has not begun, try the following, one at a time, until charging begins:
 - Ensure the charger and charging apparel are used with light clothing (<5 mm). If the clothing over the generator is very thick, the charger may not effectively charge the generator.
 - Ensure that the charger is centered over the top half of your generator.
 - Move the charger slowly in a circular motion over the generator location, slowly increasing the size of the circle until you hear the beeps begin, indicating the charger is aligned with the generator and charging has begun.
 - Slowly swipe the charger across the generator in a single direction until you hear the beeps begin, indicating the charger is aligned with the generator and charging has begun.

4. To confirm charging is occurring, note the following. If you do not note any of the indicators listed below, charging is not occurring.
 - If the charger sound is enabled in the charger settings on the patient controller, the charger beeps when charging begins. When charging is in progress, the charger will not beep.
 - The charger power icon begins blinking slowly.
 - The patient controller displays the charging status and the generator battery level.

NOTE: If the charger loses alignment with the generator for 10 seconds, the charger will beep until alignment with the generator is restored or the charger is turned off. Try repositioning the charger so it is positioned over the generator.

5. Verify that charging is complete. When the generator is fully charged, the charger beeps 3 times every 10 seconds if the sound is enabled. You can also view charging status on the patient controller.

NOTE:

- The charger automatically turns off after 90 seconds once charging is complete.
- While the charger is charging the generator, the charger cannot be turned off. If you need to turn off the charger while it is charging the generator, move it away from the generator site.

6. Turn off the charger and remove the charging apparel.

Caring for and Maintaining Your Charger and Charging Apparel

To keep your charger running its best, follow these guidelines:

- Keep the charger dry. Do not use the charger in or around water.
- Clean the charger as needed. You can use a dry cloth or a cloth slightly dampened with water or isopropyl alcohol. Ensure the charger is completely dry before use.

NOTE: To avoid damaging the charger, do not insert anything in the speaker holes.

- Clean the charging apparel as needed.
 - Hand wash in cold water.
 - Use mild soap.
 - Lay flat to dry.

NOTE: Do not machine wash or machine dry.

- Charge your charger and store your charging system in the travel case after each use.
- Store and use your charging system within the range of conditions as shown in the following table.

Table 3. Storage, transportation, and operating conditions

Storage and transportation conditions	
Long-term storage temperature	23°C (73°F)

Table 3. Storage, transportation, and operating conditions

Temperature excursions	Excursions below 15°C (59°F) or above 30°C (86°F) should be <24 hours in duration
Temperature excursion limits	-20°C to 60°C (-4°F to 140°F)
Humidity	5% to 90% RH
Pressure	70 kPa to 106 kPa
Operating conditions	
Temperature	5°C to 35°C (41°F to 95°F)
Humidity	10% to 90% RH
Pressure	70 kPa to 106 kPa

NOTE: If the charger was stored in an environment that is outside of normal operating temperature, allow it to acclimate to the current environment for approximately 30 minutes.

- When the charger is approaching its end of service, an alert message displays on the patient controller. This message indicates that you should contact your physician for a replacement charger.

Traveling with Your Charging System

If traveling with your charging system, follow these guidelines:

- Use the travel case to store your charging system.
- Be sure to pack the charging cable and power adapter.

NOTE: For short trips, if you plan to travel without the charging cable and power adapter, check the battery level of the generator and the charger to ensure continued therapy during your trip.

- If you are traveling to an international location, you may need a country-specific power adapter.
- The charger contains a lithium-ion battery. If traveling by air, the charger should be placed and kept in your carry-on baggage during flight, not in your checked baggage.
- When traveling, follow all guidelines and restrictions for use of electronic devices.

Troubleshooting

This section provides information for solving problems you may have using your charging system.

NOTE:

- If the PC Alert icon  illuminates, check your patient controller for more information.
- If problems occur other than those described in this section, contact Technical Support.

- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

Troubleshooting Charging Issues

The following table lists possible charging system problems and possible solutions.

Table 4. Troubleshooting charging issues

Problem	Possible Solution
The charger will not turn on.	Ensure the power cable is disconnected from the charger.
	Ensure the charger has sufficient charge.
The charger is not able to establish or maintain charging of the generator.	Use light clothing to reduce the distance between the charger and the surface of the skin as much as possible.
	Position the charger flat against your clothing.
	Locate the generator under your skin and center the charger over the top of your generator.
	Enable sound on the charger to use audible tones while aligning the charger over the generator. A series of tones will indicate that charging has begun.
	Avoid sitting on or against hard surfaces that may push the charger out of position during charging.
	Ensure the charger is not plugged into an electrical outlet.
	If you do not feel the generator close to your skin, center the charger over the generator site and move the charger in small circles until the charger emits a tone and charging begins.
The temperature of the generator becomes uncomfortable during charging.	If none of the charger icons are illuminated, ensure the power cable is disconnected and turn the charger off and on.
	Stop charging until the discomfort subsides and then resume charging.
	If your clinician has enabled the Charging mode feature, change the Charging mode to low. See the patient controller manual for more information about this feature.
	Ensure the area around your generator is well ventilated.

Table 4. Troubleshooting charging issues

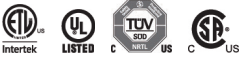
Problem	Possible Solution
	Reposition the charger, aligning the bottom of the charger with the bottom edge of the generator. 
	Ensure the charging apparel is centered over the generator.
	Tighten the charging apparel to ensure the charger is positioned correctly over the generator.
	If you can feel the generator close to your skin, try adding a thin material on your skin over the implant site.
	Consider recharging more frequently for less time.
	If the temperature continues to be uncomfortable, contact your physician.
The charger is not charging.	Ensure the charging cable is fully inserted and USB-IF certified. To determine if a cable is USB-IF certified, look for markings such as the following: 
	Ensure the power adapter is fully inserted and has one or more of the following certification markings: 
The charger is not making sounds.	The charger volume may be set too low. Turn the volume up. See your patient controller user's guide for instructions. The charger volume may be turned off. Turn the volume on. See your patient controller user's guide for instructions.
The charger is too loud.	The charger volume may be set too high. Turn the volume down. See your patient controller user's guide for instructions.

Table 4. Troubleshooting charging issues

Problem	Possible Solution
The charger is not staying in the pocket of the charging apparel.	Ensure that the top flap of the charging apparel is over the charger.
The charger is not able to maintain Bluetooth wireless connection with the patient controller.	▪ Avoid charging your patient controller while charging your generator. ▪ Decrease the distance between the devices. Ensure the patient controller is in Bluetooth wireless range of the charger within 2 m (6.5 ft). ▪ Move the patient controller and charger so they have a line of sight and maintain an uninterrupted path for the Bluetooth wireless signal. ▪ Try holding the patient controller differently. ▪ Reconnect the patient controller with the charger. ▪ Move to a different area or room away from interference in the environment or interference from other devices. ▪ Avoid operating other wireless devices at the same time. ▪ Disconnect any Bluetooth wireless media accessories (such as headphones or speakers, AirPlay[†], AirDrop[‡], CarPlay[‡] or Hotspot[‡]). ▪ Remove and reenable the Bluetooth[®] wireless technology pairing.
The charger will not turn off.	Contact Technical Support.

Service and Ordering Information

This section provides information for contacting Technical Support and for ordering replacement parts and accessories.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Ordering Information

To order parts, contact Technical Support. Refer to the following list for order numbers.

Table 5. Ordering information for the charging system

Description	Model
SCS Charging system	36700
Charging kit - lumbar	36000
Charger	16000
Charging apparel - lumbar	16750
Charging apparel - pectoral	16760
Travel case	16730
Power adapter/adaptor cable	16740

Appendix A: Regulatory Statements

Please note the following regulatory statements related to the charging system.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. The device and its battery should be disposed of according to local laws and regulations.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. This device has been tested and found to comply with the limits of an industrial, scientific, and medical (ISM) equipment, pursuant to part 18 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 6. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMCHG1

Wireless Technology Information

The following table summarizes technical details of the wireless technology of the charging system.

Table 7. Wireless technology information for charging system

Charging frequency	266 kHz to 320 kHz
Charging distance	0.5 cm to 2.5 cm

NOTE: Refer to Charging Your Generator (page 13) for instructions to successfully align and charge your generator.

Table 8. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Chip Antenna
Antenna dimensions	7.00 mm x 2.00 mm x 1.20 mm
Modulation	GFSK
Output power (EIRP*)	1.5 mW (+2 dBm) typical
Duty cycle	14.1% or less over 6 min period
Range	Up to 2 m typical
Center frequency	2.44 GHz
Channel frequency range	2.402 GHz to 2.480 GHz

Table 8. Bluetooth® Low Energy (LE) wireless technology information

Channel	40 logical channels using AFH**
Bandwidth per channel	2 MHz
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology
Semi-duplex capability	Yes

*EIRP = Equivalent isotropically radiated power (not duty cycle adjusted)

**AFH = Adaptive frequency hopping

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the charger and the clinician programmer or patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a charger, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol appears dimmed.

The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (for example, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 22).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The charger encrypts its wireless communication with the programming device using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the charger at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.
- Proprietary authentication for the patient controller or clinician programmer applications in addition to the pairing procedure specified in Bluetooth LE protocol, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized application from communicating with the charger.
- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the charger to a legitimate patient controller or clinician programmer.

Troubleshooting for Wireless, Coexistence, or Interference Issues

If you experience issues with interactions within the neurostimulation system, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the patient controller app; then turn the patient controller off and on.
- Wait a few minutes and try connecting again.
- Avoid operating other consumer electronic devices, such as a laptop, tablet, mobile phone, or cordless phone at the same time.

NOTE: Equipment such as the following can interfere with the neurostimulation system: wireless home network devices, mobile and cordless telephones, and consumer electronic devices.

Appendix B: Product Specifications

The charging system has the following product specifications and compatibility information.

Table 9. Product specifications

Charger input	5 V, 0.5 A
Charger connector type	USB Type C

Table 9. Product specifications

Charger power source	Rechargeable lithium ion cell battery
Charger IP code	IP22
Charger communication protocol	Bluetooth® Low Energy
Charger expected service life	5 years
Charging accessories expected service life	5 years

NOTE:

- The charger is considered an applied part per the 60601-1 standard when it comes into physical contact with the user during charging.
- The USB port in the charger is restricted for charging the charger and is not intended to perform any communication per the USB protocol.

Table 10. Implantable pulse generator compatibility for the charging system

Description	Model
Eterna™ implantable pulse generator	32400

Appendix C: Technical Specifications

Use the charging cable and power adapter included with this system. You may also use a charging cable and power adapter with the following ratings.

Table 11. Technical specifications

Charging cable ratings	
Voltage rating	Minimum 20 V
Current rating	Up to 3 A
Cable length	1 m
USB-IF	Certified Only use an Abbott Medical charging cable (model 16710) or a cable marked with USB-IF certification such as the following:
Power adapter ratings	
Power	5.25 W maximum
Input voltage	100 to 240 VAC
Input frequency	50 to 60 Hz

Table 11. Technical specifications

Output voltage	5 VDC
Output current	up to 1 A
Power adapter certification marking	Power adapter should have one or more of the following certification markings: 

Appendix D: Electromagnetic Compatibility Guidelines

The charging system (model 16000), hereafter the device, is medical equipment and should be used with the following guidance.

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device has essential performance, as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION:

- **The device complies with the limits for medical devices contained in IEC 60601-1-2:2014+AMD1:2020 (Ed 4.1) and CISPR11:2015+AMD1:2016+AMD2:2019 (BS EN 55011:2016+A2:2021). However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.**
- **To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by Abbott Medical with this system. Do not use Abbott Medical components with devices or systems that are not approved by Abbott Medical.**

Table 12. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power
Harmonic emissions IEC 61000-3-2	Class A*	

Table 12. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class 5 Full Compliance*	er supply network that supplies buildings used for domestic purposes.

*Only applicable to power adapter (model 16720)

Table 13. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 10%.
Electrical fast transient/burst IEC 61000-4-4*	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, or home environment.
Surge IEC 61000-4-5*	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial, hospital, or home environment.
Voltage dips, short interruptions IEC 61000-4-11*	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial, hospital, or home environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
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, hospital, or home environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output
	6 Vrms ISM/Radio bands between 150 kHz to 80 MHz 80% AM at 1 kHz	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

Table 13. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			power of the communications equipment. Recommended minimum separation distance for higher immunity test levels $E = \frac{6}{d} \sqrt{P}$ where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).

* Only applicable to power adapter (model 16720)

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 14. Guidance and Manufacturer's Declaration - Proximity Fields from RF Wireless Communication Equipment

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance $d = 0.3 \text{ m}$
	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	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 in.) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Table 15. Guidance and Manufacturer's Declaration - Enclosure Port Immunity to RF Wireless Communication Equipment

Immunity Test	Band (MHz)	Maximum Power (W)	Immunity Test Level (V/m)
IEC 61000-4-3	380 to 390	1.8	27
	430 to 470	2	28
	704 to 787	0.2	9
	800 to 960	2	28
	1700 to 1900	2	28
	2400 to 2570	2	28
	5100 to 5800	0.2	9

Table 16. Guidance and Manufacturer's Declaration - Enclosure Port Immunity to Proximity Magnetic Fields

Immunity Test	Test Frequency	Modulation	Immunity Test Level (A/m)
IEC 61000-4-39	30.0 kHz	Continuous wave	8
	134.2 kHz	Pulse modulation 2.1 kHz	65
	13.56 MHz	Pulse modulation 50 kHz	7.5

Appendix E: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 17. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
 medical.abbott/manuals	Follow instructions for use on this website
	Type BF Applied Part
	MR Unsafe

Table 17. Symbols and definitions

Symbol	Definition
	NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Non-ionizing electromagnetic radiation
	Use-by date
	Class II Equipment
	Keep dry; keep away from rain
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Date of manufacture
	Manufacturing facility
	Long term storage temperature
	Temperature limit
	Excursions permitted within this range
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged

Table 17. Symbols and definitions

Symbol	Definition
	Medical Device
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Charger
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	This product shall not be treated as household waste. The product and its battery should be disposed of according to local laws and regulations. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources.
	Authorized representative in the European Community
	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797) and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directive. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.

Table 17. Symbols and definitions

Symbol	Definition
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	Intertek Listed US and Canada. Conforms to UL STD 60601-1 Certified to CAN/CSA C22.2 STD No.601.1.
	This device is listed by the Canadian Standards Association (CSA) International as certified
	This device is a recognized component by Underwriters Laboratories (UL) Inc.
	This device complies with part 18 of the FCC rules.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

abbott.com

2024-11
ARTEN600336165 B



Paddle Lead Kit

Models 3214, 3219, 3224, 3228, 3240, 3243, 3244, 3245, 3246, 3262, 3266, 3268, 3283, 3286, 3288, 3292

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Additional Prescription Information.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	2
Adverse Effects.	3
Product Description.	3
Package Contents.	4
Directions for Use.	4
Placing Paddle Leads.	4
Final Lead Placement and Anchoring.	6
Tunneling to the Pocket.	8
Connecting the Leads.	9
Disposing of Explanted Components.	9
Technical Support.	9
Appendix A: Product Specifications.	10
Storage Specifications.	10
Product Materials.	10
Lead Specifications (4 Channel).	11
Lead Specifications (8 Channel).	13
Lead Specifications (16 Channel).	19
Appendix B: Symbols and Definitions.	26

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The leads covered in this manual are intended to be used with Abbott Medical neurostimulation systems by connecting to a compatible pulse generator, either directly or with a compatible lead extension.

Additional Prescription Information

Refer to the clinician's system manual for additional instructions and other important information, including indications for use, contraindications, warnings, precautions, and adverse effects related to the complete neurostimulation system.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. Conditions for safe scanning depend on the choice of implant model, location, and configuration. The choice of implant model may limit the availability and diagnostic quality of some MR procedures. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to these components.

Preoperative imaging. Preoperatively review imaging of the spine (for example, MRI or computerized tomography [CT] with or without myelography) in the region where the paddle is intended to be implanted to ensure adequate space for the lead.

Compressive lesions. Systematically assess the presence of any compressive lesions in the region where the paddle is intended to be implanted.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may forcefully dislodge implanted components, damage the device electronics, and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. Advise patients to inform their healthcare professional that they should not be exposed to diathermy treatment.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted IPG or lead. Contact between an active electrode and an implanted IPG or lead can cause severe injury to the patient. For additional electrosurgery information and guidance, refer to the clinician's manual for the appropriate IPG.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Device modification. To avoid damaging internal components or injuring a patient, do not modify the lead in any way, such as by cutting it or altering its shape.

Precautions

The following precautions apply to these components.

General Precautions

Physician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Implantation of multiple leads. If multiple leads are implanted, the leads should be routed to the IPG adjacent to each other in the tunnel. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

Sterilization and Storage

Single-use device. The implanted components of this neurostimulation system are intended for a single use only. The components of this kit have been sterilized using ethylene oxide (EtO) gas and are supplied in

packaging permitting direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason because of risk of infection and device malfunction.

Exposure to liquids. System components should be stored where they will not be exposed to liquids or excessive moisture, which can damage the seal integrity of the package materials.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use a component if the use-by date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Exposure of the internal metal (such as contacts on the lead, the IPG, or extension) to body fluids or saline can cause corrosion and affect stimulation. If this occurs, clean with sterile deionized water or sterile water for irrigation and dry completely prior to lead connection and implantation.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Component disposal. Return all explanted components to Abbott Medical for safe disposal.

Home and Occupational Environments

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks postimplantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in ineffective or overstimulation.

Adverse Effects

The use of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration or local skin erosion
- Implant migration
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode site or IPG site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to implant materials
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Product Description

Abbott Medical leads are designed for spinal cord stimulation (SCS) to aid in the treatment of chronic, intractable pain. SCS is a method of pain control that uses low-intensity electrical impulses to stimulate nerve

fibers within the spinal cord, often inhibiting chronic pain messages from reaching the brain. Paddle leads consist of plate-type electrodes embedded in a silicone paddle.

Package Contents

In addition to the lead, the paddle lead kit may contain the following items:

- **Lead anchor.** Made of silicone and used to secure the lead for stability.
- **Tunneling tool.** Used to create a subcutaneous tunnel for routing the lead to the IPG site.
- **Torque wrench.** Used to tighten the setscrew on the connector assemblies of the IPG and extension.
- **Lead blank.** Used after preoperative assessment to confirm available space prior to paddle lead placement.

Directions for Use

Carefully review the following suggested guidelines for implantation of a paddle lead. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

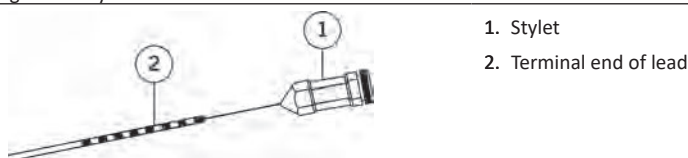
Placing Paddle Leads

Paddle leads are designed for introduction into the dorsal epidural space through a laminotomy procedure. Each paddle lead is packaged with the accessories required for implantation. See Appendix A (page 10) for specifications.

Implantation of a paddle lead should be done with the aid of fluoroscopy. Care should be taken during handling and implantation of the lead. The lead can be damaged by mishandling, such as sharp bending, kinking, applying excessive traction, or contact with sharp instruments. Carefully examine each component upon removal from its sterile container. A lead exhibiting signs of damage should not be used.

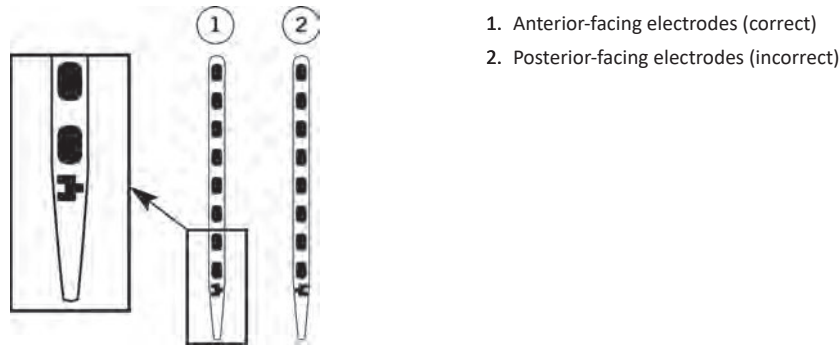
Lamitrode™ S-Series™ leads (models 3243, 3246, 3266, 3268, 3283, and 3286, also called S-Series™ leads) have a slimline design for enhanced maneuverability. They also feature removable stylets (straight and curved) that provide added stiffness to facilitate steering and control during lead placement (see the following figure).

Figure 1. Stylets available in some model leads



S-Series leads also feature an indicator that shows which direction the electrodes are facing. An anterior-posterior (AP) fluoroscopic view will allow you to see the directional indicator (see the following figure). If the indicator is pointing to the right in the AP view, the electrodes are facing anteriorly (toward the dura). If the indicator is pointing to the left, the electrodes are facing posteriorly (away from the dura).

Figure 2. Meaning of directional indicator of S-Series leads



WARNING:

- It is recommended that the physician assess the size of the spinal canal at the planned insertion and placement site. Compare with the dimensions of the lead and paddle to ensure adequate clearance and to avoid increased risk of spinal cord injury due to cord compression.
 - When implanting for upper extremity pain, it is advisable to place the lead and paddle at C1-C2 to avoid increased risk of spinal cord injury due to cord compression.
 - When selecting a placement location for a laminotomy-type lead in the thoracic spine, consideration should be given to existing spinal stenosis. Decompress the spinal canal prior to the paddle insertion if the level of the paddle insertion coincides with the level of spinal canal stenosis.
1. Externally measure and determine the appropriate spinal level for placement of the paddle and the spinal level required for the laminotomy to expose the epidural space.

CAUTION: To prevent injury, avoid inserting the paddle at vertebral levels where:

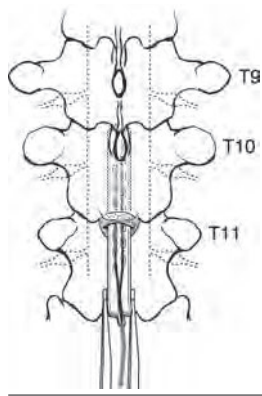
 - The thickness of the CSF layer is less than 3 mm along the width/length of the lead
 - The thickness of the paddle allows less than approximately 1 mm of CSF clearance
 - The spinal canal is narrowed by focal stenosis or degenerated discs and cannot be surgically corrected to allow for approximately 1 mm of clearance

NOTE: When placing a paddle in the cervical spine, you may need additional clearance to allow for flexion and extension of the head and neck.
 2. Select the desired approach and perform the surgical procedure. Ensure that the dissection and resultant opening of the ligamentum flavum are adequate for the paddle to pass through.
 3. Use standard operating technique to ensure that a clear pathway is established in the epidural space for placement of the lead.

WARNING: To prevent patient injury, do not apply excessive force when using surgical instruments, such as an elevator, to clear a pathway in the spinal canal during paddle lead placement.
 4. If desired, use the lead blank to help confirm that adequate space is available for placement of the paddle lead.

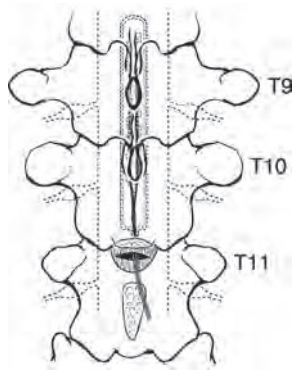
WARNING: Do not use the lead blank to clear scar tissue or open up a narrow spinal canal.
 5. Grasp the lead with rubber-tipped forceps, and pass it through the opening in the ligament, ensuring that the electrodes face the dura (see the following figure).

Figure 3. Use forceps to pass the lead through the ligament opening (cross-section view, spinous process is not shown)



6. Using fluoroscopic guidance, place the lead into the intended position. Ensure all electrodes are within the epidural space and that the lead paddle will be stabilized following implantation (see the following figure).

Figure 4. Ensure all electrodes are in the epidural space



7. Perform intraoperative testing. See the clinician's manual for the appropriate trial stimulator for instructions.

CAUTION: Exercise extreme caution when using sharp instruments around the lead to avoid damage to the lead body.

Final Lead Placement and Anchoring

Once final lead placement has been achieved, the lead should be secured with a lead anchor. Lead kits contain two styles of anchors: butterfly and long (see the following figures). Anchor selection should be based upon anatomical requirements and personal preference.

Figure 5. Butterfly anchor

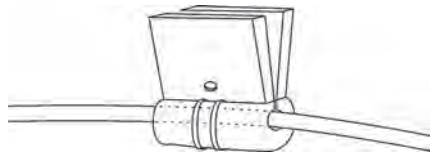
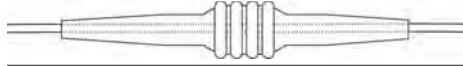


Figure 6. Long anchor

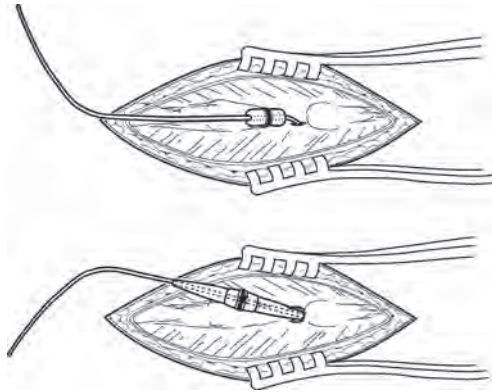


To anchor the lead:

1. Check the lead position by fluoroscopic examination, and reposition the lead if necessary.
2. Select the appropriate anchor and place it on the lead as closely as possible to where it emerges from the vertebral column (see the following figure). Use sterile water (not saline) to lubricate the anchor and facilitate sliding it down the lead. If using the long anchor, slide it down the lead until the anchor's distal strain relief is at least 1 cm (0.4 in.) into the fascia. If implanting multiple leads, tag the leads with ligature so that their position can be identified later.

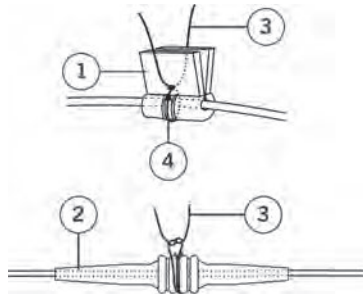
WARNING: Care should be taken not to bend the connector end of the lead when passing the long anchor over it.

Figure 7. Insert the anchor on the lead



3. Secure the lead within the lead anchor using 2-0 nonabsorbable suture (see the following figure).

Figure 8. Secure the anchor and the lead



1. Butterfly anchor
2. Long anchor
3. Suture to interspinous ligament
4. Tie suture tightly

NOTE: To ensure optimal holding force, use a surgeon's knot. A surgeon's knot is a form the square knot; the first loop of the knot has two throws, and the second loop has one.

WARNING:

- Do not use polypropylene or monofilament suture because of possible damage to the anchor and lead.
- If the lead is not properly anchored, migration may occur.

- Sutures placed directly on the lead without an anchor can cause permanent damage to the insulation and eventual failure of the lead.
 - Avoid sharp bends or kinking of the lead, or permanent damage may occur.
4. Suture the anchor to the interspinous ligament with 2-0 nonabsorbable suture. A strain relief for the lead should be created by coiling excess lead proximal to the lead anchor in loops no smaller than 2.5 cm (1 in.) in diameter.
 5. Once anchored, the lead can be connected to an extension for trial screening or tunneled to the IPG site for system internalization.

Tunneling to the Pocket

Tunneling is usually done from the lead anchor site directly to the IPG pocket. However, when an extension is used or the IPG pocket is in the abdominal region, tunneling is done from the lead anchor site to a midpoint (where an incision and appropriate dissection have been performed) and then continued to the IPG pocket site.

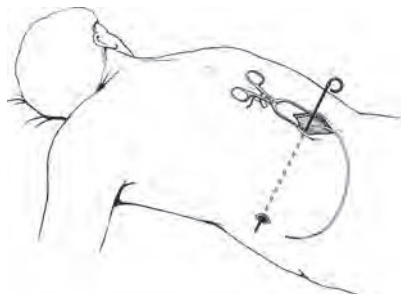
To tunnel from the lead anchor site to the IPG pocket:

CAUTION: Use extreme care so as not to damage a lead with the sharp point of the tunneling tool.

NOTE: The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.

1. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the IPG pocket.

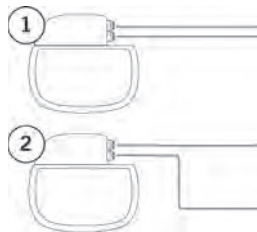
Figure 9. Suggested tunnel to the IPG pocket



2. Withdraw the tunneling tool from the cannula sleeve, leaving the cannula sleeve in the subcutaneous tunnel.

CAUTION: Multiple leads must be routed adjacent to one another. Patients with nonadjacent leads may experience changes in perceived stimulation from theft detectors and metal screening devices.

Figure 10. Correct way to route multiple leads



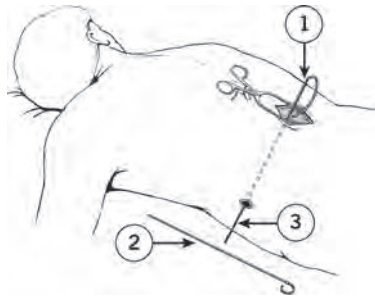
1. Correct
2. Incorrect

WARNING: It is possible that patients who are implanted with nonadjacent multiple leads may experience a momentary increase in their perceived stimulation, which has been described by some

patients as uncomfortable or jolting, when passing through antitheft devices or airport screening devices.

3. Carefully pass the end of the lead or leads through the cannula sleeve from the anchor site to the IPG pocket; or, if a two-step tunneling procedure is used, pass the lead or leads from the anchor site to the midway incision site and then to the IPG pocket. Multiple leads may be placed in the same tunnel.

Figure 11. Sequence of tunneling steps



1. Leave cannula sleeve in place
2. Remove tunneling tool
3. Pull lead through cannula sleeve to IPG pocket

4. Withdraw the cannula sleeve from the subcutaneous tunnel by passing it over the lead or leads, taking care not to cause traction on them.

Connecting the Leads

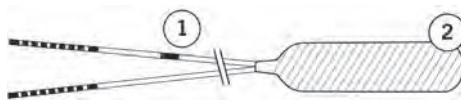
For instructions about connecting a paddle lead to an IPG or RF system, see the applicable neurostimulator clinician's manual.

WARNING: Exposure of the internal IPG contacts to body fluids or saline can cause corrosion and affect stimulation. If exposure occurs, clean the contacts with sterile deionized water or sterile water for irrigation and dry completely prior to lead connection and implantation.

Additionally, consider the following notes:

- Use clean gloves and ensure that all body fluids and saline residue are cleaned from the end of the lead.
- Use the differentiation band on 16-electrode leads (when available) to identify the correct lead body. All 16-electrode leads have two lead bodies exiting the paddle. When the paddle is facing anteriorly (toward the dura), the lead body that exits from the left side of the paddle is connected to electrodes 1 through 8. Additionally, the Lamitrode™ Tripole™ 16 leads, Penta™ leads, and TriCentrus™ leads contain a differentiation band near the terminal end of the lead that identifies the lead body for electrodes 1 through 8 (see the following figure).

Figure 12. Use the differentiation band (when available) to identify the lead body for electrodes 1 through 8



1. Differentiation band shows lead body for electrodes 1 through 8
2. Back of paddle

Disposing of Explanted Components

Explanted Abbott Medical components should be returned to Abbott Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your Abbott Medical representative or Technical Support.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components according to the following conditions.

Table 1. Storage conditions for components

Long-term storage temperature	24°C (75.2°F)
Excursion temperature	-10°C to 55°C (14°F to 131°F)
Humidity	10% to 90% (noncondensing)
Pressure	70 kPa to 150 kPa (10.2 psi to 21.8 psi)

Product Materials

The following components are intended to come into contact with tissue.

Table 2. Product materials for paddle leads

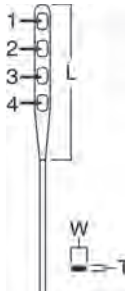
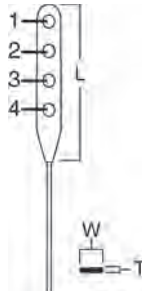
Component	Material
Electrodes and terminal end contacts	Platinum iridium
Paddle	Silicone
Insulation	Polycarbonate polyurethane
Lead blank ¹	Silicone with 20% barium sulfate ²

¹ Not all kits contain a lead blank; see the lead specifications for a list of each kit's components.

² The lead blank paddle for model 3245 contains only silicone.

Lead Specifications (4 Channel)

Table 3. Specifications for Lamitrode™ S-4 and 4 leads

Description	Lamitrode S-4		Lamitrode 4	
				
Lead length and model	30 cm	3243	–	
	60 cm	3246	3240	
	90 cm	3266	–	
Lead diameter	1.4 mm		1.4 mm	
Electrodes				
Number	4		4	
Configuration	1 column of 4		1 column of 4	
Length	4 mm		4 mm	
Width	2.5 mm		4 mm	
Longitudinal spacing	3 mm		6 mm	
Array length	25 mm		35 mm	
Array width	2.5 mm		4 mm	
Paddles				
Length (L, includes taper)	39 mm		51 mm	
Width (W)	4 mm		8 mm	
Thickness (T)	1.8 mm		1.7 mm	
Lead resistance (for all lengths)	<10 ohms		<10 ohms	
MRI status	All models listed in this table are MR Unsafe.			

