



Medtronic

SYNERGY™ 7427
SYNERGY VERSITREL™ 7427V

Dual-Program Neurostimulators for Spinal Cord
Stimulation (SCS)

Technical Manual

Rx Only

Synergy™ Model 7427

**Synergy Versitrel™ Model
7427V**

Technical Manual

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Introduction

Overview of Manual

This manual describes specifications and operation of the Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators. It includes information about the control equipment used with each neurostimulator. You will find instructions for handling, storing, implanting, replacing, and explanting the neurostimulator. General resterilization guidelines are also provided for the neurostimulator. In addition, this manual describes some items to discuss with your patient.

Device Description

The Medtronic Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators are multiprogrammable devices designed for use in spinal cord stimulation. They accommodate one or two extensions and can function in either dual-program mode or single-program mode. In dual-program mode, the amplitude, pulse width and up to 8 electrodes are set independently for each program. In single-program mode, the amplitude, pulse width, and rate are delivered to the selected electrodes; up to 8 electrodes can be selected.

The operation of the neurostimulator is supported by a clinician programmer and patient programmer.

The neurostimulator is powered by a sealed battery and directed by electronic circuitry to send pulses of controlled electrical stimulation through the implanted lead-extensions to target sites.

For a complete list of model numbers and components compatible with the neurostimulator, see the system components sheet packaged with this manual in the neurostimulator shelf box.

Introduction

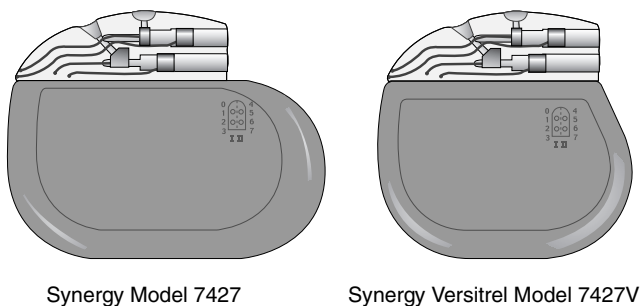


Figure 1. Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators.

Notes:

- Throughout this manual, the Model 7427 Neurostimulator is typically depicted within figure art.
- The functionality of the Synergy Versitrel and Synergy Neurostimulators is identical; however, the longevity of the Synergy Neurostimulator is longer than that of the Synergy Versitrel Neurostimulator. Refer to Table 10 on page 60 in “Specifications” for an overview of physical differences between the two models. Figure 1 is a comparison of the size and shape of the Synergy and Synergy Versitrel Neurostimulators.

Package Contents

- One Synergy Model 7427 or one Synergy Versitrel Model 7427V Neurostimulator
- One hex wrench
- Product literature

Patient Selection

The Synergy and Synergy Versitrel Neurostimulation Systems are designed to aid in the management of pain via pulsed electrical stimulation through nerve structures in the dorsal aspect of the spinal cord. Activation of these structures produces nerve impulses that can inhibit the transmission of pain.

Indications

The Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators are part of dual-program systems for spinal cord stimulation. The systems are indicated as an aid in the management of chronic, intractable pain of the trunk or limbs.

Patients should be carefully selected to assure that their pain is of physiological origin. Also, patients must be appropriate candidates for surgery.

Contraindications

Patients are contraindicated for internalization if they are clearly unsuccessful in receiving pain relief during trial stimulation, or if they are unable to properly operate the system.

After implantation of any system component, the following contraindication applies:

Diathermy – Do not use shortwave 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 can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it can also damage the neurostimulation system components resulting in loss of therapy, requiring additional surgery for system explantation and replacement. Injury or damage can occur during diathermy treatment

Warnings

whether the neurostimulation system is turned “on” or “off.” Advise your patients to inform all their health care professionals that they should not be exposed to diathermy treatment.

Warnings

Case Damage – If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Electrocautery – In certain circumstances, electrocautery can cause the neurostimulator to stop functioning which will require the neurostimulator to be replaced. It could also change the programmed parameters to “Power ON Reset” settings which include changing the output to “off” and the amplitude to zero which would require the neurostimulator to be reprogrammed with the Medtronic clinician programmer.

Based on tests to date, if use of electrocautery is necessary, follow these precautions:

- Turn off the neurostimulator before performing electrocautery.
- Only bipolar cautery is recommended.
- If unipolar cautery is necessary: Do not use high voltage modes; keep the power setting as low as possible, and keep the current path (ground plate) as far away from the neurostimulator, extension, and lead as possible.
- Confirm the neurostimulator function after electrocauterization.

The effect of electrocautery on patients with implanted neurostimulators is unknown.

Equipment Operation – Patients should not operate potentially dangerous equipment such as power tools or automobiles during stimulation.

Magnetic Resonance Imaging (MRI) – Medtronic recommends physicians not prescribe an MRI for a patient who has any component of an implanted neurostimulation system for Spinal Cord Stimulation (SCS). Exposing a patient with an implanted SCS neurostimulation system to an MRI may potentially injure the patient and/or damage the neurostimulator. The known potential risks are as follows:

- Induced electrical currents from the MRI to the neurostimulation system may cause heating, especially at the lead electrode site, resulting in tissue damage. Induced electrical currents may also stimulate or shock the patient.

Note: This warning applies even if only a lead and/or extension is implanted in the body.

Heating risks are affected by a number of factors involving the MRI equipment and the implanted neurostimulation system. Factors that increase the risks of heating and patient injury include but are not limited to the following:

- High MRI Specific Absorption Rate (SAR) Radio Frequency (RF) power levels
 - Lower impedance leads and/or extensions (Medtronic product names or model numbers designated with a “Z”, an “LZ”, or “Low Impedance”)
 - MRI RF transmit coil that is near or extends over the implanted lead system
 - Implanted lead systems with small surface area electrodes
 - Short separation distances between lead electrodes and thermally sensitive tissue
- An MRI may permanently damage the neurostimulator, which may require explant or possible replacement.
 - An MRI may affect the functional operation of the neurostimulator. The MRI may also reset the neurostimulator parameters to its default settings, which requires reprogramming with the clinician programmer.

Warnings

- The neurostimulator may move within the implant pocket and align itself with the MRI field, which may cause patient discomfort or open a recent neurostimulator implant incision.

In addition, the MRI image details may be degraded, distorted, or blocked from view by the implanted neurostimulation system.

Pediatric Use – Safety and effectiveness of this system has not been established for pediatric use.

Postural Changes – Postural changes or abrupt movements may cause an increase or decrease in the perceived level of stimulation. Higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients.

Pregnancy – Safety for use during pregnancy or delivery have not been established.

Telemetry – Do not send a patient home with “????” displayed on the clinician programmer screen for any programmable value. This indicates that the parameter or mode is invalid and must be reprogrammed.

Theft Detectors and Screening Devices – Theft detectors found in retail stores, public libraries, etc., and security screening devices found in airports, government buildings, etc., occasionally may cause intermittent stimulation or a momentary increase in stimulation intensity. When they pass through these devices, some patients may perceive intermittent stimulation as switching their neurostimulation system on and off. It is also possible that patients, especially those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation when they pass through these devices. Higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients. For information on how to minimize these interactions when passing through theft detectors and security screening devices, see “Patient Counseling Information” on page 51.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in spinal procedures and review the procedures described in this technical manual prior to implant.

Prescribing Physicians – Prescribing physicians should be experienced in the diagnosis and treatment of chronic intractable pain of the trunk or limbs and should be familiar with the use of the Synergy and Synergy Versitrel Neurostimulation Systems.

Storage and Sterilization

Resterilization Considerations – All implantable components are supplied sterile. If resterilization is necessary, refer to “Resterilization” on page 54 for further information.

Sterilization Method – The neurostimulator was sterilized with ethylene oxide before shipment.

Storage Temperature – Store the neurostimulator between 0° F (-18° C) and 125° F (52° C). Temperatures outside this range can damage components.

System and Therapy

Component Failures – The physician should be aware that all neurostimulation systems may unexpectedly cease to function. A system may fail at any time due to random failures of the system components or the battery (prior to depletion). These events, which can include electrical short or open circuits and insulation breaches, cannot be predicted.

Components – The use of non-Medtronic components with this system may result in damage to Medtronic components, less than adequate stimulation, or increased risks to the patient.

Precautions

Patient Detoxification – It is recommended that patients undergo detoxification from narcotics prior to implant.

Patient Management – To help ensure maximum benefits from the neurostimulation system, long-term postsurgical management of patients is recommended.

Implantation / Explantation

Component Disposal – If explanting a Synergy or Synergy Versitrel Neurostimulation System component, please remember the following guidelines:

- Do not incinerate the neurostimulator; explosion can result if a neurostimulator is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

Component Handling – Handle the implanted components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments.

Etched Identification – Place the neurostimulator with the etched identification side facing outward, away from the muscle layer of the body.

Extension-Neurostimulator Connection – Wipe off any body fluids from the extension connector pins or connector block before connecting them. Contamination of connections can affect neurostimulation. Do not tighten setscrews without the extension inserted. This can damage the connector block. Do not insert an extension into the neurostimulator connector block without visual verification that the setscrews are sufficiently retracted to allow insertion.

Implant Considerations – Do not implant a device when the storage package has been pierced or altered, potentially rendering it non-sterile; the component shows signs of damage; or the Use By

date has expired, because this can adversely affect storage package sterility and battery longevity.

Neurostimulator Handling – Be extremely careful when using sharp instruments around the neurostimulator to avoid nicking or damaging the neurostimulator case or the connector block. The neurostimulator can be damaged if dropped from a height of 12 inches (30 cm) or more onto a hard surface (i.e., a concrete floor). If this happens, do not implant the neurostimulator.

Lead-Extension Connection – Wipe off any body fluids from the lead or extension contacts before connecting. Contamination of connections can affect neurostimulation.

Lead-Extension Routing – It is recommended that the implanted lead-extensions in dual lead-extension systems be routed so they do not form a “loop.” When exposed to some theft detectors, looped lead-extensions increase the potential for patients to experience a momentary increase in their perceived level of stimulation. Higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients as they pass through these devices. Figure 2 illustrates proper and improper routing methods for dual lead-extensions.

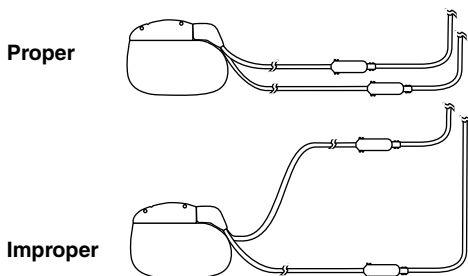


Figure 2. Proper and improper dual lead-extension routing (use fluoroscopy to verify).

Precautions

Single Use – The neurostimulator is intended for Single Use Only. **DO NOT REUSE.**

Medical Environment

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, the following precautions should be noted.

Effects on Other Medical Devices – The neurostimulation system may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient's benefit from each device.

External Defibrillators – Safety for use of external defibrillatory discharges on patients with neurostimulation systems has not been established. External defibrillation may damage a neurostimulator.

If external defibrillation is necessary, follow these precautions to minimize current flowing through the neurostimulator and lead-extension system:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the neurostimulation system.
- Use the lowest clinically appropriate energy output (watt seconds).
- Confirm neurostimulation system function following any external defibrillation.

Lithotripsy – Use of high output ultrasonic devices, such as an electrohydraulic lithotripter, is not recommended for patients with an implanted neurostimulation system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in

damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam near the neurostimulator.

Radiation Therapy – Radiation therapy can cause damage to the electronic components of a neurostimulator. It is not recommended to use radiation therapy directly over a neurostimulation device.

Home or Occupational Environment

Cellular Phones – Based on tests to date, cellular phones appear to have no effect on the Synergy and Synergy Versitrel Neurostimulation Systems. However, the effect of all cellular phones on neurostimulation systems is unknown and patients should avoid placing cellular phones directly over the device.

Electromagnetic Interference – Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to unexpectedly cease to function or cause sensitive patients to experience a momentary increase in their perceived level of stimulation. Also, severe EMI can permanently erase the neurostimulator serial number, causing “????” to be displayed in place of the serial number.

High/Low Pressure Effects – The effects of high/low pressure on patients with an implanted neurostimulation system are unknown.

Home Appliances – Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation.

Occupational Environments – Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough EMI to interfere with neurostimulator operation if approached too closely.

