



Medtronic

KINETRA[®]

7459

MemoryMod[®] Software Cartridge for Deep Brain Stimulation

Software Cartridge Application Manual

Rx Only

Kinetra[®]
Software Cartridge Application
Manual

Model 7459

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Device Description

The Medtronic Model 7459 MemoryMod Software Cartridge is a plug-in cartridge designed to control the specific functions of the Medtronic Model 7432 Programmer. The cartridge contains the necessary software to program the Model 7428 Kinetra, the Model 7427 Synergy, the Model 7427V Synergy Versitrel, and the Model 7425 Itrel 3 Neurostimulators.¹ Each neurostimulator has a unique recognition code that allows it to access the appropriate software during programming.

Note: For clinicians using the MemoryMod Model 7459 Software Cartridge to program a Synergy Model 7427, a Synergy Versitrel Model 7427V, or an Itrel 3 Model 7425 Neurostimulator, refer to the software programming guide for Synergy and Itrel 3 Neurostimulation Systems.



Warning: The Medtronic Model 7432 Physician Programmer and the installed Medtronic Model 7459 MemoryMod Software Cartridge should not be used to attempt to program any neurostimulators other than the Models 7427, 7427V, 7428, and 7425.

The specific programmer functions and neurostimulator programming instructions provided in this manual are intended to supplement the hardware description and service information in the technical manual packaged with the programmer. Review the information in the hardware manual, including the warnings and precautions, before proceeding with neurostimulator programming.

For a summary of Model 7428 Kinetra programmable functions, refer to Table 1. Detailed information on programming of the Model 7428 Neurostimulator is in “General Programming Information” on page 17, “Programming Stimulation Settings” on page 21 and “Programming Stimulation Modes” on page 29 of this manual.

¹ The terms neurostimulator and IPG (implantable pulse generator) are used interchangeably in this manual.

Table 1. Model 7428 Kinetra Neurostimulator Programmable Functions.

Component	Function	
Programmer with Software Cartridge	Switches neurostimulator ON and OFF. Programs stimulation parameters for both leads (programs)	
	Lead 1 (Program 1)	Lead 2 (Program 2)
	Amplitude	Amplitude
	Pulse Width	Pulse Width
	Rate ^a	Rate ^a
	Polarity	Polarity
	Electrodes 0-3	Electrodes 4-7
	Neurostimulator Case	Neurostimulator Case
	Selects or programs stimulation modes.	
	Continuous	Cycling
	SoftStart/Stop	
	Activates measurement functions.	
	Neurostimulator Battery (Status, Voltage, Capacity)	Load Impedance
	Stimulation Current	Patient Use Data
Selects or programs special features.		
Amplitude Resolution	Telemetry Beeper Day Cycling	
Configures neurostimulator for use with therapy controller and control magnet.		
Therapy Controller	Control Magnet	
Tracking Limits	Enable/Disable	
Custom Limits		
Therapy Controller	Switches neurostimulator ON and OFF.	
	Give neurostimulator ON/OFF status.	
	Adjusts amplitude, pulse width, and rate ^a for both leads (programs) within physician-programmed limits.	
	Monitors neurostimulator and therapy controller battery status.	
Control Magnet	Switches neurostimulator ON and OFF.	

^a The same values for rate and rate limits are programmed for both Program 1 and Program 2.

Indications¹

Bilateral stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) using Medtronic Activa Parkinson's Control Therapy is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication.

Contraindications

Implantation of an Activa Brain Stimulation System is contraindicated for:

- Patients exposed to 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 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.

- Patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area. Performing MRI with this equipment can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis or death. Refer to "Appendix B: MRI and Activa Therapy" on page 55 for comprehensive safety information and instructions.
- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the brain stimulator.

For warnings and precautions related to the Activa System implanted components, refer to the *Model 3387/89 DBS lead manual*. For adverse events related to the Activa System, refer to the Activa Therapy Clinical Summary Manual.

Warnings

Coagulopathies – Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should consider underlying factors, such as previous neurological injury, or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

¹ The dual-program Kinetra Model 7428 neurostimulator is not approved for Tremor Control Therapy since only unilateral stimulation is approved for Tremor Control Therapy.

Warnings

Avoid Excessive Stimulation – There is a potential risk of brain tissue damage for stimulation parameter settings of high amplitudes and wide pulse widths.