Each kit listed in the previous table includes the following items:

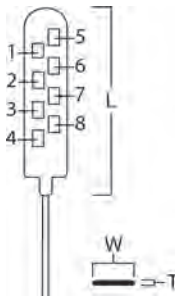
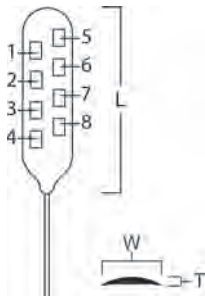
- 1 lead
- 1 torque wrench (model 1101)
- 1 lead anchor, butterfly (model 1105)
- 1 lead anchor, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

- 1 stylet, straight (model 1121, 1123, or 1125), S-4 only
- 1 stylet, curved (model 1122, 1124, or 1126), S-4 only

Lead Specifications (8 Channel)

Table 4. Specifications for Lamitrode™ 44 and 44C leads

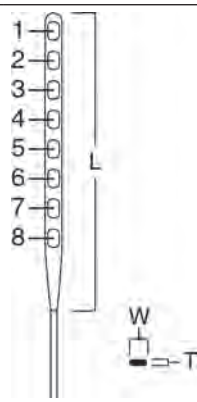
Description	Lamitrode 44		Lamitrode 44C	
Electrodes are shown facing down (anteriorly)				
				
Lead length and model	60 cm	3244	3245	
	90 cm	3262	—	
Lead diameter	1.4 mm		1.4 mm	
Electrodes				
Number	8		8	
Configuration	2 offset columns of 4		2 offset columns of 4	
Length	4 mm		4 mm	
Width	2.5 mm		2.5 mm	
Longitudinal spacing	3 mm		3 mm	
Lateral spacing	1 mm		2 mm	
Array length	28 mm		28 mm	
Array width	6 mm		7 mm	
Paddles				
Length (L, includes taper)	51 mm		51 mm	
Width (W)	10 mm		13 mm	
Thickness (T)	1.7 mm		2 mm tapering to 0.4 mm	
Lead resistance (for all lengths)	<10 ohms		<10 ohms	
MRI status	All models listed in this table are MR Unsafe.			

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank, 44C only
- 1 torque wrench (model 1101)
- 1 lead anchor, butterfly (model 1105)
- 1 lead anchor, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

Table 5. Specifications for Lamitrode™ S-8 leads

Description		Lamitrode S-8	
			
Lead length and model	30 cm	3283	
	60 cm	3286	
	90 cm	3268	
Lead diameter	1.4 mm		
Electrodes			
Number	8		
Configuration	1 column of 8		
Length	4 mm		
Width	2.5 mm		
Longitudinal spacing	3 mm		
Array length	53 mm		
Array width	2.5 mm		
Paddles			
Length (L, includes taper)	67 mm		
Width (W)	4 mm		
Thickness (T)	1.8 mm		
Lead resistance (for all lengths)	<10 ohms		
MRI status	All models listed in this table are MR Unsafe.		

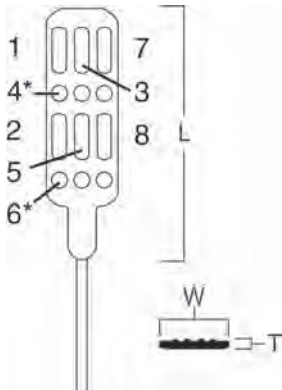
Each kit listed in the previous table includes the following items:

- 1 lead
- 1 torque wrench (model 1101)
- 1 lead anchor, butterfly (model 1105)
- 1 lead anchor, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

- 1 stylet, straight (model 1121, 1123, or 1125)
- 1 stylet, curved (model 1122, 1124, or 1126)

Table 6. Specifications for Lamitrode™ Exclaim™ leads

Description	Exclaim
Electrodes are shown facing down (anteriorly)	
Lead length and model	60 cm 3224
Lead diameter	1.4 mm
Electrodes	
Number	8
Configuration	3 columns with rows that alternate between rectangular and button electrodes
Length	Rectangular: 5.8 mm Button: 2.2 mm (diameter)
Width	Rectangular: 1.8 mm
Longitudinal spacing	1.6 mm
Lateral spacing	1 mm
Array length	21 mm
Array width	8 mm
Paddles	
Length (L, includes taper)	33 mm
Width (W)	9.5 mm
Thickness (T)	2 mm
Lead resistance (for all lengths)	<10 ohms
MRI status	All models listed in this table are MR Unsafe.

* Electrode number includes all three button electrodes.

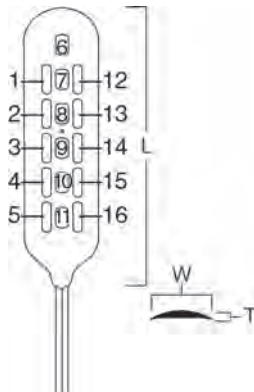
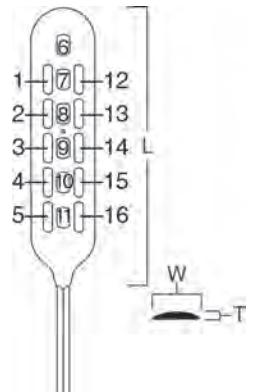
Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank
- 1 torque wrench (model 1101)
- 1 lead anchor, butterfly (model 1105)
- 1 lead anchor, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

Lead Specifications (16 Channel)

Table 7. Specifications for Lamitrode™ Tripole™ 16C and 16 leads

Description	Tripole 16C	Tripole 16
Electrodes are shown facing down (anteriorly)		
Lead length and model	60 cm 3214	3219
Lead diameter	1.4 mm	1.4 mm
Electrodes		
Number	16	16
Configuration	1 center column with 2 offset columns on either side	1 center column with 2 offset columns on either side
Length	Center column: 4 mm Outer column: 6 mm	Center column: 4 mm Outer column: 6 mm
Width	Center column: 2.5 mm Outer column: 1.8 mm	Center column: 2.5 mm Outer column: 1.8 mm
Longitudinal spacing	Center column: 3 mm Outer column: 1 mm	Center column: 3 mm Outer column: 1 mm
Lateral spacing	1 mm	1 mm
Array length	40 mm	40 mm
Array width	8 mm	8 mm
Paddles		
Length (L, includes taper)	57 mm	57 mm
Width (W)	13 mm	10 mm
Thickness (T)	2 mm tapering to 0.4 mm	2 mm tapering to 0.4 mm
Lead resistance (for all lengths)	<10 ohms	<10 ohms
Differentiation band signifies	Not available	Electrodes 1–8
MRI status*	MR Unsafe	MR Conditional

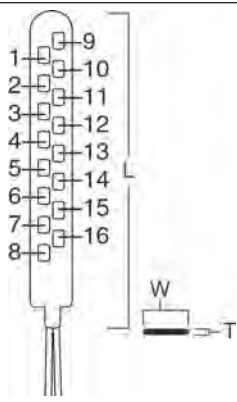
* The butterfly anchor (model 1105) and long anchor (model 1106), which are included in the lead kit, are MR Conditional components.

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank
- 1 torque wrench (model 1101)
- 2 lead anchors, butterfly (model 1105)
- 2 lead anchors, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

Table 8. Specifications for Lamitrode™ 88 leads

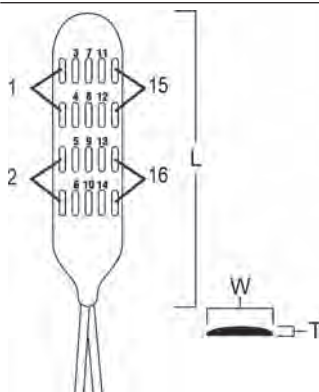
Description		Lamitrode 88
Electrodes are shown facing down (anteriorly)		
Lead length and model	60 cm	3288
Lead diameter		1.4 mm
Electrodes		
Number		16
Configuration		2 offset columns of 8
Length		4 mm
Width		2.5 mm
Longitudinal spacing		3 mm
Lateral spacing		1 mm
Array length		56 mm
Array width		6 mm
Paddles		
Length (L, includes taper)		79 mm
Width (W)		10 mm
Thickness (T)		1.7 mm
Lead resistance (for all lengths)		<5 ohms
Differentiation band signifies		Not available
MRI status		All models listed in this table are MR Unsafe.

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 torque wrench (model 1101)
- 2 lead anchors, butterfly (model 1105)
- 2 lead anchors, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

Table 9. Specifications for Penta™ leads

Description		Penta, 3 mm	
Electrodes are shown facing down (anteriorly)			
Lead length and model	60 cm	3228	
Lead diameter		1.4 mm	
Electrodes			
Number		16	
Configuration		5 columns of 4	
Length		4 mm	
Width		1 mm	
Longitudinal spacing		3 mm	
Lateral spacing		1 mm	
Array length		25 mm	
Array width		9 mm	
Paddles			
Length (L, includes taper)		46 mm	
Width (W)		11 mm	
Thickness (T)		2 mm	
Lead resistance (for all lengths)		<10 ohms	
Differentiation band signifies		Electrodes 1–8	
MRI status*		MR Conditional	

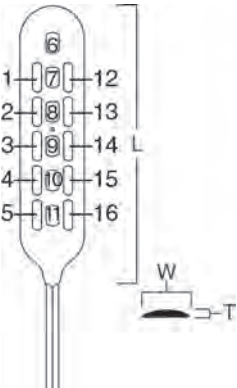
* The butterfly anchor (model 1105) and long anchor (model 1106), which are included in the lead kit, are MR Conditional components.

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank
- 1 torque wrench (model 1101)
- 1 lead anchor, butterfly (model 1105)
- 1 lead anchor, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

Table 10. Specifications for TriCentrus™ lead

Description	TriCentrus
Electrodes are shown facing down (anteriorly)	
Lead length and model	60 cm 3292
Lead diameter	1.4 mm
Electrodes	
Number	16
Configuration	1 center column with 2 offset columns on either side
Length	Center column: 4 mm Outer column: 6 mm
Width	Center column: 2.5 mm Outer column: 1.8 mm
Longitudinal spacing	Center column: 3 mm Outer column: 1 mm
Lateral spacing	1 mm
Array length	40 mm
Array width	8 mm
Paddles	
Length (L, includes taper)	57 mm
Width (W)	10 mm
Thickness (T)	2 mm tapering to 0.4 mm
Lead resistance (for all lengths)	<10 ohms
Differentiation band signifies	Electrodes 1–8
MRI status*	MR Conditional

* The butterfly anchor (model 1105) and long anchor (model 1106), which are included in the lead kit, are MR Conditional components.

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 lead blank
- 1 torque wrench (model 1101)
- 2 lead anchors, butterfly (model 1105)
- 2 lead anchors, long (model 1106)
- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

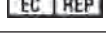
Appendix B: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 11. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Do not re-use
	Do not resterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Storage temperature limit

Table 11. Symbols and definitions

Symbol	Definition
	Excursion temperature limit
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	One lead
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	Single sterile barrier system with protective packaging outside
	Sterilized using ethylene oxide
	Authorized representative in the European Community
	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-04
ARTEN600283822 A



Percutaneous Lead Kit

Models 3143, 3146, 3149, 3153, 3156, 3159, 3183, 3186, 3189

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Additional Prescription Information.	1
MRI Safety Information.	1
Warnings.	1
Precautions.	2
Adverse Effects.	3
Product Description.	3
Package Contents.	4
Directions for Use.	4
Placing Percutaneous Leads.	4
Final Lead Placement and Anchoring.	8
Tunneling to the Pocket.	10
Disposing of Explanted Components.	11
Technical Support.	11
Appendix A: Product Specifications.	12
Storage Specifications.	12
Product Materials.	12
Lead Specifications.	13
Appendix B: Symbols and Definitions.	14

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The percutaneous leads covered in this manual are intended to be used with Abbott Medical neurostimulation systems by connecting to a compatible pulse generator, either directly or with a compatible lead extension.

Additional Prescription Information

Refer to the clinician's system manual for additional instructions and other important information, including indications for use, contraindications, warnings, precautions, and adverse effects related to the complete neurostimulation system.

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. Conditions for safe scanning depend on the choice of implant model, location, and configuration. The choice of implant model may limit the availability and diagnostic quality of some MR procedures. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Warnings

The following warnings apply to these components.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by Abbott Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may forcefully dislodge implanted components, damage the device electronics, and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. Advise patients to inform their healthcare professional that they should not be exposed to diathermy treatment.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted IPG or lead. Contact between an active electrode and an implanted IPG or lead can cause severe injury to the patient. For additional electrosurgery information and guidance, refer to the clinician's manual for the appropriate IPG.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the

implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Device modification. To avoid damaging internal components or injuring a patient, do not modify the lead in any way, such as by cutting it or altering its shape.

Precautions

The following precautions apply to these components.

General Precautions

Physician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Implantation of multiple leads. If multiple leads are implanted, the leads should be routed to the IPG adjacent to each other in the tunnel. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

Sterilization and Storage

Single-use device. The implanted components of this neurostimulation system are intended for a single use only. The components of this kit have been sterilized using ethylene oxide (EtO) gas and are supplied in packaging permitting direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason because of risk of infection and device malfunction.

Exposure to liquids. System components should be stored where they will not be exposed to liquids or excessive moisture, which can damage the seal integrity of the package materials.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use a component if the use-by date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Exposure of the internal metal (such as contacts on the lead, the IPG, or extension) to body fluids or saline can cause corrosion and affect stimulation. If this occurs, clean with sterile deionized water or sterile water for irrigation and dry completely prior to lead connection and implantation.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Component disposal. Return all explanted components to Abbott Medical for safe disposal.

Home and Occupational Environments

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) for six to eight weeks postimplantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in ineffective or overstimulation.

Adverse Effects

The use of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration or local skin erosion
- Implant migration
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode site or IPG site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to implant materials
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Product Description

Abbott Medical leads are designed for spinal cord stimulation (SCS) to aid in the treatment of chronic, intractable pain. SCS is a method of pain control that uses low-intensity electrical impulses to stimulate nerve fibers within the spinal cord, often inhibiting chronic pain messages from reaching the brain. Percutaneous leads are designed for introduction into the epidural space using a special needle. The lead assembly consists of 4 or 8 cylindrical electrodes spaced at precise intervals. Percutaneous leads are supplied with a stylet to aid in positioning.

Package Contents

The percutaneous lead kits contain the following:

Guide wire. Used to establish an appropriate pathway for the lead in the epidural space. The guide wire is 50 cm (20 in.) in length.

Lead anchor. Made of silicone and used to secure the lead to connective tissue for stability.

Tunneling tool. Used to create a subcutaneous tunnel to route the lead to the IPG site.

Epidural needle. Special 14-gauge needle designed for insertion of the percutaneous leads into the epidural space.

Introduce-AK™ lead introducer. Radiopaque sheath designed to facilitate the insertion of the percutaneous lead into the epidural space and placement at the appropriate site.

Lead stylet. Inserted in the lead body to assist in steering and positioning.

Torque wrench. Used to tighten the setscrew on the connector assemblies of the IPG and extension.

Directions for Use

Carefully review the following suggested guidelines for implantation of percutaneous leads. If implanting multiple leads, repeat the appropriate steps for each lead. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

Placing Percutaneous Leads

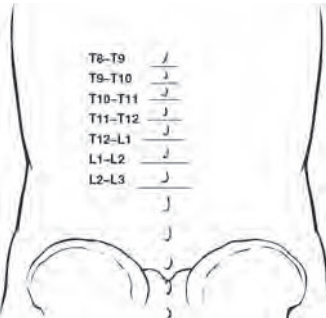
Percutaneous leads are designed for introduction into the dorsal epidural space using a special needle, a guide wire, and the optional Introduce-AK™ lead introducer. Each lead is packaged with the accessories required to place the lead percutaneously. See Appendix A (page 12) for specifications.

The following are suggested guidelines for placing percutaneous leads. For these instructions, use fluoroscopy as needed to assist in placing a device.

1. Externally measure and determine the length of lead required to extend from the appropriate spinal level to the predetermined location of the implanted IPG. The appropriate vertebral level for needle entry should be identified and marked (see the following figure) to allow approximately 20 cm (8 in.) of the lead to lie in the epidural space. This will facilitate stabilization of the lead and electrodes following implantation. Typical entry levels for lead target sites include the following.

Figure 1. Suggested vertebral entry levels based on target sites

Lead Target Site	Entry Level
T8-T9*	T11-T12
T9-T10*	T12-L1
T10-T11	L1-L2
T11-T12	L2-L3
T1-T2	T4-T6
C3-C5	T1-T3
C1-C2	C6-C7



* Paresthesia mapping is not needed for subthreshold and paresthesia free therapy. For more information that supports the clinical use of the anatomical placement of leads and BurstDR™ stimulation, refer to the clinical summaries manual for SCS systems.

CAUTION: Handle the lead with care. The lead can be damaged by mishandling, such as sharp bending, kinking, applying excessive traction, or contact with sharp instruments. Carefully examine each component upon removal from its sterile container. A lead exhibiting signs of damage should not be used.

2. After appropriate skin prepping, draping, and injection of local anesthetic, insert the epidural needle. A paramedian approach is recommended, and the needle angle should not be greater than 30° (see the following figures). Angles greater than 30° increase the risk of damage to the lead during insertion and manipulation.

Figure 2. Insert epidural needle using paramedian approach

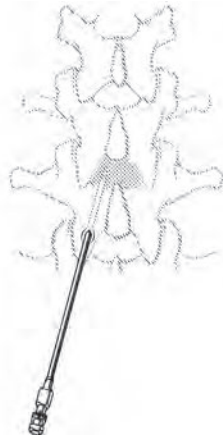
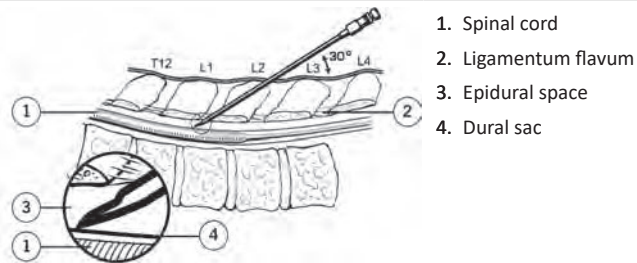
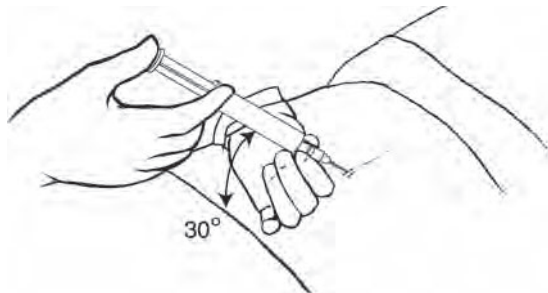


Figure 3. Insert needle at an angle of 30° or less



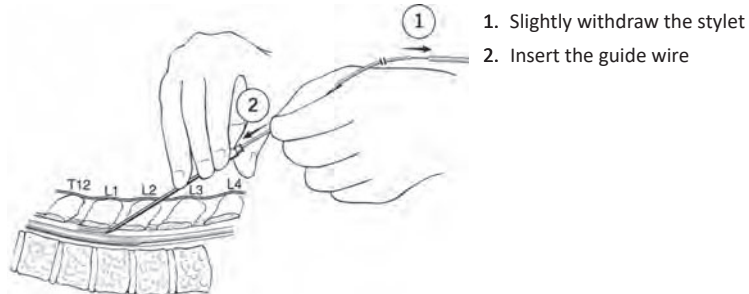
3. Confirm entry into the epidural space using standard methods such as the loss-of-resistance technique (see the following figure).

Figure 4. Use loss-of-resistance technique to confirm entry



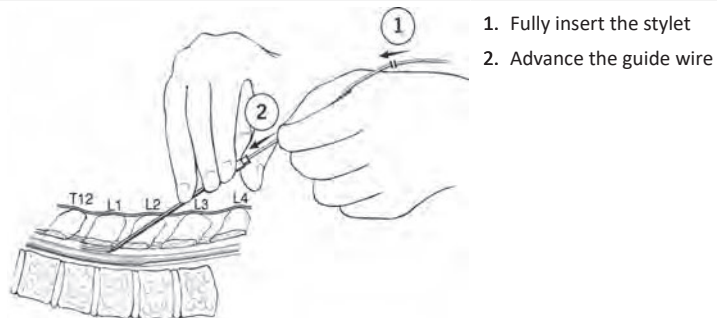
4. Under fluoroscopic guidance, insert the guide wire, with the stylet slightly withdrawn, through the needle into the epidural space (see the following figure). Withdrawing the stylet slightly increases the flexibility of the guide wire tip and minimizes the risk of a dural tear.

Figure 5. Insert the guide wire



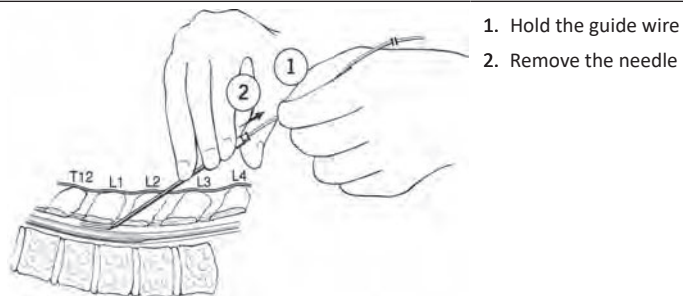
5. Once the tip of the guide wire is within the epidural space and slightly beyond the distal tip of the needle, fully reinsert the stylet and advance the guide wire to the desired target (see the following figure). When advancing the guide wire, it is very important to do so under fluoroscopic guidance and to manipulate the guide wire carefully to minimize the risk of dural tear.

Figure 6. Advance the guide wire to the target



6. If using the lead introducer to place the lead (optional), remove the needle using the hold-and-push technique, leaving the guide wire in the epidural space (see the following figure).

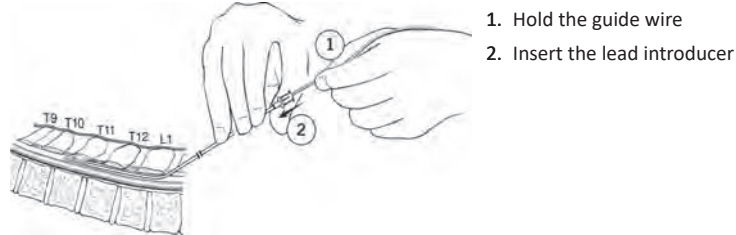
Figure 7. If using the lead introducer (optional), remove the needle



7. If using the lead introducer (optional), insert the lead introducer over the proximal end of the guide wire at the same angle (no more than 30°) as the previously placed needle (see the following figure). Advance the lead introducer into the epidural space under fluoroscopy to the target position.

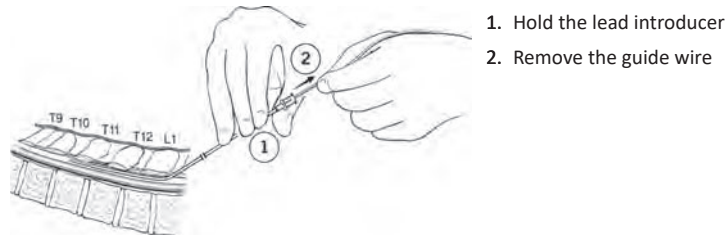
NOTE: It may be necessary to rotate the lead introducer as it passes through the ligamentum flavum.

Figure 8. If using the lead introducer (optional), insert the lead introducer



8. If using the lead introducer (optional), after the lead introducer reaches the desired spinal level for electrode placement, remove the guide wire (see the following figure).

Figure 9. If using the lead introducer (optional), remove the guide wire



9. Insert the lead through the lumen of the needle or the lead introducer (whichever is in place), and advance the lead to the target site under fluoroscopic control (see the following figure). To aid placement, percutaneous leads feature a removable stylet that provides added stiffness and facilitates control.

WARNING: If pulling the lead back through the needle, use caution to avoid severe damage to the lead due to shearing from the needle's tip.

Figure 10. Insert and advance the lead to the target

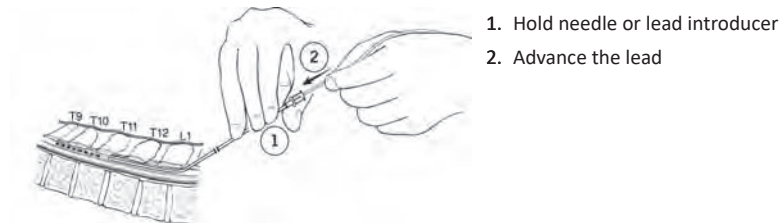
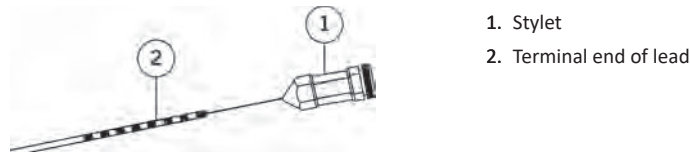


Figure 11. Use the stylet to help place the lead



10. Through fluoroscopic evaluation, confirm that the electrodes extend beyond the distal tip of the lead introducer or needle. If they do not, advance the lead or withdraw the lead introducer as necessary to expose the electrodes.

NOTE: Consider obtaining anteroposterior or lateral fluoroscopic imaging to confirm dorsal positioning of leads in the epidural space.

11. Perform intraoperative testing. See the clinician's manual for the appropriate trial stimulator for instructions.

Final Lead Placement and Anchoring

Once final lead placement has been achieved, the lead should be secured with a lead anchor. Lead kits contain two styles of anchors: butterfly and long (see the following figures). Anchor selection should be based upon anatomical requirements and personal preference.

Figure 12. Butterfly anchor

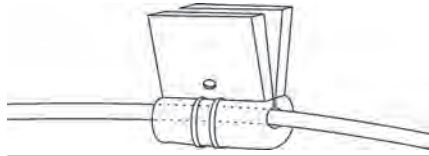
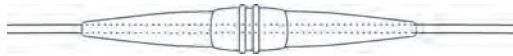


Figure 13. Long anchor

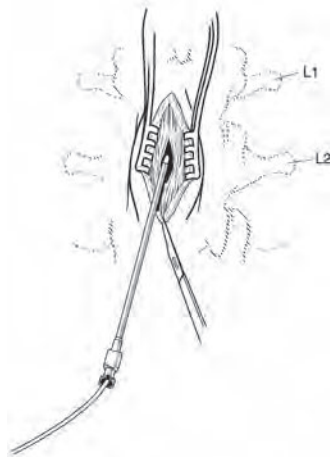


To anchor the lead:

1. Centered on the needle or lead introducer, make a longitudinal incision approximately 3 to 7 cm (1.2 to 2.8 in.) in length to the depth of the interspinous ligament. Use extreme care not to cut the lead introducer or the lead (see the following figure).

WARNING: Use extreme caution when using sharp instruments around the lead to avoid damage to the lead body.

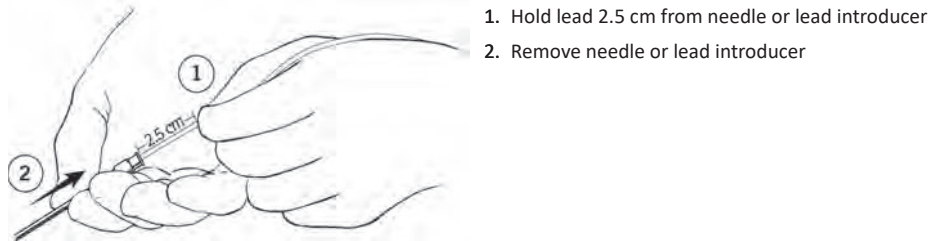
Figure 14. Make a longitudinal incision



2. Grasp the lead with two fingers and carefully remove the stylet from the lead.

3. If needed, carefully remove the lead introducer or needle using the hold-and-push technique, leaving the lead in place as follows: Grasp the lead with two fingers, approximately 2.5 cm (1 in.) away from the hub of the lead introducer or needle. With the other hand, gently push the lead introducer or needle up over the lead body until the hub and fingers meet. Repeat this procedure until it clears the tissue. Once clear, grasp the lead as close to the tissue as possible, and slowly remove the lead introducer or needle over the lead with the other hand (see the following figure).

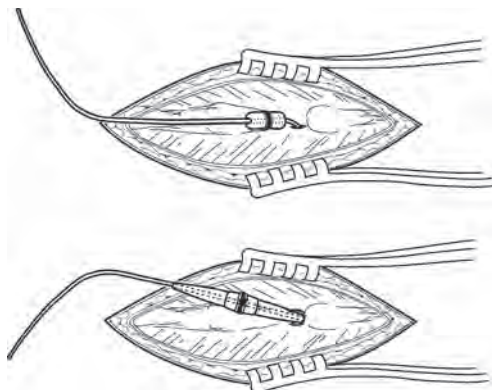
Figure 15. Carefully remove the needle or lead introducer



4. Check the lead position by fluoroscopic examination, and reposition the lead if necessary.
5. Select the appropriate anchor and place it on the lead as closely as possible to where it emerges from the vertebral column (see the following figure). Use sterile water (not saline) to lubricate the anchor and facilitate sliding it down the lead. If implanting multiple leads, tag the leads with ligature so that their position can be identified later.

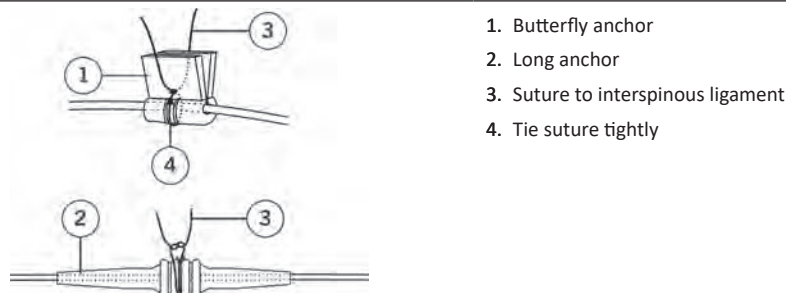
WARNING: Care should be taken not to bend the connector end of the lead when passing the long anchor over it.

Figure 16. Insert the anchor on the lead



6. Secure the lead within the lead anchor using 2-0 nonabsorbable suture (see the following figure).

Figure 17. Secure the anchor and the lead



WARNING:

- Do not use polypropylene or monofilament suture because of possible damage to the anchor and lead.
 - If the lead is not properly anchored, migration may occur.
 - Sutures placed directly on the lead without an anchor can cause permanent damage to the insulation and eventual failure of the lead.
 - Avoid sharp bends or kinking of the lead, or permanent damage may occur.
 - Suture the anchor to the interspinous ligament with 2-0 nonabsorbable suture. A strain relief for the lead should be created by coiling excess lead proximal to the lead anchor in loops no smaller than 2.5 cm (1 in.) in diameter.
7. Once anchored, the lead can be connected to an extension for trial screening or tunneled to the IPG site for system internalization.

Tunneling to the Pocket

Tunneling is usually done from the lead anchor site directly to the IPG pocket. However, when an extension is used or the IPG pocket is in the abdominal region, tunneling is done from the lead anchor site to a midpoint (where an incision and appropriate dissection have been performed) and then continued to the IPG pocket site.

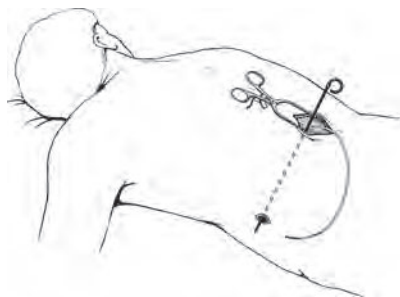
To tunnel from the lead anchor site to the IPG pocket:

CAUTION: Use extreme care so as not to damage a lead with the sharp point of the tunneling tool.

NOTE: The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.

1. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the IPG pocket.

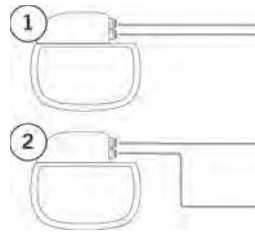
Figure 18. Suggested tunnel to the IPG pocket



2. Withdraw the tunneling tool from the cannula sleeve, leaving the cannula sleeve in the subcutaneous tunnel.

CAUTION: Multiple leads must be routed adjacent to one another. Patients with nonadjacent leads may experience changes in perceived stimulation from theft detectors and metal screening devices.

Figure 19. Correct way to route multiple leads

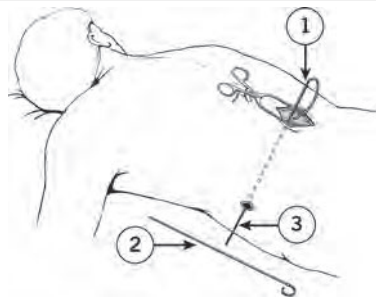


1. Correct
2. Incorrect

WARNING: It is possible that patients who are implanted with nonadjacent multiple leads may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting, when passing through antitheft devices or airport screening devices.

3. Carefully pass the end of the lead or leads through the cannula sleeve from the anchor site to the IPG pocket; or, if a two-step tunneling procedure is used, pass the lead or leads from the anchor site to the midway incision site and then to the IPG pocket. Multiple leads may be placed in the same tunnel.

Figure 20. Sequence of tunneling steps



1. Leave cannula sleeve in place
2. Remove tunneling tool
3. Pull lead through cannula sleeve to IPG pocket

4. Withdraw the cannula sleeve from the subcutaneous tunnel by passing it over the lead or leads, taking care not to cause traction on them.

Disposing of Explanted Components

Explanted Abbott Medical components should be returned to Abbott Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your Abbott Medical representative or Technical Support.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components according to the following conditions.

Table 1. Storage conditions for components

Long-term storage temperature	24°C (75.2°F)
Excursion temperature	-10°C to 55°C (14°F to 131°F)
Humidity	10% to 90% (noncondensing)
Pressure	70 kPa to 150 kPa (10.2 psi to 21.8 psi)

Product Materials

The following components are intended to come into contact with tissue.