Synergy and Synergy Versitrel Clinical Summary

The clinical use of Synergy and Synergy Versitrel Neurostimulation Systems is supported by Medtronic clinical studies of the Matrix and Itrel 3 Spinal Cord Stimulation Systems. All patients were implanted to aid in the management of chronic, intractable pain of the trunk or limbs. Following is a summary of the data from those studies that supports the clinical use of Synergy and Synergy Versitrel Systems.

The Medtronic-sponsored Matrix study was a retrospective evaluation of 89 patients. All patients implanted with dual-program radio frequency Matrix Systems before April 1996 at the four participating centers were included in the study, which allowed each patient to be followed for at least 12 months. A total of 1,261 device months of experience were acquired for this study.

The Medtronic-sponsored Itrel 3 study was a prospective, open label evaluation of 84 patients implanted at 11 centers. A total of 823 device months of experience were acquired for this study.

Combined adverse event data for these two studies represents a total of 2,084 device months of experience collected from 173 patients. The adverse event experience reported here represents this combined experience.

Adverse Events

Eighty-three of the 173 patients experienced 116 device-related and nondevice-related adverse events. Eighty-seven of the adverse events in 65 patients were considered to be device related. Device-related adverse events reported in at least 2 patients each are provided in Table 1.

Table 1. Matrix and Itrel 3 Study Combined Device-Related Adverse Events Experienced By At Least Two Patients Each^a.

Adverse Event	Number of Patients Reporting
Loss of Pain Relief	22
Lead Migration	16
Infection	8
Pain at Pocket Site	5
Receiver Migration ^b	4
Antenna Placement Problem ^b	4
Programmer/Telemetry Problem	3
Transmitter Malfunction ^b	2
Threshold Rise	2

^a Patients may have experienced more than one event.

^b These device-related adverse events are applicable only to the radio frequency Matrix System and are not applicable to a fully implantable system.

Other device-related adverse events experienced in 1 patient each included receiver malfunction, seroma at receiver site, allergic/immune response, undesirable change in stimulation, “pain relief no better than single lead stimulation/stimulation drives patients pain,” CSF leak, pocket hypersensitivity, loss of electronic serial number and Power ON Reset condition after MRI, electrode failure, lead erosion, radicular chest wall stimulation, high electrode impedance due to lead fracture, suspected lead breakage, and lead/extension infection.

Potential Adverse Events

Anticipated adverse events which may potentially occur, but were not reported in the referenced clinical trials, include:

- Neurostimulator erosion
- Extension erosion/migration
- Patients on anticoagulant therapies may be at greater risk for postoperative complications such as hematomas that can result in paralysis
- Placement of the epidural lead-extension is a surgical procedure that may expose patient to risks of epidural hemorrhage, hematoma, and/or paralysis
- Hematoma at the neurostimulator site
- Undesirable change in stimulation, possibly related to cellular changes around the electrode(s), shifts in electrode position, loose electrical connections, or lead-extension fractures, which has been described as uncomfortable (“jolting” or “shocking”) by some patients

Stimulation Parameter Use

Stimulation parameters used during the Itrel 3 study are provided in Table 2.

Table 2. Summary of Itrel 3 Study Stimulation Parameters.

Stimulation Parameter	1 Month (82 systems)	3 Months (78 systems)	6 Months (69 systems)	12 Months (63 systems)
Amplitude (V)				
Average	3.2	3.2	3.1	3.0
Standard Deviation	1.6	1.8	1.7	1.8
n	79	73	61	58
Pulse Width (μsec)				
Average	275	283	280	278
Standard Deviation	76	82	88	81
n	81	78	66	64
Pulse Rate (Hz)				
Average	79	79	81	85
Standard Deviation	25	24	25	32
n	81	78	67	64

Matrix Study Design

The Matrix 12-Month Study was a retrospective review of 12 months of implant and follow-up experience from a consecutive series of U.S. patients with Matrix systems. All patients were implanted to aid in the management of chronic, intractable pain of the trunk or limbs.

Matrix Patients Studied

Four investigational sites in the United States participated in this study. A total of 89 patients were enrolled in the study at these four sites. Fifty-two percent (46/89, 52%) of study patients were male. The mean age of study patients was 51 years (range: 29 – 84 years).

Matrix Study Methods

This study was a retrospective review of at least 12 months of implant and follow-up experience from a consecutive series of U.S. patients with Matrix systems.

Most data was collected retrospectively from clinic records of the last follow-up for patients with at least 12 months of Matrix follow-up experience. Data was gathered prospectively for patients who had less than 12 months of Matrix follow-up data in clinic records.

Matrix Study Results

Average follow-up per patient was 14.2 ± 4.5 months, with a range of 2.3 – 22.9 months. At least one year of follow-up was obtained for 82% (73/89) of the study patients. Proper device operation was reported by physicians for 93% of patients (83/89).

Sixty-nine patients (69/89, 78%) were using their Matrix devices at their last known follow-up. Of the 73 patients who had at least one year follow-up completed, 64 patients (64/73, 88%) were using their Matrix devices at their last known follow-up.

There were 14 system explants (10 device related), 4 patients for whom therapy was discontinued but no explant occurred (3 device related), and one patient death (not related to the device). Use information was not available for one patient. A system survival curve is presented in Figure 3 that examines the impact of these 13 device-related events on device use throughout the clinical study follow-up period. This standard Kaplan Meier survival curve with a 95% confidence limit presents the time to system not in use for device-related adverse events only. This graph indicates 88.3% (plus or minus 3.5%) of patients had devices in use at approximately 1 year of follow-up, where 3.5% represents the 95% confidence limit. At 1.5 years, this number drops to about 83.9%.

The system survival curve presented in Figure 4 examines the impact of all adverse events on device use throughout the clinical study follow-up period. This standard Kaplan Meier survival curve with a 95% confidence limit presents the time to system not in use for all adverse events. This graph indicates 82.6% (plus or minus 4.1%) of patients had devices in use at approximately 1 year of follow-up. At 1.5 years, this number drops to about 78.4%.

Synergy and Synergy Versitrel Clinical Summary

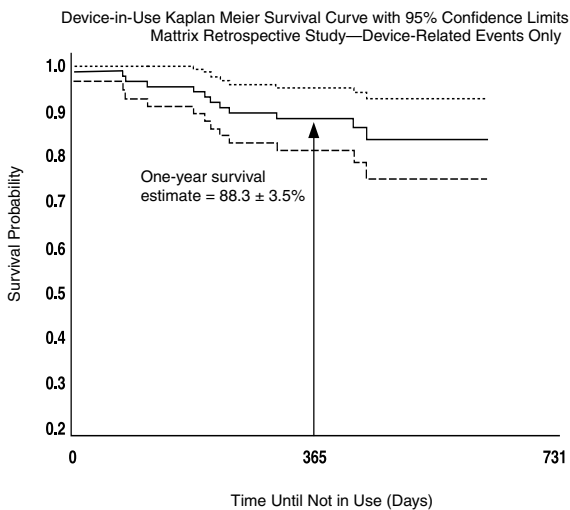


Figure 3. Device-in-use survival curve for device-related events.

Synergy and Synergy Versitrel Clinical Summary

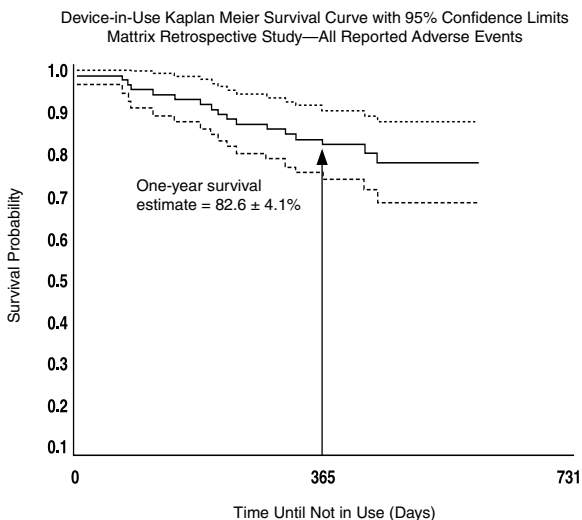


Figure 4. Device-in-use survival curve for all adverse events.

Patient satisfaction with the pain relief provided by the stimulation system after one year of use was determined by asking the following question: *“Is the patient satisfied with the pain relief provided by the Matrix System?”* Responses to patient satisfaction are summarized in Table 3. Investigators indicated that 62% of all study patients (55/89) were satisfied with pain relief. Of the 73 patients completing one year of follow-up, this satisfaction with pain relief rose to 70% (51/73 patients). “Other” responses to this satisfaction question included: “patient would not commit” (3), partial pain relief (2), pain controlled until patient fell (1), inadequate relief (1), skin irritation (1), complication before fully optimized (1), and system explanted (1).

Table 3. Investigator Evaluation of Patient Satisfaction.

Patient Group	Patient Satisfied n(%)	Patient Not Satisfied n(%)	Missing Responses n(%)	Other Responses n(%)
Patient with ≥ 12 month follow-up (n=73)	51 (70%)	14 (19%)	0 (0%)	8 (11%)
All patients (n=89)	55 (62%)	22 (25%)	2 (2%)	10 (11%)

Forty-nine of the 89 patients experienced a total of 75 device-related and nondevice-related adverse events. A total of 65 of these adverse events were considered to be device related. There were no unanticipated adverse device events reported. Device-related adverse events reported by at least 2 patients each in this study are presented in Table 4.

Table 4. Matrix Study Device-Related Adverse Events Experienced By At Least Two Patients Each.

Adverse Event	Number of Patients Reporting
Loss of Pain Relief	21
Lead Migration	12
Infection (Receiver Site)	5
Receiver Migration ^a	4
Antenna Placement Problem ^a	4
Pain at Receiver Site	3
Transmitter Malfunction ^a	2
Pain at Pocket Site	2

^a These device-related adverse events are applicable only to the radio frequency Matrix System and are not applicable to a fully implantable system.

Other device-related adverse events experienced in 1 patient each (1%) included receiver malfunction, seroma at receiver site, allergic/immune response, undesirable change in stimulation, pain relief no better than single lead stimulation/stimulation drives patients pain, and CSF leak.

Itrel 3 Study Design

The Itrel 3 study was a prospective, open-label study of 84 spinal cord stimulation patients followed for 1, 3, 6, and 12 months. All patients were implanted to aid in the management of chronic, intractable pain of the trunk or limbs.

Itrel 3 Patients Studied

A total of 11 centers throughout Europe participated in this study, enrolling 84 patients. One patient received two Itrel 3 systems;

therefore, 85 systems were evaluated. Fifty-four percent (45/84, 54%) of the study patients were male. Average age at study enrollment was 52.6 years (range: 22 – 86 years).

Itrel 3 Study Methods

Data was prospectively collected in this study for a set of 84 European patients. Follow-up visits were scheduled at 1, 3, 6, and 12 months. Safety data collected in the study included adverse event experiences and reasons for study discontinuation.

Itrel 3 Study Results

Average daily duration of pain was significantly reduced ($p < 0.0001$) at each follow-up interval when compared to the duration at baseline. Patients reported an average of at least 63% pain relief throughout the follow-up evaluation.

Of the 62 patients completing 12-month follow-up, 97% (60/62, 97%) indicated stimulation was beneficial and 95% (59/62, 95%) indicated they would agree to stimulation again for the same benefits.

A total of 34 patients experienced 41 device-related and nondevice-related adverse events. Twenty-two of the adverse events in 21 patients were considered to be device related. There were no unanticipated adverse device events reported. Device-related adverse events reported in at least 2 patients each are provided in Table 5.

Table 5. Itrel 3 Study Device-Related Adverse Events Experienced By At Least Two Patients Each.

Adverse Event	Number of Patients Reporting
Lead Migration ^a	4
Infection	3
Programmer/Telemetry Problem	3
Threshold Rise	2

^a One patient reported two lead migrations.

Other device-related adverse events experienced in one patient each included pocket hypersensitivity, loss of electronic serial number and Power ON Reset condition after MRI, electrode failure, loss of pain relief, lead erosion, radicular chest wall stimulation, high electrode impedance due to lead fracture, suspected lead breakage, and lead/extension infection.

Individualization of Treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Implantation of the Synergy or Synergy Versitrel Neurostimulation System may be appropriate for patients who meet the following criteria:

- Patients should have chronic, intractable pain of physiological origin.
- Patients should be appropriate candidates for surgery.

Before the Synergy or Synergy Versitrel Neurostimulation System is implanted, the following conditions should be met:

- Satisfactory paresthesia coverage should be demonstrated by:
 - intraoperative screening, or
 - pre-existing spinal cord stimulation system.