The Activa System is capable of parameter settings out of the range of those used in the clinical studies. Suppression of symptoms should occur at amplitudes of 1 to 3.5 V, pulse widths of 60 to 120 μ sec, and rates of 130 to 185 Hz. Higher amplitudes and pulse widths may indicate a system problem or less than optimal lead placement. Parameter values exceeding the recommended output settings should only be programmed with due consideration of the warnings concerning charge densities and charge imbalance described in “General Programming Information” on page 17.

If programming of stimulation parameters exceeds charge density limits, the following programmer warning appears: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE.** The use of rates less than 30 pps may “drive” tremor, i.e., cause it to occur at the same frequency as the programmed frequency. For this reason, rates should not be programmed below 30 pps.

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

Placement of Lead-Extension Connector in Neck – Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture.

Theft Detectors and Screening Devices – Theft detectors found in retail stores, public libraries, etc., and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch ON or OFF¹. It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. For other indications, higher levels of stimulation have been described as uncomfortable (“jolting” or “shocking”) by some patients as they pass through these devices. Refer to “Patient Counseling Information” on page 43 for more information.

Magnetic Resonance Imaging – Do not conduct an MRI examination on a patient with any implanted Activa System component until you read and fully understand all MRI information in this manual. Do not conduct an MRI examination at parameters other than those described in this guideline. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death. Refer to “Appendix B: MRI and Activa Therapy” on page 55 for comprehensive safety information and instructions.

¹ Unexpected ON/OFF switching of the Kinetra Model 7428 Neurostimulator, as described throughout the Warnings and Precautions sections of this manual, may be avoided by disabling the magnet control circuit with the clinician programmer software. If the magnet control circuit is disabled, patients will require a Model 7436 Therapy Controller to turn their therapy ON or OFF.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to “Physician Training Information” on page 43 for further information.

Prescribing Physicians – Prescribing physicians should be experienced in the diagnosis and treatment of movement disorders and should be familiar with the use of the Activa System.

System and Therapy

Battery Longevity and Brain Target Selection – Stimulation settings for systems implanted in the internal Globus Pallidus (GPI) may be higher than stimulation settings for systems implanted in the Subthalamic Nucleus (STN). Consequently, systems implanted in the GPI may have shorter battery life than systems implanted in the STN.

Component Failures – The Activa System may unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical short or open circuits, conductor (wire) fracture, and insulation breaches, cannot be predicted. The patient’s disease symptoms will return if the device ceases to function.

Components – The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Inadvertent Programming – If more than one neurostimulator is implanted, then the potential for unintentional programming changes to the other neurostimulator exists. If two neurostimulators are implanted, they must be implanted at least 8 inches apart to minimize interference. Verify final programmed parameters by reviewing both devices at the conclusion of any programming session.

Lead Materials – The polyurethane tubing of the lead may release neurotoxic or carcinogenic compounds. Data are insufficient to assess the likelihood of these effects occurring in patients who receive the device.

Long-Term Safety and Effectiveness of Activa Therapy – The long-term safety and effectiveness of Activa Therapy has not been established.

Operating Temperature – Do not use the Physician Programmer or MemoryMod Cartridge immediately after transportation or storage at temperatures above or below the specified operating temperature range (10° C to 43° C/50° F to 100° F). Allow the equipment to stabilize at a temperature within the range specified before using it to program.

Preparation for Programming – Programming should be done only after careful study of the applicable neurostimulator technical manual. Refer to the technical manual for details regarding neurostimulator operation and for complete indications, contraindications, warnings, and precautions.

Precautions

Programming Head Placement – If the programming head is not properly aligned over the neurostimulator, programmed parameters may not change. The programming head must be held steady over the neurostimulator for at least 3 seconds after the [PROGRAM] key is pressed.

Reprogramming – Do not make large changes in the programmable parameters. Parameter changes should be made gradually and in small increments, otherwise undesirable stimulation can result.

Use in Specific Populations – The safety and effectiveness of this therapy has not been established for the following:

- Patients with neurological disease origins other than idiopathic Parkinson's disease
- Patients with a previous surgical ablation procedure
- Patients who are pregnant
- Patients under the age of 18 years
- Patients over the age of 75 years
- Patients with dementia
- Patients with coagulopathies
- Patients with moderate to severe depression

Electromagnetic Interference (EMI)

Electromagnetic interference is a field (electrical, magnetic or a combination of both) that is generated by various medical or environmental devices. These medical and environmental (home, occupational, and other) devices may generate enough interference to change the parameters of a neurostimulator; turn a neurostimulator OFF and ON, or cause a neurostimulator to surge, shock, or jolt the patient.