Table 2. Product materials for percutaneous leads

Component	Material
Electrodes and terminal end contacts	Platinum iridium
Insulation	Polycarbonate polyurethane

Lead Specifications

Table 3. Percutaneous lead specifications

Description		Octrode™	Quattrode™ 3/4	Quattrode™ 3/6
				
Lead length and model	30 cm	3183	3143	3153
	60 cm	3186	3146	3156
	90 cm	3189	3149	3159
Lead diameter		1.4 mm	1.4 mm	1.4 mm
Electrodes				
Number		8	4	4
Length		3 mm	3 mm	3 mm
Longitudinal spacing		4 mm	4 mm	6 mm
Center-to-center spacing		7 mm	7 mm	9 mm
Array length		52 mm	24 mm	30 mm
Lead resistance (for all lengths)		<10 ohms	<10 ohms	<10 ohms
MRI status*				
MR Conditional		Model	3186, 3189	
MR Unsafe		Model	3143, 3146, 3149, 3153, 3156, 3159, 3183	

* The butterfly anchor (model 1105) and long anchor (model 1106), which are included in the lead kit, are MR Conditional components.

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 torque wrench (model 1101)
- 1 guide wire for percutaneous leads (model 1102)
- 1 Introduce-AK™ lead introducer (model 1103)
- 1 anchor, butterfly (model 1105)
- 1 anchor, long (model 1106)

- 1 tunneling tool, 12 in. (model 1112)

NOTE: A longer tunneling tool, 20 in. (model 1120) is available individually and can also be used with this kit.

- 1 epidural needle, 14 gauge, 4 in. (model 1114)

NOTE: Another epidural needle, 14 gauge, 6 in. (model 1116) is available individually and can also be used with this kit.

- 1 stylet, straight (model 1121, 1123, or 1125)
- 1 stylet, curved (model 1122, 1124, or 1126)

Appendix B: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 4. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Do not re-use
	Do not re-sterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Storage temperature limit

Table 4. Symbols and definitions

Symbol	Definition
	Excursion temperature limit
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Number of electrodes
	One lead
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	Single sterile barrier system with protective packaging outside
	Sterilized using ethylene oxide
	Authorized representative in the European Community

Table 4. Symbols and definitions

Symbol	Definition
	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-04
ARTEN600283823 A



Percutaneous Trial Lead Kit
Models 3046, 3086

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.	1
Intended Use.	1
Additional Prescription Information.	1
Warnings.	1
Precautions.	2
Adverse Effects.	3
Individualization of Treatment.	4
Product Description.	4
Package Contents.	4
Directions for Use.	4
Placing Percutaneous Leads.	4
Securing the Trial Lead.	8
Technical Support.	9
Appendix A: Product Specifications.	9
Storage Specifications.	9
Product Materials.	9
Compatibility Guidelines.	9
Lead Specifications.	10
Appendix B: Symbols and Definitions.	11

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The percutaneous leads covered in this manual are intended to be used with Abbott Medical neurostimulation systems by connecting to a compatible pulse generator, either directly or with a compatible lead extension during a trial period that shall not exceed 30 days.

Additional Prescription Information

Refer to the clinician's system manual for additional instructions and other important information, including indications for use, contraindications, warnings, precautions, and adverse effects related to the complete neurostimulation system.

Warnings

The following warnings apply to these components.

Magnetic resonance imaging (MRI). Patients with implanted neurostimulation systems should not be subjected to MRI. The electromagnetic field generated by an MRI may dislodge implanted components, damage the device electronics, and induce voltage through the lead that could jolt or shock the patient.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. Advise patients to inform their healthcare professional that they should not be exposed to diathermy treatment.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted IPG or lead. Contact between an active electrode and an implanted IPG or lead can cause severe injury to the patient. For additional electrosurgery information and guidance, refer to the clinician's manual for the appropriate IPG.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Device components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Precautions

The following precautions apply to these components.

General Precautions

Physician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. Caution should be exercised when spinal cord stimulation is used to control pain in patients with a psychiatric dependency upon their pain or upon drugs; in patients who will not be able to properly operate the device; or in patients who have a rapidly progressing disorder or a short life expectancy.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Implantation of two systems. If two systems are implanted, ensure that at least 30.5 cm (12 in.) separates the implanted IPGs to minimize the possibility of interference between the systems.

Implantation of multiple leads. If multiple leads are implanted, the leads should be routed to the IPG adjacent to each other in the tunnel. Nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy that could cause unwanted stimulation in the patient.

Stimulation parameters. Patients should be cautioned that stimulation parameters must be determined under the supervision of a physician and that they should not adjust stimulation parameters within prescribed programs except under direct orders from their physician.

Sterilization and Storage

Single-use device. The implanted components of this neurostimulation system are intended for a single use only. The components of this kit have been sterilized using ethylene oxide (EtO) gas and are supplied in packaging permitting direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason because of risk of infection and device malfunction.

Exposure to liquids. System components should be stored where they will not be exposed to liquids or excessive moisture, which can damage the seal integrity of the package materials.

Handling and Implementation

Expiration date. An expiration date (or “use-by” date) is printed on the packaging. Do not use a component if the use-by date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to Abbott Medical for evaluation.

Exposure to body fluids or saline. Exposure of the internal metal (such as contacts on the lead, the IPG, or extension) to body fluids or saline can cause corrosion and affect stimulation. If this occurs, clean with sterile deionized water or sterile water for irrigation and dry completely prior to lead connection and implantation.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Component disposal. Return all explanted components to Abbott Medical for safe disposal.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotripter, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted IPG.

External defibrillators. The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead.

Home and Occupational Environments

Lead movement. Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) during the trial period. Extension of the upper torso or neck may cause lead movement and alter the stimulation field (especially with leads in the cervical area), resulting in ineffective or overstimulation.

Adverse Effects

The use of a neurostimulation system involves risk. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration or local skin erosion
- Implant migration
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode site or IPG site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to implant materials
- Changes in blood glucose levels in response to any adverse effect

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Individualization of Treatment

Best results are obtained when the patient is fully informed about the therapy risks and benefits, implantation procedure, follow-up requirements, and self-care responsibilities. Spinal cord stimulation is appropriate for patients who meet the following criteria:

- Patients with chronic pain of the trunk or limbs, whose pain is physiological in origin and of the type treatable with neurostimulation
- Patients who are able to operate the device
- Patients who are suitable candidates for surgery and free of active general infections

Before a spinal cord stimulation system is implanted, the following conditions should be met:

- Patients have undergone a successful trial period
- Patients have demonstrated a willingness to participate in the treatment protocol

Product Description

Abbott Medical leads are designed for spinal cord stimulation (SCS) to aid in the treatment of chronic, intractable pain. SCS is a method of pain control that uses low-intensity electrical impulses to stimulate nerve fibers within the spinal cord, often inhibiting chronic pain messages from reaching the brain. Percutaneous leads are designed for introduction into the epidural space using a special needle. The lead assembly consists of 4 or 8 cylindrical electrodes spaced at precise intervals. Percutaneous leads are supplied with a stylet to aid in positioning.

Package Contents

The percutaneous trial lead kits contain the following:

Guide wire. Used to establish an appropriate pathway for the lead in the epidural space. The guide wire is 50 cm (20 in.) in length.

Lead anchor. Made of silicone and used to secure the lead to connective tissue for stability.

Epidural needle. Special 14-gauge needle designed for insertion of the percutaneous leads into the epidural space.

Introduce-AK™ lead introducer. (optional) Radiopaque sheath designed to facilitate the insertion of the percutaneous lead into the epidural space and placement at the appropriate site.

NOTE: The optional lead introducer is not available in some kit configurations.

Lead stylet. Inserted in the lead body to assist in steering and positioning.

Directions for Use

Carefully review the following suggested guidelines for implantation of percutaneous trial leads. If implanting multiple leads, repeat the appropriate steps for each lead. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

Placing Percutaneous Leads

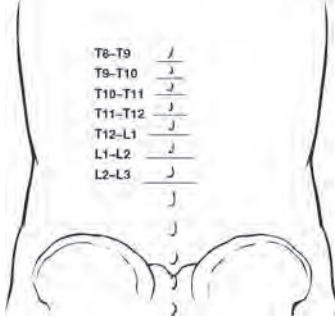
Percutaneous trial leads are designed for use during a trial implantation period **not to exceed 30 days**. They are designed for introduction into the dorsal epidural space using a special needle, a guide wire, and the optional Introduce AK™ lead introducer. Each lead is packaged with the accessories required to place the lead percutaneously. See Appendix A (page 9) for specifications.

The following are suggested guidelines for placing percutaneous leads. For these instructions, use fluoroscopy as needed to assist in placing a device.

1. Externally measure and determine the length of lead required to extend from the appropriate spinal level to the predetermined location of the implanted IPG. The appropriate vertebral level for needle entry should be identified and marked (see the following figure) to allow approximately 20 cm (8 in.) of the lead to lie in the epidural space. This will facilitate stabilization of the lead and electrodes following implantation. Typical entry levels for lead target sites include the following.

Figure 1. Suggested vertebral entry levels based on target sites

Lead Target Site	Entry Level
T8-T9*	T11-T12
T9-T10*	T12-L1
T10-T11	L1-L2
T11-T12	L2-L3
T1-T2	T4-T6
C3-C5	T1-T3
C1-C2	C6-C7



* Paresthesia mapping is not needed for subthreshold and paresthesia free therapy. For more information that supports the clinical use of the anatomical placement of leads and BurstDR™ stimulation, refer to the clinical summaries manual for SCS systems.

CAUTION: Handle the lead with care. The lead can be damaged by mishandling, such as sharp bending, kinking, applying excessive traction, or contact with sharp instruments. Carefully examine each component upon removal from its sterile container. A lead exhibiting signs of damage should not be used.

- After appropriate skin prepping, draping, and injection of local anesthetic, insert the epidural needle. A paramedian approach is recommended, and the needle angle should not be greater than 30° (see the following figures). Angles greater than 30° increase the risk of damage to the lead during insertion and manipulation.

Figure 2. Insert epidural needle using paramedian approach

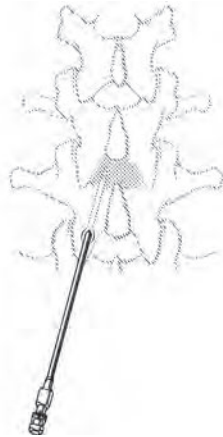
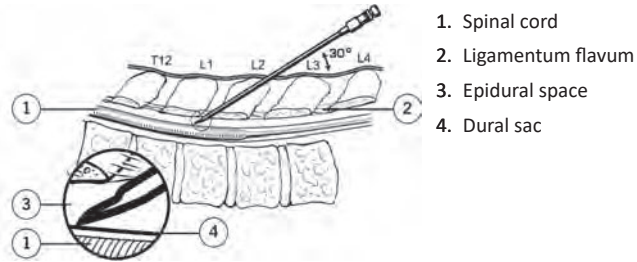
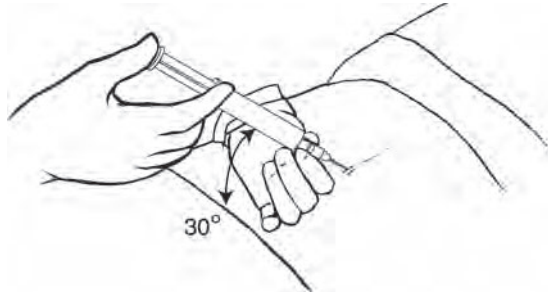


Figure 3. Insert needle at an angle of 30° or less



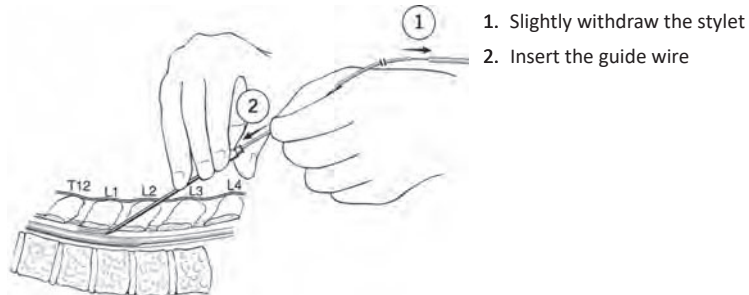
3. Confirm entry into the epidural space using standard methods such as the loss-of-resistance technique (see the following figure).

Figure 4. Use loss-of-resistance technique to confirm entry



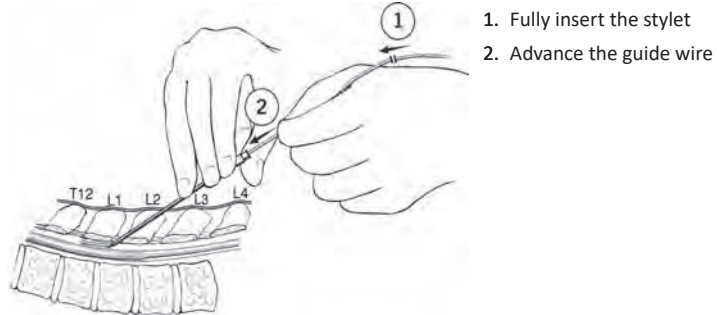
4. Under fluoroscopic guidance, insert the guide wire, with the stylet slightly withdrawn, through the needle into the epidural space (see the following figure). Withdrawing the stylet slightly increases the flexibility of the guide wire tip and minimizes the risk of a dural tear.

Figure 5. Insert the guide wire



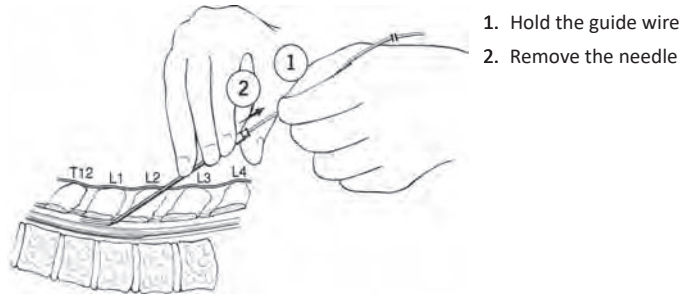
5. Once the tip of the guide wire is within the epidural space and slightly beyond the distal tip of the needle, fully reinsert the stylet and advance the guide wire to the desired target (see the following figure). When advancing the guide wire, it is very important to do so under fluoroscopic guidance and to manipulate the guide wire carefully to minimize the risk of dural tear.

Figure 6. Advance the guide wire to the target



6. If using the lead introducer to place the lead (optional), remove the needle using the hold-and-push technique, leaving the guide wire in the epidural space (see the following figure).

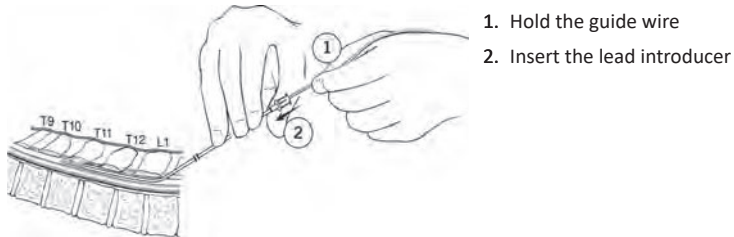
Figure 7. If using the lead introducer (optional), remove the needle



7. If using the lead introducer (optional), insert the lead introducer over the proximal end of the guide wire at the same angle (no more than 30°) as the previously placed needle (see the following figure). Advance the lead introducer into the epidural space under fluoroscopy to the target position.

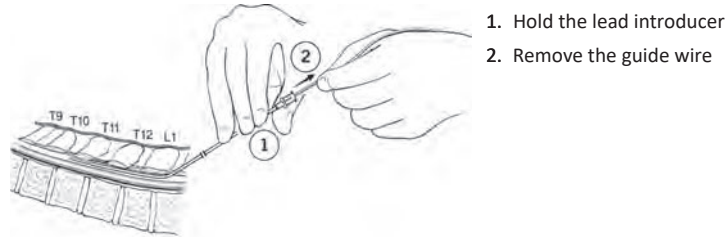
NOTE: It may be necessary to rotate the lead introducer as it passes through the ligamentum flavum.

Figure 8. If using the lead introducer (optional), insert the lead introducer



8. If using the lead introducer (optional), after the lead introducer reaches the desired spinal level for electrode placement, remove the guide wire (see the following figure).

Figure 9. If using the lead introducer (optional), remove the guide wire



9. Insert the lead through the lumen of the needle or the lead introducer (whichever is in place), and advance the lead to the target site under fluoroscopic control (see the following figure). To aid placement, percutaneous leads feature a removable stylet that provides added stiffness and facilitates control.

WARNING: If pulling the lead back through the needle, use caution to avoid severe damage to the lead due to shearing from the needle's tip.

Figure 10. Insert and advance the lead to the target

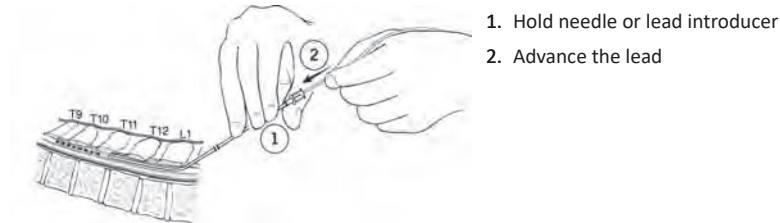
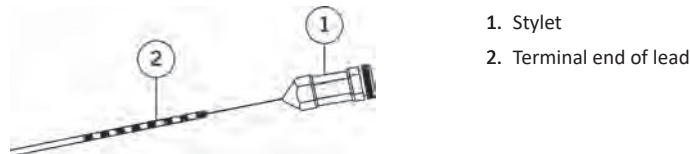


Figure 11. Use the stylet to help place the lead



10. Through fluoroscopic evaluation, confirm that the electrodes extend beyond the distal tip of the lead introducer or needle. If they do not, advance the lead or withdraw the lead introducer as necessary to expose the electrodes.

NOTE: Consider obtaining anteroposterior or lateral fluoroscopic imaging to confirm dorsal positioning of leads in the epidural space.

11. Perform intraoperative testing. See the clinician's manual for the appropriate trial stimulator for instructions.

Securing the Trial Lead

After the lead has been externalized, it should be connected to the trial cable and secured to the skin to guard against movement during the trial period. For instructions about using the trial cable, see the clinician's manual for that component.

1. Once proper lead placement has been confirmed, tape the trial lead securely to the skin with small adhesive strips.
2. Connect the trial cable to the trial lead if disconnected.
3. Loop the externalized lead and excess trial cable, and secure it to the patient's back with an appropriately sized adhesive drape. Leave sufficient trial cable length exposed to allow convenient connection to the trial stimulator.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components according to the following conditions.

Table 1. Storage conditions for components

Temperature	-10°C–55°C (14°F–131°F)
Humidity	10%–90% (noncondensing)
Pressure	70–150 kPa (10.2–21.8 psi)

Product Materials

The following components are intended to come into contact with tissue.

Table 2. Product materials for percutaneous leads

Component	Material
Electrodes and terminal end contacts	Platinum iridium
Insulation	Polycarbonate polyurethane

Compatibility Guidelines

Percutaneous leads are compatible with the following devices. For more information on these components, refer to the applicable clinician's manual.

Table 3. Devices compatible with the percutaneous leads

Device	Model Number
Introduce-AK™ lead introducer	1103
SCS accessory kit	1701

Lead Specifications

Table 4. Percutaneous lead specifications

Description		Octrode™	Quattrode™ 3/4
			
Lead length and model	60 cm	3086	3046
Lead diameter		1.4 mm	1.4 mm
Electrodes			
Number		8	4
Length		3 mm	3 mm
Longitudinal spacing		4 mm	4 mm
Center-to-center spacing		7 mm	7 mm
Array length		52 mm	24 mm
Lead resistance		<5 ohms	<5 ohms

Each kit listed in the previous table includes the following items:

- 1 lead
- 1 guide wire for percutaneous leads (Model 1102)
- 1 Introduce-AK™ lead introducer (optional) (Model 1103)

NOTE: The optional lead introducer is not available in some kit configurations.

- 1 anchor, butterfly (Model 1105)
- 1 anchor, long (Model 1106)
- 1 epidural needle, 14 gauge, 4 in. (Model 1114)

NOTE: Another epidural needle, 14 gauge, 6 in. (Model 1116) is available individually and can also be used with this kit.

- 1 stylet, straight (Model 1123)
- 1 stylet, curved (Model 1124)

Appendix B: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 5. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	Trial
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Do not re-use
	Do not re-sterilize
	Use-by date
	Date of manufacture
	Manufacturing facility
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Catalog number NOTE: This symbol also refers to the model number.

Table 5. Symbols and definitions

Symbol	Definition
	Manufacturer
	Packaging unit
	Number of electrodes
	One lead
	Accessories
	Serial number
	Batch code
	Unique Device Identifier
	Prescription use only
	Sterilized using ethylene oxide
	Authorized representative in the European Community
	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-04
ARTEN600283820 A



Abbott Medical External Pulse Generator
Spinal Cord Stimulation Systems
Model 3599

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.....	1
Intended Use.....	1
Indications for Use.....	1
Contraindications.....	1
Additional Prescription Information.....	1
Warnings.....	1
Precautions.....	4
Adverse Effects.....	7
Product Description.....	8
Overview of the EPG and EPG Header.....	9
Package Contents.....	10
Getting Started.....	11
Overview of the EPG Procedure.....	11
Replacing the EPG Batteries.....	12
Checking the Status of the EPG Batteries.....	15
Setting Up Communication Between the EPG and the Clinician Programmer and Patient Controller.....	16
EPG Indicator Light.....	16
Starting and Stopping Stimulation.....	17
Using the EPG.....	18
Compatibility Guidelines.....	19
Connecting the Multilead Trial Cable to the EPG.....	19
Disconnecting the Multilead Trial Cable from the EPG.....	20
Securing the Leads or Extensions.....	21

Connecting the EPG Header to the EPG.....	22
Connecting the Leads or Extensions to the EPG Header.....	22
Securing the EPG.....	24
Programming the EPG.....	24
Caring for the EPG.....	25
Handling the EPG.....	25
Cleaning the EPG.....	25
Storing and Transporting the EPG.....	26
Service and Ordering Information.....	27
Technical Support.....	27
Ordering Information.....	27
Appendix A: Product Specifications.....	28
EPG with Header.....	28
Appendix B: Regulatory Statements.....	31
Disposal Guidelines for Battery-Powered Devices.....	31
Statement of FCC Compliance.....	31
Statement of Compliance With License-Exempt RSS Standard (Canada).....	32
Statement of Compliance With Interference-Causing Equipment Standard (Canada).....	32
Identification Information for Product Registration.....	32
Product Classification Statement (CISPR 11, Class B).....	33
Wireless Technology Information.....	33
Radio Transmitter, Cables, Transducers.....	34
Quality of Service for Wireless Technology.....	35
Appendix C: Electromagnetic Compatibility Guidelines.....	37
Radio Frequency Information.....	42

Appendix D: Symbols and Definitions.	43

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The St. Jude Medical™ invisible trial system is intended to be used externally with Abbott Medical-approved trial leads and extensions to deliver trial stimulation for a maximum of 30 days.

Indications for Use

Refer to the Indications for Use Data Sheet for Abbott Medical spinal cord stimulation systems.

Contraindications

This neurostimulation system is contraindicated for patients who are unable to use the system. Neurostimulation should not be used on patients who are poor surgical risks, such as those with multiple illnesses or active general infections.

Additional Prescription Information

For information that supports the clinical use of the neurostimulation system and the anatomical placement of leads, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems (available online at medical.abbott/manuals).

Warnings

The following warnings apply to these components.

Other system components. Refer to the individual system component manuals for additional warnings and precautions related to those devices.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Explosive or flammable gases. Do not use the stimulator in an environment where explosive or flammable gas fumes or vapors are present, including hyperbaric chambers. The operation of the stimulator could cause them to ignite, causing severe burns, injury or death.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation device. Contact between an active electrode and an implanted lead or extension can cause direct stimulation of the tissue at the electrode site and cause severe injury to the patient. If use of electrocautery is necessary, first turn off the neurostimulation system.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can

as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Magnetic resonance imaging (MRI). Patients with an EPG should not be subjected to MRI. Even if the leads are removed the patient should not have an MRI if any part of a lead is still implanted.

Lead movement. Patients should avoid bending, twisting, stretching, or lifting objects over 2 kg (5 lb) for six to eight weeks postimplantation. Extension of the upper torso or neck may cause lead movement and alter the stimulation field, resulting in overstimulation or ineffective stimulation.

Operation of machines, equipment, and vehicles. Patients using therapy that generates paresthesia should turn off stimulation before operating motorized vehicles, such as automobiles, or potentially dangerous machinery and equipment because sudden stimulation changes may distract them from properly operating it. However, current data shows that most patients using BurstDR™ stimulation therapy do not experience paresthesia. For patients who do not feel paresthesia, sudden stimulation changes are less likely to occur and distract them while operating motorized vehicles, machinery, or equipment.

Postural changes. Changes in posture or abrupt movements can change the level of stimulation and potentially cause unpleasant sensations. Patients should turn stimulation off or lower the amplitude before stretching, lifting their arms over their head, or exercising. If unpleasant sensations occur, turn off stimulation.

Pediatric use. Safety and effectiveness of neurostimulation for pediatric use have not been established.

Pregnancy and nursing. Safety and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Use in patients with diabetes. Surgical complications and adverse effects may be more frequent and severe in patients with diabetes. The following additional considerations should be made for patients with diabetes:

- A pre-operative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) $\geq 8\%$ (64 mmol/mol).

- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor glucose levels as they may fluctuate as a response to surgery or to complications. Implanting physicians or anesthesiologists should consult practice guidelines for the intraoperative management of patients with diabetes.
- Closely monitor patients for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in patients with diabetes.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

System components. The use of components not approved for use by Abbott Medical with this system may result in damage to the system and increased risk to the patient.

Power supply. Use only the CR2450 batteries supplied with the device. CR2450 batteries have a nominal voltage of 3V and nominal capacity of at least 600 mAh.

Precautions

The following precautions apply to these components.

General Precautions

Clinician training. Clinicians should be experienced in implanting neurostimulation devices and should have undergone sufficient surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures and inform patients to avoid showering and touching the bandages.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the EPG and proceed with caution, being sure to move through the detector quickly.

Implantation of multiple leads. If multiple leads are implanted, leads and extensions should be routed in close proximity. Nonadjacent leads can possibly create a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.

Handling and Implementation

Single use only. The EPG header is intended for single use only.

Exposure to liquids. Device components should be stored where they will not be exposed to liquids or excessive moisture, which can damage the package materials and components.

Care and handling of components. Use extreme care when handling system components prior to use. Excessive heat, traction, bending, and twisting, or the use of sharp instruments may damage components and cause them to fail.

Package or component damage. Do not use the device if the package or components show signs of damage. Return any suspect components to Abbott Medical for evaluation.

System testing. To ensure correct operation, the system should always be tested before the patient leaves the surgery suite.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Component disposal. Dispose of the EPG header and pouch with other medical waste. Return the EPG to Abbott Medical for safe disposal when necessary.

Hospital and Medical Environments

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of a neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, computerized tomography (CT) scans, cobalt machines, and linear accelerators. If radiation therapy is required, disconnect the EPG from the leads or extensions. Damage to the system may not be immediately detectable.

Home and Occupational Environments

Electromagnetic interference (EMI). Certain commercial electrical equipment (for example, arc welders, induction furnaces, and resistance welders), communication equipment (for example, microwave transmitters, linear power amplifiers, and high power amateur transmitters), high voltage power lines, and radiofrequency identification (RFID) devices may generate sufficient EMI to interfere with the operation of the neurostimulation system if approached too closely. Keep the neurostimulation system at least 10 cm (4 in.) away from RFID devices.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, in hospitals, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the device and generator; however, it will not change the prescribed programmed parameters. Patients should be advised to keep their

mobile phones and smart watches at least 15 cm (6 in.) away from the generator and avoid placing any smart device in a pocket near the generator. If a patient is concerned about a smart device interacting with their neurostimulation system, consider disabling magnet mode. For more information about setting the magnet mode, refer to the clinician programmer manual or contact Technical Support.

Adverse Effects

The use of a neurostimulation system involves risks. In addition to those risks commonly associated with surgery, the following risks are also associated with use of a neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off stimulation immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Stimulation in unwanted places (such as radicular stimulation of the chest wall)
- Lead migration, causing changes in stimulation or reduced pain relief
- Epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space
- Cerebrospinal fluid (CSF) leakage
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the electrode or IPG site
- Seroma (mass or swelling) at the implant site
- Allergic or rejection response to device or implant materials
- Implant migration or skin erosion around the implant

- Battery failure
 - Changes in blood glucose levels in response to any adverse effect
- NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control. For adverse effects observed in the use of diabetic peripheral neuropathy, refer to the clinical summaries manual for SCS systems.

Product Description

The Abbott Medical External Pulse Generator (EPG) is an external trial generator that when connected to trial neurostimulation leads delivers therapeutic stimulation to parts of the body. The EPG communicates wirelessly with system programmers and controllers.

The EPG header connects directly to the EPG for a neurostimulation trial. The EPG header can hold one or more leads or extensions with up to 16 electrodes total.

NOTE:

- Patients may experience a sensation of tingling, “pins and needles”, pricking, or even burning called paresthesia. Paresthesia may be brief or it may last a long time.
- For more information about the neurostimulation system, see the clinician’s programming manual for this system.
- The EPG is supplied nonsterile and is intended to be used multiple times. The EPG header is also supplied nonsterile, but is single use only.

- In this document, the term “clinician programmer” refers to the NeuroSphere™ Clinician Programmer device, “patient controller” refers to the NeuroSphere™ Patient Controller device, “clinician programmer app” refers to the NeuroSphere™ Clinician Programmer app, and “patient controller app” refers to the NeuroSphere™ Patient Controller app.

Overview of the EPG and EPG Header

The following figures show the EPG and EPG header features.

Figure 1. EPG features

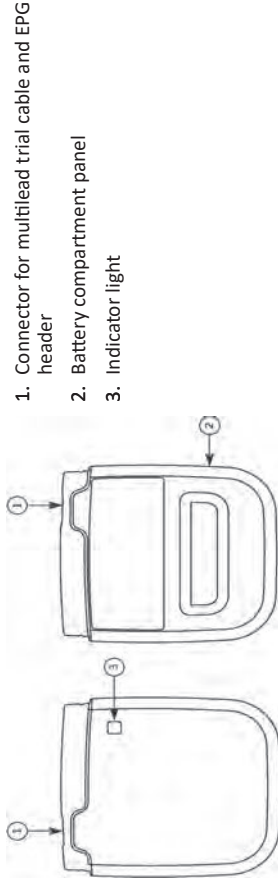


Figure 2. EPG header features



1. Button
2. Port 1, electrodes 1-8
3. Port 2, electrodes 9-16

Package Contents

In addition to the product documentation, the External Pulse Generator, 16 channel kit (Model 3599) contains the following items:

- 1 EPG (Model 3599)
- 1 EPG header cap
- 1 battery door

In addition to the product documentation, the External Pulse Generator, 2 Port Header kit (Model 3032) contains the following items:

- 1 EPG header
- 2 CR2450 Batteries
- Cleaning cloths
- 1 EPG pouch with adhesive

Getting Started

This section provides a general overview of the EPG procedure and instructions for tasks, such as replacing the batteries and setting up communication between the EPG and the clinician programmer and patient controller.

Overview of the EPG Procedure

The following steps provide a general overview of the EPG procedure. Refer to the following sections for more information about each of these steps.

1. Replace the EPG batteries.
2. Set up communication between the EPG and the clinician programmer and patient controller.
3. Implant the leads or extensions.
4. Connect the leads or extensions to the multilead trial cable.
5. Connect the multilead trial cable to the EPG.
6. Test the system.
7. Disconnect the multilead trial cable from the EPG.
8. Disconnect the multilead trial cable from the leads or extensions.
9. Secure the leads or extensions and bandage the lead entry site.
10. Connect the EPG header to the EPG.
11. Insert the leads or extensions into the EPG header.
12. Place the EPG into the pouch and secure to the patient.
13. Program the system.

Replacing the EPG Batteries

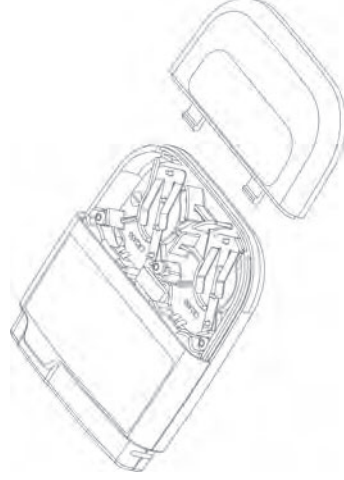
The EPG uses two nonrechargeable CR2450 coin cell batteries. Abbott Medical recommends replacing the batteries before starting a new trial and only using the batteries included in the External Pulse Generator, 2 Port Header.

NOTE: Dispose of batteries safely. Do not treat them as household waste. Refer to the guidelines in Appendix B (page 31) for more information.

To replace the batteries:

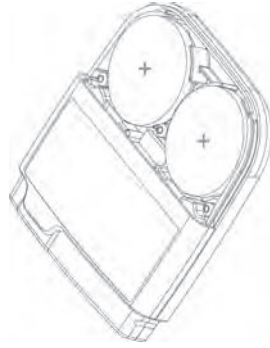
1. Disconnect the EPG header or multilead trial cable from the EPG if either is connected. Also, if the EPG is communicating with the clinician programmer or patient controller, end the session. Refer to the clinician's programming or user's controller manual for instructions.
2. Press and slide the battery compartment panel outward to open the battery compartment and remove the panel.