- Ensure that satisfactory paresthesia coverage can be obtained for patients within the parameter limits of the Synergy or Synergy Versitrel device. Refer to Table 7 on page 38 for a summary of maximum stimulation voltage available from the Synergy or Synergy Versitrel device given set values for pulse width and rate.
 - If the pulse rate is greater than 130 Hz, trial stimulation should be repeated using a pulse rate of 130 Hz or lower.
 - If the pulse width is greater than 450 μ sec, trial stimulation should be repeated using a pulse width of 450 μ sec and increasing the pulse amplitude by 5-10%.
 - If both pulse rate and pulse width are within the parameter capabilities of Synergy or Synergy Versitrel, but the trial stimulation amplitude is greater than the corresponding amplitude shown in Table 7, trial stimulation should be repeated using a lower pulse rate to achieve the necessary amplitude. If this cannot be accomplished, the high-energy use patient should be evaluated for treatment with a Matrix System.
- Ensure that unipolar mode stimulation is not required to obtain satisfactory paresthesia coverage (unipolar mode stimulation is not available with the Synergy or Synergy Versitrel Neurostimulation Systems).

Neurostimulator Hardware Description

The neurostimulator is powered by a hermetically sealed silver vanadium oxide cell and uses an integrated circuit to generate electrical stimulation pulses. To protect the neurostimulator components from body fluids, the electronics and power source are hermetically sealed within an oval-shaped titanium shield.

Neurostimulator Hardware Description

The neurostimulator has a self-sealing connector block and four setscrews. The connector block accommodates one or two extensions to form a dual-program system. Securing the extensions to the neurostimulator requires the use of a hex wrench that is packaged with the neurostimulator.

Other features of the neurostimulator include: two suture holes to enable you to secure the neurostimulator within the subcutaneous pocket; Power ON Reset (POR); and an x-ray identification symbol.

Identification

Standard x-rays show the Medtronic logo and NFE inside the connector block. The Medtronic logo identifies the manufacturer. The letters NFE identify both the Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators (see Figure 5).

The clinician programmer identifies both neurostimulators as a Model 7427 because both Synergy Model 7427 and Synergy Versitrel Model 7427V offer the same features and same programmability. If necessary, there are several ways to distinguish the Model 7427 from the Model 7427V:

- The clinician programmer displays the neurostimulator serial number. Synergy Model 7427 serial numbers begin with NFE followed by a number beginning with 1, 2, 3, or 6. Synergy Versitrel Model 7427V serial numbers begin with NFE followed by a number beginning with 4, 5, 7, or 9. Should Power ON Reset occur and erase the serial number, standard x-ray procedures or palpation may be used to identify the neurostimulator. Loss of the serial number does not impact the ability to correctly program the Synergy or Synergy Versitrel Neurostimulator.
- Standard x-ray procedures and palpation allow identification of the neurostimulator. The Synergy Neurostimulator is approximately 3 inches long and 2.4 inches wide. The Synergy

Versitel Neurostimulator is approximately 2.4 inches long and 2.4 inches wide. See Figure 1 on page 6.

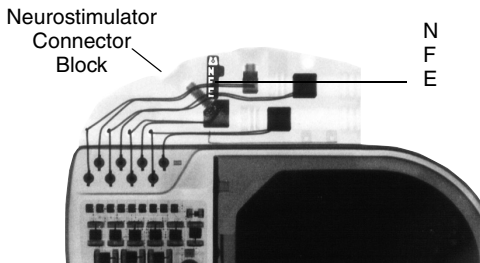


Figure 5. X-ray identification location.

Power ON Reset

As a safety feature, if there is a temporary fluctuation in battery output, the neurostimulator programmed settings and serial number will be lost and reprogramming will be necessary. This is called Power ON Reset (POR) and may be caused by strong electromagnetic interference such as use of an electrocautery tip near the neurostimulator or defibrillation. POR also occurs as the neurostimulator battery nears depletion.

Battery Depletion

As the neurostimulator battery nears total depletion (as indicated by the blinking green light on the patient programmer) stimulation will gradually decrease and then vanish completely when the neurostimulator automatically shuts off. Refer to “Appendix A: Battery Longevity Reference” on page 62 to estimate neurostimulator battery life.

Caution: Patients should be instructed that as their neurostimulator battery approaches total depletion, they may need to adjust the

neurostimulator amplitude more often to maintain their desired level of stimulation.

Neurostimulator Software Description

Models 7427 and 7427V Neurostimulators have a wide range of noninvasively programmable parameters and stimulation modes. The neurostimulators are part of a dual-program system and offer dual-program and single-program modes.

Programs

The stimulation pulses delivered are determined by a program. A program is a specific combination of amplitude, rate, and pulse width parameters, acting on a specific set of electrodes.

Note: Programs have been referred to in previous literature and software as channels.

Dual-Program Stimulation

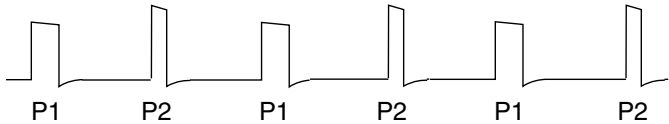
In dual-program operation, the neurostimulator has two programs (P1 and P2). Amplitude, pulse width, and all eight electrodes are independently set for each program. Rate, however, is the same for both programs.

A single rate determines the frequency of pulses for Program 1 and Program 2. The dual-program pulses are delivered alternately rather than simultaneously. Program 1 delivers an output pulse at its selected parameters of amplitude and pulse width, followed by the Program 2 output pulse at its selected parameters of amplitude and pulse width. This sequence is repeated, with single output pulses alternately delivered (Figure 6).

Single-Program Stimulation

In single-program operation, only one program is active and up to eight electrodes are available on the single program (Figure 6).

Dual-Program Operation



Program 1 Settings:
Amplitude = 3.0 V
Pulse Width = 210 μ sec
Electrode Polarity:
#1 = Pos.
#2 = Neg.

Program 2 Settings:
Amplitude = 3.5 V
Pulse Width = 150 μ sec
Electrode Polarity:
#3 = Neg.
#5 = Pos.
#6 = Neg.

Rate = 70 Hz

Single-Program Operation



Settings:
Amplitude = 3.0 V
Pulse Width = 210 μ sec
Electrode Polarity:
#1 = Pos.
#2 = Neg.

Rate = 70 Hz

Figure 6. Dual-program and single-program waveforms.

Neurostimulator Software Description

The neurostimulator provides currently selected parameter information, via telemetry, when used with the clinician programmer. The portable patient programmer enables your patient to make changes within the stimulation limits you set with the clinician programmer.

Programmable Functions

The Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators may be programmed with the clinician programmer or the Synergy EZ Model 7435 Patient Programmer.

The clinician programmer is used to set the stimulation parameters for both programs by telemetry. It controls various parameters and stimulation modes (Table 6). The display provides instruction “prompts” and parameter data. A printout can also be produced during a programming sequence. Some features include dual-program and single-program modes, Day Cycling, and SoftStart/Stop. Patient use information is also available. For example, neurostimulator internal counters automatically monitor items such as total therapy time and total number of output activations.

The Synergy EZ Patient Programmer is a hand-held, battery-powered device for programming the amplitude, pulse width, and rate within the stimulation limits you have approved for both programs. It can also switch the neurostimulator ON or OFF and check the neurostimulator battery status.

For a complete description of programmable functions, refer to the manual supplied with the software and the manual supplied with each programmer. Programmers made by other manufacturers are not compatible with the Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators.

Table 6. Synergy Model 7427 and Synergy Versitrel Model 7427V Control Equipment and Functions.

Controlling Device	Function	Programmable Parameters
Clinician Programmers:	Switches Neurostimulator On/Off	
<ul style="list-style-type: none"> Model 8840 Clinician Programmer with Model 8870 Application Card 	Programs Stimulation Parameters for Programs 1 and 2 Selects or Programs Stimulation Modes	Amplitude and Limits Pulse Width and Limits Rate and Limits ^a Electrode Polarity Continuous Cycling SoftStart/Stop
<ul style="list-style-type: none"> Model 7432 Clinician Programmer with MemoryMod Model 7459 Software 	Activates Measurement Functions Special Features Monitors Neurostimulator Battery Status	Neurostimulator Battery Load Impedance Patient Use Data Dual-Program, Single-Program, Day Cycling Printout
Synergy EZ Model 7435 Patient Programmer	Switches Neurostimulator Output On/Off	
	Gives Neurostimulator On/Off Status	
	Adjusts Stimulation Parameters Within Physician-Approved Limits for Both Programs	Pulse Width Amplitude Rate
	Monitors Neurostimulator/ Patient Programmer Battery Status	

^a The rate is the same for both programs.

Lead-Extension Options

The Synergy and Synergy Versitrel Neurostimulators provide flexibility based on the selection of leads, extensions, and electrode polarity. A variety of stimulation options are available and any polarity combination may be selected as long as at least one electrode is positive and at least one electrode is negative. To help maximize battery longevity, always use the minimum number of active electrodes necessary for effective stimulation.

For complete information on use of the leads and extensions, see the appropriate technical manual.

Warning: Use only those leads which are compatible with the output capabilities of the Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators. Refer to the system components sheet packaged with the neurostimulator for a complete list of components compatible with the Synergy and Synergy Versitrel Neurostimulation Systems.

Screening Procedure

An intraoperative screening phase during the lead implant procedure may be used to determine the patient's optimum lead position, parameter settings, and electrode polarity. Refer to the *MemoryMod Model 7459 Software: Programming Guide for Synergy, Synergy Versitrel, and Itrel 3 Neurostimulation Systems* for Synergy and Synergy Versitrel System screening instructions. A screening period after lead implant and before internalizing the neurostimulator is also recommended.

Warning: When screening a patient with dual leads implanted, do not simultaneously use two screeners; simultaneously operated screeners can interfere with the screening therapy signals and result in incorrect screening results.

Notes:

- Refer to the *DualScreen Model 3628 Screener Kit Technical Manual* for a description of the screener and detailed instructions on screener operation.
- Some Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulator capabilities cannot be simulated with the screener. For example, although the screener will simulate stimulation in an eight-electrode system with one program, it does not have the capability to provide simultaneous delivery of two programs with eight electrodes each.
- Synergy and Synergy Versitrel Neurostimulator output is not identical to screener output at the same settings. Some adjustment to the neurostimulator settings will be required to reproduce the stimulation results achieved during intraoperative screening.
- To ensure patient eligibility for a Synergy or a Synergy Versitrel Neurostimulation System, verify that the screening parameters (for a new implant) or programmed parameters (for a replacement) are appropriate for a Synergy or Synergy Versitrel Neurostimulation System implant. Refer to “Synergy and Synergy Versitrel Systems Eligibility” for more information.

Synergy and Synergy Versitrel Systems Eligibility

Prior to neurostimulator/receiver implant or replacement, ensure that the Synergy or Synergy Versitrel Neurostimulation System is appropriate for your patient.

New Implants: To ensure patient eligibility for the Synergy or Synergy Versitrel Neurostimulation System, verify that the screening parameters do not exceed the parameters described in Table 7 on page 38. If actual values exceed the values in Table 7, adjustments may be indicated.

Neurostimulator/Receiver Replacements: When using a Synergy or Synergy Versitrel Neurostimulator as a replacement device, it is important to note that not all neurostimulators have identical features. For example, the Synergy and Synergy Versitrel Neurostimulators do not provide unipolar stimulation; therefore, they may not be appropriate replacement devices for a neurostimulator using unipolar stimulation.

Before replacing an Itrel II, Itrel 3, or X-trel with a Synergy or Synergy Versitrel Neurostimulation System intended for dual-program use, a screening procedure using the DualScreen Model 3628 Screener is necessary.

To ensure patient eligibility for the Synergy or Synergy Versitrel Neurostimulation System, verify that the screening/programmed parameters for the replacement neurostimulator/receiver do not exceed the parameters described in Table 7. If actual values exceed the values in Table 7, adjustments may be indicated.

For new implants or neurostimulator/receiver replacements, the following tips will assist in establishing satisfactory paresthesia within specific parameter combinations described in Table 7.

- If the screening/programmed pulse width value is greater than 450 microseconds, reduce the pulse width of the screener to 450 microseconds and gradually increase amplitude to confirm satisfactory paresthesia. A five to ten percent increase in amplitude should be expected.
- If the screening/programmed rate is greater than 130 hertz, reduce the screener rate to 130 hertz and confirm satisfactory paresthesia.
- If the screening/programmed amplitude exceeds the maximum amplitude value provided in Table 7 for a specific rate and pulse width combination, reduce the rate until you have a rate/pulse width/amplitude combination displayed in the table.