In addition, it is possible for the extension, lead or both to “pick up” electromagnetic interference and deliver an excess voltage, which can in turn deliver an excessive amount of heat to the brain. Refer to the following sections for guidelines on the interaction of electromagnetic interference and an implanted Activa System.

Medical Environment

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, because of higher energy levels, sources such as transmitting antennas found on various diagnostic and therapeutic equipment may interfere with the Activa System.

Effects on Other Medical Devices – The Activa 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.

Electrocautery – Electrocautery can damage the lead, the extension, or both. It can also cause temporary suppression of neurostimulator output and/or reprogramming of the neurostimulator. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the neurostimulator, extension, and lead as possible, and use of bipolar electrocautery is recommended.

External Defibrillators – If a patient requires external defibrillation, the first consideration should be patient survival. 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 system:

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

High Radiation Sources – High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. If a patient requires radiation therapy in the vicinity of the neurostimulator, place lead shielding over the device to prevent radiation damage.

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.

Psychotherapeutic Procedures – The safety of psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroshock therapy, transcranial magnetic stimulation) has not been established.

Home or Occupational Environment

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. However, items with magnets (e.g., stereo speakers, refrigerators, freezers, power tools) may cause the neurostimulator to switch ON or OFF.

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 electromagnetic interference (EMI) to interfere with neurostimulator operation if approached too closely.

Patient Activities/Environmental Precautions – 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 switch ON or OFF. The system also may unexpectedly cease to function due to battery depletion or other causes. For these reasons, the patient should be advised about any activities that would be potentially unsafe if their symptoms unexpectedly return. For additional information about devices which generate electromagnetic interference, call Medtronic at 1-800-707-0933.

Patient Magnet – The magnet provided to the patient for device activation and deactivation may damage televisions, computer disks, computer monitors, credit cards, and other items affected by strong magnetic fields.

Radio Frequency Sources – Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones may contain permanent magnets. To prevent undesired turning ON or OFF of the stimulation, these devices should be kept at least four inches away from the implanted neurostimulator.

Therapeutic Magnets – Therapeutic magnets (for example, those found in bracelets, back braces, shoe inserts and mattress pads) can cause inadvertent ON or OFF activations of the neurostimulator. Therefore, patients should be advised not to use them.

Clinical Studies and Adverse Events

The clinical use of the Kinetra Model 7428 Neurostimulator is supported by the Medtronic Parkinson's disease clinical studies using the Itrel II Model 7424 Neurostimulator. For results of the Parkinson's disease clinical trials and a complete list of adverse events reported during the Parkinson's disease clinical trials, refer to the *Activa Clinical Summary* packaged with this product.

Because safety and effectiveness of the Activa Parkinson's Control therapy was established using bilateral Itrel II neurostimulators, clinical results and adverse event rates associated with a single dual-channel Kinetra neurostimulator may not be identical.

Individualization of Treatment

For information about individualization of treatment for Activa Therapy, refer to the *Activa Clinical Summary* packaged with the implanted components of the Activa System.

Programmer Console Description

The Medtronic Model 7432 Physician Programmer keyboard panel consists of an upper and a lower Liquid Crystal Display (LCD) with push button keys and a separate function key pad with several push buttons (Figure 1). You control all programming functions using these keyboard keys and the programming head keys. To program the desired therapy for your patient, refer to the prompts on the displays and press the applicable keys. When you complete the correct programming sequence, position the programming head over the neurostimulator and press [PROGRAM], you program the neurostimulator.

The physician programmer software selectively activates the keys that you can use. That is, specific keys are active depending on the parameter you select. Pressing an inactive key does not enter or program any data.

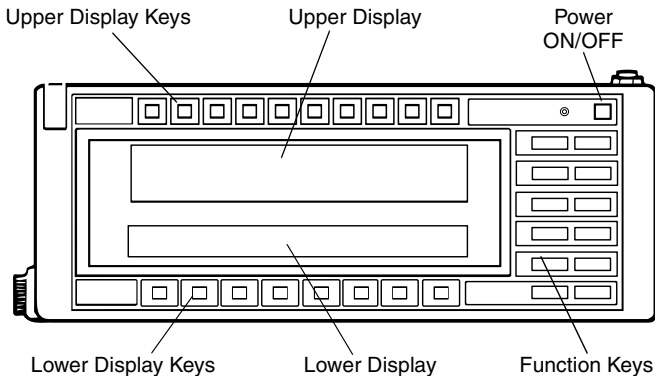


Figure 1. Programmer keyboard and display panel.