Figure 3. Battery compartment panel



3. Remove the batteries by either:
 - turning the EPG over so the battery compartment is facing down and lightly tapping the EPG in the palm of your hand, or
 - pressing down on one side of the battery so the opposite side pops up, lifting the battery out, and repeating the process with the remaining battery.
4. Insert a new battery into the battery compartment, paying attention to the polarity directions provided on the inside of the battery compartment.
5. Insert the second battery into the second battery compartment.

Figure 4. Inserting batteries into the battery compartment



6. Place the battery compartment panel flush to the EPG, lining up the tabs with the coordinating indentation.

Figure 5. Replacing the battery compartment panel



7. Slide the panel closed flush with the EPG until it snaps into place.

NOTE:

- When you insert the batteries, the indicator light is solid. You must wait until the indicator light is flashing or off to set up communication.

- If you replace the batteries but the generator battery indicator on the clinician programmer app or patient controller app indicates the batteries are low, make sure the batteries are inserted correctly.

Checking the Status of the EPG Batteries

Check the status of the EPG's batteries using the clinician programmer app or the patient controller app. Refer to the clinician's programming or user's controller manual for these directions.

NOTE: Battery life depends on usage and stimulation settings, with batteries lasting at least 14 days under nominal or practical high output tonic settings, with 500 ohm impedance and stimulation on for 16 hours per day. (High output is based on actual patient use collected in Abbott Medical clinical studies, not the maximum device output.)

The following information provides general guidelines for the battery status:

- The battery status icon on the clinician programmer app or patient controller app shows a decreasing fill as the batteries are used.
- A warning will appear on the clinician programmer app or patient controller app when the batteries are critically low.
- Stimulation will automatically turn off when the batteries cannot support stimulation. Replace the EPG's batteries to communicate with the EPG, turn stimulation on, change stimulation settings, or retrieve stimulation usage information.

NOTE: If the batteries deplete during a trial, instruct the patient to refrain from replacing the batteries to avoid disturbing the bandaging and lead position.

Setting Up Communication Between the EPG and the Clinician Programmer and Patient Controller

Before starting the surgical procedure, set up communication between the EPG and the clinician programmer and patient controller. The following steps outline the procedure for setting up communication. For further instructions, refer to the clinician's programming manual.

1. Place the magnet perpendicular to and centered directly over the front of the EPG for 10 seconds.

The indicator light on the EPG will start flashing.

2. Set up communication using the clinician programmer app or the patient controller app following the directions shown on the screen.

After setting up communication, the EPG is paired with that clinician programmer and patient controller. You will not need to pair them again unless another patient controller or more than four clinician programmers are paired to the EPG.

NOTE: Store paired EPGs and patient controllers together to reduce the number of times you need to set up communication.

EPG Indicator Light

The indicator light on the EPG will flash for the following reasons:

- When batteries are inserted into the EPG
- When a communication session with the clinician programmer app or patient controller app is started

- When the magnet is held for approximately 10 seconds over the EPG (signaling the EPG is ready to pair with the clinician programmer or patient controller)

NOTE: The EPG indicator light flashes faster when it is ready to pair than when batteries are inserted or a communication session is started.

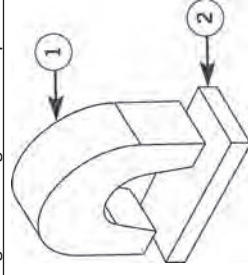
Starting and Stopping Stimulation

Use the clinician programmer app or the patient controller app to start or stop stimulation. You may also use the magnet (Model 1210) to start or stop stimulation if Magnet Mode is programmed to On/Off or Off.

To use the magnet:

1. Take the keeper bar off the magnet.

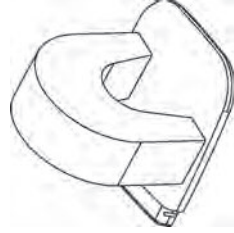
Figure 6. Magnet and keeper bar



1. Magnet
2. Keeper bar

2. Hold the magnet perpendicular to and centered directly over the EPG for 2 seconds.

Figure 7. Holding the magnet over the EPG



3. Remove the magnet, replace the keeper bar, and store the magnet.

CAUTION: Do not use the magnet around magnetically sensitive items to avoid damaging them.

Using the EPG

Read this section for directions for use related to the EPG and EPG header. For directions for use of other system components not covered in this document, see the clinician's manual for the appropriate device.

NOTE: Well in advance of the surgical procedure, set up communication between the EPG and the programmer and controller to ensure it is functional. Refer to "Setting Up Communication Between the EPG and the Clinician Programmer or Patient Controller" (page 16) for instructions.

CAUTION: Before the EPG or associated components are used or secured to the patient, determine if a patient may have an allergic reaction to the materials.

Compatibility Guidelines

The following table lists the trial cable and leads compatible with the EPG. For more information on these components, refer to the applicable clinician's manual.

Table 1. Trial cable and leads compatible with the EPG

Device	Model Number
Multilead trial cable	3013
Percutaneous trial leads	3046, 3086

Connecting the Multilead Trial Cable to the EPG

To connect a multilead trial cable to the EPG:

NOTE: For further instructions, refer to the clinician's manual for the multilead trial cable.

1. Remove the EPG header cap to expose the EPG stimulator port.
2. Carefully slide the connector end of the multilead trial cable into the EPG stimulator port.

CAUTION:

- The EPG is not sterile. When connecting and testing the EPG with the multilead trial cable, keep the EPG outside of the sterile field.
- To avoid delivering jolting stimulation to the patient, turn off stimulation before plugging in the multilead trial cable.

Figure 8. Inserting the connector into the EPG stimulator port



Disconnecting the Multilead Trial Cable from the EPG

To disconnect the multilead trial cable from the EPG:

NOTE: For further instructions, refer to the clinician's manual for the multilead trial cable.

1. Turn off stimulation on the EPG using the clinician programmer app.
2. Grasp the connector end of the multilead trial cable and gently pull the connector from the EPG stimulator port.

Securing the Leads or Extensions

The following information outlines the suggested procedure for securing the leads or extensions to the patient:

- Secure the leads or extensions and bandage the lead entry site. For further instructions, refer to the clinician's manual for the applicable leads or extensions.

Connecting the EPG Header to the EPG

To connect the EPG header to the EPG, align the tab indentation on the EPG header with the tab on the EPG and carefully insert the EPG header into the EPG body until it clicks into place.

Figure 9. Connecting the EPG header to the EPG



Connecting the Leads or Extensions to the EPG Header

To connect a lead or extension to the EPG header:

CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

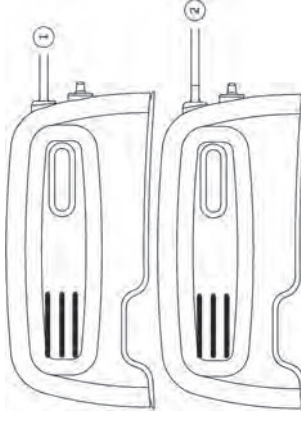
1. If any of the lead or extension contacts came in contact with body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.

CAUTION: Do not bend the lead sharply or it may be damaged.

NOTE: The EPG header comes with open ports and attached port plugs. Do not remove the port plugs from the header. If only using one lead or extension, use the lower port labeled 1-8 and insert a port plug in the unused port.

2. Push and hold the button on the EPG header to open the EPG header ports.
3. Using clean gloves, carefully slide the lead or extension into the EPG header until you reach a hard stop and all the contact bands are fully inside the connector assembly and hidden from view.

Figure 10. Insert the lead or extension fully into the EPG header



4. Release the button to lock the lead or extension into place.
5. If applicable, repeat the previous steps to insert the remaining lead or extension. Do not disturb the already inserted lead or extension.

Securing the EPG

To secure the EPG to the patient:

1. Place the EPG into the provided pouch.
2. Remove the adhesive liner on the pouch flap.
3. Use the flap to secure the leads in place and seal the pouch.

NOTE: The EPG meets the IP22 rating when sealed in the pouch.

4. Remove the adhesive liner on the back of the pouch and press the pouch onto the patient's skin until it is secure.

NOTE:

- It is good practice to secure the EPG pouch away from the lead entry site bandaging.
- Leave some slack in the leads or extensions when securing the EPG onto the patient.
- 5. Use additional medical tape to secure the pouch and leads or extensions further as needed.

Programming the EPG

Use the clinician programmer app to program the system for the trial period. For information on using the clinician programmer app for programming, refer to the clinician's programming manual.

Caring for the EPG

The EPG is an important part of the neurostimulation system. This section provides tips and other information about caring for the EPG.

Handling the EPG

- Do not expose the EPG to prolonged direct sunlight.
- Avoid exposing the EPG to sand, dust, and other environmental hazards.
- Do not put heavy or sharp objects on the EPG.
- Keep the EPG away from food and beverages, and avoid getting the EPG wet.
- If the EPG does get wet, do not use it. Contact Technical Support for help.

Cleaning the EPG

- Using two PDI Sani-Cloths, wipe the EPG for 2 minutes front and back, then allow to air dry. Once the EPG is dry, attach the header cap.

NOTE: Clean the EPG before attaching the header cap.

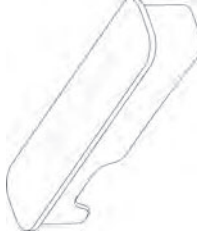
- Clean the EPG by thoroughly wiping off its outer surface using the provided cleaning cloths. Do not wipe over the stimulator port. Do not submerge the EPG in fluid or use a cloth that is soaking wet.
- Never use ammonia, acidic, or alkaline cleaners or organic chemicals such as paint thinner, acetone, propyl alcohol, or kerosene. They may damage surface finishes of the EPG.

Storing and Transporting the EPG

- Store the EPG and batteries in a cool, dry place. Do not store the EPG or batteries in your car or garage.
- Transport the EPG in a carrying case.
- If you are carrying the EPG in a briefcase or other carrying case, make sure no objects in the case are pressing on the device.
- Store paired EPGs and patient controllers together to reduce the number of times you need to set up communication.
- At the end of a trial, disable stimulation, clean the EPG, and attach the header cap before storing the EPG.

NOTE: During a trial store the header cap for reuse.

Figure 11. EPG header cap



Service and Ordering Information

This section provides information for contacting Technical Support and for ordering replacement parts and accessories.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Ordering Information

To order parts, contact Technical Support. Refer to the following list for model numbers.

Table 2. Ordering information for the EPG

Model	Description
3599	External Pulse Generator, 16 channel
3032	External Pulse Generator, 2 Port Header
1212	Coin cell batteries
1917	Battery door

Table 2. Ordering information for the EPG

Model	Description
3013	MLTC
1210	Magnet
1203	Box of cleaning cloths
1216	EPG header cap
1213	Pouch with adhesive (5)
1214	Pouch without adhesive and belt (5)
1218	Carrying case

Appendix A: Product Specifications
EPG with Header

The EPG (Model 3599) and EPG header (Model 3032) has the following physical specifications.

Table 3. EPG and EPG header specifications

Height	79.8 mm (3.14 in.)
Width	57.2 mm (2.25 in.)

Table 3. EPG and EPG header specifications

Thickness	11 mm (0.433 in.)
Weight (with batteries)	44 g (1.55 oz)
Volume	44.57 cc (2.72 cu in.)
Power source	Nonrechargeable CR2450 coin cell
Lead or extension compatibility	2 Octrode™ leads
Expected service life	5 years
Storage temperature	-25°C - 70°C (-13°F - 158°F)
Operating temperature	5°C - 40°C (41°F - 104°F)
Storage humidity	up to 93% (noncondensing)
Operating humidity	15% - 93% (noncondensing)
Storage pressure	70 - 106 kPa (10.2 - 15.4 psi)
Operating pressure	70 - 106 kPa (10.2 - 15.4 psi)

Table 4. Operating parameters for the EPG

	Tonic Range	Tonic Steps	Burst Range *	Burst Steps*
Pulse width	50 - 500 μ s	10 μ s	50 - 1000 μ s	50 μ s
Frequency	2 - 200 Hz	2 Hz	—	—
	200 - 500 Hz	10 Hz		
	500 - 1200 Hz	20 Hz		
Burst rate frequency	—	—	10 - 60 Hz	10 Hz
Intra-Burst frequency	—	—	250 - 500 Hz 500 - 1000 Hz	10 Hz 20 Hz
Amplitude	0 - 25.5 mA	0.1 - 1.0 mA	0 - 12.75 mA	0.05 - 0.50 mA
Stimulation output	Constant current		Constant current	

NOTE:

- Columns with * represent operating parameters for BurstDR™ stimulation programs on EPGs capable of BurstDR stimulation mode.
- The maximum current depends on the impedance, frequency, and pulse width settings.

Appendix B: Regulatory Statements

Disposal Guidelines for Battery-Powered Devices

Do not dispose of this device or its battery along with general waste. Follow local regulations for the safe disposal of the battery, and return the device to Abbott Medical at the end of its operating life.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.
- Operation is subject to the following two conditions:
- This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause undesired operation.
- Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Statement of Compliance With License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Statement of Compliance With Interference-Causing Equipment Standard (Canada)

This ISM device complies with Canadian ICES-001.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 5. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2SJMX59EPG
Industry Canada (IC) Registration Number	8454A-SJMX59EPG

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® Low Energy (LE) wireless technology as it is implemented in the device.

Table 6. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Embedded ceramic antenna
Antenna dimensions	4 mm x 3 mm x 1.1 mm
Modulation	GFSK
Magnetic Field Strength (at 10 m distance)	0.000145 A/m maximum
Electric Field Strength	0.055 V/m maximum
Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
Range	2 meters typical
Center frequency	2.44 GHz
Channel	40 logical channels

Table 6. Bluetooth® Low Energy (LE) wireless technology information

Bandwidth	2 MHz per channel
Data rate	1 Mbit/s
Data flow	Bi-directional
Protocol	Bluetooth LE wireless technology

*EIRP = Equivalent isotropically radiated power

Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15 dB): 2.398 to 2.4855 GHz
- Channel: 40 logical channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- Magnetic field strength: 0.000145 A/m
- Duty Cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the EPG and the clinician programmer or patient controller. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol is grayed out.

The raw Bluetooth LE data rate is approximately 2.5 KB/sec and the effective data rate is approximately 1.5 – 2 KB/sec. Other requirements include a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully. Each key press may transmit up to 8 data packets, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator will encrypt its wireless communication.
- Only one patient controller or clinician programmer may communicate with the generator at the same time.
- A unique key for each unit that is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth® Low Energy (LE) wireless technology, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator.

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the generator and the clinician programmer or patient controller, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the clinician programmer or patient controller app, and turn the clinician programmer or patient controller off and on.
- Wait a few minutes and try connecting again.

- Do not operate other wireless devices (such as laptop, tablet, mobile phone, or cordless phone) at the same time.

NOTE: Wireless communication equipment (such as wireless home network devices, mobile and cordless telephones, and tablets) can affect the device.

Appendix C: Electromagnetic Compatibility Guidelines

The EPG, hereafter the device, is medical equipment and should be used with the following guidance.

The device requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The device was tested for basic safety and essential performance, as defined by IEC 60601-1/AMD1:2012 (Edition 3.1). Performance of the device was maintained during electromagnetic disturbance testing.

The device is intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

CAUTION:

- The device complies with the limits for medical devices contained in IEC 60601-1-2:2014-04, CISPR11:2015 (BS EN 55011:2016), and ETSI EN 300 328 V2.1.1 (2016-11). However, the device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device.
- To avoid increasing emissions or decreasing immunity from a device or system, use only components approved by Abbott Medical with this system. Do not use Abbott Medical components with devices or systems that are not approved by Abbott Medical.

Table 7. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The device produces RF emissions as a result of its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 8. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 15%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	No guidance for battery-powered devices.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	Not applicable	No guidance for battery-powered devices.
Voltage dips, short interruptions IEC 61000-4-11	<5% U _T 40% U _T 70% U _T	Not applicable	No guidance for battery-powered 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.

Table 8. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	The device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Recommended minimum separation distance for higher immunity test levels
	6 Vrms (ISM/Radio bands between 150 kHz to 80 MHz) 80% AM at 1 kHz	6 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m	

$$E = \frac{6}{d} \sqrt{P}$$

where P is the maximum power in watts (W), d is the recommended separation distance in meters (m), and E is the immunity test level in volts per meter (V/m).

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 9. Guidance and Manufacturer's Declaration – Proximity Fields

Proximity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz pulse modulation	27 V/m	Recommended minimum separation distance $d = 0.3$ m
	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	
	810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz pulse modulation	28 V/m	
	1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz pulse modulation	28 V/m	
	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	

WARNING: Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the device, including cables specified by Abbott Medical. Otherwise, performance degradation may occur.

Radio Frequency Information

The effective radiated power is below the limits as specified in:

- USA: FCC 47 CFR Part 15:2012
- Canada: RSS-210 Issue 8
- Europe: ETSI EN 301 489-1 V2.2.0 (2017-03) and ETSI EN 301 489-17 V3.2.0 (2017-03)

NOTE: Maintain a reasonable distance between other electronic equipment and the device.

CAUTION: The ISM band used by this device has been approved by the Federal Communications Commission for unlicensed use. However, there is no guarantee that this device will not receive interference or that any particular transmission from this device will be free from interference.

Appendix D: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

Table 10. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
	Follow instructions for use on this website
	Type BF Applied Part

Table 10. Symbols and definitions

Symbol	Definition
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Non-ionizing electromagnetic radiation
	Keep dry; keep away from rain
	Do not re-use
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Use-by date

Table 10. Symbols and definitions

Symbol	Definition
	Date of manufacture
	Manufacturing facility
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged

Table 10. Symbols and definitions

Symbol	Definition
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturer
	Packaging unit
	Implantable device
	Accessories
	Prescription use only
	Serial number
	Batch code

Table 10. Symbols and definitions

Symbol	Definition
	Unique Device Identifier
	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
	Authorized representative in the European Community
	European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.neuromodulation.abbott/euconformity.

Table 10. Symbols and definitions

Symbol	Definition
	This device is listed by Nationally Recognized Testing Laboratory (NRTL) as certified.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-04
ARTEN600283817 A



NeuroSphere™ Clinician Programmer
Eterna™ Spinal Cord Stimulation System
Model 55600

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2023 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.....	1
Intended Use.....	1
Indication for Use.....	1
Contraindications.....	1
Additional Prescription Information.....	1
MRI Safety Information.....	2
Warnings.....	2
Precautions.....	4
Adverse Effects.....	6
Product Description.....	7
Overview of the Clinician Programmer.....	7
Setting Up the Clinician Programmer.....	8
Initial Setup.....	8
Installing the Hub App.....	9
Installing the Clinician Programmer App.....	10
Registering the Clinician Programmer.....	11
Navigating the Home Screen.....	12
Pairing Devices With the Clinician Programmer and Patient Controller.....	13
Pairing the Clinician Programmer With a Generator.....	13
Enrolling a Patient.....	15
Pairing the Clinician Programmer With a Charger.....	17
Preparing the Generator for Implantation.....	18
Charging the Generator Before Implantation.....	18

Entering the Generator Name and Implant Date.....	19
Entering Patient Information.....	19
Placing the Generator in Surgery Mode.....	20
Programming with the Clinician Programmer App.....	21
Creating a New Programming Session.....	21
Selecting the Lead Configuration.....	24
Configuring Electrode Polarities.....	25
Starting and Stopping Stimulation During a Programming Session.....	26
Switching Between Tonic Mode and BurstDR™ Mode.....	27
Adjusting Pulse Width.....	28
Adjusting Amplitude and Step Size.....	28
Adjusting Frequency for Tonic Programs.....	29
Setting Perception and Comfort Amplitudes for Tonic Programs.....	29
Adjusting Frequency for BurstDR™ Programs.....	31
Setting the Target Amplitude for BurstDR™ Programs.....	31
Adding an Area to a Tonic Program.....	32
Removing or Editing an Area in a Tonic Program.....	32
Increasing or Decreasing the Number of Burst Pulses.....	33
Setting the Patient Controller Custom Settings.....	33
Creating a Stimulation Map.....	33
Measuring Impedance.....	34
Using the Shifting Programming Feature.....	35
Using the MultiSteering™ Programming Feature.....	36
Adding a New Program.....	37
Changing the Active Program.....	37
Copying a Selected Program.....	37

Modifying Program Options.....	38
Using the Active Balancing™ Programming Feature.....	41
Saving a Program.....	42
Setting Personally Identifiable Information (PII).....	43
Managing Programs on the Generator.....	45
Adding, Deleting, or Renaming a Program.....	46
Modifying Patient Settings.....	47
Viewing Generator Details.....	48
Setting a Generator to MRI Mode.....	49
Emailing a Generator Log.....	50
Viewing Charger Details.....	50
Updating Generator and Charger Software.....	51
Checking the Status of the Generator Battery.....	53
Checking the Status of the Charger Battery.....	54
Managing Patient Records.....	55
Deleting a Patient Record from the Database.....	57
Viewing, Emailing, and Printing a Report.....	57
Maintaining the Clinician Programmer.....	62
Checking the Status of the Clinician Programmer Battery.....	62
Caring for the Clinician Programmer.....	63
Cybersecurity.....	63
Legal and Privacy Notice.....	64
Troubleshooting.....	65
Troubleshooting Chart.....	66
Technical Support.....	79

Appendix A: Group ID List.	79
Appendix B: Buttons and Icons on Screens and Popovers.	81
Appendix C: Regulatory Statements.	90
Statement of FCC Compliance.	90
Identification Information for Product Registration.	91
Product Classification Statement (CISPR 11, Class B).	92
Wireless Technology Information.	92
Quality of Service for Wireless Technology.	93
Wireless Security Measures.	94
Troubleshooting for Wireless, Coexistence, or Interference Issues.	95
Appendix D: Radio Frequency Information.	96
Appendix E: Electromagnetic Compatibility Guidelines.	96
Appendix F: Symbols and Definitions.	97

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The clinician programmer and the patient controller applications are intended to communicate with pulse generators to manage stimulation programs. The applications allow clinicians to create customized therapy and help patients manage their prescribed stimulation programs.

Indication for Use

Refer to the clinician's manual for the appropriate neurostimulation system.

Contraindications

Refer to the clinician's manual for the appropriate neurostimulation system.

Additional Prescription Information

Refer to the clinician's manual for the appropriate neurostimulation system to get additional prescription information, including indications for use and contraindications. For specific instructions, warnings, precautions, and adverse effects about other system components, see the clinician's manual for those components.

For information that supports the clinical use of the neurostimulation system and the anatomical placement of leads, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems (available online at medical.abbott/manuals).

MRI Safety Information

For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Do not bring the clinician programmer into a scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is considered MR Unsafe.

Warnings

The following warnings apply to the clinician programmer and application.

NOTE: For nontherapy-related warnings regarding the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/guide.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off.

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an

electrosurgery device, place the neurostimulator in Surgery Mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure.

During implant procedures, if electrosurgery devices must be used, take the following actions:

- Use bipolar electrosurgery only.
- Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Set the electrosurgery device to the lowest possible energy setting.
- Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.

Interference with other devices. Some of this system's electronic equipment, such as the programmer and controller, can radiate radiofrequency (RF) energy that may interfere with other electronic devices, including other active implanted devices. Avoid placing equipment components directly over other electronic devices. To correct the effect of interference with other devices, turn off the equipment or increase the distance between the equipment and the device being affected.

Keep dry to avoid damage. Your clinician programmer is not waterproof. Keep it dry to avoid damage. Do not use the clinician programmer when engaging in activities that might cause them to get wet.

System components. The use of components not approved for use by Abbott Medical may result in damage to the system and increased risk to the patient.

Device modification. This clinician programmer is not serviceable by the customer. To prevent injury or damage to the system, do not modify the clinician programmer.

Application modification. To prevent unintended stimulation, do not modify the operating system or application in any way.

Stimulation modes. The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

Precautions

The following precautions apply to the clinician programmer and application.

NOTE: For nontherapy-related precautions regarding the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/guide.

General Precautions

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances or render the patient incapable of controlling the generator. If unpleasant sensations occur, turn off stimulation immediately.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite information on radiation effects is available. Sources of therapeutic radiation include therapeutic X-rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted generator should be shielded with lead. Damage to the system may not be immediately detectable.

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent

multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Patients should cautiously approach such devices and should request help to bypass them. If they must go through a gate or doorway containing this type of device, patients should turn off their generator and proceed with caution, being sure to move through the device quickly.

Device Precautions

Nonsterile device. The clinician programmer is a nonsterile device and must be kept out of the sterile field (patient environment).

Device inspection. Before operating the system each time, inspect the clinician programmer and all its components for mechanical and electrical integrity. Avoid using the system if the clinician programmer or its components are damaged. If damage is observed, contact Technical Support.

Handle the device with care. The clinician programmer is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground, or exposure to extreme hot or cold temperatures. For more information, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/guide.

Programmer use. Allow only authorized use of the clinician programmer to avoid any programming changes that may injure a patient.

Application Precautions

Clinician training. Clinicians should be familiar with neurostimulation therapy and be experienced diagnosing and treating the indication for which the neurostimulation system is being used.

Patient training. Instruct patients to use their neurostimulation system only after an authorized clinician has programmed the generator and has trained the patient on how to safely control stimulation and to charge the system.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Consumer goods and electronic devices. Magnetic interference with consumer goods or electronic devices that contain magnets, such as mobile phones and smart watches, may unintentionally cause the neurostimulation system to turn on or turn off or affect communication between the device and generator; however, it will not change the prescribed programmed parameters. Patients should be advised to keep their mobile phones and smart watches at least 15 cm (6 in.) away from the generator and avoid placing any smart device in a pocket near the generator. If a patient is concerned about a smart device interacting with their neurostimulation system, consider disabling magnet mode. For more information about setting the magnet mode, refer to the clinician programmer manual or contact Technical Support.

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this clinician programmer, please ask for authorization to use it before turning it on.

Adverse Effects

Refer to the Eterna™ implantable pulse generator clinician's manual for a complete list of adverse effects related to the use of the Eterna™ SCS system.

Product Description

The NeuroSphere™ Clinician Programmer application (app) (model 55600) allows the clinician to communicate wirelessly through Bluetooth® wireless technology with the Eterna™ implantable pulse generator (also referred to as IPG, neurostimulator, or generator) and to create and modify therapy programs for generators paired with the clinician programmer. The clinician programmer app also allows the clinician to retrieve diagnostic data from generators and to view and retrieve data from the charging system.

NOTE:

- For more information about a system component not covered in this manual, see the applicable clinician's manual for the component.
- In this document, the term “clinician programmer” refers to the NeuroSphere™ Clinician Programmer device, “patient controller” refers to the NeuroSphere™ Patient Controller device, “clinician programmer app” refers to the NeuroSphere™ Clinician Programmer app, and “patient controller app” refers to the NeuroSphere™ Patient Controller app.

Overview of the Clinician Programmer

The clinician programmer is an Apple® iOS® device provided by Abbott Medical.

Before you begin, be sure you are familiar with how to perform these basic operational functions on the clinician programmer.

- Turning the clinician programmer on and off
- Placing the clinician programmer in sleep mode
- Waking the clinician programmer from sleep mode
- Locking and unlocking the clinician programmer

- Using touchscreen functions such as tap and screen swipe actions
- Returning to the Home screen

NOTE: For nontherapy-related information on how to use the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals.

Setting Up the Clinician Programmer

This section contains information about setting up the clinician programmer in order to install, register, and begin using the clinician programmer app.

Initial Setup

To perform the initial setup of the clinician programmer:

1. Turn on the device.
2. Follow the prompts until you reach the home screen.
3. Enter the following web address in the browser: <https://sjm.awmdm.com>
4. When prompted, enter the Group ID and tap **Next**.

NOTE: The Group ID varies depending on where the device is used. See “Appendix A: Group ID List” (page 79) for the Group ID of your location.
5. Enter your Abbott Medical username and password and tap **Next**.
6. If prompted to save this password, tap **Never for This Website**.
7. Tap **Download Profile** when the Enable Device Management screen appears.
8. Tap **Allow** when prompted to download a configuration profile.

9. Tap **Close** when the Profile Downloaded message appears.
10. Open the Settings app and tap **Profile Downloaded**.

NOTE: If Profile Downloaded does not appear, tap **General > VPN & Device Management > Workspace Services**.

11. Follow the prompts and confirm all messages to install the mobile device profile, Intelligent Hub app, and clinician programmer app.

NOTE: It may take 1 or 2 minutes for the prompts to appear.

12. Open the Hub app and follow the prompts to activate the Hub app.

NOTE: The Hub app is required and must be activated to use the clinician programmer app. It may take 1 or 2 minutes for the prompts to appear after opening the Hub app. If the Hub app is not installed, follow “Installing the Hub App” (page 9) instructions.

13. Proceed to the “Registering the Clinician Programmer” (page 11) section.

Installing the Hub App

The Hub app is required and must be activated in order to use the clinician programmer app.

If the Hub app is not installed, follow these steps to install the Hub app:

1. Make sure the device is turned on and connected to the internet.
2. Open the App Catalog app.

NOTE: The App Catalog app is automatically installed on the clinician programmer after completing the initial setup.

3. Tap **Install** or **Update** next to the Hub app. If the Hub app does not appear, tap **MENU** in the top-left corner and tap **Abbott Neuromodulation** under CATEGORIES.
4. If prompted to confirm the installation, tap **Install**.

When the installation is complete, the Hub app icon automatically appears on the device's home screen. If the app icon does not appear after a few minutes, repeat the steps above for installing the Hub app. Tap **Processing** if it appears next to the Hub app in step 3, then proceed with step 4.

Installing the Clinician Programmer App

NOTE: The clinician programmer app is compatible with the Apple® iPad® mobile digital device provided by Abbott Medical. The patient controller app is compatible with an Apple iOS® mobile digital device (either a device provided by Abbott Medical or a compatible personal Apple iOS device).

If the clinician programmer app is not installed, follow these steps to install the clinician programmer app.

1. Make sure the device is turned on and connected to the internet.
2. Open the App Catalog app.

NOTE: The App Catalog app is automatically installed on the clinician programmer after completing the initial setup.

3. Tap **Install** or **Update** next to the CP app for Eterna™ SCS System. If the CP app for Eterna™ SCS System does not appear, tap **MENU** in the top-left corner and tap **Abbott Neuromodulation** under CATEGORIES.

4. If prompted to confirm the installation, tap **Install**.
When the installation is complete, the CP app icon automatically appears on the device's home screen. If the app icon does not appear after a few minutes, repeat the steps for installing the clinician programmer app. Tap **Processing** if it appears next to the CP app in step 3, then proceed with step 4.

Registering the Clinician Programmer

To register the clinician programmer, you must enter a one-time verification code. The one-time verification code is sent through the Hub app and appears in the Notification Center.

NOTE: You must allow notifications for the Hub app in order to receive the one-time verification code. You can enable notifications in the Hub app popover or in the iOS® settings.

To register the clinician programmer, follow these steps:

1. Ensure the device is turned on and connected to the internet.
2. Open the clinician programmer app.

NOTE: The first time you launch the clinician programmer app, you must accept the terms of use and privacy policy. Each time the terms of use or privacy policy is updated, you will receive a notification. You can view these notices at any time by tapping ⓘ on the clinician programmer Home screen and navigating to the Legal & Regulatory tab.

3. Enter the device passcode or scan your biometric.

NOTE: Biometrics such as Touch ID are configured in the iOS settings.

4. Enter the one-time verification code.

NOTE: If needed, tap **Send New Code** to receive a new one-time verification code.

5. Tap **Register**.

NOTE: Your registration has an expiration date that requires registering again in order to enroll new patient generators. When your registration is nearing expiration, you will receive a notification to register your clinician programmer.

Navigating the Home Screen

When you start a session with the clinician programmer app, the Home screen appears. From the Home screen, you can do the following:

- Tap **Devices** to locate a generator for programming.
- Tap **Patient Records** to add and edit patient information.
- Tap **Demonstration Mode** to view and edit simulated programs.
- Tap ⓘ to open the Information popover.
 - Tap ⓘ to edit clinician contact information and to choose whether or not to include clinician information when sending reports.
 - Tap ⓘ to export the programmer log and programmer database as well as view general information such as software and legal and regulatory information.

Pairing Devices With the Clinician Programmer and Patient Controller

For the clinician programmer and patient controller to communicate with a generator and charger, the clinician programmer and patient controller must be paired with the generator and charger. The clinician must also enroll the patient on the clinician programmer for the patient to use the patient controller app. This section contains information about pairing the clinician programmer with a generator, enrolling a patient, and pairing the clinician programmer with a charger.

Pairing the Clinician Programmer With a Generator

Pairing refers to setting up communication between the clinician programmer and the generator.

NOTE:

- You can pair the clinician programmer with multiple generators; however, only one communication session can be active at a time. Additionally, the clinician programmer cannot be paired with a generator while the generator is communicating with a patient controller.
- A generator can be paired with multiple clinician programmers and patient controllers, for a total of 8 devices. Once the maximum number of pairings is reached, the generator will automatically delete the oldest pairing.
- Before the app can establish communication with the generator, a prompt may display requesting the user to allow Bluetooth® wireless technology access. Tap **OK** to allow Bluetooth® wireless technology access. Otherwise, the app will be unable to communicate with the generator. You can also enable Bluetooth® wireless technology in the iOS® settings.

To pair the clinician programmer with the generator, follow these steps:

1. Ensure the clinician programmer is turned on and connected to the internet.
2. Tap the clinician programmer app. The clinician programmer app launches.
3. Place the clinician programmer within Bluetooth® wireless technology range (3 ft or 0.9 m) of the generator.
4. Place the magnet over the generator for approximately 15 seconds.
5. Tap **Devices** on the clinician programmer Home screen. The Select Device popover opens. Devices that are ready to be paired appear with an unlock symbol. Devices associated with a patient will appear with the patient name under the device name. Upon successful pairing, the Program screen appears on the clinician programmer.