Synergy and Synergy Versitrel Systems Eligibility

Note: If the programmed amplitude is close to the maximum amplitude indicated in Table 7, consider reducing the programmed rate to allow future increases in amplitude.

To use Table 7, locate the intersection of the screening rate and pulse width. The value displayed at this intersection reflects the maximum amplitude possible for that specific rate/pulse width combination using the Synergy or Synergy Versitrel Neurostimulation System.

If satisfactory paresthesia cannot be achieved within the parameters provided in Table 7, the Synergy or Synergy Versitrel Neurostimulator will not be an appropriate device for the patient.

Neurostimulator Implantation or Replacement

Table 7. Maximum Amplitude (Volts) Available for Specific Rate/Pulse Width Combinations.

Rate (Hz)	Pulse Width (Microseconds)				
	450	360	240	150	60
130	4.5	5.2	6.2	7.0	7.3
120	5.0	5.4	6.3	7.1	7.4
110	5.2	5.5	6.4	7.3	7.5
100	5.3	5.8	6.5	7.4	7.5
90	5.5	6.1	6.8	7.5	7.6
80	5.8	6.2	7.0	7.6	7.6
70	6.0	6.4	7.1	7.7	7.7
60	6.2	6.5	7.4	7.7	7.7
50	6.5	6.9	7.6	7.8	7.8
40	7.1	7.5	7.8	7.8	7.8
30	7.6	7.9	7.9	7.9	7.9
≤ 20	7.8	7.9	7.9	7.9	7.9

Neurostimulator Implantation or Replacement

This section outlines the basic steps of the suggested procedure for implanting or replacing the neurostimulator. For detailed information about the lead or extension, refer to the applicable technical manual.

Caution: It is recommended that the implanted lead-extensions in dual lead-extension systems be routed so they do not form a “loop.” When exposed to some theft detectors, looped lead-extensions increase the potential for patients to experience a momentary

increase in their perceived level of stimulation. Higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients as they pass through these devices. Figure 7 illustrates proper and improper routing methods for dual lead-extensions.

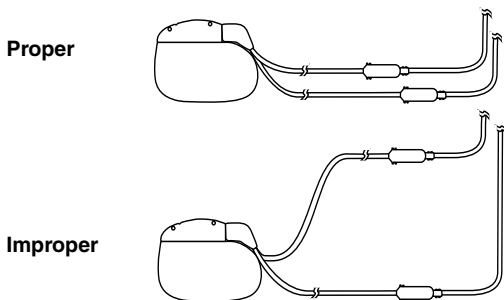


Figure 7. Proper and improper dual lead-extension routing (use fluoroscopy to verify).

Neurostimulator Implantation

Note: Verify that the screening parameters do not exceed the parameters described in Table 7 on page 38. If actual values exceed the values in Table 7, adjustments may be indicated. Refer to “Synergy and Synergy Versitrel Systems Eligibility” on page 35.

1. If installed, remove the percutaneous extension(s) in accordance with the procedure outlined in the appropriate extension technical manual.
2. Create a subcutaneous pocket for the neurostimulator by blunt dissection in the upper abdomen area, typically below the rib

Neurostimulator Implantation or Replacement

cage. The pocket may also be formed in the subclavicular, depending on the application of the system.

Note: The neurostimulator should be located no more than 1.5 inches (4 cm) beneath the surface of the skin to ensure proper programming. If more than one neurostimulator is used (e.g., for various therapies), they must be separated by a minimum of 8 inches (20 cm).

3. Place the neurostimulator in the pocket to assure proper fit and then remove it.
4. Tunnel from the lead incision site(s) to the neurostimulator pocket.
5. Route the extension(s) from the neurostimulator site to where the lead(s) lie(s) exposed.
6. Push the boot(s) over the lead(s) (Figure 8).

Note: In a dual lead-extension system, most extensions will have different boots to help distinguish between the different leads.

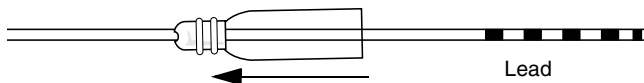


Figure 8. Push boot over lead.

7. Connect the lead(s) and extension(s), and secure the protective boot(s).
8. Close the incision above the lead-extension connection.
9. Check the neurostimulator connector block and determine if any setscrews obstruct the socket space. If necessary, back out the setscrews.
10. Insert the extension connector pins for electrodes 0–3 (or plug labeled 0, 1, 2, 3) fully into Socket I (Figure 9).

11. Insert the extension connector pins for electrodes 4–7 (or plug labeled 4, 5, 6, 7) fully into Socket II (Figure 9).

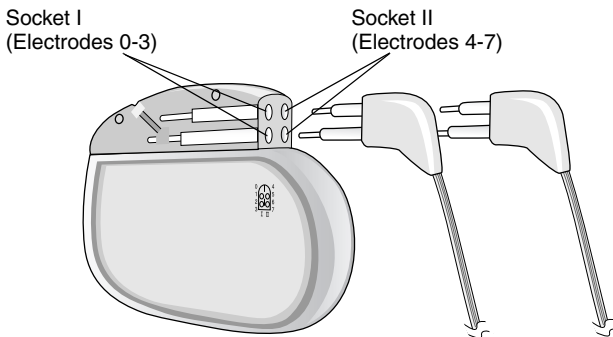


Figure 9. Insert extension connector pins fully.

12. Using the hex wrench included in the package, tighten each setscrew clockwise (Figure 10) until it touches the connector pin—continue tightening for **a maximum of 1/4 turn only**.
Caution: To prevent under tightening the neurostimulator setscrews, **do not** use the torque wrench from the lead or extension kit. Under tightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.
13. Remove the hex wrench while maintaining slight tension on the clockwise action. After you remove the hex wrench, check that the sealing rubber grommet has closed.
Note: In the Synergy and Synergy Versitrel Neurostimulators, four setscrews are located on the top of the connector block, two for each plug. Two setscrews are oriented at a 90° angle and two are oriented at a 45° angle. When tightening the setscrews, the hex wrench must be oriented at the same angle as the setscrews (Figure 10).

Neurostimulator Implantation or Replacement

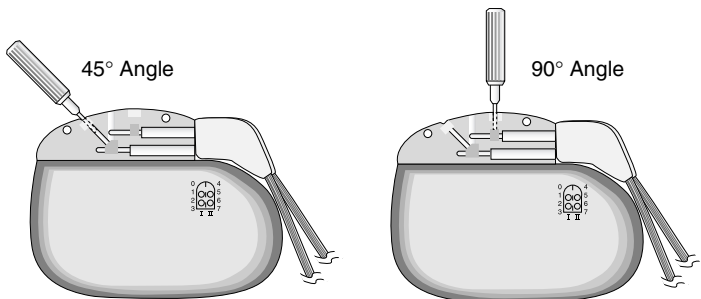


Figure 10. Tighten setscrew in rubber grommet.

Cautions:

- Be sure the hex wrench is fully inserted to prevent damage to the setscrew.
 - Verify that the sealing rubber grommet has closed after the hex wrench is withdrawn.
14. Place the neurostimulator into the subcutaneous pocket, with the etched identification side facing outward away from the muscle layer of the body (Figure 11).

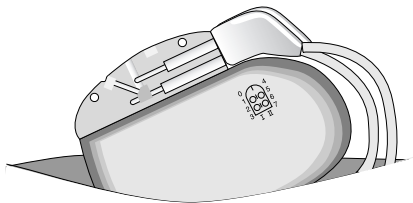


Figure 11. Implant neurostimulator.

Caution: Do not place any excess extension on top of the neurostimulator etched side. Wrap any excess extension wire **around the perimeter of the neurostimulator**. This avoids any increase in the subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension.

15. Use the suture holes in the connector block to secure the neurostimulator in the subcutaneous pocket. Use normally available surgical needles and silk, nonabsorbable sutures, or equivalent.

Note: If only one lead is implanted, perform the following steps using the accessories from the Model 3550-09 Accessory Kit to either seal the unused neurostimulator socket or the unused extension:

- Seal the unused neurostimulator socket (1 extension with 1 lead)—Insert the neurostimulator connector plug into the unused socket of the neurostimulator connector, and tighten the setscrews (Figure 12).

Neurostimulator Implantation or Replacement

19. Fill out the *Patient Identification Card*, and give it to the patient.

Neurostimulator Replacement

Complete the following steps to replace a Medtronic Itrel II Neurostimulator, Itrel 3 Neurostimulator, Synergy or Synergy Versitrel Neurostimulator, or an X-trel Receiver with a Synergy or Synergy Versitrel Neurostimulator. If replacing a Matrix Receiver or an extension, refer to steps 4a – 4c.

Notes:

- Prior to neurostimulator/receiver replacement, ensure that the Synergy or Synergy Versitrel Neurostimulation System is appropriate for your patient. When using a Synergy or Synergy Versitrel Neurostimulator as a replacement device, it is important to note that not all neurostimulators have identical features. For example, the Synergy and Synergy Versitrel Neurostimulators do not provide unipolar stimulation; therefore, they may not be appropriate replacement devices for a neurostimulator using unipolar stimulation.
 - Before replacing an Itrel II, Itrel 3, or X-trel with a Synergy or Synergy Versitrel Neurostimulation System intended for dual-program use, a screening procedure using the DualScreen Model 3628 Screener is necessary.
 - Verify that the screening/programmed parameters of the replaced device do not exceed the parameters described in Table 7 on page 38. If actual values exceed the values in Table 7, adjustments may be indicated. Refer to “Synergy and Synergy Versitrel Systems Eligibility” on page 35.
1. After ensuring that the neurostimulator output is OFF, open the neurostimulator implant site per normal surgical procedure, and carefully remove the neurostimulator from the subcutaneous pocket.

Neurostimulator Implantation or Replacement

2. Clean the neurostimulator connector block and extension connector with sterile water; wipe both dry with surgical sponges.
3. Insert a hex wrench through the pre-pierced hole in the rubber grommets, and loosen the setscrews by turning them counterclockwise.
4. Gently retract the extension connector pins from the neurostimulator connector block. If the extension connector pins show any signs of pitting or corrosion, the extension should be replaced. Clean and dry the extension connector pins and body(ies)—they must be free of fluids or tissue.

Note: If an extension needs to be replaced or if a Matrix Model 3272 Receiver is being replaced, do the following:

- a. Make an incision above the lead-extension setscrew connector, and disconnect the extension from the lead.
 - b. Sever the distal end of the extension just proximal to the extension-lead connection.
 - c. Carefully pull the extension out through the neurostimulator pocket incision.
5. Set aside the explanted components for return to Medtronic. Refer to “Explanted Component Disposal” on page 51 for more information.
 6. Check the neurostimulator connector block and determine if any setscrews obstruct the socket. If necessary, back out the setscrews.
 7. Insert the extension connector pins for electrodes 0–3 (or plug labeled 0, 1, 2, 3) fully into Socket I (Figure 14).
 8. Insert the extension connector pins for electrodes 4–7 (or plug labeled 4, 5, 6, 7) fully into Socket II (Figure 14).

Neurostimulator Implantation or Replacement

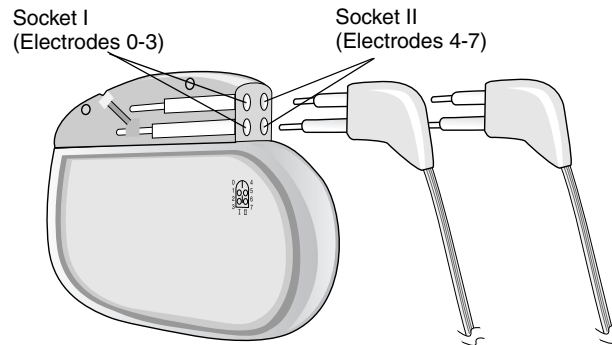


Figure 14. Insert extension connector pins fully into neurostimulator.

- Using the hex wrench included in the package, tighten each setscrew clockwise (Figure 15) until it touches the extension connector pin—continue tightening for a **maximum of 1/4 turn only**.

Caution: To prevent under tightening the neurostimulator setscrews, **do not** use the torque wrench from the lead or extension kit. Under tightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.

- Remove the hex wrench while maintaining slight tension on the clockwise action. After you remove the hex wrench, check that the rubber grommet has closed.