Display Keys

Use the keys above and below the upper and lower displays to select parameters, modes, and values for programming. During a programming session, the upper and lower displays show the appropriate prompts and messages to help guide you. When you select a parameter, mode or value, its options appear in the displays below or above the corresponding key. Pressing a key makes a selection.

Lower Display Keys

At the beginning of a programming session, the lower display prompts you to review your patient's neurostimulator parameters. Place the programming head over the neurostimulator and press [REVIEW] to provide the telemetry that reads the neurostimulator's current therapy settings. After this parameter review, the lower display advances to the "home" state, where the SELECT PARAMETER message is shown.

Programmer Console Description

When you select a parameter from the information above the upper display keys, the lower display shows the stimulation modes, parameter values, or special functions that you can choose. Graphics along the bottom border of the display divide it into eight segments. These correspond to the eight keys located below the display. If you press one of these keys, it selects the mode, value, or function listed above the key.

Upper Display Keys

The top line of the upper display becomes active only after you have reviewed your patient's neurostimulator parameters. This top line is designed to display the neurostimulator parameter values that were obtained by telemetry or programmed during the session.

The lower line of the upper display is used for prompts and selection messages. It also displays the software revision number immediately after you turn the programmer ON.

Abbreviations for the parameters appear at fixed locations within the outlined sections of the display. The segments of the upper display correspond to the 10 parameter selection keys located above the display.

Note: If a parameter (or mode) from the neurostimulator is invalid, the upper display shows ??? below the parameter/mode name. Whenever this happens, you must reprogram the neurostimulator with a valid parameter value or mode.

Question marks (???) are also displayed before you check the battery status if no parameter or mode was programmed.

Pressing an upper display key when the message SELECT PARAMETER appears on the lower display, selects the parameter or mode to be programmed: AMPL (amplitude), PULSE WIDTH, RATE, MODE, IPG BATT (battery), IPG OUTPUT, ELECTRODE (electrode polarity), and SPECIAL (special functions).

As previously explained, you can select a parameter for programming only after the [REVIEW] key has been used to examine your patient's neurostimulator parameters.

Function Keys

With the exception of the [PRINTER ON/OFF] key and [IPG OFF] key, the function keys are inoperative until you review the neurostimulator's parameters. Only the [IPG OFF], [INCREASE, DECREASE], and [PROGRAM] keys actually send programming transmissions. The [INCREASE] and [DECREASE] keys may be used only after you press the [AMPL] key.

The following is a brief summary of each key's function:

REVIEW

The [REVIEW] key initiates telemetry and interrogates the neurostimulator, providing the stimulation mode and parameter values. If invalid values are received, question marks (????) appear below the applicable parameter or mode. You must properly center the programming head over the neurostimulator and hold it in position for at least 3 seconds to initiate a telemetry link. You may use the [REVIEW] key when the physician programmer is in the “home” state, with the SELECT PARAMETER message shown on the lower display.

PRINTER ON/OFF

Pressing the [PRINTER ON/OFF] key alternately turns the printer ON or OFF (the printer itself must be ON for this key to function). The printer may be turned ON at any time during a programming session. The letter P appears in the lower right corner of the upper display whenever the printer is ON.

If the printer cable is disconnected, or if printer power is OFF when the [PRINTER ON/OFF] key is pressed, the display reads CONNECT AND TURN ON THE 7451 PRINTER.

CLEAR

If you have selected a stimulation mode and/or parameter value for programming (as shown on the upper display), pressing the [CLEAR] key once moves the sequence back one step. Pressing the [CLEAR] key again moves the sequence back one more step, and so on, until the parameter review, or “home” state, is reached.

INCREASE

To increment the amplitude of the neurostimulator during amplitude programming, press the [INCREASE] key. The [INCREASE] key sends a programming transmission directly to the neurostimulator — the [PROGRAM] key is not needed. This key increases the amplitude of the neurostimulator by 0.1 volt per second (or 0.05 V per second for fine resolution) when you press and hold the key. (**Note:** Amplitude programming requires that the programming head be held in position over the neurostimulator.)

DECREASE

To decrement the amplitude of the neurostimulator during amplitude programming, press the [DECREASE] key. The [DECREASE] key sends a programming transmission directly to the neurostimulator — the [PROGRAM] key is not used. This key decreases the amplitude of the neurostimulator by 0.1 volt per second (or 0.05 V per second for fine resolution) when you press and hold the key. (**Note:** Amplitude programming requires that the programming head be held in position over the neurostimulator.)