NOTE: If a No Device Found message appears, tap  to try again. If the pairing was not successful, the generator may be out of range of the clinician programmer.

If a pairing is lost between the clinician programmer and a generator, follow these steps:

1. In the clinician programmer iOS® settings, tap **Bluetooth**.
2. Tap the generator or charger.
3. Tap .
4. Tap **Forget This Device**.
5. If desired, pair the clinician programmer and generator again.

Enrolling a Patient

Enrolling refers to assigning a patient to a generator. A patient can be enrolled during or after the initial pairing.

To enroll a patient during initial pairing, do the following:

1. On the Select Device popover, tap the generator you are pairing. The Enroll Patient popover opens.
2. Enter the patient name and date of birth to assign the generator to a new patient or select an existing patient to assign to the generator.

NOTE:

- The same date of birth must be used by the patient to access the generator on the patient controller.
- When pairing a generator for the first time, the patient name field is populated with a generic name and can be edited.

3. Tap **Enroll** to complete the pairing of the clinician programmer and the generator; otherwise, tap **Skip** to enroll the patient at a later time.

NOTE:

- The Enroll button is only active when the date of birth of the patient is populated. If you tap **Skip**, the dialog box closes and a generic patient name is assigned to the generator.
- The date of birth cannot be edited after enrollment is submitted. To change the date of birth, create a new enrollment. To change the generator assigned to a patient, create a new pairing and enrollment.

To enroll a patient after the initial pairing by creating a new patient record, do the following:

1. From the Patient Records screen, tap **Create New Patient**. The Add Patient popover opens.

2. Enter the patient information.
 3. Tap **Add** to create the new record and return to the Patient Records screen. Or tap **Cancel** to return to the Patient Records screen without creating a new record.
 4. Tap the name of the patient record you just created. The patient's record screen opens.
 5. Tap **Patient Devices**. The Patient Devices panel opens.
- To enroll patient from an existing record after the initial pairing, do the following:
1. From the Patient Records screen, tap the name of the patient you want to enroll. The patient's record opens.
 2. Tap **Patient Devices**. The Patient Devices panel opens.
 3. Tap  next to the enrollment status for the desired generator. The Enroll Patient popover opens.
 4. Select an existing patient to assign to the generator.

NOTE: The same date of birth must be used by the patient to access the generator on the patient controller.

5. Tap **Enroll**.

NOTE:

- The Enroll button is only active when the date of birth of the patient is populated.
- The date of birth cannot be edited after enrollment is submitted. To change the date of birth, create a new enrollment. To change the generator assigned to a patient, create a new pairing and enrollment.

To reassign a generator to a different patient, do the following:

1. Ensure the generator you want to reassign is connected to the clinician programmer.

2. On the Program screen, tap . The Generator popover opens.
3. Tap **About**. The About Popover opens.
4. Tap **Reassign Patient**. The Select a Patient popover opens.
5. Tap the patient name you want to associate with the generator.
6. Tap **Reassign** and the generator will be reassigned to that patient; or tap **Cancel** to return to the About popover without reassigning the generator.

Pairing the Clinician Programmer With a Charger

Pairing refers to setting up communication between the clinician programmer and the charger. This pairing allows the clinician to update software on the charger and access charger logs.

To pair the clinician programmer with the charger, follow these steps:

1. Make sure the clinician programmer is turned on and connected to the internet.
2. Place the clinician programmer within Bluetooth® wireless technology range (3 ft or 0.9 m) of the charger.
3. Launch the clinician programmer app.
4. Turn on the charger by pressing the charger power button. The three icons illuminate briefly.
5. To start the pairing process, press and hold the charger power button for 5 seconds.

6. On the clinician programmer app, tap **Devices** on the Home screen. The Select Device popover opens. Paired devices appear with an unlock symbol and the serial number of the device. Upon successful pairing, the connected charger appears on the Select Device popover.

If a pairing is lost between the clinician programmer and a charger, follow these steps:

1. In the clinician programmer iOS® settings, tap **Bluetooth**.
2. Tap the generator or charger.

3. Tap .
4. Tap **Forget This Device**.
5. If desired, pair the clinician programmer and charger again.

Preparing the Generator for Implantation

Prior to implantation, the generator must be charged and placed in surgery mode. The generator should be charged while it is still in the sterile package. The generator name and implant date can be entered at this time.

Charging the Generator Before Implantation

To charge the generator in the sterile package:

1. Remove the charger from the box.
2. Turn on the charger by pressing the power button. The three charger icons illuminate.
3. Place the charger over the generator image, indicated on the generator packaging.

NOTE: When the charger enters the generator charge zone, it beeps multiple times, followed by a confirmation beep. While the charger is charging the generator, the power button on the charger blinks.

4. When the generator is fully charged, the charger beeps 3 times every 10 seconds. Turn off the charger by pressing the power button.

NOTE: The charger automatically turns off after 90 seconds of inactivity.

5. Return the charger to the box.

Entering the Generator Name and Implant Date

To enter the name of the generator and implant date:

1. From the Home screen, tap **Devices**. The Select Device popover opens. Paired devices appear with an unlock icon and the serial number of the device.
2. In the Select Device popover, tap the generator to be implanted. The Program screen appears.
3. At the top of the Program screen, tap . The Generator popover opens.
4. On the Generator popover, tap **Name**.
5. Enter name of the generator to be implanted.
6. Tap **Back**. The name entered appears in the Generator popover.
7. Tap **Implant Date**.
8. Tap **On Date** and select the implant date. If the implant date is unknown, select **Not Available**.
9. Tap **Back**. The date entered appears in the Generator popover.

Entering Patient Information

To enter patient information:

1. From the Home screen, tap **Devices**. The Select Device popover opens. Paired devices appear with the serial number of the device.
2. Tap the generator to be implanted. The Program screen appears.
3. At the top left of the Program screen, tap . The Patients screen appears.
4. Tap **Patient Information**. The Patient Records popover opens.
5. Tap .

6. Enter the patient information.
7. Tap **Save**.

NOTE: Patient information can also be edited on the Home screen by tapping the Patient Records button.

Placing the Generator in Surgery Mode

The generator must be placed in surgery mode before the implantation procedure and other surgical procedures. To place the generator in surgery mode, follow these steps:

1. From the Home screen on the clinician programmer, tap **Devices**.
2. Tap the generator to be implanted. The Program screen appears.
3. At the top of the Program screen, tap . The Generator popover opens.
4. On the Generator popover, tap **Surgery Mode**. The Surgery Mode popover opens.

NOTE: Place the generator in surgery mode before entering the operating room. While in the operating room, keep the generator in surgery mode unless you are actively programming.

5. Tap the Surgery Mode button. If stimulation is active, stimulation stops and the patient may undergo their surgical procedure.

NOTE:

- If surgery mode is on, you will not be able to perform any programming actions or turn on stimulation. The generator remains in surgery mode until you tap **Exit Surgery Mode** on the screen.

- If the generator detects high current, you will not be able to exit Surgery mode. When you leave the high current environment and high current is no longer detected, you will be able to exit Surgery mode.

Programming with the Clinician Programmer App

This section provides instructions and information about programming therapy for patients using the clinician programmer app.

NOTE:

- Do not navigate away from the clinician programmer app while you are in a programming session. Enabling Do Not Disturb mode prior to your programming will prevent interruption from occurring during a programming session. See “Do Not Disturb” instructions from Apple, which are located at support.apple.com/guide.
- Battery life depends on communication usage and stimulation settings. Programs with higher outputs (pulse width, frequency, or amplitude) will deplete the generator battery faster. For information about viewing the estimated generator charging time and charging interval for a program, see “Managing Programs on the Generator” (page 45).

Creating a New Programming Session

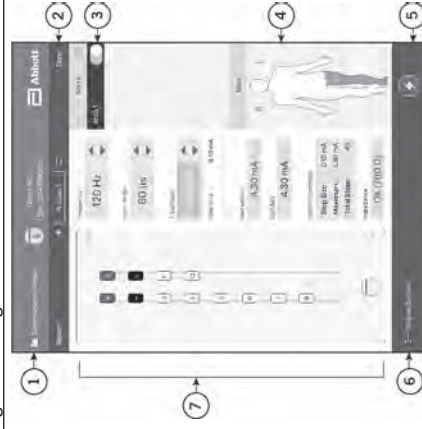
To start a new programming session, follow these steps:

1. Tap **Devices** on the clinician programmer app Home screen. The Select Devices popover opens.
2. Select an available generator. The Program screen appears. A patient name is displayed under the generator if this clinician programmer was used to program this generator previously.
 - Swipe up or down to display more available generators, if applicable.

3. Set the desired parameters. See the corresponding sections in this manual for instructions.
4. Enter patient information as needed. See “Managing Patient Records” (page 55) for more information.
5. When finished, tap **Done**. The Session Report popover opens.
6. Select to include or remove PII. (See “Setting Personally Identifiable Information (PII)” (page 43) for more information regarding PII).
7. Tap **End Session**.

NOTE: During intraoperative testing, you do not need to save the program. To exit an intraoperative testing session and return to the clinician programmer app Home screen, tap **Done** and then tap **End Session** on the Program screen. When asked by the system if you want to discard the changes, tap **Yes**.

Figure 1. Program screen



1. Program Header

- Tap  to view patient record.
- Tap  to view generator details.

2. Program Navigation Bar

- Tap **Revert** to discard changes and return to initial program settings.
- Tap  to add program or copy active program.
- Tap the program name to edit current program name or access other programs.
- Tap  to view program details.
- Tap **Done** to end the session.

3. Areas

- Tap  to create a new area in a Tonic program or to increase the number of pulses in a BurstDR™ program.
- Tap  to open the Area Options popover for a Tonic program.
- Tap  to increase the number of pulses for a BurstDR™ program.

- Tap  to decrease the number of pulses for a BurstDR™ program.
4. Tap the stimulation map to edit a selected area.
 5. Tap  to stop stimulation.
 6. Tap  to view program options.
 7. Lead configuration area

Selecting the Lead Configuration

NOTE: If a lead model is an approved MR Conditional component, an MR Conditional icon () is displayed beside the model number. If you select an MR Conditional lead, a message appears asking if a lead extension is used with the system. Tap **Yes** or **No** appropriately because this information is critical for determining if all the implanted components meet the MR Conditional requirements.

To add a new lead or edit an existing lead in the Program screen, follow these steps:

1. In the lead configuration area, tap **Edit**. The Lead Options popover opens.
2. To add a new lead, tap . The Lead Options popover opens.
3. To edit an existing lead, tap the lead diagram. The Lead Options popover opens.
4. Tap **Model**. The Model popover opens. You have the following options for adding a lead:
 - Search for a lead using a partial model name or model number
 - Tap the model name and then select the model number from the popover
5. Tap **Done** to save changes and close the popover.

To remove a lead, follow these steps:

1. Tap **Edit**.
2. Tap . The Delete Lead popover opens.
3. Tap **Delete Lead** to remove the lead or tap outside the popover to cancel removing the lead.
4. Tap **Done**. A confirmation popover opens.

NOTE: Removing a lead will delete existing programs.

5. Tap **Delete** to save changes or tap **Cancel** to make no changes to the lead configuration.

To edit the lead options, follow these steps:

1. Tap **Edit**. The Lead Options popover opens.
2. Set the desired lead options.

NOTE:

- A 16-channel lead only allows the Reverse Ports option, not the Port option.
 - Changing lead options may result in deletion of existing programs.
3. Tap **Done** to save changes.
 4. Tap **Done** to exit the lead diagram panel.

Configuring Electrode Polarities

Individual electrodes on a lead may be set to positive (anode), negative (cathode), or neutral.

NOTE: If you manually change polarities while stimulation is active, stimulation turns off. Additionally, the perception and comfort amplitude values clear on Tonic programs and any previous area impedance results

will also clear. For BurstDr™ stimulation programs, the target amplitude value clears and the program impedance result also clears.

To configure electrode polarities, do the following:

1. On the Program screen, tap the numbered electrode in the lead diagram area.

NOTE: Once at least one anode or cathode is set, the selected electrode configuration appears.

The Electrode popover opens.

- Tap – (cathode) to set the electrode to cathode.
- Tap + (anode) to set the electrode to anode.
- Tap the generator icon to set the can to anode.
- Tap OFF to turn the electrode off.
- Tap outside the Electrode popover to close the popover.

NOTE: The anode option is unavailable for electrodes if the generator is set to function as an anode.

Starting and Stopping Stimulation During a Programming Session

During a programming session, you can start or stop stimulation in multiple ways: by managing the amplitude, by turning stimulation on and off in the Areas section, or by tapping the Stop Stimulation button.

To start and stop stimulation on the Program screen, you can do any of the following:

- In the Amplitude area, tap the Up arrow to start stimulation or tap the Down arrow to decrease stimulation to 0 mA to stop stimulation.
- In Areas, tap the toggle button to turn stimulation on (green) or off (gray).

To immediately stop stimulation on the Program screen, do the following:

- Tap .

Switching Between Tonic Mode and BurstDR™ Mode

On the clinician programmer app, you may create and modify two types of programs:

- Tonic program. A program where the stimulation frequency consists of a single, repeating pulse that can be delivered to multiple areas.

- BurstDR™ program. A program where the stimulation frequency consists of a group of pulses in rapid succession followed by a period without pulses, delivered to a specific area.

You may switch to BurstDR stimulation programming mode on the Program screen.

NOTE:

- When creating a new program, you start programming in Tonic programming mode by default.
- When you switch between BurstDR mode and Tonic mode, all programmed values reset to default except the electrode configuration.

To switch between Tonic mode and BurstDR mode, follow these steps:

1. On the Program screen, tap  to open the Program Options popover.
2. Tap the BurstDR Mode toggle button to switch between Tonic stimulation and BurstDR stimulation.
 - Off (toggle button to the left, gray), means Tonic stimulation is selected
 - On (toggle button to the right, green), means BurstDR stimulation is selected
3. Tap **Change** to confirm switching the program mode.

When BurstDR mode is active, the Program screen displays the features for BurstDR stimulation programming.

Adjusting Pulse Width

When creating a new program, the Pulse Width area on the Program screen displays a default value, which is determined by programming mode (Tonic or BurstDR™ mode).

To change the pulse width value, do either of the following:

- Tap the Up or Down arrows in the Pulse Width area.
- Tap the Pulse Width value, and then tap the desired value in the pulse width drop-down list.

Adjusting Amplitude and Step Size

On the Program screen, you may adjust amplitude and step size. Amplitude is the strength of the electrical pulse delivered from the lead. Step size is the amount by which amplitude increases or decreases when adjusted.

NOTE:

- At any time, you can immediately stop the patient's stimulation by tapping .
- When the generator reaches its energy or charge density limit, a notification appears. If a notification appears, reduce the frequency, pulse width, and amplitude.
- When the generator reaches its output limit, the parameter area turns yellow. You may still increase amplitude but cannot save the program. To reduce the generator output, reduce the amplitude or pulse width or set additional anodes or cathodes on the lead configuration.
- If you change electrode polarities after setting the amplitude value, the amplitude value clears.
- For BurstDR™ stimulation, when adjusting a program, the amplitude value clears. A reset notification will appear, which will require confirmation of the change.

To adjust amplitude, perform the following actions:

- To change the step size, tap and drag the slider to the right to increase or to the left to decrease the step size.
- Tap the Up or Down arrows in the Amplitude area to increase or decrease stimulation.
- If stimulation is off, increase amplitude to greater than 0 mA to turn on stimulation. If a program has multiple areas, tap the desired Area and then increase amplitude to greater than 0 mA to turn on stimulation for the area.

NOTE: When creating a Tonic program, you may choose between two minimum step sizes (0.05 mA or 0.10 mA), which determine the maximum available amplitude (12.75 mA or 25.5 mA, respectively). See “To Set the Step Size Increment (Tonic Only)” (page 40).

Adjusting Frequency for Tonic Programs

When creating new Tonic programs, the Frequency area on the Program screen displays a default value.

To change the frequency value, do either of the following:

- Tap the Up or Down arrows in the Frequency area.
- Tap the Frequency area; then tap the desired value in the frequency drop-down list.

NOTE: When you change the frequency value, stimulation turns off and the amplitude value clears.

Setting Perception and Comfort Amplitudes for Tonic Programs

To complete a Tonic program, you must set values for perception and comfort amplitudes for each area. The perception amplitude is the value at which the patient first feels stimulation. The comfort amplitude is the value at which the stimulation feels comfortable to the patient.

NOTE:

- When the generator reaches its output limit, the parameter areas will turn yellow and you will not be able to set perception and comfort amplitude values. To reduce the output of the generator, reduce the amplitude or set additional anodes or cathodes on the lead configuration.
- If you change electrode polarities after you have set the values for perception and comfort amplitude, the perception and comfort amplitude values will clear.

To set a patient's perception and comfort amplitudes, follow these steps:

NOTE: Amplitude must be a value greater than zero before perception and comfort amplitudes can be adjusted.

1. In the Amplitude area, tap the Up or Down arrow to reach the patient's perception amplitude.
2. Tap the Perception area. The Perception popover opens.
3. Tap **Set to xx mA** to set the patient's perception amplitude.
4. In the Amplitude area, tap the Up or Down arrow to reach the desired comfort amplitude.
5. Tap the Comfort area. The Comfort popover opens.
6. Tap **Set to xx mA** to set the patient's comfort amplitude.

NOTE: Once you have set the perception and comfort amplitudes, you can tap **Ramp to – mA** (where “–” is the perception or comfort amplitude) in the Perception and Comfort popovers to increase the amplitude to the set perception or comfort value.

Adjusting Frequency for BurstDR™ Programs

BurstDR™ stimulation programs have two adjustable frequency values: the overall frequency (Burst frequency) and the frequency of each individual pulse in a pulse group (Intra-burst rate). When creating new BurstDR stimulation programs, the burst frequency and intra-burst rate areas on the Program screen display system default values.

To change the frequency values for a BurstDR stimulation program, do either of the following:

- Tap the **Burst Frequency** or **Intra-burst Rate** up or down arrow.
- Tap the **Burst Frequency** or **Intra-burst Rate** area; then tap the desired value in the frequency drop-down list.

Setting the Target Amplitude for BurstDR™ Programs

To complete a BurstDR™ stimulation program, you must set the target amplitude value for the intended area.

NOTE:

- When the generator reaches its output limit, the parameter areas will turn yellow and you will not be able to set the target amplitude value. To reduce the output of the generator, reduce the amplitude or set additional anodes or cathodes on the lead configuration.
- If you change electrode polarities after you have set the value for target amplitude, the target amplitude value will clear.
- Once you have set the target amplitude, you can tap **Ramp to – mA** (where “–” is the target amplitude) in the Target popover to increase the amplitude to the target value.

To set a patient's target amplitude, do the following:

1. Adjust the amplitude in the Amplitude field to the desired level.

2. Set Target amplitude to the current active amplitude by tapping the Target area.

NOTE: Alternatively, tap the 60% Target button to set the target amplitude to 60 percent of the current active amplitude. After doing so, the 60% Target button becomes inactive until the amplitude is changed.

Adding an Area to a Tonic Program

To add an area to a tonic program, follow these steps:

1. On the Program screen, tap  in the Areas section.
2. Set stimulation parameters as needed for each area.

Removing or Editing an Area in a Tonic Program

To delete or rename an area in a tonic program, follow these steps:

1. On the Program screen, tap  in the Areas section.
2. In the Areas popover, tap **Edit**.
 - To delete an area name, tap . Tap **Delete**. Tap **Done**.
 - To rename the area using the on-screen keypad, tap the area name using the on-screen keypad.

NOTE: Areas are automatically numbered unless you enter a custom name. Duplicate names are not allowed.

Increasing or Decreasing the Number of Burst Pulses

To add or remove a burst pulse on a BurstDR™ stimulation area:

- Tap  to increase the number of pulses.
- Tap  to decrease the number of pulses.

Setting the Patient Controller Custom Settings

The clinician programmer provides a recommended maximum output value for the patient controller based on program settings. You may override the recommended value and customize the allowable output for the patient controller.

To customize the output for the patient controller, follow these steps:

1. Tap the Patient Controller area. The Patient Controller popover opens.
2. Tap the Use Custom Settings toggle button. The Maximum Amplitude list appears.
3. Select Maximum Amplitude for the patient controller. The Total Steps value changes according to the maximum amplitude value.
4. Tap **Done** or tap outside the popover to save changes and close the popover.

Creating a Stimulation Map

You may create a stimulation map to show where the patient senses stimulation. The stimulation map also appears on the user's patient controller app.

To create a stimulation map, follow these steps:

1. On the Program screen, tap the graphical representation of the human body.

2. Select or remove an area on the graphic that corresponds to the area where the patient is receiving stimulation by tapping the area on the graphic or tapping and dragging to highlight multiple areas. A selected area will be highlighted in blue. A deselected area will be gray.

NOTE: Tonic programs can have one stimulation map per area. BurstDR™ programs can have one stimulation map per program.

3. To save the stimulation map and return to the Program screen, tap **Done**. Otherwise, tap **Cancel** to cancel any changes and return to the Program screen.

Measuring Impedance

You may want to measure lead impedance periodically as a diagnostic tool to ensure that current is flowing through the system properly. Impedance measurements may help you troubleshoot issues with the neurostimulation system.

NOTE: To measure system or program impedance, ensure the generator is not being charged. For program impedance, also ensure stimulation is on. The Impedance button is disabled if stimulation is off or the generator is charging.

To measure impedance for the programmed electrode configuration and current stimulation settings, follow these steps:

1. Tap the Impedance area. The Check Impedance popover opens.
2. If not previously selected, tap to include or remove PII in the impedance report.
3. Tap **Program**. Impedance is checked and the value is displayed in the Impedance field.

To measure impedance on all electrodes, follow these steps:

1. Tap the Impedance area. The Check Impedance popover opens.

2. If not previously selected, tap to include or remove PII in the impedance report.
 3. Tap **System**. The System Impedance popover opens.
 4. Tap **Start** to check impedance on all electrodes. A Check Complete message appears.
 5. Tap **Dismiss** to return to the electrode map. Or tap **View Report** to view the impedance report.
- NOTE: To view, email, or print impedance reports, see “Viewing, Emailing, and Printing a Report” (page 57).
6. Tap **Done** to exit and return to the Program screen.

Using the Shifting Programming Feature

The Shifting programming feature, which is only available with certain lead types, provides a simplified method for setting the electrode configuration by moving the entire electrode combinations up or down as a unit. During Shifting programming, stimulation is turned off.

To use the Shifting programming feature:

- Configure electrode polarities until the Shifting buttons become active.
 - Tap the Shifting buttons to steer the electrode array.
- NOTE:
- When you use Shifting programming, both the programmed perception and comfort amplitudes clear.
 - The Shifting programming feature is not available in BurstDR™ mode.

Using the MultiSteering™ Programming Feature

The MultiSteering™ programming feature provides a simplified method for shaping and fine-tuning the electrical field in real time. During MultiSteering programming, certain electrode combinations can be moved while stimulation remains active.

To use the MultiSteering programming feature:

- Configure electrode polarities until the MultiSteering buttons become active.
- Tap the MultiSteering buttons to steer the stimulation through a set of optimized electrode combinations designed to incrementally shift stimulation.

NOTE:

- When you use MultiSteering programming the programmed comfort amplitude clears.
- The MultiSteering feature is not available in BurstDR™ mode.
- Tap the Amplitude area to open the Auto Decrement popover.
 - The default is Set Amplitude to Perception. This option lowers the amplitude to perception when electrodes are changed using MultiSteering programming.
 - Tap **Do Not Change Amplitude** to keep the amplitude the same when electrodes are changed using MultiSteering programming.

NOTE: Some nerve fibers may be more sensitive to electrical fields than others. Before steering to the next combination, adjust the amplitude to the patient's perception level or lower.

Adding a New Program

To add a new program, follow these steps:

1. On the Program screen, tap . A popover opens.
 2. Tap **Add New Program**. A new program is automatically named according to the next available number.
- NOTE: The Program screen defaults to tonic programming mode when you create a new program.

3. Set the desired parameters.

Changing the Active Program

To change the active program, follow these steps:

1. On the Program screen, tap the program name. The Programs popover opens.
2. Tap a program in the list. The selected program becomes the active program.

Copying a Selected Program

To copy the active program, follow these steps:

1. On the Program screen, tap . A popover opens.
2. Tap **Copy Active Program**. The duplicated program appears as the next available program number.

Modifying Program Options

You may modify the active program options. To access the options, do the following:

- Tap  at the bottom of the Program screen to open the Program Options popover. From the Program Options popover, you may perform the following actions:
 - Set the BurstDR™ mode (visible if BurstDR mode is unlocked)
 - Set the dosage
 - Set the intermittent dosage on and off times
 - Set the step size increment (Tonic only)
 - Set the magnet mode
 - Set the ramp time for continuous dosage
- Tap **Done** or tap outside the popover to save the changes and close the popover.

To Set the Dosage

The dosage setting controls the delivery of stimulation. The following table provides definitions of the dosage options that may be available.

Table 1. Definitions of Dosage Options

Dosage	Definition
Continuous	Stimulation is delivered continuously while the generator is on and the program is running.

Table 1. Definitions of Dosage Options

Dosage	Definition
Intermittent	Stimulation is on for a programmed amount of time (on time) and off for a programmed amount of time (off time). Stimulation alternates between on and off states until the generator is turned off or the program is stopped.

NOTE: In neurostimulation therapy, “dose” refers to the delivery of a quantity of energy to tissue. A difference in “dose” in this context does not imply differences in expected effectiveness response as it would with a drug. There is no demonstrated difference in safety or effectiveness among these doses.

To set the dosage, follow these steps:

1. Tap **Dosage** on the Program Options popover. The Dosage popover opens.
2. Tap the desired dosage.

NOTE: If you tap Intermittent for a BurstDR™ stimulation program, you can select the desired BoldXR™ dosing program. You can also set custom dosing, which allows you to program dosing on time and off time.

To Set the On Time and Off Time for Tonic and BurstDR™ Programs

The On Time and Off Time setting controls the amount of time intermittent stimulation is on and off.

To set the on and off time for Tonic programs, follow these steps:

1. On the Program Options popover, tap **On Time** or **Off Time**.
2. Tap the + and – buttons to increase or decrease the time.

To set the on and off time for BurstDR™ programs, follow these steps:

NOTE: On and off time is visible only when dosage is set to intermittent.

1. Tap **Dosage** on the Program Options popover. The Dosage popover opens.
2. Tap **Intermittent** on the Dosage popover. Two dosing options are available, along with an option to set a custom on time and off time.
3. Select one of the dosing options or tap **Custom** on the Dosage popover.
4. If Custom was selected, tap the + or – buttons to increase or decrease the time.

NOTE: You can set the intermittent on and off times to a minimum of 2 seconds and a maximum of 24 hours.

To Set the Step Size Increment (Tonic Only)

The step size increment setting controls the available step sizes when adjusting amplitude.

To set the step size increment, follow these steps:

1. On the Program Options popover, tap **Step Size Increment**. The Step Size Increment popover opens.
2. Tap the desired step size increment.

To Set the Magnet Mode

The magnet mode setting controls how the generator responds when it detects a magnet. The default magnet mode is Turns Stimulation On/Off.

To set the magnet mode, follow these steps:

1. Tap **Magnet** to open the Magnet popover.

2. Tap the desired magnet option:
 - Tap **Disabled** to disable magnet mode so stimulation is unaffected if the generator detects a magnet.
 - Tap **Turns Stimulation On/Off** to turn generator stimulation on or off each time the generator detects a magnet.
 - Tap **Turns Stimulation Off Only** to turn generator stimulation off when the generator detects a magnet.

To Set the Ramp Time

Ramp time is the approximate number of seconds that the generator takes when starting stimulation to arrive at the perception amplitude. This ramp time is used when stimulation is turned on using the patient controller; it is not the ramp time used while programming. The default ramp time is 4 seconds.

NOTE: Ramp time is visible only when dosage is set to continuous.

To change the ramp time, follow these steps:

1. Tap **Ramp Time** on the Program Options popover. The Ramp Time popover opens.
2. Tap on the desired ramp time from the list. To scroll to a ramp time that is not displayed, swipe up or down on the screen.

Using the Active Balancing™ Programming Feature

The Active Balancing™ programming feature allows you to adjust the amplitude of all areas within a program either simultaneously or individually, which helps balance the feeling of stimulation delivered to a patient.

NOTE: This feature is available only for tonic stimulation programs. Active Balancing is not available until Perception and Comfort amplitudes are set for two or more areas.

To balance a program, follow these steps:

1. On the Program screen, tap  next to Areas. The Areas popover opens.
2. Tap **Balance**. The Active Balancing popover opens.
3. Tap the right arrow in the Master Amplitude area. The amplitude ramps up to the perception value (Perc).

NOTE: To stop stimulation, tap . This button turns off the master amplitude, disables the ability to increase or decrease an area amplitude, and the level indicator bars turn gray.

4. Tap the right arrow to increase and left arrow to decrease the master amplitude until the patient indicates that stimulation is comfortable.

5. Tap the right arrow to increase and left arrow to decrease the amplitude level of an area.

NOTE:

- If an overhead state is detected, the Maximum Generator Output Reached alert appears and the green level indicator bars turn yellow for the areas in overhead. Programs cannot be saved if the generator is in an overhead state.
 - To reset all sliders to zero, tap .
6. If the program contains more than four areas, scroll down to display the remaining areas and adjust the areas if necessary.

7. Tap **Done**.

Saving a Program

When you complete programming and exit the session, programs are automatically saved and a Session report opens. You may manually exit the programming session by performing the following actions:

1. Tap **Done** on the Program screen.

2. Tap **End Session** in the popover.

NOTE:

- If desired, select the Personally Identifiable Information (PII) setting to include or exclude PII in the session report.
- When you save the program, it is automatically saved to the generator.
- If any parameters of an area are incomplete for a program, a message appears when you try to save the program. To correct this issue, ensure that you have configured valid electrode polarity combinations and have set all stimulation parameters.

Setting Personally Identifiable Information (PII)

Personally identifiable information can be included in or removed from reports. In the Patient Records screen, you can configure the PII setting to always include or remove PII from a report. You can also choose to include or remove PII when ending a programming session, generating reports, or exporting a database.

NOTE: If using the AirPlay, AirDrop, CarPlay, or the Hotspot features of the Apple® iPad®, PII stored in the clinician programmer app may be accessible to unauthorized users.

To configure the PII setting to always include or remove personally identifiable information, follow these steps:

1. On the Patient Records screen, tap the patient's name. The patient record opens.
2. Under Reports, tap the report you would like to configure.
3. Under Personally Identifiable Information, Tap **PII**. The PII popover opens.
4. Tap **Remove** or **Include**.

NOTE: The PII selection saves for that type of report.

To include or remove personally identifiable information from a session report, follow these steps:

1. At the end of the programming session, tap **Done**. The Session Report popover opens.
2. Tap **PII**. The PII popover opens.
3. Tap **Remove** or **Include**. The Session Report popover opens.
4. Tap **End Session**.

NOTE: The PII selection saves for that report and program.

To include or remove personally identifiable information from the user-generated System Impedance report, follow these steps:

1. On the Program screen, tap the Impedance area. The Check Impedance popover opens.
2. Tap **PII**. The PII popover opens.
3. Tap **Remove** or **Include**.
4. Tap outside of the popover to close the popover and return to the Program screen.

NOTE: The PII selection saves for that report and program.

To include or remove personally identifiable information from the logs and database, from the Home screen, follow these steps:

1. Tap ⓘ. The Information popover opens.
2. Tap ⓘ. The Programmer Information popover opens.
3. Tap **Programmer Log** or **Programmer Database**. The Programmer Log or Programmer Database popover opens.
4. Tap **PII**. The PII popover opens.

5. Tap **Remove** or **Include**.

Managing Programs on the Generator

In the Manage Programs popover, you can view program settings, select the active program, and view estimated generator charging time and charging interval for a program. You can also add, delete, or rename programs on the generator.

NOTE: For a description of the buttons and icons that appear on the program screens and popovers, see “Appendix B: Buttons and Icons on Screens and Popovers” (page 81).

To view program settings or select a program as the active program, follow these steps:

1. Tap  next to the program name on the Programs screen. The Manage Programs popover opens.
2. Tap **Manage Programs**. The list of available programs opens, with the active program selected by default.
3. To view program settings, tap a program name on the list.
4. To make that program the active program, tap **Select**. The Programs screen appears for the selected program.

NOTE: If the selected program is not valid, an alert appears notifying you the program must be fixed or deleted before another program can be edited.

To view the estimated full-to-empty and weekly charge time for a program, follow these steps:

1. Tap  next to the program name on the Programs screen. The Manage Programs popover opens.

2. Tap **Manage Programs**. The Programs screen appears with the active program selected by default. Ensure stimulation is turned on.

NOTE:

- To view the estimated full-to-empty and weekly charge time for another program, return to the Manage Programs popover and change the active program. Then turn on stimulation.
- Estimated full-to-empty and weekly charge time are available only when stimulation is on because they are calculated using program parameters.

3. View the estimated full-to-empty and weekly charge time for the active program under Battery Estimates.

NOTE: Estimates may vary. As a program is used, estimates will become more accurate.

Adding, Deleting, or Renaming a Program

To add or copy a program, follow these steps:

1. On the Program screen, tap . A popover opens.
2. Tap **Add New Program** or **Copy Active Program**.

NOTE: If you tap **Add New Program**, a program number will be assigned automatically. If you tap **Copy Active Program**, the Programs popover opens and you may select the program you would like to copy.