Note: In the Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulators, four setscrews are located on the top of the connector block, two for each plug. Two setscrews are oriented at a 90° angle and two are oriented at a 45° angle. When tightening the setscrews, the hex wrench must be oriented at the same angle as the setscrews (Figure 15).

Neurostimulator Implantation or Replacement

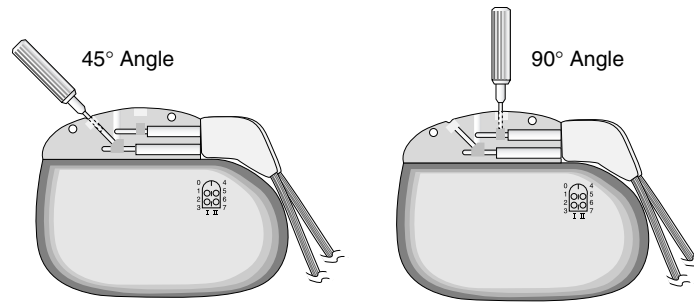


Figure 15. Tighten setscrew in rubber grommet.

Cautions:

- Be sure the hex wrench is fully inserted to prevent damage to the setscrew.
- Verify that the sealing rubber grommet has closed after the hex wrench is withdrawn.

11. Place the neurostimulator into the subcutaneous pocket, with the etched identification side facing outward away from the muscle layer of the body (Figure 16).

Note: The neurostimulator should be located no more than 1.5 inches (4 cm) beneath the surface of the skin to ensure proper programming. If more than one neurostimulator is used (e.g., for various therapies), they must be separated by a minimum of 8 inches (20 cm).

Neurostimulator Implantation or Replacement

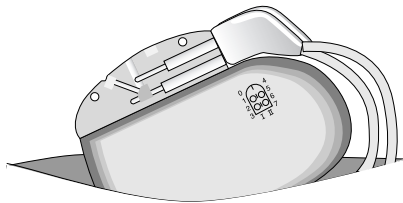


Figure 16. Implant neurostimulator.

Caution: Do not place any excess extension on top of the neurostimulator etched side. Wrap any excess extension wire around the perimeter of the neurostimulator. This avoids any increase in the subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension.

12. Use the suture holes in the connector block to secure the neurostimulator in the subcutaneous pocket. Use normally available surgical needles and silk, nonabsorbable sutures, or equivalent.

Note: If only one lead is implanted, perform the following steps using the accessories from the Model 3550-09 Accessory Kit to either seal the unused neurostimulator socket or the unused extension:

- Seal the unused neurostimulator socket (1 extension with 1 lead)—Insert the neurostimulator connector plug into the unused socket of the neurostimulator connector, and tighten the setscrews (Figure 17).

Neurostimulator Implantation or Replacement

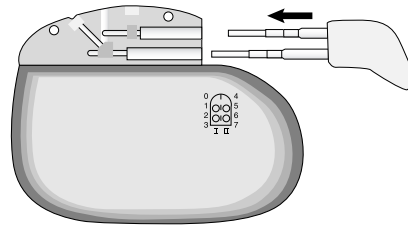


Figure 17. Insert connector plug into unused neurostimulator socket.

- Seal the unused extension (2 extensions with 1 lead)—
Slide the closed boot over the extension setscrew
connector, and secure with the sutures (Figure 18).

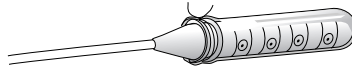


Figure 18. Slide closed boot over extension setscrew connector and suture.

13. Program the initial stimulation parameters. Begin with the pulse width and rate that were programmed in the replacement device or resulted in satisfactory paresthesia during the screening period. Increase amplitude gradually from 0.0 volts until patient response indicates satisfactory paresthesia is achieved. Refer to the appropriate programming guide for detailed programming instructions.

Note: Synergy and Synergy Versitrel Neurostimulator output is not identical to screener output at the same settings. Some adjustment to the Synergy or Synergy Versitrel Neurostimulator settings will be required to reproduce the stimulation results achieved during intraoperative screening.

14. Confirm that the desired program is stimulating the desired area.
15. Close the neurostimulator pocket incision.

Explanted Component Disposal

16. Fill out the *Patient Identification Card*, and give it to your patient.
17. Return explanted components to Medtronic. Refer to “Explanted Component Disposal” for more information.

Explanted Component Disposal

Explanted products should be returned to Medtronic for proper disposal. Return explanted products to:

Medtronic, Inc.
Neurological Division
Product Performance Department
MSN600
P.O. Box 1250
Minneapolis, MN 55440-9087

Note: Self-addressed mailer kits are available from Medtronic sales representatives.

Patient Counseling Information

The patient should be advised of the known risks of the surgical procedure and the therapy, as discussed in other sections of this manual, as well as the potential benefits. The patient should also be advised to read the *Synergy EZ Patient Programmer User Manual*.

Note: Additional safety information about diathermy is located in “Contraindications” on page 7 of this manual.

As always, physicians should use their medical and professional judgment as to what is meaningful and useful to each particular patient in their individual circumstances.

Patient Counseling Information

Theft Detectors and Security Screening Devices

Patients should be advised to use care when approaching theft detector and security screening devices (such as those found in airports, libraries, and some department stores). When approaching these devices, patients should do the following:

1. If possible, request to bypass these devices. The patient should show the security personnel their patient identification card for the neurostimulator and request a manual search. Security personnel may use a handheld security wand but the patient should ask the security personnel not to hold the security wand near the neurostimulator any longer than is absolutely necessary. The patient may wish to ask for another form of personal search.
2. If patients must pass through the theft detector or security screening device, they should turn their neurostimulator off, approach the center of the device and walk through normally (Figure 19).
 - a. If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
 - b. If one gate is present, they should walk as far away as possible from it.

Note: Some theft detectors may not be visible.
3. Proceed through the security device. Do not linger near or lean on the screening device.

Patient Registration

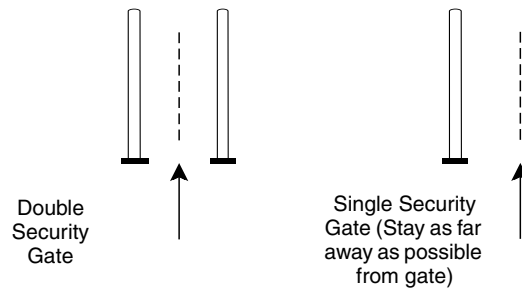


Figure 19. Approaching security gates.

4. After patients pass through the security device, they should turn their neurostimulator on again.

Patient Registration

Inside the shipping container for each Synergy and Synergy Versitrel Neurostimulator is an implant registration form that creates a permanent record of your patient's implant. It is important that you **complete the form and promptly return the original to Medtronic, Inc.** Three copies are provided for the patient's medical records.

Medtronic will transfer vital information to a wallet-sized, plastic-coated identification card and will mail it directly to the patient. A temporary identification card is packaged with the neurostimulator for the patient's use until the permanent card arrives.

In addition to the patient identification card, the information on the form registers the device warranties and creates a record of the implant in Medtronic's implant data system. The information in this system ensures compliance with the **Safe Medical Devices Act (USA)**.

Resterilization

Resterilization

The implantable components of the Synergy Model 7427 and Synergy Versitrel Model 7427V Systems were sterilized with ethylene oxide prior to shipment. The package should be inspected for damage prior to use. If you are unsure of the components' sterility for any reason (except when the "Use By" date has expired), they can be resterilized at the hospital site.

Note: If contamination is suspected because of a defective sterile package seal, the neurostimulator and accessories can be returned to Medtronic for replacement or they can be resterilized at the hospital. Medtronic does not accept returned neurostimulators or accessories for resterilization and return them to customers.

Due to variations in hospital sterilizers, precise instructions for sterilization or aeration cannot be given here. If further information is necessary regarding the procedures to be used, contact the manufacturer of the sterilizer unit. Use biological indicators or other acceptable methods to validate the effectiveness of the hospital's sterilizer unit.

Medtronic cannot accept the responsibility for the hospital's resterilization of any components. If, however, the hospital decides to resterilize, usual and customary sterilization methods should be used.

Cautions:

- Do not resterilize and use the neurostimulator or accessories after exposure to body tissues or fluids.
- Do not use radiation to resterilize any component. **DO NOT AUTOCLAVE THE NEUROSTIMULATOR. DO NOT CLEAN THE NEUROSTIMULATOR IN ULTRASONIC CLEANERS.** Permanent damage can result.

Subject to the foregoing, the following may be considered:

Ethylene oxide is an acceptable method for resterilization when the neurostimulator and accessories are repackaged in an ethylene

Resterilization

oxide-permeable package. The temperature during the process should not exceed 130° F (55° C). The maximum possible aeration must be allowed before implanting the neurostimulator and using the accessories.

Steam autoclaving may be used for the **hex wrench only**.

For autoclave, a standard cycle of 30 minutes at 250° F (121° C) and 15 psig is recommended. For “flash” autoclave, a standard cycle of 5 minutes at 270° F (132° C) and 27 psig is recommended. **Do not** autoclave the neurostimulator.

Resterilization of a neurostimulator does not change the “Use By” date established at the time of manufacture because that date is based on battery life.

Specifications

Specifications

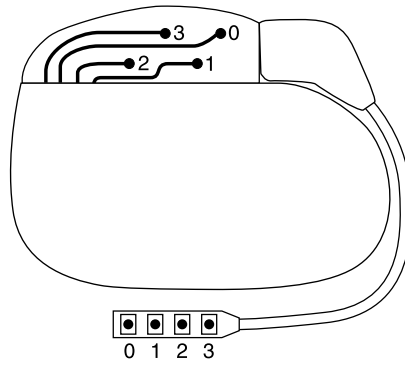
Table 8. Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulator Operating Ranges.

Programmable Parameters	Values^a
Amplitude (Peak Voltage) and Limits for Programs 1 and 2	0 to 10.5 volts, Programmable, Normal Resolution (100 mV steps) 0 to 6.35 volts Programmable, Fine Resolution (50 mV steps)
Pulse Width and Limits for Programs 1 and 2	60, 90, 120, 150, 180, 210, 240, 270 300, 330, 360, 390, 420, 450 μ sec
Mode	Continuous or Cycling
Rate and Limits	36 values from 3 to 130 Hz
Cycle ON/OFF Time	0.1 second to 24 hours
Cycle ON/OFF/Time w/ SoftStart/Stop	2 seconds to 24 hours
SoftStart/Stop	Allows selection of 1, 2, 4, or 8 seconds ramp increasing gradually from 0 (zero) to the selected amplitude and vice versa for Stop
Dual-Program or Single-Program Operation	Either Dual-Program or Single-Program Operation Selected
Electrode Polarity for Programs 1 and 2	Electrodes 0, 1, 2, 3, 4, 5, 6, and 7: Off, Negative, or Positive
Day Cycling ON/OFF Time	30 minutes to 24 hours
Power ON Reset (POR)	1.9 to 2.1 volts

^a **Note:** All values are approximate.

Specifications

Front



Back

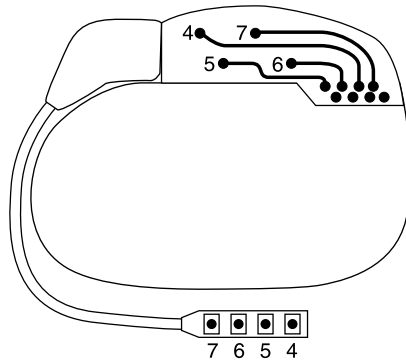


Figure 20. Electrode configuration with dual extension.

Specifications

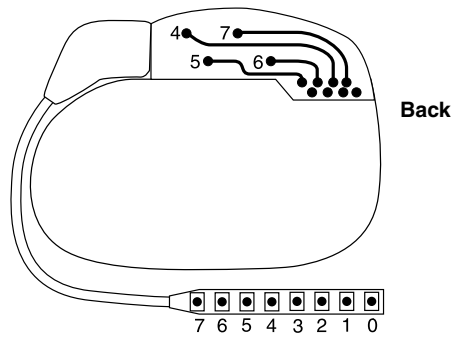
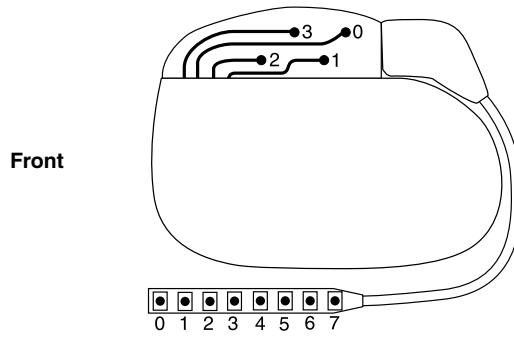


Figure 21. Electrode configuration with bifurcated extension.

Specifications

**Table 9. Synergy Model 7427 and Synergy Versitrel Model 7427V
Neurostimulator Shipping Values.**

Parameter	Value
Amplitude for Programs 1 and 2 (Normal Resolution)	0 volts
Upper Limit	+3 tracking
Lower Limit	0 volts
Rate	30 Hz
Upper Limit	+30 Hz tracking
Lower Limit	3.0 Hz
Pulse Width for Programs 1 and 2	210 μ sec
Upper Limit	+30 μ sec tracking
Lower Limit	60 μ sec
Output On/Off	Off
Mode	Dual-Program Continuous
SoftStart/Stop	4 seconds
Electrode Polarity for Program 1	0 = Negative 1 = Off 2 = Off 3 = Positive 4 = Off 5 = Off 6 = Off 7 = Off
Electrode Polarity for Program 2	0 = Off 1 = Off 2 = Off 3 = Off 4 = Negative 5 = Off 6 = Off 7 = Positive

Specifications

Table 10. Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulator Descriptions.

Description	Synergy Value ^a	Synergy Versitrel Value ^a
Height	2.4 in (61 mm)	2.4 in (61 mm)
Length	3.0 in (76 mm)	2.4 in (61 mm)
Thickness	0.6 in (15 mm)	0.6 in (15 mm)
Weight	2.8 oz (83 g)	2.3 oz (65 g)
Volume	3.1 in ³ (51 cm ³)	2.5 in ³ (40 cm ³)
External Shield	Titanium ^b	Titanium ^b
Power Source	3.2 volt CSVO ^c Cell	3.2 volt CSVO ^c Cell
Storage Temperature	0° to +125° F -18° to +52° C	0° to +125° F -18° to +52° C

^a All values are approximate.

^b **Note:** Materials that come in contact with human tissue. All have been certified to be biocompatible.

^c Combined Silver Vanadium Oxide

Table 11. Synergy Model 7427 and Synergy Versitrel Model 7427V Neurostimulator Material Biocompatibility.

Structure	Materials ^a
Case	Sheet titanium
Connector Block	Polyurethane
Grommets, Seals	Silicone rubber
Setscrews	Titanium alloy
Adhesive	Silicone adhesive

^a **Note:** Materials that come in contact with human tissue. All have been certified to be biocompatible.

Conformance to Standards

Conformance to Standards

Table 12. Conformance to Standards.

Standard Category	Standard Number
Active Implantable Medical Devices: General Requirements for Safety, Marking and Information to be provided by the Manufacturer	EN 45502 - 1

Appendix A: Battery Longevity Reference

Appendix A: Battery Longevity Reference

With the Synergy and Synergy Versitrel Neurostimulators, you can expect battery life to range from months to years, **depending on the parameters you have selected for your patient**. Appendix A provides reference information that will assist you in estimating Synergy and Synergy Versitrel Neurostimulator battery longevity prior to neurostimulator internalization and maximize battery life during use. It contains the procedure, tables, and formulas needed to estimate battery longevity plus tips for maximizing battery life. These estimates are based on programmed parameters, lead selection, and correction factors for electrode selection and expected usage time. Actual battery life may vary from the estimate due to factors such as tissue impedance, changes in stimulation requirements over time, and stimulation parameters selected within the programmed limits for amplitude, rate, and pulse width. The longevity of the Synergy Model 7427 Neurostimulator is longer than that of the Synergy Versitrel Model 7427V Neurostimulator.

Tips for Maximizing Battery Life

The following tips will help optimize Synergy and Synergy Versitrel Neurostimulator battery life:

- Program cycling mode with the shortest ON time and longest OFF time that still provides effective stimulation. A cycle of 15 seconds ON and 15 seconds OFF may be a good starting point and will double the life of the system (over continuous mode).
- Use the minimum number of active electrodes necessary for effective stimulation.
- Use the lowest effective settings for all parameters, especially rate. A device programmed at a rate of 30 Hz will last approximately three times longer than a device programmed at 90 Hz, with all other parameters constant.
- Program Day Cycling for patients who can tolerate no stimulation during sleep.

Appendix A: Battery Longevity Reference

- Set the upper parameter limits in the neurostimulator to the lowest effective settings. Higher limits may encourage unnecessary patient use, thereby reducing battery life.
- Instruct the patient to use the neurostimulator only when needed.

Estimating Battery Life Prior to Neurostimulator Internalization

Follow this procedure to estimate Synergy and Synergy Versitrel Neurostimulator battery life prior to neurostimulator internalization. Use the worksheet beginning on page 69 to record settings and calculate longevity.

Note: Ensure the appropriate tables are referenced for the lead(s) used:

- For Pisces Z Quad brand leads use Table 13 (page 71) and Table 14 (page 72).
 - For Pisces-Octad, Pisces-Quad, Pisces-Quad Compact, Pisces-Quad Plus, Resume TL, Resume II, or Specify brand leads use Table 15 (page 73) and Table 16 (page 74).
 - For a mixed pair of leads (one Pisces Z Quad brand lead and any other lead) use Table 13 (page 71) and Table 14 (page 72).
1. Determine the expected Program 1 operating parameters for the neurostimulator, including amplitude, rate, pulse width, number of active electrodes, cycle ON/OFF times, and hours of stimulation per day.
 2. Determine the Program 1 Energy Use (EU) from Table 13 (page 71) or Table 15 (page 73) using the expected values for amplitude, rate, and pulse width.

Notes:

- Use the table values that are closest to the expected values. Be aware that when values do not match, there will be a discrepancy between calculated longevity estimates and actual results.

Appendix A: Battery Longevity Reference

- Table 13 and Table 15 assume neurostimulator usage of 12 hours per day. If neurostimulator usage is different from 12 hours, adjustments will be made in later calculations.

3. Determine the Program 1 Electrode Correction Factor (ECF) from Table 14 (page 72) or Table 16 (page 74) for the number of active electrodes.

Note: If selecting an electrode configuration for this program with only one positive and only one negative electrode, you may skip step 3 because the Electrode Correction Factor is 1.0.

4. Multiply the Program 1 Energy Use by the Program 1 Electrode Correction Factor to obtain the Program 1 Factor (P1F).

5. Repeat steps 1 through 4 for Program 2 to obtain the Program 2 Factor (P2F).

6. Add the Program 1 Factor and the Program 2 Factor to obtain the Dual-Program Factor (DPF).

7. Determine the Usage Correction Factor (UCF) from the following formula (the value will be between 0 and 2):

Usage Correction Factor = Usage Ratio x Cycling Ratio
[Usage Ratio = hours of stimulation (per day) ÷ 12 hours]
[Cycling Ratio = cycle ON time ÷ (cycle ON time + cycle OFF time)]

Notes:

- If Cycling is not programmed, the formula becomes: Usage Correction Factor = Usage Ratio.
- If using Continuous mode with 12 hours of stimulation, you may skip step 7 because the Usage Correction Factor is 1.0.

Appendix A: Battery Longevity Reference

8. Multiply the results of steps 6 and 7 to obtain the adjusted Energy Use value:
 $DPF \times UCF = \text{adjusted Energy Use}$
Note: If using single-program mode instead of dual-program mode, skip steps 5 and 6 and multiply the results of steps 4 and 7 to obtain the adjusted Energy Use value:
 $P1F \times UCF = \text{adjusted Energy Use}$
9. Take the adjusted Energy Use value and determine the battery longevity in years from Figure 22 (page 75).
10. Determine the model number correction factor (1 for Synergy; 0.56 for Synergy Versitrel).
11. Calculate the estimated battery longevity in years. Multiply the battery longevity in years by the model number correction factor associated with the neurostimulator in use.

Appendix A: Battery Longevity Reference

Example 1

Assume the patient's neurostimulator is a Synergy Model 7427 and will be programmed to these settings using two Pisces Z Quad brand leads and dual-program mode:

Amplitude: Program 1 = 3.3 V; Program 2 = 4.0 V
Rate (for Programs 1 and 2) = 30 Hz
Pulse Width: Program 1 = 330 μ sec; Program 2 = 450 μ sec
Electrodes: Program 1 = 0 +, 6 -, remaining Off;
Program 2 = 3 -, 4 -, 5 +, remaining Off
Cycling = 0.1 seconds ON and 0.1 seconds OFF
Hours of Stimulation = 12 hours

The Energy Use from Table 13 (page 71) would be 46 for Program 1 and 105 for Program 2.

The Electrode Correction Factor from Table 14 (page 72) would be 1.0 for Program 1 and 1.4 for Program 2.

Thus, the Program 1 Factor would be $46 \times 1.0 = 46$, and the Program 2 Factor would be $105 \times 1.4 = 147$, making the Dual-Program Factor $46 + 147 = 193$.

The Usage Correction Factor would be:

Usage Ratio = $12 \div 12 = 1.0$
Cycling Ratio = $0.1 \div (0.1 + 0.1) = 0.5$
Usage Correction Factor = $1.0 \times 0.5 = 0.5$

The adjusted Energy Use would be:

$193 \times 0.5 = 96.5$

The battery longevity from Figure 22 (page 75) would be approximately 6.5 years.

The model number correction factor for this example using Synergy is 1. The estimated battery longevity would be: battery longevity (6.5 years) \times model number correction factor (1) = 6.5 years estimated longevity.

Appendix A: Battery Longevity Reference

Example 2A

Assume the patient's neurostimulator is a Synergy Versitrel Model 7427V and will be programmed to these settings using one Pisces-Octad, Pisces-Quad, Pisces-Quad Compact, Pisces-Quad Plus, Resume TL, Resume II, or Specify brand lead and single-program mode:

Amplitude: Program 1 = 4.2 V
Rate: Program 1 = 30 Hz
Pulse Width: Program 1 = 450 μ sec
Electrodes: Program 1 = 1 +, 2 -
Hours of Stimulation = 18 hours

The Energy Use from Table 15 (page 73) is 79 for Program 1.

The Electrode Correction Factor from Table 16 (page 74) is 1.0 for Program 1.

Thus, the Program 1 Factor would be $79 \times 1.0 = 79$.

The Usage Correction Factor would be:

Usage Ratio = $18 \div 12 = 1.5$
Usage Correction Factor = 1.5

The adjusted Energy Use would be:

$79 \times 1.5 = 118.5$

The battery longevity from Figure 22 (page 75) would be approximately 5.5 years.

The model number correction factor for this example using Synergy Versitrel is 0.56.

The estimated battery longevity would be: battery longevity (5.5 years) \times model number correction factor (0.56) = 3.1 years estimated longevity.

Appendix A: Battery Longevity Reference

Example 2B

Assume the patient's neurostimulator is a Synergy Versitrel Model 7427V and will be programmed to these settings using one Pisces Z Quad brand lead and single-program mode:

Note: These settings correspond directly to the settings used in Example 2A with the amplitude adjusted to account for lower lead impedance.

Amplitude: Program 1 = 3.0 V
Rate: Program 1 = 30 Hz
Pulse Width: Program 1 = 450 μ sec
Electrodes: Program 1 = 1 +, 2 -
Hours of Stimulation = 18 hours

The Energy Use from Table 13 (page 71) is 60 for Program 1.

The Electrode Correction Factor from Table 14 (page 72) is 1.0 for Program 1.

Thus, the Program 1 Factor would be $60 \times 1.0 = 60$.

The Usage Correction Factor would be:

Usage Ratio = $18 \div 12 = 1.5$
Usage Correction Factor = 1.5

The adjusted Energy Use would be:

$60 \times 1.5 = 90$

The battery longevity from Figure 22 (page 75) would be approximately 7.0 years.

The model number correction factor for this example using Synergy Versitrel is 0.56.

The estimated battery longevity would be: battery longevity 7.0 x model number correction factor (0.56) = 3.9 years estimated longevity.