To rename a program on the list, follow these steps:

1. On the Program screen, tap . The Manage Programs popover opens.
2. Tap **Manage Programs**. The list of available programs opens, with the currently active program selected by default.
3. Tap **Edit**.

4. Tap a program name and enter the custom program name.
 5. Tap < to return to the Edit screen.
 6. Tap **Done** to save changes and return to the Program screen.
- To delete a program on the list, follow these steps:
1. On the Program screen, tap . The Manage Programs popover opens.
 2. Tap **Manage Programs**. The list of available programs opens, with the currently active program selected by default.
 3. Tap **Edit**.
 4. Tap  next to the program you want to delete. The Delete button appears.
 5. Tap **Delete**.

NOTE: If all custom programs are deleted, the popover closes and a default program is created.

6. Tap **Done** to save changes and return to the Manage Programs screen.

Modifying Patient Settings

You can enable or disable the following features on the patient controller:

- **Time Remaining.** Allows patients to view approximately how many days or weeks remain until the generator battery is low and must be charged to provide therapy.
- **Sleep Schedule.** Allows patients to schedule a time of day to turn stimulation on and off.
- **Charging Timer.** Allows patients to view the time remaining for the generator to be charged fully during a charging session.

- **Charging Mode.** Allows patients who are sensitive to generator warming to select the setting that is most comfortable for them while charging. For example, setting the mode to low will keep the generator cooler during charging but could lead to longer charging sessions.
 - Low is recommended for longer charging sessions.
 - Medium is recommended for average-length charging sessions.
 - High (default setting) is recommended for short charging sessions.
- To enable or disable features on the patient controller, do the following:
1. From the Program screen, tap the generator icon. The Generator popover opens.
 2. Tap **Patient Settings**. The Patient Settings popover opens.
 3. Tap the option you wish to enable or disable; then tap the toggle button.

NOTE: If enabling Charging mode, you can change the mode that will appear as the default mode on the patient controller. Then tap **Save This Setting**.

Viewing Generator Details

The Generator popover provides information about the generator, such as the total usage time, generator settings that can be modified, and access to generator logs.

To view the generator details, do the following:

- On the Program screen, tap . The Generator popover opens.
- From the Generator popover, you may perform the following actions:
- View information about the generator, such as the model and serial number on the About popover.

- Change the generator name from the Name popover. This name is displayed on the generators list for both the clinician and patient.
- Change the implant date on the Implant Date popover.
- View and edit patient settings.
- Set the generator to surgery mode.
- Set the generator to MRI mode, if applicable.
- Update generator software if a software update is available.
- Email a generator log that contains information such as how stimulation was used, which may help when troubleshooting.

Setting a Generator to MRI Mode

To set an applicable generator to MRI mode, follow these steps:

1. Tap **MRI Mode** on the Generator popover. The MRI Mode popover opens.
2. Tap the **MRI Mode** toggle button.
3. When the “Set Generator to MRI Mode?” message appears, tap **Continue**. Stimulation stops, and the clinician programmer app checks the system for any issues. If the checks are successful, a message appears indicating that generator is in MRI mode.

NOTE:

- Remind patients to charge their patient controller before the MRI procedure and to bring their patient ID card, their patient controller, and their charger with them to the procedure.
- Advise patients not to bring their magnet, patient controller, or charger into the MRI magnet room.

- If any of the implanted components are not MR Conditional, **MRI is Not Permitted** (MRI) is displayed in the Generator popover instead of the **MRI Mode** (MRI) option. If a warning message appears indicating that MRI is not advised or an unsupported generator is in MRI mode, the patient cannot receive an MRI scan.
- If MRI mode is on, you will not be able to perform any programming actions. The generator remains in MRI Mode until you tap **Exit MRI Mode** on the screen.

Emailing a Generator Log

To email a generator log, follow these steps:

1. Tap **Generator Log** on the Generator popover.

NOTE: The Personally Identifiable Information (PII) setting will be set to Include.

2. Tap **Email Log**. The popover closes.
3. To ensure typical clinical standards are used when transferring PII data electronically and to proceed with emailing generator log, tap **I Agree**.
4. Enter the email address.

Viewing Charger Details

The Connected Charger popover provides information about the charger, such as the estimated charge available to charge the generator, charger settings that can be modified, and access to charger logs. In the device list, tap the charger you want to connect to.

- The battery icon with the three segments and the percentage to the left represent the battery level of the charger.

- The small generator icon under the charger name estimates how much charge that percentage can provide to the generator. For example, a battery icon with two green segments can charge a generator fully.
 - Tap **About** to view charger information such as the software version and model number. You may also reassign the charger to an existing patient.
 - Tap **Charger Name** to edit charger name in the Edit Name popover.
 - Tap **Charging Timer** to turn on or off the display on the patient controller indicating the time remaining until the generator is fully charged.
 - Tap **Charger Log** and then tap **Email Log** to email the charger log to Technical Support.

Updating Generator and Charger Software

When new software is available for the generator or charger, a message will appear on the Home screen when you connect to the device with the pending update. Software can be updated using either of the following methods:

Software update method 1:

1. On the Home screen, tap **Devices**.
2. Tap the device you want to view. If an update is available, an update software message appears.
3. Read and follow the information on the Update Software screen before updating.

NOTE: Make sure the clinician programmer is charged before installing the generator software. Do not close the app, lock the clinician programmer, remove a pairing, or otherwise interrupt communication while installing the generator software or the generator may become unresponsive.

4. If updating generator software, place the magnet over the generator to confirm the update when prompted. An Update Software screen appears, showing the status of the update for the generator. When the software installation is complete, a confirmation message appears.

5. If updating charger software, press the charger power button to confirm the update when prompted. An Update Software screen appears, showing the status of the update for the charger. When the software installation is complete, a confirmation message appears.

Software update method 2:

1. In a program, tap the generator or charger icon.

2. Tap **About**. The About screen appears.

3. If a software update is available, the Update Software option appears. Tap **Update Software**.

NOTE: Update Software is only visible if the clinician programmer is connected to that device and an update is available.

4. Read and follow the information on the Update Software screen before updating.

NOTE: Make sure the clinician programmer is charged before installing the generator software. Do not close the app, lock the clinician programmer, or interrupt communication while installing the generator software or the generator may become unresponsive.

5. If updating generator software, place the magnet over the generator to confirm the update when prompted. An Update Software screen appears, showing the status of the update for the generator. When the software installation is complete, a confirmation message appears.

6. If updating charger software, press the charger power button to confirm the update when prompted. An Update Software screen appears, showing the status of the update for the charger. When the software installation is complete, a confirmation message appears.

NOTE: If there is a new software version available, you will receive a message to update software and the Update Software button will appear at the bottom of the About section of the Connected Charger popover. Ensure the clinician programmer battery is charged before installing charger software. Do not close the app, lock the clinician programmer, or interrupt communication while installing charger software.

Checking the Status of the Generator Battery

The clinician programmer app allows you to view the charge level of the generator battery and will also indicate when the generator is approaching its end of service. The clinician programmer app displays alert messages when the charge level of the generator battery is low, when therapy is turned off due to the low battery level, and when the generator is approaching its end of service.

NOTE:

- With rechargeable batteries, intervals between charging may become more frequent with use over time.
- See “Managing Programs on the Generator” (page 45) for information about the estimated generator charging time and charging interval for a program.

To view the generator battery level, do the following:

1. In the Program screen, tap the generator icon. The Generator popover opens.

The battery icon and the percentage represent the remaining generator battery level.

NOTE:

- When the connected generator is charging, the charging icon  appears.

- If the generator battery is too low to provide therapy, or if therapy has turned off due to a low battery, the battery status on the clinician programmer and patient controller display as N/A.
Battery longevity depends on the patient's stimulation settings and daily usage time. As the generator approaches its end of service, a warning called the elective replacement indicator (ERI) appears on the clinician programmer and patient controller indicating that the generator will need to be replaced soon. The warning directs the user to contact the physician to schedule a replacement.

Checking the Status of the Charger Battery

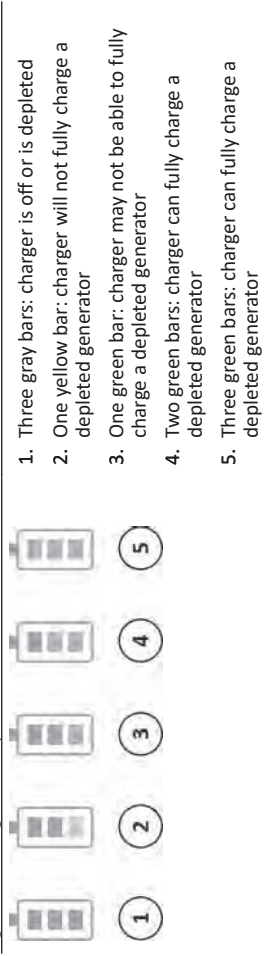
The clinician programmer app allows you to view the status of the charger battery and how much charge it can provide to the generator. From the clinician programmer app, you can also view when the generator is charging and when the charger is charging.

To view the charger battery level:

1. From the Home screen, tap **Devices**. The Select Device popover opens.
2. Tap the charger icon. The Connected Charger popover opens.
The battery icon and the percentage to the left of the icon represent the remaining charger battery level.

NOTE: When the connected charger is charging, the charging icon  appears.

Figure 2. Charger battery level indicator



NOTE: Two or more green bars indicate that the charger can charge a depleted generator fully.

Managing Patient Records

The Patient Records screen for each patient contains patient, device, and enrollment information. It also allows clinicians to assign a patient to a generator or charger outside of a session, to enter notes, and to access the following reports: session, program impedance, system impedance, therapy events, and charging history.

NOTE:

- For a description of the buttons and icons that appear on the Patient Records screen and popovers, see “Appendix B: Buttons and Icons on Screens and Popovers” (page 81).
- For instructions on enrolling or assigning a patient to a generator, see “Enrolling a Patient” (page 15).

To access a patient record from the Home screen, do the following:

1. Tap **Patient Records**. The Patient Records screen appears with a list of patient names.
2. Select a patient name or search for a patient name.

NOTE: The number shown on the Patient Records button on the Home screen refers to any pending generator requests in the queue.

To add a new patient from the Patient Records screen, do the following:

1. Tap **Create New Patient**. The New Patient popover opens.
2. Tap the field you want to complete and enter the information using the on-screen keypad.
3. Tap **Add** to add and save the patient's information and return to the Patient Records screen.

NOTE: The Add button is not available until you enter a first name.

To access a patient record from the Program screen, do the following:

1. From the Program screen, tap . The patient's record appears.
2. Tap **Patient Information**. The Patient Information panel opens.
3. Tap  to edit fields.
4. Tap the field you want to complete and enter the information using the on-screen keypad.
5. Tap **Save** to save the changes.

NOTE: The chosen Personally Identifiable Information (PII) setting is displayed in each patient record. You will be able to choose whether to include or remove PII from all reports.

Deleting a Patient Record from the Database

To delete a patient from the database, follow these steps:

1. On the Patient Records screen, tap **Edit**.
2. Tap the patient name to select or deselect a patient. If a patient is selected, a check mark will appear to the left of his or her name. You may select multiple patients to delete.
3. Tap **Delete**.

Viewing, Emailing, and Printing a Report

The following reports can be generated from the Patient Records screen: Session, Program Impedance, System Impedance, Therapy Events, and Charging History. Previous report data associated with a patient can also be viewed from the patient's record.

NOTE:

- Configure mail and printer support before using the email and print report functionalities.
- Each report category has a configurable PII setting. See "Setting Personally Identifiable Information (PII)" (page 43) for more information regarding PII.

Session Reports

At the end of a programming session, a session report generates automatically and appears on the screen. This report contains patient and device information, details about this session and the prior session, a list of other devices associated with the patient, and any session notes.

To email or print a session report, follow these steps:

1. From the Patient Records screen, tap the patient's name. The patient's record opens.

2. Tap **Session Reports**.
3. Select the desired session date. The report for that session date appears.
4. Tap  to open the Share popover.
5. Tap  to email or tap  to print the report.

Program Impedance Reports

For any active program, program impedance information is collected daily and is available in a program impedance report. A program impedance report provides a summary of impedance results of active programs since the last programming session, if the session was within the last 90 days. If the last programming session was beyond 90 days, the report will show impedance results only for the last 90 days. While program impedance is being collected, stimulation is not interrupted.

To generate a program impedance report, follow these steps:

1. From the Patient Records screen, tap the patient's name. The patient's record opens.
2. Tap **Program Impedance**.
3. On the top left of the screen, tap . The Create Report popover opens.
4. Tap **Create Report**. The program impedance report appears.
5. Tap **Done** to return to the Patient Records screen or tap  to email or print the report. The Share popover opens.
6. Tap  to email or tap  to print the report.

If program impedance logging is interrupted, an impedance measurement may not be recorded. The following events can interrupt program impedance logging:

- The generator is in MRI mode or surgery mode

- The generator firmware is being updated
- The generator is in active communication with the clinician programmer or patient controller
- The generator battery is too low
- The generator is being charged

System Impedance Reports

Two types of system impedance reports are available: user-initiated and generator-initiated reports. User-generated reports can be created by the clinician at any time during a session. Generator-initiated reports can be set to generate automatically at a specific time on a regular basis. The generator-initiated report provides a summary of the impedance results for each electrode since the last programming session, if the session was within the last 90 days. If the last programming session was beyond 90 days, the report will show impedance results only for the last 90 days.

NOTE:

- System impedance information for active BurstDR™ programs is collected daily and does not interrupt stimulation while it is being collected.
- System impedance information for Tonic programs is not automatically collected daily; however, it can be enabled and set to collect at a specific time of day. While system impedance information is being collected, stimulation will be interrupted.

To enable daily system impedance information for Tonic programs, follow these steps:

1. In the Tonic Program screen, tap **Program Options**. The Program Options popover opens.
2. Tap the toggle button for Daily System Impedance.

3. If desired, set the start time to collect the daily system impedance for all programs.

- Tap **Start Time**. The Start Time popover opens.
- Tap the time you want system impedance to be measured daily.
- Tap **Back**. The Program Options popover opens.

4. Tap **Done**.

To generate a system impedance report, follow these steps:

1. From the Patient Records screen, tap the patient name. The patient's record opens.
2. Tap **System Impedance**.
3. Tap  to choose a user-initiated system impedance report or tap  to choose a generator-initiated system impedance report.
4. On the top left of the screen, tap . The Create Report popover opens.
5. Tap **Create Report**. The system impedance report appears.
6. Tap **Done** to return to the Patient Records screen or tap  to email or print the report. The Share popover opens.
7. Tap  to email or tap  to print the report.

If system impedance logging is interrupted, an impedance measurement may not be recorded. The following events can interrupt system impedance logging:

- The generator is in MRI mode or surgery mode
- The generator firmware is being updated
- The generator is in active communication with the clinician programmer or patient controller
- The generator battery is too low

- The generator is being charged

Therapy Events Reports

Therapy events reports provide information about the adjustments the patient has been making to the programs since the last programming session, if the session was within the last 90 days. If the last programming session was beyond 90 days, the report will show therapy events only for the last 90 days. The report also shows how long the stimulation was on for each program and the percentage of time each program was used.

To generate a therapy events report, follow these steps:

1. From the Patient Records screen, tap the patient name. The patient's record opens.
2. Tap **Therapy Events**.
3. On the top left of the screen, tap . The Create Report popover opens.
4. Tap **Create Report**. The therapy events report appears.
5. Tap **Done** to return to the Patient Records screen or tap  to email or print the report. The Share popover opens.
6. Tap  to email or tap  to print the report.

Charging History Reports

A charging history report provides information about the patient's charging sessions since the last programming session, if the session was within the last 90 days. If the last programming session was beyond 90 days, the report will show the charging history only for the last 90 days. The charging history report includes the number of charging sessions and details about each charging sessions, such as the charge level of

the generator battery at the start and end of each charging session. It also shows the duration of each session and if any interruptions or overheating occurred during the session.

To generate a charging history report, follow these steps:

1. From the Patient Records screen, tap the patient name. The patient's record opens.
2. Tap **Charging History**.
3. On the top left of the screen, tap . The Create Report popover opens.
4. Tap **Create Report**. The charging history report appears.
5. Tap **Done** to return to the Patient Records screen or tap  to email or print the report. The Share popover opens.
6. Tap  to email or tap  to print the report.

Maintaining the Clinician Programmer

This section provides tips and other information to help you maintain the clinician programmer.

Checking the Status of the Clinician Programmer Battery

Be sure to monitor the clinician programmer battery status in the top right corner of the screen. As the battery is used, the battery indicator shows the remaining charge. Charge the clinician programmer using the provided Apple® charging cord.

NOTE: Keep the clinician programmer charged or have a power supply nearby. Familiarize yourself with the clinician programmer's battery life. For further information, refer to the user guide for the provided Apple iOS® device available at support.apple.com/guide.

Caring for the Clinician Programmer

For information on how to care for the clinician programmer, including cleaning, storage and handling, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/guide.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your patient device.

To keep patient data and communications secure, and to prevent unauthorized remote programming access, the system includes the following IT security measures.

- Use of a device passcode is required to access the mobile device. Use unique numeric sequences that you can remember easily.
 - Data at rest on the mobile device is stored in encrypted form.
 - Backups may be created using the iTunes® software with instructions from Apple, which are located at support.apple.com by typing “backup” or “back up” in the Search Support box.
 - Backups created using iTunes are encrypted.
- In addition, users should adhere to the following guidelines when using the system:
- Do not use the application if the operating system is compromised (for example, jailbroken).
 - Do not share your Apple® ID login information or device passcode.
 - Do not allow other users to access the mobile device.

- Installation of apps that are not approved by Abbott Medical for use in the system is restricted.
- Secure networks to which the Apple device will connect with a Wi-Fi password or other similar security measures.
- Connect only to trusted secured networks.
- If the Apple device is lost or stolen, contact your Abbott Medical representative to remotely erase your patient information from the device. Use the Apple instructions at support.apple.com by typing “lost” or “stolen” in the Search Support box to disable or erase your device.
- If you receive a “Device Not Secure” notification in the App, contact Abbott Medical.
- Install iOS software upgrades on your device as they are made available by Apple, after contacting Abbott Medical to ensure compatibility with the Clinician Programmer App.
- Install the clinician programmer app updates as they are released.

Legal and Privacy Notice

The terms of use and privacy policy are displayed the first time the clinician programmer app is launched after installing or updating the app. To view this information again, tap ⓘ on the clinician programmer app Home screen.

Abbott Medical is committed to protecting the privacy of our customers and patients. This privacy statement summarizes how we protect, gather, and use personal information of users. For more information, view our US or Global Privacy Policies online at www.abbott.com/privacy-policy.html.

We may amend these terms of use, privacy statements, and privacy policies from time to time, so please check for updates.

Troubleshooting

This section provides troubleshooting suggestions for issues you may experience with the clinician programmer or clinician programmer app. For additional information, call “Technical Support” (page 79). When you call, be ready to give the representative information about what you were doing when the error occurred and what error messages appeared. See “Viewing Generator Details” (page 48) for instructions about creating a generator log and the steps below for instructions about creating a programmer log.

NOTE:

- If your device is lost or damaged, contact Technical Support.
- Refer to the terms and conditions for repair or replacement of Abbott Medical neurostimulation system components as stated in the Limited Warranty card included in your product documentation.

To create and email a programmer log:

1. On the clinician programmer app Home screen, tap  to open the Information popover.
2. Tap **Programmer Log**. The Programmer Log popover opens.
3. Enable or disable the Personally Identifiable Information (PII) setting.
The popover closes. An “Exporting Logs” system message is displayed while the system is generating the log file and email.
4. Choose between all logs or from a selected range of dates.
5. Tap **Email** and enter the email address.

NOTE: Configure mail support before using the Email Programmer Log functionality.

To create and email the programmer database:

1. On the clinician programmer app Home screen, tap  to open the Information popover.

- 2. Tap **Programmer Database**.
- 3. Select the Personally Identifiable Information (PII) setting.
- 4. Tap **Email** and enter the email address.

NOTE: Configure mail support before using the Email Programmer Log functionality.

Troubleshooting Chart

Typically, the clinician programmer app displays a message for issues associated with programming patients and managing records. If you are experiencing issues, check the clinician programmer screen for a message and follow any instructions it gives to correct the issue. If you still experience the issue or if you experience an issue without receiving an on-screen message, refer to the following table for possible causes and solutions.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Clinician Programmer Device		
Clinician programmer is not accessible.	Clinician programmer is lost or damaged.	Contact Technical Support.
Clinician programmer has no power or has lost power.	Clinician programmer's battery is drained.	Charge the clinician programmer.
	Clinician programmer is damaged or malfunctioning.	Contact Technical Support.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Clinician programmer will not charge.	Charger is disconnected from the clinician programmer.	Connect the charger to the clinician programmer.
	Correct plug adapter (voltage converter) is not connected to the charger.	Connect the appropriate plug adapter (voltage converter) to the charger.
	The charging cable is defective.	Replace the charging cable.
	Clinician programmer is damaged or malfunctioning.	Contact Technical Support.
Nothing is displayed on the screen.	Clinician programmer is off or is in Sleep mode.	Turn on the clinician programmer.
	Clinician programmer's battery is drained.	Charge the battery using the charger.
	Screen is damaged or malfunctioning.	If the clinician programmer appears to be powered on but without display, the screen may be defective. Contact Technical Support.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Clinician programmer will not respond to input.	Clinician programmer has locked up.	Perform a soft reset by turning the clinician programmer off and back on.
Clinician Programmer App		
Cannot locate clinician programmer app.	Clinician programmer app is not on clinician programmer Home screen.	Swipe through screens from the clinician programmer Home screen to locate app.
		Search for the app using the iOS search function.
		Ensure you have the clinician programmer app for the Eterna™ SCS system and see this icon: 
		Reregister and download the app again.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Did not receive a one-time verification code for registration.	Clinician programmer is not connected to the internet. Notifications are not enabled.	Connect to a wireless network. In Settings, allow notifications for the Hub app.
Bluetooth® Wireless Technology Communication or Connection		
Clinician programmer cannot establish Bluetooth connection with the generator or charger, or	Interference in the environment, including temporary interference (for example, from power cleaners, Wi-Fi routers, areas of high Wi-Fi or Bluetooth® wireless technology usage, or voltage surge produced by lightning).	Move to another location so the clinician programmer and generator or charger are away from other devices or environment that may be causing interference.
▪ connection was lost or is intermittent.		
▪ app returns to home screen.		Reconnect the clinician programmer with the generator or charger. Start new session.
▪ clinician programmer does not respond to input.		
	The user's hand is blocking the Bluetooth® wireless technology antenna.	Try holding the clinician programmer differently.
	Bluetooth® wireless technology connection is not strong.	Decrease the distance between the devices.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
		Move to another location so the clinician programmer and generator are away from other devices that may be causing interference.
		Move the clinician programmer and generator so that they have line of sight.
		Disable Wi-Fi in the iOS® settings. Do not operate other wireless devices at the same time.
		Disconnect any Bluetooth® wireless technology media accessories (such as headphones or speakers, AirPods, AirPods Pro, CarPlay, or Hotspot).
		Turn on Bluetooth® wireless technology using the iOS® settings.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Cannot find or connect to the generator or charger.		1. Return to the clinician programmer Home screen and tap Settings. 2. Tap Bluetooth, then tap the Bluetooth toggle button.
		Close the clinician programmer app and then turn the clinician programmer off and on.
Cannot find or connect to the generator or charger.	Unsupported device.	Download the clinician programmer app for the Eterna™ SCS system.
	The clinician programmer pairing with the generator or charger was lost or removed.	1. Follow the alert message to remove the existing pairing from the clinician programmer iOS® settings. 2. Pair the clinician programmer with the generator or charger. See “Pairing Devices With the Clinician Programmer and Patient Controller” (page 13).

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
		Ensure the clinician programmer is in Bluetooth® wireless technology range of the generator (within 3 ft or 0.9 m) or charger (within 6.5 ft or 2 m).
	The generator or charger battery is low.	Charge the generator or charger.
Impedance Issues		
Impedance values are incorrect.	Lead is incorrectly inserted.	Check that the leads are properly inserted.
	Lead is damaged or has become disconnected.	If impedance remains high despite changes to program settings, then the lead may be damaged or disconnected. Check the connections or consider replacing the lead. For more information, refer to the clinician manual for the applicable components. Refer to “Measuring Impedance” (page 34) for more information.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
An impedance report is missing or unavailable.	Program or system impedance logging was interrupted by one of the following: ▪ Generator was in MRI mode or surgery mode ▪ Generator firmware was being updated ▪ Generator was in active communication with the clinician programmer or patient controller ▪ Generator battery was too low ▪ Generator was being charged	Missing or unavailable reports cannot be retrieved. When generating impedance reports, avoid the interruptions listed under Possible Cause.
Stimulation		

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Parameter areas on the Program screen turn yellow.	Generator has reached its output limit and is in overhead.	You may test stimulation while the generator is in overhead, but you cannot save the program. Reduce the amplitude or pulse width. OR Set additional polarities (anode or cathode) on the lead.
Patient is not receiving stimulation or stimulation turned off unexpectedly.	Stimulation is off, possibly due to a generator reset or magnet was used and turned off stimulation.	Turn on stimulation using the patient controller or magnet.
	Generator battery is low and stimulation shut off.	Check the battery status using the clinician programmer app to determine if the generator battery needs to be charged or is nearing the end of service. For more information, refer to the clinician manual for the generator.
	The therapy schedule or the system impedance measurement	Check the therapy schedule or system impedance schedule.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
	has temporarily stopped stimulation.	
	A magnet was used to turn off stimulation.	Turn on stimulation to resume therapy.
	The generator performed a reset.	Turn on stimulation to resume therapy.
	The generator battery depleted.	Charge the generator.
	The generator entered Surgery mode.	If Surgery mode was triggered in error, follow the on-screen notification to exit Surgery mode.
MRI Mode		If the generator detected high current, move the source of the high current away from the generator or move the generator away from the source of the high current. When the generator no longer detects high current, follow the steps to exit Surgery mode.

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
MRI is Not Permitted is displayed instead of the MRI Mode option on the Generator popover.	A part of the implanted system is not MR Conditional.	Confirm the implanted models of the system. If any implanted part is not MR Conditional, the patient cannot receive an MRI scan.
MRI is Not Advised appears while trying to set the generator to MRI mode.	A problem occurred during the system checks while setting MRI mode.	The generator is not in MRI mode, and an MRI scan cannot be performed.
Surgery Mode		
Generator automatically enters Surgery mode and user cannot exit Surgery mode.	The generator has detected high current.	If possible, move the source of the high current away from the generator, or move the generator away from the source of the high current. When the generator no longer detects high current, follow the steps to exit Surgery mode.
Generator automatically enters Surgery mode when no high current source is present.	Surgery mode was triggered in error.	Follow the on-screen notification to exit Surgery mode.
Battery		

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
Replace Generator Soon message appears.	Generator is approaching its end of service.	Consider reprogramming or replacing the generator.
Generator requires frequent charging.	Programs can affect charging frequency.	Check estimated generator charging time and charging interval for a program. Check the charging history report for frequent interruptions. Consider reprogramming the generator. See “Managing Programs on the Generator” (page 45).
Software Update		
Generator or charger software update was not successful.	Generator or charger software update was interrupted.	Try installing the generator or charger software again. If unsuccessful, wait a while and try again. If you cannot locate the generator or charger on the clinician

Table 2. Possible causes and solutions for potential issues

Issue	Possible Cause	Possible Solution
	Pairing was removed between the clinician programmer and the generator or charger.	programmer app, contact Technical Support. Do not remove a pairing during a software update.
Cannot locate programs after updating generator software.	After installing generator software, the previous program data was lost.	1. On the patient records screen, locate the patient history. 2. Reprogram the patient.
Software update is not available for clinician programmer app, generator, or charger.	An update is not available at this time.	You should see a notification when a software update is available. Generator and charger software updates can be viewed in the About popover of the connected device.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Group ID List

Following is the Group ID list you will use when installing the clinician programmer app and patient controller app.

Table 3. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Algeria	PRODEU	Lebanon	PRODLBN
Argentina	PRODLATAM	Luxembourg	PRODEU
Australia	PRODAUSNZ	Malaysia	PRODEU
Austria	PRODEU	Mexico	PRODLATAM
Belgium	PRODEU	Netherlands	PRODEU
Brazil	PRODLATAM	New Zealand	PRODAUSNZ
Canada	PRODCAN	Norway	PRODEU

Table 3. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Chile	PRODLATAM	Panama	PRODLATAM
China	PRODCHN	Peru	PRODLATAM
Colombia	PRODLATAM	Poland	PRODEU
Costa Rica	PRODLATAM	Portugal	PRODEU
Cyprus	PRODEU	Puerto Rico	PRODUSA
Czech Republic	PRODEU	Russia	PRODRUS
Denmark	PRODEU	Saudi Arabia	PRODAPAC
Ecuador	PRODLATAM	Singapore	PRODSGP
Finland	PRODEU	South Africa	PRODEMEA2
France	PRODEU	South Korea	PRODAPAC
Germany	PRODEU	Spain	PRODEU
Greece	PRODEU	Sweden	PRODEU
Hong Kong	PRODAPAC	Switzerland	PRODEU
Iceland	PRODEU	Taiwan	PRODAPAC

Table 3. Group ID list

Country/Region	Group ID	Country/Region	Group ID
India	PRODAPAC	Thailand	PRODAPAC
Ireland	PRODEU	Turkey	PRODEMEA2
Israel	PRODAPAC	UK	PRODEU
Italy	PRODEU	US	PRODUSA
Japan	PRODJPN	Country Not Listed	PRODOTHER

Appendix B: Buttons and Icons on Screens and Popovers

The following tables provide definitions for buttons and icons that you may encounter on the device and program screens and popovers.

NOTE: Not all buttons or icons will be available on all screens.

Table 4. Select Device popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Refresh button	Tap to update the device list.
	Generator icon	Tap to view this connected generator.

Table 4. Select Device popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Charger icon	Tap to view this connected charger.
	Unpaired generator icon	Tap to pair this generator.
	Unpaired charger icon	Tap to pair this charger.

Table 5. Program screen and popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Patient Information button	Tap to view or edit patient information.
	Clinician tab	Tap to view and edit clinician information.
	Programmer tab	Tap to view general system information and export programmer logs and database.
	Patient Record button	Tap to display the Patient Record screen.

Table 5. Program screen and popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Generator icon	Tap to view generator information or change generator preferences.
	Generator charging icon	Tap to view generator charging status.
	Charger charging icon	Tap to view charger charging status.
Revert	Revert button	Tap to revert to the last saved program settings.
	Add/Copy Program button	Tap to add or copy a program.
Program 1	Program Name button	Tap to view and edit the list of available programs.
	Manage Programs button	Tap to view, select, or delete programs or view estimated charge time for the active program.
Done	Done button	On the Program screen, tap to include or remove personal identifiable information in the session report or tap End Session to exit the program.
	Areas button	Tap to add an area to the program.

Table 5. Program screen and popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Decrease/Increase Pulse button	Tap to decrease or increase the number of pulses (BurstDR™ stimulation only).
	Area Options button	Tap to edit an area name or delete an area. For tonic stimulation, also tap to balance areas.
	60% Burst Target button	Tap to set the target amplitude to 60% of the active amplitude (BurstDR™ stimulation only).
Edit	Edit button	Tap to edit the lead diagram settings.
	Electrode button	Tap to change the electrode settings.
	Up button	Tap to shift the electrode polarities up. This feature is only available with certain lead types.
	Down button	Tap to shift the electrode polarities down. This feature is only available with certain lead types.
	Up button	Use the MultiSteering programming feature to steer the electrical field up. This feature is only available with certain lead types.

Table 5. Program screen and popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Down button	Use the MultiSteering programming feature to steer the electrical field down. This feature is only available with certain lead types.
	Left button	Tap to decrease amplitude.
	Right button	Tap to increase amplitude.
	Left button	Use the MultiSteering programming feature to steer the electrical field left. This feature is only available with certain lead types.
	Right button	Use the MultiSteering programming feature to steer the electrical field right. This feature is only available with certain lead types.
	Generator anode button	Tap to change the generator to anode. A red generator icon with a plus sign appears. This option clears anodes from the leads (Tonic only).
	Program Options button (at bottom of screen)	Tap to change the active program options.

Table 5. Program screen and popover buttons and icons

Button or Icon	Button or Icon Name	Description
	Stop stimulation button	Tap to stop stimulation.
	Clear button	Tap to clear the contents of a text field.
	Delete button (visible in popovers)	Tap to reveal or hide the Delete button.
	Reset button	Tap to reset to the most recently saved settings.
Back	Back button	Tap to save changes and return to the previous screen or popover.
Cancel	Cancel button	Tap to discard changes and return to the previous screen or popover.
	Share report button	Tap to email or print the report.

Table 6. Patient Records screen and popover buttons and icons

Button or Icon	Action
< Home	Tap to return to Home screen

Table 6. Patient Records screen and popover buttons and icons

Button or Icon	Action
Edit	Tap to edit patient list
Cancel	Tap to exit edit mode
Select All	Tap to select all patients
Done	Tap to exit screen
Search	Tap to search for a patient name
	Tap to clear contents from text field
Retry Pending	Tap to enroll a patient to a pending generator
Create New Patient	Tap to open New Patient popover
Delete	Tap to delete selected patients
< Back	Tap to go to the Patients screen (if not in a session) or the Program screen (if in a session)
	Tap to delete the patient record
Patient Devices	Tap to view active patient devices

Table 6. Patient Records screen and popover buttons and icons

Button or Icon	Action
Patient Information	Tap to view and edit patient information
Notes	Tap the text field to enter notes
Sessions	Tap to view the session history list
Program Impedance	Tap to view program impedance information
System Impedance	Tap to view system impedance information
Therapy Events	Tap to view therapy events
Charging History	Tap to view charging history
	Tap to edit
	Indicates PII option must be selected
	Indicates PII is included in the report
	Indicates PII has been removed from the report
	Tap to email the backup file. (Only available when a backup file exists.)