Appendix A: Battery Longevity Reference

Battery Longevity Worksheet

Program 1 Energy Use (P1 EU)

Amp _____ V Rate _____ Hz PW _____ μ sec

The Program 1 Energy Use (EU) from Table 13 on page 71 or Table 15 on page 73 is: _____

Program 1 Electrode Correction Factor (P1 ECF)

If the electrode configuration for Program 1 is one positive and one negative electrode, skip this step. Otherwise, the Program 1 Electrode Correction Factor (ECF) from Table 14 on page 72 or Table 16 on page 74 is: _____

Program 1 Factor (P1F)

Compute the Program 1 Factor:

$$(P1\ EU) \text{ ______ } \times (P1\ ECF) \text{ ______ } = \text{ ______ } (P1F)$$

Program 2 Energy Use (P2 EU)

Amp _____ V Rate _____ Hz PW _____ μ sec

The Program 2 Energy Use (EU) from Table 13 on page 71 or Table 15 on page 73 is: _____

Program 2 Electrode Correction Factor (P2 ECF)

If the electrode configuration for Program 2 is one positive and one negative electrode, skip this step. Otherwise, the Program 2 Electrode Correction Factor (ECF) from Table 14 on page 72 or Table 16 on page 74 is: _____

Program 2 Factor (P2F)

Compute the Program 2 Factor:

$$(P2\ EU) \text{ ______ } \times (P2\ ECF) \text{ ______ } = \text{ ______ } (P2F)$$

Dual-Program Factor (DPF)

Compute the Dual-Program Factor:

$$(P1F) \text{ ______ } + (P2F) \text{ ______ } = \text{ ______ } (DPF)$$

Appendix A: Battery Longevity Reference

Usage Correction Factor (UCF)

If using Continuous mode with 12 hours of stimulation, skip this step.
Otherwise, calculate the Usage Correction Factor as follows:

Hours of stimulation (per day): _____ hours

Cycle ON time: _____

Cycle OFF time: _____

Compute the Usage Ratio:

_____ hours of stimulation ÷ 12 hours = _____

And the Cycling Ratio:

_____ cycle ON ÷ (_____ cycle ON + _____ cycle OFF) = _____

With the Usage Ratio (UR) and the Cycling Ratio (CR), compute the
Usage Correction Factor (UCF):

(UR) _____ x (CR) _____ = _____ (UCF) or if Cycling is not used:

(UR) _____ = _____ (UCF)

Longevity Estimate

Now calculate the adjusted Energy Use:

(DPF) _____ x (UCF) _____ = _____ (adj EU)

or if Single-Program mode is used:

(P1F) _____ x (UCF) _____ = _____ (adj EU)

The battery longevity from Figure 22 on page 75 is:

_____ years

The model number correction factor for Synergy is 1.

The model number correction factor for Synergy Versitrel is 0.56.

The battery longevity x the model number correction factor =
_____ years.

Appendix A: Battery Longevity Reference

Table 13. For use with Pisces Z Quad Brand Leads—Synergy and Synergy Versitrel Neurostimulator Energy Use^a for 2 Active Electrodes/ Programs for 12 Hours/Day Usage.

Amplitude	Rate	Pulse Width			
		60	210	330	450
1.0	30	2	7	10	13
	70	5	15	22	29
	130	9	27	41	53
2.0	30	6	18	28	37
	70	13	42	64	84
	130	24	79	118	154
3.0	30	9	30	46	60
	70	21	69	104	137
	130	39	127	191	250
4.0	30	16	53	80	105
	70	37	121	182	239
	130	68	222	333	435
5.0	30	25	82	125	163
	70	57	188	283	371
	130	105	343	516	673
6.0	30	36	119	180	236
	70	82	270	407	533
	130	150	492	739	965
7.0	30	50	164	247	324
	70	112	371	560	733
	130	204	673	1013	1322
8.0	30	66	218	328	429
	70	148	490	741	966
	130	270	891	1340	1661
9.0	30	86	283	425	558
	70	191	635	956	1254
	130	347	1146	1658	1701

Appendix A: Battery Longevity Reference

Table 13. For use with Pisces Z Quad Brand Leads—Synergy and Synergy Versitrel Neurostimulator Energy Use^a for 2 Active Electrodes/Programs for 12 Hours/Day Usage. (continued)

Amplitude	Rate	Pulse Width			
		60	210	330	450
10.0	30	109	363	545	715
	70	244	815	1228	1612
	130	444	1476	1700	1699

^a This Table was created from data collected using 500 ohms system impedance. If measured impedance differs from this value, results will vary.

Table 14. For use with Pisces Z Quad Brand Leads—Synergy and Synergy Versitrel Neurostimulator Electrode Correction Factor (ECF).

Number of Active Positive Electrodes	Number of Active Negative Electrodes						
	1	2	3	4	5	6	7
1	1.0	1.4	1.5	1.6	1.6	1.6	1.7
2	1.4	1.9	2.2	2.3	2.4	2.5	
3	1.5	2.2	2.5	2.8	2.9		
4	1.6	2.3	2.8	3.1			
5	1.6	2.4	2.9				
6	1.6	2.5					
7	1.7						

Appendix A: Battery Longevity Reference

Table 15. For Use with Pisces-Octad, Pisces-Quad, Pisces-Quad Compact, Pisces-Quad Plus, Resume TL, Resume II, or Specify Brand Leads—Synergy and Synergy Versitrel Neurostimulator Energy Use^a for 2 Active Electrodes/Programs for 12 Hours/Day Usage.

Amplitude	Rate	Pulse Width			
		60	210	330	450
1.0	30	1	4	7	9
	70	3	10	16	21
	130	6	20	30	39
2.0	30	3	13	20	27
	70	9	31	47	63
	130	17	57	87	115
3.0	30	6	22	34	45
	70	15	51	77	102
	130	29	94	142	187
4.0	30	11	39	59	79
	70	27	90	136	180
	130	50	165	249	328
5.0	30	18	61	93	123
	70	42	139	212	280
	130	77	255	385	507
6.0	30	26	88	134	178
	70	60	201	306	403
	130	111	366	553	725
7.0	30	36	121	185	244
	70	83	276	419	553
	130	151	502	759	996
8.0	30	48	161	245	323
	70	109	365	555	732
	130	200	662	1001	1315
9.0	30	62	208	316	419
	70	141	471	716	943
	130	256	849	1285	1672

Appendix A: Battery Longevity Reference

Table 15. For Use with Pisces-Octad, Pisces-Quad, Pisces-Quad Compact, Pisces-Quad Plus, Resume TL, Resume II, or Specify Brand Leads—Synergy and Synergy Versitrel Neurostimulator Energy Use^a for 2 Active Electrodes/Programs for 12 Hours/Day Usage.

Amplitude	Rate	Pulse Width			
		60	210	330	450
10.0	30	80	267	404	535
	70	181	602	917	1210
	130	327	1091	1637	1773

^a This table was created from data collected using 700 ohms system impedance (700 ohms is a typical impedance for a patient with a 51 cm 7495 Extension and a 28 cm 3487A Lead). If measured impedance differs from this value, results will vary.

Table 16. For Use with Pisces-Octad, Pisces-Quad, Pisces-Quad Compact, Pisces-Quad Plus, Resume TL, Resume II, or Specify Brand Leads—Synergy and Synergy Versitrel Neurostimulator Electrode Correction Factor (ECF).

Number of Active Positive Electrodes	Number of Active Negative Electrodes						
	1	2	3	4	5	6	7
1	1.0	1.5	1.6	1.7	1.7	1.8	1.8
2	1.5	2.0	2.3	2.5	2.6	2.7	
3	1.6	2.3	2.8	3.0	3.2		
4	1.7	2.5	3.0	3.4			
5	1.7	2.6	3.2				
6	1.8	2.7					
7	1.8						

Appendix A: Battery Longevity Reference

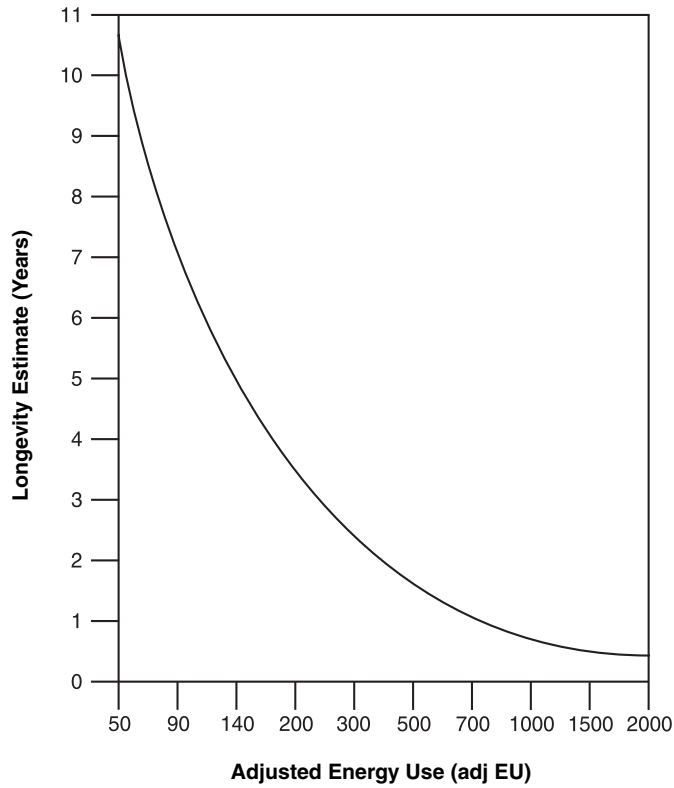


Figure 22. Synergy and Synergy Versitrel Neurostimulator longevity estimates (years) for energy use.

Appendix B: Synergy EZ Patient Programmer

Appendix B: Synergy EZ Patient Programmer

A Synergy EZ Model 7435 Patient Programmer is required for use with each Synergy and Synergy Versitrel Neurostimulation System. The patient programmer enables your patient to turn the neurostimulator on or off and adjust the amplitude, pulse width, and rate within the ranges programmed with the clinician programmer.

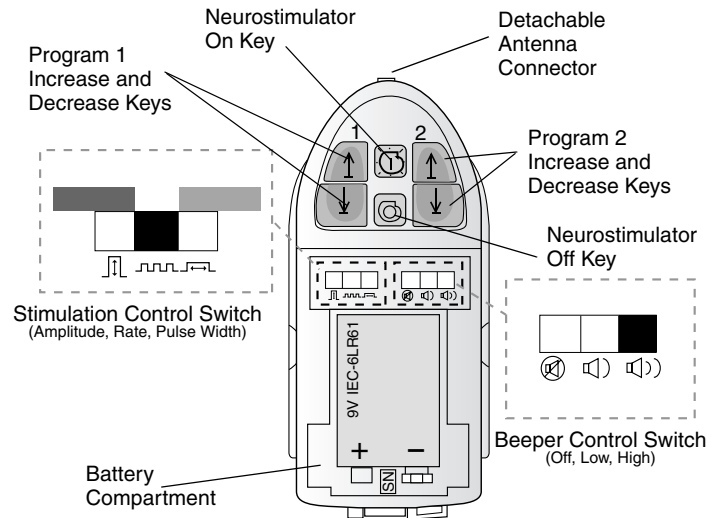


Figure 23. Front of Synergy EZ Model 7435 Patient Programmer without battery cover.

Detailed instructions on patient programmer use and care can be found in the patient manual packaged with the patient programmer.

When the patient programmer is placed over the implanted neurostimulator and the keys are pressed, coded radio-frequency

Appendix B: Synergy EZ Patient Programmer

signals are sent to the neurostimulator. The coded signals tell the neurostimulator to turn on or off and change amplitude, pulse width, or rate. The patient programmer also monitors neurostimulator battery status and its own battery status. The patient uses internal stimulation control switches and an external keypad to operate the patient programmer. A detachable antenna is available for patients who have difficulty reaching their neurostimulator.

Note: Keep the rubber plug in the detachable antenna connector when not using the detachable antenna to help maintain the water resistance of the device.

Cautions:

- The Synergy EZ Model 7435 Patient Programmer is used only with the Synergy Model 7427 or Synergy Versitrel Model 7427V Neurostimulator. DO NOT attempt to use the patient programmer on any other devices.
- Radio signals (telemetry) from the patient programmer may interfere with the performance of other implantable devices.
- When troubleshooting your patient's system for a possible problem (e.g., no stimulation), use the clinician programmer to verify the cause. Do not depend only on the patient programmer lights and beeper.





Keypad

The keypad consists of On/Off keys and Increase/Decrease keys. Refer to Table 17 for a description of the keys.

Note: For the Synergy EZ Model 7435 Patient Programmer, the Increase/Decrease keys located under the number "1" correspond to Program 1 of the implanted system. Similarly, the Increase/Decrease keys located under the number "2" correspond to Program 2 of the implanted system.

Appendix B: Synergy EZ Patient Programmer

Table 17. Patient Programmer Keypad and Function.

Key	Function
	Turns the neurostimulator on.
	Turns the neurostimulator off.
	Increases the amplitude, pulse width, or rate within physician-approved limits.
	Decreases the amplitude, pulse width, or rate within physician-approved limits.

Control Switches

The control switches are located inside the battery cover. (Press the release tab to remove the cover.) The Stimulation Control switch (Figure 24) allows the patient to select amplitude, rate, or pulse width, which are designated with symbols and color coding. This selection determines which parameter is adjusted by the Increase/Decrease keys.

The Beeper Control switch (Figure 24), designated with symbols, lets your patient turn the beeper off or set the volume to low or high (Figure 24). The beeper provides the patient with audible feedback during programming. One beep confirms a completed programming step. Three rapid beeps mean unsuccessful telemetry due to one of the following reasons:

Appendix B: Synergy EZ Patient Programmer

- Patient tried to adjust the neurostimulator parameters outside the physician-approved limits.
- Neurostimulator was off when the patient tried to increase amplitude, rate, or pulse width.

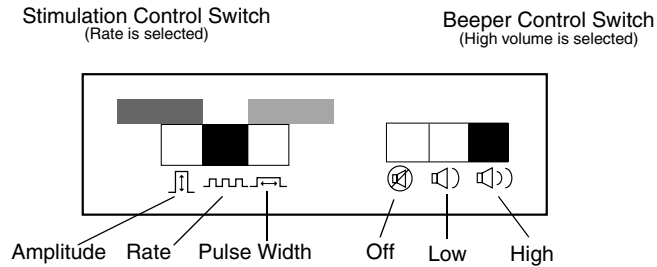


Figure 24. Stimulation Control and Beeper Control switches.

Programmer Battery

The patient programmer operates with a 9-volt rectangular battery. You may use an alkaline or carbon-zinc battery. An alkaline battery is recommended for longest battery life.

Warning: Do not use a mercury or zinc-air battery.

A label under the battery shows the battery position and how to place the battery by polarity symbols (+ and -). The "9-volt" label is a reminder to use a 9-volt battery.

Note: When not using the programmer for more than 4 weeks, remove the battery to prevent corrosive damage to the device.

Appendix B: Synergy EZ Patient Programmer

Symbols and Indicator Lights

A target symbol, an antenna symbol, and indicator lights are located on the back of the patient programmer (Figure 25).

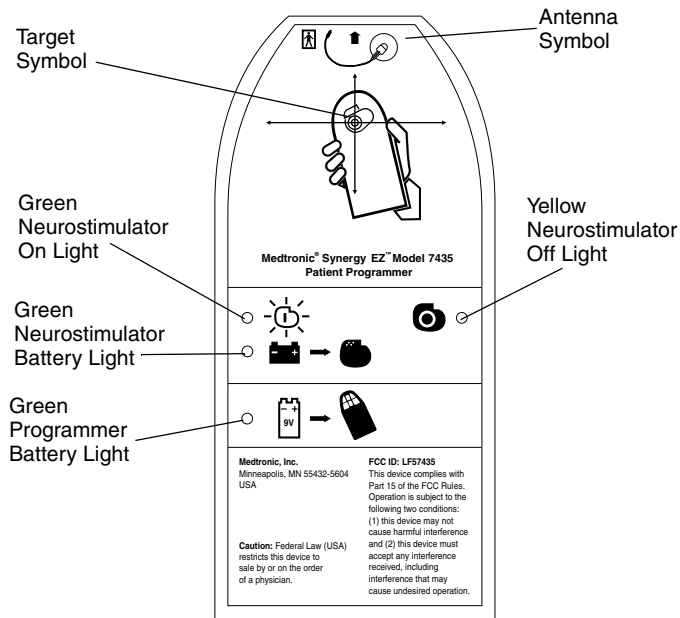


Figure 25. Back view of patient programmer.

Target Symbol – A target symbol helps patients place the programmer over their neurostimulator site. The internal antenna (which is located underneath the keypad in the patient programmer) must be placed over the implanted neurostimulator as shown in Figure 26.

Appendix B: Synergy EZ Patient Programmer

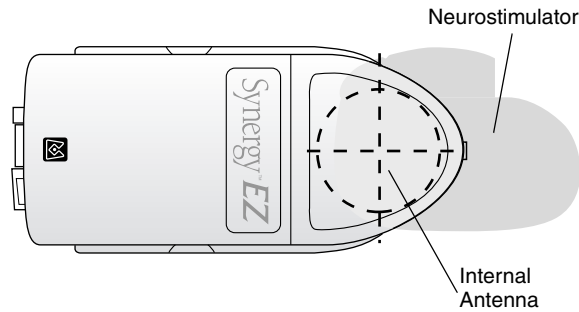


Figure 26. Place patient programmer over implanted neurostimulator. (Place against clothing or skin.)

Antenna Symbol – The antenna symbol shows the location of the detachable antenna connector. The detachable antenna enables the patient to program the neurostimulator without placing the programmer over the neurostimulator. A detachable antenna may be prescribed for those patients who have difficulty reaching their neurostimulator.

Indicator Lights – The indicator lights provide neurostimulator and patient programmer status. When the patient programmer is placed over the neurostimulator and the keys are pressed, the lights on the back of the programmer light up. Refer to Table 18 for a description of the lights and what they mean.

Appendix B: Synergy EZ Patient Programmer

Table 18. Patient Programmer Indicator Lights.

Neurostimulator ON/OFF Lights

When:	It means:
The green Neurostimulator On light is lit. ^a	The neurostimulator is on.
The yellow Neurostimulator Off light is lit. ^a	The neurostimulator is off.
Neither the Neurostimulator On nor the Neurostimulator Off light is lit.	The patient programmer does not know if the neurostimulator is on or off. ^b

Neurostimulator Battery Light

When:	It means:
The green Neurostimulator Battery light is lit. ^a	The neurostimulator battery is good.
The green Neurostimulator Battery light is blinking. ^a	The neurostimulator battery is low. The clinician should check the battery with the clinician programmer.
The green Neurostimulator Battery light is not lit.	See note below. ^b

Patient Programmer Battery Light

When:	It means:
The green Programmer Battery light is lit. ^a	The programmer battery is OK.
The green Programmer Battery light is blinking. ^a	The programmer battery is low. Replace it with a new 9-volt battery.
The green Programmer Battery light is not lit.	See note below. ^b

^a The Synergy EZ Model 7435 Patient Programmer indicator lights stay lit or blink for 8 seconds.

^b Retry programming to ensure successful telemetry:
- Check that the antenna or patient programmer is positioned correctly over the neurostimulator.
- Remove the detachable antenna and try telemetry with the patient programmer placed over the neurostimulator.
- Check and possibly replace the patient programmer 9-volt battery.

Appendix B: Synergy EZ Patient Programmer

Patient Programmer Specifications

Table 19. Patient Programmer Specifications.

Description	Value^a
Height	2.4 in. (61 mm)
Length	5.3 in. (135 mm)
Thickness	1.2 in. (31 mm)
Weight (including battery)	6 oz. (170 g)
Power Source	9-volt alkaline battery (type 6LR61 or 6F22E)
Battery Life	3 months (average)
Operating Temperature	49° F to 110° F (9° C to 43° C)

^a All values are approximate.

FCC Information

The following is communications regulation information on the Synergy EZ Model 7435 Patient Programmer.

FCC ID: LF57435

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

Important: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

Special Notice

Special Notice

Medtronic Neurostimulator kits consist of a neurostimulator and tools to connect the neurostimulator to implantable extensions. Neurostimulators are used with extensions, which are implanted in the extremely hostile environment of the human body. Neurostimulators may fail to function for a variety of causes, including but not limited to, medical complications, body rejection phenomena, or component failure. In addition, neurostimulators and tools may be easily damaged by improper handling or use. For tools, Medtronic disclaims all warranties, both express and implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Medtronic shall not be liable to any person or entity for any medical expenses or any direct incidental or consequential damages caused by any defect, failure or malfunction of any tool, whether a claim for such damage is based upon warranty, contract, tort or otherwise. No person has any authority to bind Medtronic to any representation or warranty with respect to tools.

Warranty

Warranty

MEDTRONIC NEUROLOGICAL NEUROSTIMULATOR LIMITED WARRANTY¹ (U.S. Customers Only)

- A. This Limited Warranty provides the following assurance to the patient who receives a Medtronic Synergy Model 7427 or Synergy Versitrel Model 7427V Neurological Neurostimulator hereafter referred to as Neurostimulator:
- (1) Should the Neurostimulator fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the date of implantation of the Neurostimulator, Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Neurostimulator equal to the Purchase Price, as defined in Subsection A(3), against the purchase of any Neurostimulator requested as its replacement, or, (b) provide a functionally comparable replacement Neurostimulator at no charge.
 - (2) Battery cell depletion will occur with time and is not considered to be a defect in materials or workmanship. The batteries have a specified capacity which may deplete at different rates depending on settings and requirements for neurostimulation functions. Therefore, no representation is made that the Neurostimulator will last the entire term of this Limited Warranty.
 - (3) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original or current functionally comparable, or replacement Neurostimulator.

¹ This Limited Warranty is provided by Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432-5604. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

Warranty

B. To qualify for this Limited Warranty, these conditions must be met:

- (1) The Neurostimulator must be implanted prior to its "Use By" date in conjunction with Medtronic leads or leads of equal quality and comparable electrical characteristics.
- (2) All device registration materials must be completed and returned to Medtronic within thirty (30) days of implantation of the Neurostimulator.
- (3) Replaced Neurostimulators must be returned to Medtronic within thirty (30) days of explantation and shall be the property of Medtronic.

C. This Limited Warranty is limited to its express terms. In particular:

- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE NEUROSTIMULATOR TO FUNCTION WITHIN NORMAL TOLERANCES WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.
- (2) This Limited Warranty is made only to the patient in whom the Neurostimulator was implanted. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

Warranty

- (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the patient specific legal rights. The patient may also have other rights which vary from state to state.
- (4) No person has any authority to bind Medtronic to any representation, condition, or warranty, except this Limited Warranty.
- (5) This Limited Warranty is not applicable to leads, extensions, or accessories used with this Neurostimulator.

Glossary

Glossary

Amplitude – A measure of the electrical intensity delivered in a stimulating pulse, measured in volts.

Channel – Refer to Program.

Cycle Time OFF – In a cycling mode, the length of time between stimulation periods, that is, the time of the “resting” period.

Cycle Time ON – In a cycling mode, the length of time that stimulation is delivered.

Day Cycling – A method of synchronizing a patient’s therapy schedule to the 24-hour clock.

Dual-Program Mode – An operation in which both programs are active. In dual-program mode, amplitude, pulse width, and electrode polarity are programmed independently for each program.

Interference – Anything that reduces the effectiveness of the neurostimulator, a programming transmission, or telemetry reception.

Mode – The type of stimulation (continuous, cycling). Continuous and cycling modes can be delivered with or without a SoftStart/Stop.

Parameter – The output waveform conditions that can be varied to affect the type of stimulation for the patient. These are amplitude, pulse width, and rate.

Program – (Previously referred to as Channel.) A group of selected electrodes and parameter values. Refer to Single-Program Mode or Dual-Program Mode.

Pulse Width – A measure, in microseconds, of the duration of each stimulating pulse.

Rate – A measure, in pulses-per-second, that provides the number of times stimulating pulses are delivered each second.

Glossary

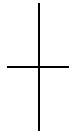
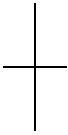
Single-Program Mode – An operation in which only one program is active; all electrodes are available on the single program and within that program they have the same amplitude, pulse width, and rate.

SoftStart/Stop – The SoftStart/Stop feature allows stimulation to begin with a ramped output. It is designed to prevent the sensation of a sudden “burst” of stimulation when the neurostimulator turns on normally. This is done by gradually increasing the amplitude of the stimulation up to the programmed value. The SoftStart/Stop feature also gradually decreases the amplitude of the stimulation back down to zero when the neurostimulator output is turned off, or when the off cycle begins.

Telemetry – A radio frequency type of communication.

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package_R01

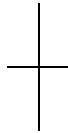
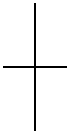
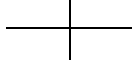


221319002 Rev X



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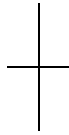
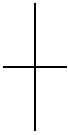


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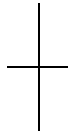
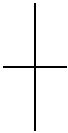
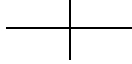


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