Table 6. Patient Records screen and popover buttons and icons

Button or Icon	Action
	Tap to open Enroll Patient popover
About	Tap to view patient device information
	Tap to open Create Report popover
	Tap to open Share Report popover
	Tap to view user-initiated system impedance reports
	Tap to view generator-initiated system impedance reports
	Tap to access device email
	Tap to access device notes function
	Tap to save to Books
	Tap for more options

Table 6. Patient Records screen and popover buttons and icons

Button or Icon	Action
	Tap to email report as an XML attachment
	To enable the markup function
	Tap to open printer options
	Tap to save to files

Appendix C: Regulatory Statements

These statements are applicable to the generator. For Regulatory Statements regarding the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/guide; or, on the clinician programmer Home screen, tap  and then tap **Legal & Regulatory**.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular

installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format.

Table 7. Registration identification information

Identifier Type	Registration Identifier
FCC Registration Number	PX2-GMIPG1

Product Classification Statement (CISPR 11, Class B)

This product is class B equipment, which is intended primarily for use in the domestic environment.

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® wireless technology as it is implemented in the device.

Table 8. Bluetooth® Low Energy (LE) wireless technology information

Antenna type	Modified monopole
Antenna dimensions	10.7 mm x 4.3 mm x 3.0 mm
Modulation	GFSK
Output power (EIRP*)	2 mW (+3 dBm) typical
Duty cycle	14.1% or less over 6 min period
Range	Up to 2 m typical
Center frequency	2.44 GHz
Channel frequency range	2.402 GHz to 2.480 GHz
Channel	40 logical channels using AFH**
Bandwidth per channel	2 MHz

Table 8. Bluetooth® Low Energy (LE) wireless technology information

Data flow	Bi-directional	
Protocol	Bluetooth LE wireless technology	
Semi-duplex capability	Yes	

*EIRP = Equivalent isotropically radiated power (not duty cycle adjusted)

**AFH = Adaptive frequency hopping

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.



Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Low Energy (LE) wireless technology enables communication between the generator or charger and the clinician programmer or patient controller. The quality of the wireless communication link varies depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator or charger, the Bluetooth® wireless technology symbol is visible on the clinician programmer or patient controller in the upper right corner of the screen. When the Bluetooth wireless connection is not active, the symbol appears dimmed.

The standard Bluetooth® wireless technology data rate is 1 Mbit/s. The quality of service (QoS) should allow wireless data to be transferred at a net rate of 2.5 kB/sec. Each connection interval includes a semi-duplex transmission with a required acknowledgment, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not successfully received. Each key press may transmit up to 4 data packets with up to 20 bytes per packet, depending on the number of packets that need to be transmitted (that is, if there is only one packet to transmit, only one packet will be transmitted). If the interference is high (for example, the bit error rate exceeds 0.1%), the user may experience what appears to be a slow connection, difficulty pairing devices, and a need to decrease the distance between connected devices. For information on how to improve connection issues, please refer to Troubleshooting for Wireless, Coexistence, or Interference Issues (page 95).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator and charger encrypt wireless communication with the programming device using a key that is unique to that link.
- Only one patient controller or clinician programmer may communicate with the generator or charger at a time.
- Standard Bluetooth® Low Energy (LE) pairing methods ensure valid and legitimate pairing among devices.
- Proprietary authentication for the patient controller or clinician programmer apps in addition to the pairing procedure specified in Bluetooth LE, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized app from communicating with the generator and charger.

- Whitelisting methods that prevent unauthorized devices from using Bluetooth LE scanning to interfere with communication from the generator or charger to a legitimate patient controller or clinician programmer.

Troubleshooting for Wireless, Coexistence, or Interference Issues

If you experience issues with interactions within the neurostimulation system, try the following:

- Decrease the distance between the devices.
- Move the devices so they share line of sight.
- Move the devices away from other devices that may be causing interference.
- Close the clinician programmer app; then turn the clinician programmer off and on.
- Wait a few minutes and try connecting again.
- Avoid operating other consumer electronic devices, such as a laptop, tablet, mobile phone, or cordless phone at the same time.

NOTE: Equipment such as the following can interfere with the neurostimulation system: radiation-based imaging devices, electrosurgery devices, medical monitoring devices, radiofrequency identification devices (RFID), diathermy devices, wireless home network devices, and consumer electronic devices.

Appendix D: Radio Frequency Information

The effective radiated power is below the limits as specified in:

- USA: FCC 47 CFR Part 15

NOTE: Maintain a reasonable distance between other electronic equipment and the device.

CAUTION: The ISM band used by this device has been approved by the Federal Communications Commission for unlicensed use. However, there is no guarantee that this device will not receive interference or that any particular transmission from this device will be free from interference.

Appendix E: Electromagnetic Compatibility Guidelines

The clinician programmer app (Model 55600) operates on an Apple® iOS® device as part of the Eterna™ SCS system. Refer to the precautions in this guide for information on sources of EMI, the effect of EMI on the patient and the Eterna™ SCS system, and instructions on how to reduce the risk of EMI (see “Precautions” (page 4)). Failure of the Apple® iOS® device will not result in an unacceptable risk to the user.

The Eterna™ SCS system has undergone electromagnetic disturbance testing to confirm essential performance of the associated medical equipment as defined by IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Ed 3.2). Refer to the manuals for the implantable pulse generator and charging systems for information regarding electromagnetic declaration and intended use environments.

NOTE:

- Apple® iOS® devices were included in the Eterna™ SCS system testing for electrostatic discharge (ESD), power frequency, radiated electric fields, and radiated magnetic fields.

- The non-Abbott Medical accessories supporting the clinician programmer, such as charging cords, adapters, should not be used while running the clinician programmer app. The effect of use of such accessories while running the app has not been evaluated.

Appendix F: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

NOTE: For symbols and definitions for the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals; or, on the clinician programmer Home screen, tap ⓘ > Legal & Regulatory.

Table 9. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website

Table 9. Symbols and definitions

Symbol	Definition
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment.
	Manufacturing facility
	Manufacturer
	Authorized representative in the European Community
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2023-05
ARTEN600283838 B



NeuroSphere™ Clinician Programmer
Spinal Cord Stimulation Systems
Model 3874

Clinician's Manual



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

[™] Indicates a trademark of the Abbott group of companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

Pat. <http://www.abbott.com/patents>

© 2022 Abbott. All Rights Reserved.

Contents

Prescription and Safety Information.....	1
Intended Use.....	1
Additional Prescription Information.....	1
MRI Safety Information.....	2
Warnings.....	2
Precautions.....	3
Product Description.....	5
Overview of the Clinician Programmer.....	6
Getting Started.....	7
Downloading the Clinician Programmer App.....	7
Navigating the Home Screen.....	9
Pairing the Clinician Programmer to the Generator.....	10
Pairing the Patient Controller to the Generator.....	12
Programming with the Clinician Programmer App.....	14
Navigating the Program Screen.....	14
Creating a New Programming Session.....	19

Reassigning a Generator.	20
Selecting the Lead Configuration.	21
Configuring Electrode Polarities.	23
Switching Between Tonic Mode and Burst Mode.	24
Adjusting Pulse Width.	25
Adjusting Amplitude and Step Size.	25
Adjusting Frequency for Tonic Programs.	27
Setting Perception and Comfort Amplitudes for Tonic Programs.	27
Adjusting Frequency for Burst Programs.	28
Setting the Target Amplitude for Burst Programs.	29
Adding an Area to a Program.	30
Removing or Editing an Area in a Program.	30
Increasing or Decreasing the Number of Burst Pulses for An Area.	31
Setting the Patient Controller Custom Settings.	31
Creating a Stimulation Map.	32
Measuring Impedance.	32
Using the Shifting Programming Feature.	34
Using the MultiSteering™ Programming Feature.	35
Adding a New Program.	36

Changing the Active Program.....	37
Copying a Selected Program.....	37
Renaming a Selected Program.....	37
Deleting a Selected Program.....	38
Modifying Program Options.....	39
Using the Active Balancing™ Programming Feature.....	43
Saving a Program.....	45
Managing Programs on the Generator.....	45
Viewing Generator Details.....	47
Selecting a Personally Identifiable Information (PII) Setting.....	50
Managing Patient Records.....	51
Buttons and Icons on the Patient Records Screens and Popovers.....	51
Adding a Patient.....	54
Editing a Patient's Information.....	54
Deleting a Patient from the Database.....	55
Viewing, Emailing, and Printing a Report.....	55
Checking the Generator Battery Status.....	56
Maintaining the Clinician Programmer.....	58
Checking the Clinician Programmer Battery Status.....	59

Caring for the Clinician Programmer.....	59
Cybersecurity.....	59
Legal and Privacy Notice.....	61
Troubleshooting.....	61
Troubleshooting Chart.....	62
Technical Support.....	69
Appendix A: Group ID List.....	70
Appendix B: Regulatory Statements.....	72
Appendix C: Symbols and Definitions.....	72

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The Clinician Programmer Application is intended to help clinicians program stimulation parameters for Abbott Medical neurostimulation systems and create customized therapy for patients.

Additional Prescription Information

Refer to the clinician's manual for the appropriate neurostimulation system to get additional prescription information, including indications for use and contraindications. For specific instructions, warnings, precautions, and adverse effects about other system components, see the clinician's manual for those components.

For information that supports the clinical use of the neurostimulation system and the anatomical placement of leads, refer to the clinical summaries manual for spinal cord stimulation (SCS) systems.

MRI Safety Information

For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

Do not bring the clinician programmer into a scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is considered MR Unsafe.

Warnings

The following warnings apply to these components.

NOTE: For nontherapy-related warnings for the NeuroSphere™ Clinician Programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals.

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an electrosurgery device, place the neurostimulator in Surgery Mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure. During implant procedures, if electrosurgery devices must be used, take the following actions:

- Use bipolar electrosurgery only.

- Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Set the electrosurgery device to the lowest possible energy setting.
- Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.

System components. The use of components not approved for use by Abbott Medical may result in damage to the system and increased risk to the patient.

Application modification. To prevent unintended stimulation, do not modify the operating system or application in any way.

Explosive or flammable gases. Do not use the device in an environment where explosive or flammable gas fumes or vapors are present, including hyperbaric chambers. Operating the device could cause it to ignite, causing severe burns, injury, or death.

Precautions

The following precautions apply to these components.

NOTE: For nontherapy-related precautions for the NeuroSphere™ Clinician Programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals.

Device Precautions

Nonsterile device. The medical device system comprised of the programmer and other Abbott Medical devices as specified in this document must be used in accordance with IEC 60601-1 for patient programming. This device is a nonsterile device and must be kept out of the sterile field (patient environment).

Device inspection. Before operating the system each time, inspect the device and all its components for mechanical and electrical integrity. Avoid using the system if the device or its components are damaged. Return damaged components to Abbott Medical for evaluation.

Handle the device with care. The device is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Programmer use. Allow only authorized use of the clinician programmer to avoid any programming changes that may injure a patient.

Application Precautions

Clinician training. Clinicians should be familiar with neurostimulation therapy and be experienced diagnosing and treating the indication for which the neurostimulation system components are being used.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces),

communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth wireless technology) may be restricted. Such restrictions may apply aboard airplanes, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the stimulator. If unpleasant sensations occur, the device should be turned off immediately.

Product Description

The NeuroSphere™ Clinician Programmer application (app) (Model 3874) interfaces with Abbott Medical neurostimulation systems and is intended to be used to noninvasively program and control device parameters. The NeuroSphere™ Clinician Programmer communicates wirelessly with the generator.

NOTE:

- For more information about the neurostimulation system, see the clinician's manual for the compatible components.

- In this document, the term “clinician programmer” refers to the NeuroSphere™ Clinician Programmer device, “patient controller” refers to the NeuroSphere™ Patient Controller device, “clinician programmer app” refers to the NeuroSphere™ Clinician Programmer app, and “patient controller app” refers to the NeuroSphere™ Patient Controller app.

Overview of the Clinician Programmer

The clinician programmer is an Apple® iOS® device provided by Abbott Medical.

Before you begin, be sure you are familiar with how to perform these basic operational functions on the clinician programmer.

- Turning the clinician programmer on and off
- Placing the clinician programmer in sleep mode
- Waking the clinician programmer from sleep mode
- Locking and unlocking the clinician programmer
- Using touchscreen functions such as tap and screen swipe actions
- Returning to the Home screen

NOTE: For nontherapy-related information on how to use the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals.

Getting Started

This section contains information about navigating the clinician programmer app Home screen and instructions for pairing and connecting the clinician programmer to a generator.

Downloading the Clinician Programmer App

NOTE:

- The clinician programmer app is compatible with the Apple® iPad® mobile digital device provided by Abbott Medical. The patient controller app is compatible with an Apple iOS® mobile digital device (either a device provided by Abbott Medical or a compatible personal Apple iOS device).
- Install the apps well before you need to use them in case you encounter network or server issues.
- If managing patients programmed with FlexBurst360™ stimulation technology, always use the latest version of the NeuroSphere™ Clinician Programmer Application in the App Catalog.
- FlexBurst360™ stimulation technology is not available on every IPG model. For more information about product eligibility, please contact your local Abbott Medical representative.

The following steps provide instruction for downloading the clinician programmer app. For instructions on downloading the patient controller app, see the user's guide.

1. Make sure the device is turned on and connected to the internet.
2. Enter the following web address in your web browser: <https://sjm.awmdm.com>

NOTE: Most devices will already have the web address bookmarked.

3. Follow the onscreen instructions.
4. When prompted, enter the Group ID.
NOTE: The Group ID varies depending on where the device is used. See Appendix A (page 70) for the Group ID for your location.
5. Enter your Abbott Medical username and passcode.
You may wait a minute or longer while the device connects to the server.
6. Tap **Install** on the Install Profile screen.
7. Tap **Install** when prompted to Install Profile.
8. Tap **Install** on the Mobile Device Management Warning screen.
9. Tap **Trust** on the Remote Management screen.
10. Tap **Done** on the Profile Installed screen.
11. Exit your web browser when you reach the Enrollment Complete screen.
The app icon automatically appears on the clinician programmer Home screen, though it may take a few minutes.

Figure 1. Clinician programmer app icon



If the app icon does not appear after a few minutes:

1. Tap  on the clinician programmer Home screen.
The App Catalog screen opens.
2. Tap the Internal tab.
You will see the clinician programmer app.
3. Tap **Install**.
4. Tap **Install** when prompted.
It may take a few minutes for the app to appear on the clinician programmer Home screen.

Navigating the Home Screen

When you launch the clinician programmer app, the clinician programmer app Home screen appears. From this screen, you can access the following areas.

- Tap **Generators** to locate a generator for programming.
- Tap **Patient Records** to open the patient records screen.
- Tap **Demonstration Mode** to open a software demonstration. Demonstration Mode provides representative functionality for the clinician programmer app, including creating programs and adjusting parameter limits within available combinations.

- Tap **i** to open the Information popover where you can view clinician and programmer information (including the clinician programmer app model number and software version), as well as create and email a programmer log and programmer database (see “Troubleshooting” (page 61) for instructions). From here, you can also view the Intended Use and open the Instructions for Use by tapping View IFU at the bottom of the popover.
NOTE: If you have not previously launched the clinician programmer app after installation or update and accepted the Terms of Use and the Privacy Policy, screens will display requiring your agreement before you can use the app.
- Tap **Accept** after reading the Terms of Use and **Acknowledge** after reading the Privacy Policy. To view this information again, tap **Terms of Use** or **Privacy Policy** in the programmer Information popover.
NOTE: The first time you launch the clinician programmer app, a prompt opens requesting you to allow Bluetooth® wireless communication access.
- Tap **OK** to allow the app to communicate with the generator. If not accepted, you can return to the clinician programmer Home screen later. Tap **Settings** > **Bluetooth** and enable access.
NOTE: The clinician programmer app times out after 30 minutes of inactivity; however, if you navigate away from the app, the app times out after 3 minutes of inactivity.

Pairing the Clinician Programmer to the Generator

Pairing is when you set up communication between the clinician programmer or patient controller and generator. The following instructions outline the steps for pairing the clinician programmer to the generator. For further instructions, refer to the clinician’s manual for the generator.

NOTE:

- If the IPG has never established communication with a programmer, you must first activate the IPG for communication (“wake up” the IPG) by holding a magnet over the IPG for 10 seconds, and then move the magnet away from the generator.
- You cannot pair the generator to the clinician programmer if the generator is currently communicating with the patient controller. See “Troubleshooting” (page 61) for instructions on ending the session early.
- Before the app can establish communication with the IPG, a prompt may display requesting the user to allow Bluetooth® wireless communication access. Tap **OK** to allow access. Otherwise, the application will be unable to communicate with the generator. Visit support.apple.com for more information.

1. Place the magnet perpendicular to the generator for 10 seconds, and then move the magnet away from the generator.
If pairing with an External Pulse Generator (EPG), the indicator light on the generator will start flashing.
2. Tap the clinician programmer app.
The clinician programmer app launches.
3. Tap **Generators** on the clinician programmer app Home screen.
The Select Generator popover opens.
4. Select an available generator. A white unlock icon is displayed over the generator if the generator is ready to pair.
If the “No Supported Generators Found” message displays, tap  to search for available generators again and refresh the generator list.

5. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
 6. Tap **Pair** to pair the clinician programmer and generator.
- Once you have paired the clinician programmer to a generator, you will not need to pair the clinician programmer to that generator again unless more than four clinician programmers also pair with the generator.

Pairing the Patient Controller to the Generator

The following instructions outline the steps for pairing the patient controller to the generator. For further instructions, refer to the clinician's manual for the generator.

NOTE: You cannot pair the generator to the patient controller if the generator is currently communicating with the clinician programmer. Tap **Done**, select the Personally Identifiable Information (PII) setting, and then **End Session** in the clinician programmer app to end the session. (See "Selecting a Personally Identifiable Information (PII) Setting" (page 50) for more information regarding PII).

1. Place the magnet perpendicular to the generator for 10 seconds, and then move the magnet away from the generator.
If pairing with an EPG, the indicator light on the generator will start flashing.
2. Tap the patient controller app.
The patient controller app launches.
3. Tap .
The Add Generator screen opens.

4. Tap an available generator in the “Select a Generator...” list.
If the “No Generators Found” message displays, tap  to search for available generators again and refresh the generator list.
5. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
6. Tap **Pair** to pair the patient controller and generator.
The “Connecting to Generator...” message displays while the patient controller is connecting to the generator.

NOTE: Store paired patient controllers and trial generators together to reduce the number of times you need to set up communication.

You may pair the patient controller with up to four different generators. To delete a generator from the patient controller app:

1. On the Generators screen, tap **Edit**.
2. Tap  next to the generator you want to delete.
The Delete button appears next to the generator.
3. Tap **Delete**.
A confirmation pops up.
4. Tap **Delete** to remove the generator.

Programming with the Clinician Programmer App

This section provides instructions and information about programming using the clinician programmer app.

NOTE:

- Some functionality included in the manual may be unavailable in your region. Consult your local Abbott representative for more information.
- Do not navigate away from the clinician programmer app while you are in a programming session. Enabling Do Not Disturb mode prior to your programming will prevent interruption from occurring during a programming session. Find 'Do Not Disturb' instructions from Apple, which are located at support.apple.com by typing "Do Not Disturb" in the Search Support box.
- Place the IPG into Surgery Mode before entering the operating room. While in the operating room, leave the IPG in Surgery Mode unless you are actively programming. See "Viewing Generator Details" (page 47) for information about placing a generator into Surgery Mode.

Navigating the Program Screen

The Program screen opens once you successfully connect to a generator. See "Switching Between Tonic Mode and Burst Mode" (page 24) for more information.

Buttons and Icons on the Program Screens and Popovers

The following table provides definitions for buttons and icons that you may encounter.

NOTE: Not all buttons or icons will be available on all screens.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Patient Information button (at top of screen)	Tap to view or edit patient information.
	Generator Icon (at top of screen)	Tap to view generator information.
Revert	Revert button	Tap to revert to the last saved program settings.
	Add/Copy Program button	Tap to add or copy a program.
Program 1	Program Name button	Tap to view and edit the list of available programs.
	Manage Programs button (at top center of screen)	Tap to view, select, or delete the programs on the generator communicating with the clinician programmer app.
Done	Done button	On the Program screen, tap to save the program and end the session. On a popover, tap to save changes and return to the previous screen or popover.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Add Area	Tap to add an area to the program.
	Decrease/Increase Pulse button	Tap to decrease or increase the number of pulses (BurstDR™ stimulation only).
	Area Options button (at top right of screen)	Tap to edit an area name or delete an area. For tonic stimulation, also tap to balance areas.
	60% Burst Target button	Tap to set the target amplitude to 60% of the active amplitude (BurstDR stimulation only).
Edit	Edit button	Tap to edit the lead diagram settings.
	Electrode button	Tap to change the electrode settings.
	Up button	Shift the electrode polarities up. This feature is only available with certain lead types.
	Down button	Shift the electrode polarities down. This feature is only available with certain lead types.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Up button	Use the MultiSteering™ programming feature to steer the electrical field up.
	Down button	Use the MultiSteering programming feature to steer the electrical field down.
	Left button	Use the MultiSteering programming feature to steer the electrical field left.
	Right button	Use the MultiSteering programming feature to steer the electrical field right.
	Generator anode button (at bottom of the lead configuration screen)	Tap to change the generator to anode. This option removes anodes from the leads (IPG only; Tonic only).
	Program Options button (at bottom of screen)	Tap to change the active program options.
	Stop stimulation button	Tap to stop stimulation.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Clear button	Tap to clear the contents of a text field.
	Delete button control (visible in popovers)	Tap to reveal or hide the Delete button.
	Reset button	Tap to reset to the most recently saved settings.
Back	Back button	Tap to save changes and return to the previous screen or popover.
Cancel	Cancel button	Tap to discard changes and return to the previous screen or popover.
	Share report button	Tap to email or print the report.

Creating a New Programming Session

NOTE: Battery life depends on communication usage and stimulation settings. Programs with higher outputs (pulse width, frequency, or amplitude) will deplete the generator battery faster.

To start a new programming session:

1. Tap **Generators** on the clinician programmer app Home screen.
The Select Generator popover opens.
2. Select an available generator. A patient name is displayed under the generator previously associated with a patient if the clinician programmer was used to program this generator before.
 - Swipe up or down to display more available generators, if applicable.
3. If this is a trial generator, tap **New Trial** or **Continue Trial** on the “Continue Trial or Start New Trial?” popover.
The Program screen opens.
4. Set the desired parameters. See the corresponding sections in this manual for instructions.
5. Enter patient information as needed. See “Managing Patient Records” (page 51) for more information.
6. When finished, tap **Done**, select the Personally Identifiable Information (PII) setting, and **End Session**.
(See “Selecting a Personally Identifiable Information (PII) Setting” (page 50) for more information regarding PII).

Reassigning a Generator

When starting a new trial you have the option to reassign a generator to a new patient. The records for the previous patient assigned to the generator are retained in the patient records.

To reassign a generator to a new patient:

1. Tap **New Trial** on the “Continue Trial or Start New Trial?” popover.

The generator is assigned to a default patient.

2. From the Program screen, tap . The Patient popover opens.
3. Tap **Edit** and then edit the default patient information to create a new patient.
4. Tap **Done** to return to the Patient popover.

When creating a programming session for a new patient, you may assign the generator to an existing patient by editing the default patient information.

To assign the generator to an existing patient:

1. From the Program screen, tap . The Patient popover opens.
2. Select **Edit**.
3. Tap **Select a Patient**. The Select a Patient popover opens.
 - Tap in the Search field and enter a patient’s first or last name to search for a patient.
 - Swipe to scroll through the patient list.
4. Tap a patient name to select that patient.

5. Tap **Done**. The Reassign Generator popover opens.
6. Tap **Reassign** to reassign the generator and close the popover.

Selecting the Lead Configuration

NOTE: If a lead model is an approved MR Conditional component, an MR Conditional icon () is displayed beside the model number. If you select an MR Conditional lead, a message appears asking if a lead extension is used with the system. Tap **Yes** or **No** appropriately because this information is critical for determining if all the implanted components meet the MR Conditional requirements.

To add a lead:

1. Tap **Edit** in the lead diagram area on the Program screen.
2. Tap **+**.

The Lead Options popover opens.

3. Tap **Model**.

The Model popover opens.

From the Model popover, you have the following options for adding a lead:

- Search for a lead using a partial model name or model number.
- Tap the model name and then select the model number from the popover.

4. Select **Yes** or **No** if you are using a lead extension.
This popover only opens if you select an MR Conditional lead.
5. Tap **Done** or tap outside the popover to save changes and close the popover.
To select the patient's lead configuration:
 1. On the Program screen, tap **Edit** in the lead diagram area.
 2. Tap  to add a lead to the first available port.
To remove the lead:
 1. Tap .
 - The Delete Lead popover opens.
 2. Tap **Delete Lead** to remove the lead or outside the popover to cancel removing the lead.
To edit the lead options:
 1. Tap the lead to open the Lead Options popover.
 2. Set the desired lead options.

NOTE: A 16 channel lead only allows the Reverse Ports option, not the Port option.

NOTE: If you change the lead configuration, you may need to delete existing programs.
 3. Tap **Done** or tap outside the popover to save changes and close the popover.

Configuring Electrode Polarities

Individual electrodes on a lead may be set to positive (anode), negative (cathode) or neutral.

NOTE: If you manually change polarities while stimulation is active, stimulation turns off. Additionally, the perception and comfort amplitude values clear on tonic programs or the target amplitude value clears on BurstDR™ stimulation programs, as well as any previous area impedance results.

To configure electrode polarities:

1. On the Program screen, tap the desired area in the Area section, then tap a numbered electrode.

NOTE: For most lead configurations, once at least one anode or cathode is set, a box indicating the selected electrode configuration will appear. The electrode configuration for the currently selected area will be shaded green if amplitude is above 0 mA. Electrode configurations for other areas will appear as a dashed line box.

The electrode popover opens.

- Tap – (Cathode) to set the electrode to cathode.
- Tap + (Anode) to set the electrode to anode.
- Tap outside the electrode popover to close the popover.
- Tap OFF to turn the electrode off.

NOTE: The anode option is unavailable for leads if the generator is set to function as an anode.

Switching Between Tonic Mode and Burst Mode

On the clinician programmer app you may create and modify two types of programs:

- Tonic program. A program where the stimulation frequency consists of a single, repeating pulse.
- Burst program. A program where the stimulation frequency consists of a group of pulses in rapid succession followed by a period without pulses before repeating the group.

NOTE: An “Area” refers to a combination of selected stimulation parameters. For tonic stimulation, stimulation parameters for each area include electrode configuration, amplitude, frequency and pulse width. For BurstDR™ stimulation, stimulation parameters for each area include electrode configuration, amplitude, pulse width, burst frequency, intra-burst rate and number of pulses. FlexBurst360™ stimulation technology enables the creation of multiple areas within a BurstDR™ stimulation program.

You may switch to BurstDR™ stimulation programming mode on the Program screen.

NOTE:

- When creating a new program, you start programming in tonic programming mode by default.
- When you switch between burst mode and tonic mode, all programmed values reset to default except the electrode configuration.

To switch between tonic mode and burst mode:

1. On the Program screen, tap  to open the Program Options popover.

2. Tap the BurstDR™ Mode toggle button to switch between tonic stimulation and BurstDR stimulation.
 - Off (toggle button to the left, white), means tonic stimulation is selected
 - On (toggle button to the right, blue), means BurstDR stimulation is selected
3. Tap **Change** to confirm switching the program mode.
When burst mode is active, the Program screen displays the features for BurstDR stimulation programming.

Adjusting Pulse Width

When creating a new program, the Pulse Width box on the Program screen displays a default value, which is determined by programming mode (tonic or burst).

To change the pulse width value, do either of the following:

- Tap the Up or Down buttons next to the Pulse Width box.
- Tap the Pulse Width box, and then tap a value in the Pulse Width popover.

Adjusting Amplitude and Step Size

On the Program screen, you may adjust amplitude and step size. Amplitude is the strength of the electrical pulse delivered from the lead. Step size is the increment at which amplitude will change when you adjust amplitude.

NOTE:

- At any time, you can immediately stop the patient's stimulation by tapping .
- When the generator reaches its energy or charge density limit, a notification appears. Try reducing the frequency, pulse width, and amplitude.
- When the generator reaches its output limit, the parameter boxes turn yellow. You may still increase amplitude but cannot save the program. To reduce the generator output, try reducing the amplitude or pulse width or setting additional anodes or cathodes on the lead configuration.
- If you change electrode polarities after setting the amplitude value, the amplitude value clears.
- For BurstDR™ stimulation, if adding or removing an area would result in a change to Burst Frequency, the amplitude value clears. A reset notification will appear, which will require confirmation of the change.

To adjust amplitude:

- To change the step size, tap and drag the slider to the right or left to increase or decrease the step size accordingly. This determines how much the amplitude is increased or decreased when adjusting amplitude.
- Tap the Up or Down buttons next to the Amplitude box to increase or decrease stimulation.
- Tap a toggle button in the Areas section on the Program screen to turn stimulation on.

NOTE: When creating a tonic program, you may choose between two minimum step sizes (0.05 or 0.10 mA), which determine the maximum available amplitude (12.75 or 25.5 mA, respectively).

Adjusting Frequency for Tonic Programs

When creating new tonic programs, the Frequency box on the Program screen displays a default value.

To change the frequency value, do either of the following:

- Tap the Up or Down buttons next to the Frequency box.
- Tap the Frequency box, and then tap a value in the Frequency popover.

NOTE: When you change the frequency value using the Frequency box, stimulation turns off and the amplitude value clears.

NOTE: The buttons are not available when the programmed maximum (Up) or minimum (Down) frequency is reached.

Setting Perception and Comfort Amplitudes for Tonic Programs

To complete a tonic program, you must set values for perception and comfort amplitudes for each area. The perception amplitude is the value at which the patient first feels stimulation. The comfort amplitude is the value at which the stimulation feels comfortable to the patient.

NOTE:

- When the generator reaches its output limit, the parameter boxes will turn yellow and you cannot set perception and comfort amplitude values. To reduce the output of the generator, try reducing the amplitude or setting additional anodes or cathodes on the lead configuration.

- If you change electrode polarities after you have set the values for perception and comfort amplitude, the perception and comfort amplitude values will clear.

To set a patient's perception and comfort amplitudes:

1. Tap the Perception box to open the Perception popover and set the patient's perception amplitude.
2. Tap the Comfort box to open the Comfort popover and set the patient's comfort amplitude.

NOTE: Once you have set the perception and comfort amplitudes, you can tap **Ramp to – mA** (where “–” is the perception or comfort amplitude) in the Perception and Comfort popovers to ramp the amplitude to the perception or comfort value.

Adjusting Frequency for Burst Programs

BurstDR™ stimulation programs have two adjustable frequency values: the overall frequency (Burst Frequency) and the frequency of each individual pulse in a pulse group (Intra-burst Rate). When creating new BurstDR stimulation programs, the Burst Frequency and Intra-burst Rate boxes on the Program screen display system default values.

To change the frequency values for a BurstDR stimulation program, do either of the following:

- Tap the Up or Down buttons next to the respective box.
 - Tap the respective box, and then tap a value in the popover.
- NOTE: Burst Frequency may be constrained when FlexBurst360™ stimulation technology is used.

Setting the Target Amplitude for Burst Programs

To complete a BurstDR™ stimulation program, you must set the target amplitude value for all areas.

NOTE:

- When the generator reaches its output limit, the parameter boxes will turn yellow and you cannot set the target amplitude value. To reduce the output of the generator, try reducing the amplitude or pulse width or try setting additional anodes or cathodes on the lead configuration.
- If you change electrode polarities after you have set the value for target amplitude, the target amplitude value will clear.
- For BurstDR stimulation, if adding or removing an area would result in a change to Burst Frequency, the target amplitude value clears. A reset notification will appear, which will require confirmation of the change.
- Once you have set the target amplitude, you can tap **Ramp to – mA** (where “–” is the target amplitude) in the Target popover to ramp the amplitude to the target value.

To set a patient’s target amplitude:

1. Adjust the amplitude in the Amplitude field to the desired level.
2. Set Target amplitude to the current active amplitude by tapping the Target box.

NOTE: Alternatively, tap the 60% Target button to set the target amplitude to 60 percent of the current active amplitude. After doing so, the 60% Target button becomes inactive until the amplitude is changed.

Adding an Area to a Program

To add another area to a tonic or burst program:

1. On the Program screen, tap  in the Area section.
 2. Set stimulation parameters as needed for each Area.
- NOTE: If using FlexBurst360™ stimulation technology, ensure the patient controller app has been updated to the latest version. Otherwise, the patient controller will be unable to connect to the patient's generator.

Removing or Editing an Area in a Program

To delete or rename an area:

1. On the Program screen, tap  to open the Areas section.
 2. Tap Edit in the Areas popover.
 - Tap  to delete an area name.
 - Tap the area name to rename the area using the keyboard.
- NOTE: Areas are automatically numbered unless you enter a custom name. Duplicate names are not allowed.

Increasing or Decreasing the Number of Burst Pulses for An Area

To add or remove a burst pulse on a BurstDR™ stimulation area:

- Tap  in the Area section of the Program screen to decrease the number of pulses on an Area.
- Tap  in the Area section of the Program screen to increase the number of pulses on an Area.

Setting the Patient Controller Custom Settings

The system creates default patient controller app maximum output based on program settings, then autopopulates the Patient Controller area accordingly. You may override the recommended value and customize the output the patient controller app allows.

To customize the output for the patient controller app:

1. Tap the Patient Controller box to open the Patient Controller popover.
2. Tap the Use Custom Settings toggle button and select the maximum amplitude for the patient controller app.
3. Tap **Done** or tap outside the popover to save changes and close the popover.

Creating a Stimulation Map

You may create a stimulation map to show where the patient senses stimulation for a specific area. The stimulation map also appears on the user's patient controller app.

To create a stimulation map:

1. On the Program screen, tap the Stim Map. The Map popover opens with a graphic representation of the human body.
2. Tap the areas on the graphic that correspond to the areas where the patient is receiving stimulation. To select multiple areas, tap and drag on the stim map. The tapped areas are highlighted in blue.
3. To remove a highlighted area, tap the area on the stim map. To remove multiple areas, tap and drag on the stim map.
4. To save the stimulation map and return to the Program screen, tap **Done**.
5. To cancel any changes and return to the Program screen, tap **Cancel**.

Measuring Impedance

While programming you may want to periodically measure the impedance on the electrode array as a diagnostic tool to ensure that current is flowing through the system properly. Impedance measurements may help you troubleshoot issues with the neurostimulation system.

To measure impedance for the programmed electrode array:

1. Tap the Impedance box to open the Check Impedance popover.

2. Select the Personally Identifiable Information (PII) setting.
3. Tap **Program** to check the impedance on the electrode configuration for the current program. Impedance is checked and the value is displayed in the Impedance box.
4. Tap **System** to check the impedance on the lead configuration.
 - a. Tap **Start** to start an impedance check on all electrodes. Stimulation turns off during the impedance check.
 - b. Tap **Dismiss** to view the impedance results for each electrode or **View Report** to view the System Impedance report.
 - c. After tapping Dismiss, tap an electrode to open the popover with the impedance results for that electrode.
 - d. Tap **Done** to exit the Full System impedance view.

NOTE: If electrodes on the Program screen turn yellow, your impedance measurement is high or low. See "Troubleshooting" (page 61) for more information.
5. Tap **System (90 Days)** to check the system impedance for the last 90 days.

NOTE: This feature is only visible after you turn on automatic impedance logging on the Generator screen. Turning on this feature will briefly turn patient stimulation off every 23 hours. The 90 Day Impedance Report is displayed.

 - a. Tap  to open the Share popover.
 - b. Tap  to email or tap  to print a PDF of the report.
6. When you are finished, tap outside the popover to return to the Program screen.

To turn on impedance logging:

1. Tap **Impedance Log** on the generator popover. The impedance log popover opens.
2. Tap the impedance log toggle button.

Using the Shifting Programming Feature

The Shifting programming feature, which is only available with certain lead types, provides a simplified method for setting the electrode configuration by moving the entire electrode combinations up or down as a unit. Shifting can continue past the upper and lower boundaries of the lead, resulting in any electrodes moved beyond the boundary to be removed from the electrode combinations. During Shifting programming, stimulation is turned off.

To use the Shifting programming feature:

- Configure electrode polarities until the Shifting buttons become active.
- Tap the Shifting buttons to steer the electrode array.

NOTE: When you use Shifting programming, both the programmed perception and comfort amplitudes automatically clear.

Using the MultiSteering™ Programming Feature

The MultiSteering™ programming feature provides a simplified method for shaping and fine-tuning the electrical field in real time. During MultiSteering programming, certain electrode combinations can be moved while stimulation remains active.

To use the MultiSteering programming feature:

- Configure electrode polarities until the MultiSteering buttons become active.
- Tap the MultiSteering buttons to steer the stimulation through a set of optimized electrode combinations designed to incrementally shift stimulation.

NOTE: When you use MultiSteering programming the programmed comfort amplitude automatically clears.

- Tap the Amplitude box to open the Auto Decrement popover.
 - The default is Set Amplitude to Perception. This option lowers the amplitude to perception when electrodes are changed using MultiSteering programming.
 - Tap **Do Not Change Amplitude** to keep the amplitude the same when electrodes are changed using MultiSteering programming.
- NOTE: Adjust the amplitude to the patient's perception level (Perc) or lower each time before steering to the next combination since some nerve fibers may be more sensitive to electrical fields than others.

Adding a New Program

To add a new program:

1. On the Program screen, tap **+**.
2. Tap **Add New Program** in the popover. A new program is automatically named according to the next available number.
3. Set the desired parameters.

NOTE: The Program screen defaults to tonic programming mode when you create a new program.

Changing the Active Program

To change the active program :

1. On the Program screen, tap the program name.
The Programs popover opens.
2. Tap a program in the list.
The selected program becomes the active program.

Copying a Selected Program

To copy the active program :

1. On the Program screen, tap .
2. Tap **Copy Active Program** in the popover. The duplicated program appears as the next available program number.

Renaming a Selected Program

To rename a program :

1. On Program screen, tap the program name. The Programs popover opens.
2. Tap **Edit**. The Programs popover changes to edit mode.

3. Tap the program name you want to rename. The Edit Name popover opens.
4. Enter a custom name.
5. Tap  to clear the program name field.
6. Tap < to save changes and return to the Programs popover.
7. Tap **Done** to save changes and outside the popover to close the popover.

Deleting a Selected Program

To delete a program:

1. On Program screen, tap the program name. The Programs popover opens.
2. Tap **Edit**. The Programs popover changes to edit mode.
3. Tap  next to the program you want to delete. The Delete button appears.
4. Tap **Delete**.
If all programs are deleted, the popover closes and a default program is created; otherwise, the selected program is deleted.
5. Tap **Done** or outside the popover to save changes and close the popover.

Modifying Program Options

You may modify the active program options. To access the options:

- Tap  at the bottom of the Program screen to open the Program Options screen. From the Program Options screen, you may perform the following actions:
 - Set the burst mode (visible if Burst Mode is unlocked)
 - Set the dosage
 - Set the intermittent dosage on and off times
 - Set the step size increment (IPG only; Tonic only)
 - Set the sleep on time (EPG only)
 - Set the magnet mode
 - Set the ramp time for sleep (EPG only) or continuous dosage

To modify program options:

1. On the Program Options screen, modify the settings as desired. The following subsections provide more information about using these settings.
2. When you are finished, tap **Done** or tap outside the popover to save changes and close the popover.

To Set the Dosage

The dosage setting controls the delivery of stimulation. The following table provides definitions of the dosage options that may be available.

Table 2. Definitions of Dosage Options

Dosage	Definition
Continuous	Stimulation is delivered continuously while the generator is on and the program is running.
Intermittent	Stimulation is on for a programmed amount of time (on time) and off for a programmed amount of time (off time). Stimulation alternates between on and off states until the generator is turned off or the program is stopped.
Sleep	Stimulation is on for a programmed amount of time (on time), after which stimulation turns off and stays off until stimulation is manually turned on. (EPG only)

NOTE: In neurostimulation therapy, “dose” refers to the delivery of a quantity of energy to tissue. A difference in “dose” in this context does not imply differences in expected effectiveness response as it would with a drug. There is no demonstrated difference in safety or effectiveness among these doses.

To set the dosage:

1. Tap **Dosage** on the Program Options screen.
2. Tap the desired dosage.
 - If you tap Intermittent for a BurstDR™ stimulation program, three dosing options are available, along with an option to set custom On Time and Off Time through the custom Dosage popover screen. For Tonic programs, the custom On and Off Times are located in the Program Options popover.

- For the EPG, if you tap Sleep, On Time becomes available on the Program Options screen.

To Set the On Time and Off Time

The On Time and Off Time setting controls the amount of time stimulation is on and off.

To set the on and off time for Tonic programs:

1. Tap **On Time** or **Off Time** on the Program Options screen.

The On & Off Time popover opens.

2. Tap the + and – buttons to increase or decrease the time.
3. Tap **Back** to return to the Program Options screen or outside the popover to save any changes and return to the Program screen.

To set the on and off time for BurstDR™ programs:

1. Tap **Dosage** on the Program Options screen.

The Dosage popover opens.

2. Tap **Intermittent** on the Dosage popover.

Three dosing options are available, along with an option to set custom On Time and Off Time

3. Select one of the dosing options or tap **Custom** on the Dosage popover.

Tap the + and – buttons to increase or decrease the time if Custom was selected.

NOTE: You can set the intermittent dosage on and off times to a minimum of 2 seconds (5 seconds for the EPG) and a maximum of 24 hours. For the EPG, you can set the sleep on time to a minimum of 1 minute and a maximum of 18 hours.

To Set the Step Size Increment (IPG Only; Tonic Only)

The step size increment setting controls what step sizes are available when you adjust the amplitude.

To set the step size increment:

1. Tap **Step Size Increment** on the Program Options screen.
The Step Size Increment popover opens.
2. Tap the desired step size increment.
3. Tap **Done** or outside the popover to save any changes and close the popover.

To Set the Magnet Mode

The magnet mode setting controls how the generator responds when it senses a magnet. The default magnet mode is Turns Stimulation On/Off.

To set the magnet mode, tap **Magnet** to open the Magnet popover:

- Tap **Disabled** to disable magnet mode so stimulation is unaffected if the generator senses a magnet.
(IPG only)
- Tap **Turns Stimulation On/Off** to turn generator stimulation on or off each time the generator senses a magnet.
- Tap **Only Turns Stimulation Off** to turn generator stimulation off when the generator senses a magnet.
- Tap **Done** or outside the popover to save any changes and close the popover.

To Set the Ramp Time

Ramp time is the approximate number of seconds that the generator takes when starting stimulation to arrive at the perception amplitude for tonic programs or the target amplitude for BurstDR™ stimulation programs and is only available for sleep (EPG only) or continuous dosage. This ramp time is used when stimulation is turned on using the patient controller; it is not the ramp time that you use while programming. The default ramp time is 4 seconds.

To change the ramp time:

1. Tap **Ramp Time** on the Program Options popover.
The Ramp Time popover opens.
2. Tap on the desired ramp time from the list. To scroll to a ramp time that is not displayed, swipe up or down on the screen.
3. Tap **Done** or outside the popover to save any changes and close the popover.

Using the Active Balancing™ Programming Feature

The Active Balancing™ programming feature allows you to adjust the amplitude of all areas within a program at the same time or individually, which helps balance the feeling of stimulation delivered to a patient.

NOTE: This feature is available only for tonic stimulation programs. Active Balancing is not available until Perception and Comfort amplitudes are set for two or more areas.

To balance a program:

1. On the Program screen, tap  next to Areas to open the Areas popover.
2. In the Areas popover, tap **Balance** to open the Active Balancing popover.
3. Tap the Increase button beside the master amplitude box. The amplitude ramps up to the perception value (Perc).

NOTE: To stop stimulation, tap . This button turns off the master amplitude, disables the area increase and decrease buttons, and grays out the level indicator bars.

4. Tap the Increase and Decrease buttons to adjust the master amplitude until the patient indicates that stimulation is comfortable.
5. Tap the Increase and Decrease buttons in an area to increase or decrease the amplitude level of an area.

NOTE:

- If an overhead state is detected, the Maximum Generator Output Reached alert pops up and the green level indicator bars turn yellow for the areas in overhead. You cannot save the program if it is in overhead.
 - To reset all sliders to zero, tap .
6. If the program contains more than four areas, scroll down to display the remaining areas and adjust the areas if necessary.

7. Tap **Done**.

Saving a Program

When you complete programming and exit the session, programs are automatically saved and a Session report opens. You may manually exit the programming session by performing the following actions:

1. Tap **Done** on the Program screen.
2. Select the Personally Identifiable Information (PII) setting.
3. Tap **End Session** in the popover.

NOTE:

- When you save the program, it is automatically saved to the generator.
- During intraoperative testing, you do not need to save the program. To exit an intraoperative testing session and return to the clinician programmer app Home screen, tap **Done** and then **End Session** on the Program screen. When asked by the system if you want to discard the changes, tap **Yes**.
- If any parameters of an area are incomplete for a program, a message appears when you try to save the program. To correct this issue, ensure that you have configured valid electrode polarity combinations and have set all stimulation parameters.

Managing Programs on the Generator

After completing a programming session, you can view, select, or delete the programs on the generator communicating with the clinician programmer app.

1. Tap  next to the program name on the Program screen. The Manage Programs popover opens.

2. Tap Manage Programs to open the list of available programs.

The list of available programs opens, with the currently active program selected by default.

To rename a program on the list:

1. Tap **Edit**.
2. Tap a program name and enter the custom program name.
3. Tap < to return to the Edit screen.
4. Tap **Done** to save changes and return to the Program screen.

To select a program as the active program or view the program settings:

1. Tap a program name on the list.
2. Tap **Select**.

The Program screen opens for the selected program.

NOTE: If the selected program is not valid, an alert pops up notifying you the program must be fixed or deleted before another program can be edited.

To delete a program on the list:

1. Tap **Edit**.
2. Tap  next to the program you want to delete. The Delete button appears.
3. Tap **Delete**.
If all programs are deleted, the popover closes and a default program is created.
4. Tap **Done** to save changes and return to the Programs screen.

Viewing Generator Details

The Generator popover provides information about the generator, such as the total amount of time stimulation has been on for the generator. Tap  at the top of the screen to open the Generator popover. From the Generator popover, you may perform the following actions:

- View information about the generator, such as the model and serial number on the About popover.
- Install new generator software from the About popover.
- View and change the generator name from the Name popover. This name is displayed on the generators list for both the clinician and patient.
- View and change the implant date on the Implant Date popover (IPG only).
- Set an IPG to Surgery Mode.
- Set an IPG into MRI mode, if applicable. (If any of the implanted components are not MR Conditional, **MRI is Not Permitted**  is displayed instead of the **MRI Mode**  option.)
- View how long stimulation has been on.
- View the generator battery status. See “Checking the Generator Battery Status” (page 56) for more information.
- Turn impedance logging on or off. See “Measuring Impedance” (page 32) for more information (IPG only).

- Email a generator log, which contains information such as how stimulation was used, that may help when troubleshooting.

When a new generator software version is available, you will receive a message notifying you it is included with the new clinician programmer app version. Additionally, you will receive a message when you connect to the generator if you have not installed the new version yet.

To install the new generator software, do either of the following:

- Tap **Update** in the “Update Generator Software” message.
- Tap **Install Software** in the About popover.

NOTE: Make sure the clinician programmer is charged before installing the generator software. Do not close the app, lock the clinician programmer, or interrupt communication while installing the generator software or the generator may become unresponsive.

To email a generator log:

1. Tap **Generator Log** on the Generator popover.

NOTE: The Personally Identifiable Information (PII) setting will be set to Include. Tap **Agree** to ensure typical clinical standards are used when transferring PII data electronically and to proceed with emailing generator log.

2. Tap **Email Basic Generator Log** or **Email Complete Generator Log** as directed.

The popover closes. The “Exporting Log File” message displays while the system is generating the log file and email.

3. Enter the email address.
NOTE: Configure mail support before using the Email Generator Diagnostic Log functionality.

To set an IPG into Surgery Mode:

1. Tap **Surgery Mode** on the Generator popover. The Surgery Mode popover opens.

NOTE: Place the IPG into Surgery Mode before entering the operating room. While in the operating room, leave the IPG in Surgery Mode unless you are actively programming. See “Viewing Generator Details” (page 47) for information about placing a generator into Surgery Mode.

2. Tap the **Surgery Mode** toggle button.

Stimulation stops and the patient may undergo their surgical procedure.

NOTE: If Surgery Mode is on, you will not be able to perform any programming actions. The IPG remains in Surgery Mode until you tap **Exit Surgery Mode** on the screen.

To set an applicable IPG into MRI mode:

1. Tap **MRI Mode** on the Generator popover. The MRI Mode popover opens.
2. Tap the **MRI Mode** toggle button.

3. When the “Set Generator to MRI Mode” message appears, tap **Continue**. Stimulation stops, and the clinician programmer app checks the system for any issues. If the checks are successful, a message appears indicating that IPG is in MRI mode.

CAUTION: Do not delete the paired Bluetooth® wireless connection between the IPG and the clinician programmer (under Settings > Bluetooth on the clinician programmer) while the system is in MRI mode. Doing so will prevent the system from disabling MRI mode, which may prevent therapy from being turned on again.

CAUTION: Carefully monitor which clinician programmer is paired with an IPG that is in MRI mode. It is not possible to create a new pairing with an IPG while it is in MRI mode, so a previously paired clinician programmer is necessary to disable MRI mode.

NOTE:

- If a warning screen appears indicating that MRI is not advised, you cannot set the IPG to MRI mode and the patient cannot receive and MRI scan. See “Troubleshooting” (page 61) for more information.
- If MRI mode is on, you will not be able to perform any programming actions. The IPG remains in MRI Mode until you tap **Exit MRI Mode** on the screen.

Selecting a Personally Identifiable Information (PII) Setting

When ending a session, generating reports, or exporting logs or a database or diagnostic report, select whether to include or remove Personally Identifiable Information (PII) to proceed. Red text will indicate if no PII setting has been selected.

NOTE:

- If the PII setting is set to Include, tap **Agree** to ensure typical clinical standards are used when transferring PII data electronically.
- After choosing to include or remove PII, the selection will be retained for future sessions. The selection can be changed at any time by tapping the PII setting.

Managing Patient Records

The patient records screen displays the device history for each patient, including indication, device and system information, session history, stimulation settings, and usage diagnostics. The clinician programmer app allows you to manage patient records by adding or deleting patient data. Tap **Patient Records** on the clinician programmer app Home screen to open the patient records screen.

NOTE:

- Patient information is not displayed on the right side of the screen until a patient is selected.
- The chosen Personally Identifiable Information (PII) setting is displayed in each patient record. You will be able to choose whether to include or remove PII from this screen.

Buttons and Icons on the Patient Records Screens and Popovers

The following table provides definitions for buttons and icons that you may encounter while managing patient records.

NOTE: Not all buttons or icons will be available on all screens.

Table 3. Buttons and icons on the patient records screens

Button or Icon	Button or Icon Name	Action
	Clinician programmer Home screen button	Tap to go to the clinician programmer app Home screen.
Edit	Edit patient list button	Tap to edit the patient list.
	Add patient button	Tap to add a patient.
	Patient information button	Tap to view patient information.
	Delete patient button	Tap to delete the patient.
Search	Name Search field	Tap to search for a patient name.
Patient name	Patient name in patient list	Tap to open the patient overview for the selected patient.
	Delete generator button	Tap to delete the generator.
	Generator Backup button	Tap to email the backup file. (Only available when a backup file exists.)

Table 3. Buttons and icons on the patient records screens

Button or Icon	Button or Icon Name	Action
Sessions	Sessions	Tap to view the session history list.
Diagnostics	Diagnostics	Tap to view the diagnostics history list.
>	Session detail button	Tap to open the selected session summary.
	Clear button	Tap to clear the contents of a text field.
Cancel	Cancel button	Tap to cancel the action and close the popover.
	Share report button	Tap to email or print the report.
	Email button	Tap to email the report.
	Print button	Tap to print the report.
	Email XML button	Tap to launch Email App and attach XML file.

Adding a Patient

To add a patient:

1. From the patient records screen, tap . The New Patient popover opens.
NOTE: The Add button is not available until you enter a first name.
2. Tap a field you want to complete and enter the information using the on-screen keyboard.
3. Tap **Add** to save the patient's information and return to the Patients screen.

Editing a Patient's Information

To edit a patient's information:

1. From the Program screen, tap . The Patient popover opens.
2. Tap **Edit**.
The Patient popover changes to the editable state.
3. Tap a field you want to complete and enter the information using the on-screen keyboard.
4. Tap **Done** to save the changes and return to the Program screen.

Deleting a Patient from the Database

To delete a patient from the database:

1. On the Patients screen, tap **Edit**.

The patient list changes to the editable state.

2. Tap a patient name to select or unselect a patient. If a patient is selected, a check mark will appear to the left of their name. You may select multiple patients to delete.
3. Tap **Delete**.

Viewing, Emailing, and Printing a Report

Two types of reports are available on the patient records screen, the Session report and the Diagnostics report. A Session report is automatically generated and opens when you end a programming session. This report provides information such as the programmed stimulation settings and information about how stimulation was used since the programs were last modified. The Diagnostics report provides system impedance information. You may email or print the reports. For information about the 90 Day Diagnostics report, see “Measuring Impedance” (page 32).

- Swipe up or down to scroll through information for all the programs.

NOTE:

- If a program was not saved to the generator, a message will appear under the program name.

- Configure mail support before using the email report functionality.
- Red text within the Sessions or Diagnostics report screens indicates if no Personally Identifiable Information (PII) setting has been selected. Choose to include or remove PII to proceed.

To generate a Session report:

1. Tap **Sessions** on the right side of the screen.
2. Select a session date.
3. Swipe up or down to scroll through and view the program information.
4. Tap  to open the Share popover.
5. Tap  to email or tap  to print a PDF of the report.

To generate a Diagnostics report:

1. Tap **Diagnostics** on the right side of the screen.
2. Select a session date.
3. Tap  to open the Share popover.
4. Tap  to email or tap  to print a PDF of the report.

Checking the Generator Battery Status

Refer to the IPG and EPG information below for instructions on viewing the generator battery status. Battery life depends on communication usage and stimulation settings. For instance, programs with multiple stimulation areas or higher outputs will drain the battery faster.

NOTE: You may also receive low battery warnings regarding the clinician programmer, so make sure to read the warning before dismissing.

To view the IPG battery status:

You can view the IPG generator battery status in the Generator popover. When the IPG status is good,  is displayed; and when the battery is approaching the end of service,  is displayed. The battery voltage reading is provided next to the status icon until the battery voltage reaches the set elective replacement indication voltage limit. After the battery voltage reaches this limit, the reading only shows the battery voltage is less than the set limit.

NOTE:

- The IPG battery status is calculated from recent voltage measurements. If usage habits change for a period of time, this may affect the battery status. The IPG battery status is available one day after first using the clinician programmer app to program the IPG. For more information, as well as information about battery longevity estimates, refer to the clinician's manual for the generator.
- When the IPG battery is approaching the end of service a warning pops up on your clinician programmer app.

To view the EPG battery status:

You can view the EPG generator battery status in the generator icon on the Program screen and in the Generator popover. The Generator popover displays the remaining life for the EPG battery (the figure below shows the EPG battery indicator progression).

Figure 2. EPG battery indicator progression



NOTE:

- When the remaining EPG battery charge reaches 2 or 1, a warning pops up on your clinician programmer app.
- When the EPG battery is too low to support stimulation (0), you may not be able to initiate a programming session with the clinician programmer. Replace the generator batteries to connect and communicate with the generator.
- When the EPG battery is too low to support stimulation (0), generator stimulation automatically turns off and the clinician programmer app ends the programming session. Replace the generator batteries to connect and communicate with the generator.

WARNING: Turn stimulation off before removing the batteries. Removing the batteries while stimulation is on could cause unintended stimulation.

Maintaining the Clinician Programmer

This section provides tips and other information to help you maintain the clinician programmer.

Checking the Clinician Programmer Battery Status

Be sure to monitor the clinician programmer battery status in the top right corner of the screen. As the battery is used, the battery indicator shows the remaining charge. Recharge the clinician programmer using the provided Apple® charging cord.

NOTE: Keep the clinician programmer charged or have a power supply nearby. Familiarize yourself with the clinician programmer's battery life. For further information, refer to the user guide for the provided Apple iOS® device available at support.apple.com/manuals.

Caring for the Clinician Programmer

For information on how to care for the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your device.

To keep patient data and communications secure, and to prevent unauthorized remote programming access, the system includes the following IT security measures.

- Use of a device passcode is required to access the mobile device. Use unique numeric sequences that you can remember easily.
- Data at rest on the mobile device is stored in encrypted form.
- Backups may be created using the iTunes® software with instructions from Apple, which are located at support.apple.com by typing “backup” or “back up” in the Search Support box.
- Backups created using iTunes are encrypted.

In addition, users should adhere to the following guidelines when using the system:

- Do not use the application if the operating system is compromised (for example, jailbroken).
- Do not share your Apple® ID login information or device passcode.
- Do not allow other users to access the mobile device.
- Installation of apps that are not approved by Abbott Medical for use in the system is restricted.
- Secure networks to which the Apple device will connect with a Wi-Fi password or other similar security measures.
- Connect only to trusted secured networks.
- If the Apple device is lost or stolen, contact your Abbott Medical representative to remotely erase your patient information from the device. Use the Apple instructions at support.apple.com by typing “lost” or “stolen” in the Search Support box to disable or erase your device.

- If you receive a “Device Not Secure” notification in the App, contact Abbott Medical.
- Install iOS® software upgrades on your device as they are made available by Apple, after contacting Abbott Medical to ensure compatibility with the Clinician Programmer App.
- Install Clinician Programmer app updates as they are released.

Legal and Privacy Notice

The terms of use and privacy policy are displayed the first time the clinician programmer app is launched after installing or updating the app. To view this information again, tap ⓘ on the clinician programmer app Home screen or view online at <https://www.virtualclinic.abbott/policies>.

Abbott Medical is committed to protecting the privacy of our customers and patients. This privacy statement summarizes how we protect, gather, and use personal information of users. For more information, view our US or Global Privacy Policies online at www.abbott.com/privacy-policy.html.

We may amend these terms of use, privacy statements, and privacy policies from time to time, so please check for updates.

Troubleshooting

This section provides troubleshooting suggestions for issues you may experience with the clinician programmer or clinician programmer app. For additional information, call Technical Support. When you call, be ready to give the representative information about what you were doing when the error occurred and what error messages appeared. See “Viewing Generator Details” (page 47) for instructions about creating a generator log and the steps below for instructions about creating a programmer log.

NOTE: If your device is lost or damaged, contact Technical Support.

To create and email a programmer log:

1. On the clinician programmer app Home screen, tap  to open the Information popover.
2. Tap **Email Programmer Log**.
3. Select the Personally Identifiable Information (PII) setting.
The popover closes. An "Exporting Logs" system message is displayed while the system is generating the log file and email.
4. Enter the email address.

NOTE: Configure mail support before using the Email Programmer Log functionality.

To create and email the programmer database:

1. On the clinician programmer app Home screen, tap  to open the Information popover.
2. Tap **Programmer Database**.
3. Select the Personally Identifiable Information (PII) setting.
4. Tap **Email** and enter the email address.

NOTE: Configure mail support before using the Email Programmer Log functionality.

Troubleshooting Chart

Typically, the clinician programmer app displays a message for issues associated with programming patients and managing records. If you are experiencing issues, check the clinician programmer app screen for a

message and follow any instructions it gives to correct the issue. If you still experience the issue or if you experience an issue without receiving an on-screen message, refer to the following table for possible causes and solutions.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Clinician programmer has no power or has lost power.	Clinician programmer's battery is drained.	Recharge the battery using the charger.
	Clinician programmer is damaged or malfunctioning.	Replace the clinician programmer.
Clinician programmer will not charge.	Charger is disconnected from the clinician programmer.	Connect the charger to the clinician programmer.
	Correct plug adapter (voltage converter) is not connected to the charger.	Connect the appropriate plug adapter (voltage converter) to the charger.
	Charger is defective.	Replace the charger.
	Clinician programmer is damaged or malfunctioning.	Replace the clinician programmer.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Nothing is displayed on the screen.	Clinician programmer is off or has timed out.	Turn on the clinician programmer.
	Clinician programmer's battery is drained.	Recharge the battery using the charger.
	Screen is damaged or malfunctioning.	If the clinician programmer appears to be powered on but without display, the screen may be defective. Contact Technical Support.
Clinician programmer will not respond to input.	Clinician programmer has locked up.	Perform a soft reset by turning the clinician programmer off and back on.
	Touchscreen interface is damaged or malfunctioning.	Replace the clinician programmer.
	Clinician programmer battery is drained.	Charge the clinician programmer battery.
	Bluetooth® wireless connection is not strong or turned off.	Decrease the distance between the devices.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Move away from sources of interference such as appliances, Wi-Fi routers, or electrical equipment.
		Move the devices so they share line of sight.
		Do not operate other wireless devices at the same time.
		Disconnect any Bluetooth® wireless media accessories (such as headphones or speakers).
		Wait a few minutes and try connecting again.
		Turn on Bluetooth wireless connection if connectivity is disabled:
		Return to the clinician programmer Home screen, tap Settings , tap Bluetooth , and then tap the Bluetooth toggle button.
		Replace the clinician programmer.
	Clinician programmer is damaged or malfunctioning.	

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Patient is not receiving stimulation.	Stimulation is off.	Turn on stimulation using the patient controller app.
	Generator battery is low and stimulation shut off.	Replace the EPG batteries. For more information, refer to the clinician's manual for the generator.
	Lead is damaged or has become disconnected.	Check impedance on the lead using the clinician programmer app. If impedance is high, then the lead may be damaged or disconnected. Check the connections or consider replacing the lead. For more information, refer to the clinician's manual for the applicable components. See "Measuring Impedance" (page 32) for more information.
Parameter boxes on the Program screen turn yellow.	Generator is damaged or malfunctioning.	Replace the generator. Contact Technical Support.
	Generator has reached its output limit and is in overload.	You may test stimulation while the generator is in overload, but you cannot save the program. Reduce the amplitude or pulse width. OR

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Set additional polarities (anode or cathode) on the lead.
	Lead is damaged or has become disconnected.	Check impedance on the lead using the clinician programmer app. If impedance remains high despite changes to program settings, then the lead may be damaged or disconnected. Check the connections or consider replacing the lead. For more information, refer to the clinician's manual for the applicable components. See "Measuring Impedance" (page 32) for more information.
Cannot locate clinician programmer app.	Clinician programmer app is not on clinician programmer Home screen.	Swipe through screens from the clinician programmer Home screen to locate app. Search for the app using the iOS® search function. Re-install the app. See "Downloading the Clinician Programmer App" (page 7).

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Surgery Mode is Not Available is displayed.	The IPG has the maximum number of allowed programs.	Delete a program and try setting Surgery Mode again.
Cannot place the IPG into Surgery Mode.	The IPG is not connected to the clinician programmer.	Try connecting to the IPG again. If the problem persists, contact Technical Support.
MRI is Not Permitted is displayed instead of the MRI Mode option on the Generator popover.	A part of the implanted system is not MR Conditional.	Confirm the implanted models of the system. If any implanted part is not MR Conditional, the patient cannot receive an MRI scan.
MRI is Not Advised message appears while trying to set the IPG to MRI mode.	A problem was detected during the system checks while setting MRI mode.	The IPG is not in MRI mode, and an MRI scan cannot be performed.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Generator software upgrade was not successful.	Generator software upgrade was interrupted.	Try installing the generator software again. If you cannot locate the generator on the clinician programmer app, contact Technical Support.
Cannot locate programs after upgrading generator software.	After installing generator software, the previous program data was lost.	1. On the patient records screen, locate the patient history. 2. Reprogram the patient.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott Medical representative.

Appendix A: Group ID List

Following is the Group ID list you will use when installing the clinician programmer app and patient controller app.

Table 5. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Algeria	PRODEU	Lebanon	PRODLBN
Argentina	PRODLATAM	Luxembourg	PRODEU
Australia	PRODAUSNZ	Malaysia	PRODEU
Austria	PRODEU	Mexico	PRODLATAM
Belgium	PRODEU	Netherlands	PRODEU
Brazil	PRODLATAM	New Zealand	PRODAUSNZ
Canada	PRODCAN	Norway	PRODEU
Chile	PRODLATAM	Panama	PRODLATAM
China	PRODCHN	Peru	PRODLATAM

Table 5. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Colombia	PRODLATAM	Poland	PRODEU
Costa Rica	PRODLATAM	Portugal	PRODEU
Cyprus	PRODEU	Puerto Rico	PRODUSA
Czech Republic	PRODEU	Russia	PRODRUS
Denmark	PRODEU	Saudi Arabia	PRODAPAC
Ecuador	PRODLATAM	Singapore	PRODSGP
Finland	PRODEU	South Africa	PRODEMEA2
France	PRODEU	South Korea	PRODAPAC
Germany	PRODEU	Spain	PRODEU
Greece	PRODEU	Sweden	PRODEU
Hong Kong	PRODAPAC	Switzerland	PRODEU
Iceland	PRODEU	Taiwan	PRODAPAC

Table 5. Group ID list

Country/Region	Group ID	Country/Region	Group ID
India	PRODAPAC	Thailand	PRODAPAC
Ireland	PRODEU	Turkey	PRODEMEA2
Israel	PRODAPAC	UK	PRODEU
Italy	PRODEU	US	PRODUSA
Japan	PRODJPN	Country Not Listed	PRODOTHER

Appendix B: Regulatory Statements

NOTE: For Regulatory Statements regarding the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals; or, on the clinician programmer Home screen, tap **Settings** > **General** > **Legal & Regulatory**.

Appendix C: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

NOTE: For symbols and definitions for the clinician programmer, refer to the user guide for the provided Apple® iOS® device available at support.apple.com/manuals; or, on the clinician programmer Home screen, tap **Settings > General > Legal & Regulatory**.

Table 6. Symbols and definitions

Symbol	Definition
	Caution
	Consult instructions for use
	Follow instructions for use on this website
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.

Table 6. Symbols and definitions

Symbol	Definition
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Manufacturing facility
	Manufacturer
	Authorized representative in the European Community
	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

Abbott Medical
6901 Preston Road
Plano, Texas 75024 USA
+1 855 478 5833
+1 651 756 5833

Abbott Medical
The Corporate Village
De Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

2022-08
ARTEN600266400 A