Programmer Console Description

DISPLAY HOLD	When you press the [DISPLAY HOLD] key, the automatic progression of display prompts is stopped. The display does not advance again until you press the [DISPLAY ADVANCE] key.
DISPLAY ADVANCE	Use the [DISPLAY ADVANCE] key in conjunction with the [DISPLAY HOLD] key to manually step through the display prompts and messages as slowly or as quickly as desired.
IPG ON	Use the orange [IPG ON] key, in conjunction with the [PROGRAM] key, to switch the neurostimulator output ON. Press [IPG ON] first and then [PROGRAM] to send the transmission. No other neurostimulator parameters are changed. IPG ON is active when in the “home” state and after you select a parameter, but before you select the parameter value.
IPG OFF	Use the orange [IPG OFF] key to immediately switch the neurostimulator output OFF. No other neurostimulator parameters are changed. The [IPG OFF] key is the only function key that is always active when the programmer is ON. It is not necessary to press the [PROGRAM] key to switch the neurostimulator OFF.
PROGRAM	Pressing the [PROGRAM] key transmits selected parameter values/stimulation modes to the neurostimulator. The return telemetry feature updates the display to the newly programmed values. The programming head must be properly centered over the neurostimulator to allow programming and telemetry.
TELEMETRY BYPASS	The [TELEMETRY BYPASS] key is not used with the Model 7428 Neurostimulator.

General Programming Information


Setting Up the System

The Model 7459 MemoryMod Software Cartridge must be used whenever you use the Model 7432 Physician Programmer for your patient's therapy. The software cartridge is required for all programmer functions. Other models of MemoryMod software cartridges must not be used.

To install the cartridge:

1. Insert it, connector end first, into the cartridge receptacle (Figure 2).

Note: The cartridge locking tab must face toward the front of the programmer.

 **Caution:** Do not force the software cartridge into programmer. If it is difficult to insert, check that locking tab is facing the front of the programmer.

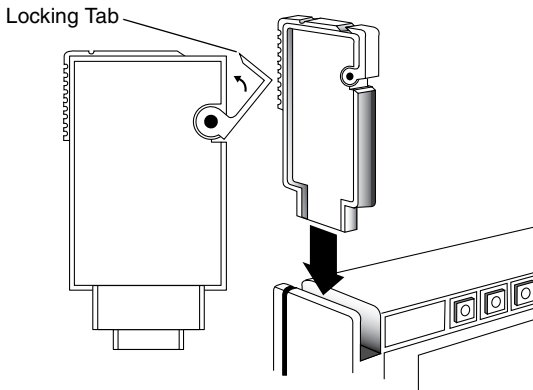


Figure 2. Insert software cartridge.

2. Push down on the cartridge until it is fully seated.
3. Push the locking tab shut until the cartridge is flush with the body of the programmer.

To remove the cartridge:

1. Flip out the locking tab to free the cartridge from the programmer.
2. Pull the cartridge straight out of the programmer.
3. Store in the physician programmer case for future use.

Refer to the *Model 7432 Physician Programmer* hardware manual supplied with the programmer for a detailed description of the physician programmer setup and maintenance.

Programming: An Overview

This section provides the basic programming instructions for using the Model 7432 Physician Programmer with the Model 7459 Software Cartridge. The specific parameters and values entered will be determined by the therapy you prescribe for your patient.

To help ensure an optimum therapy for your patient, programming changes should be incremental. When making electrode or pulse width changes, reduce the amplitude first to help prevent stimulation that may be perceived as unpleasant. This helps avoid “shocking” or “jolting” the patient when the system is turned ON. To obtain patient feedback, amplitude programming should be done with the neurostimulator output ON.

You must have the programming head correctly positioned when pressing the [PROGRAM] key. Hold the programming head in place for at least 3 seconds after the transmission. If programming errors occur, it may be necessary to reposition the programmer head or move to a new location. The basic steps for programming the Model 7428 Neurostimulator are shown in the “Programming Overview” section.



Cautions:

- When using the programming head in a sterile field, place it in a sterile bag. It is not sterile and cannot be sterilized.
- Radio signals (telemetry) from the physician programmer may interfere with the performance of other implantable devices.
- Always decrease the amplitude to zero before changing electrodes or pulse width. After the change, slowly increase the amplitude to avoid causing unpleasant stimulation.
- Do not send a patient home with ???? displayed on the Programmer screen for any value except IPG BATT. This indicates that the parameter or mode is invalid and must be reprogrammed. Note that severe EMI (e.g., electrocautery, defibrillatory discharge, MRI) can erase the neurostimulator serial number, causing ???? to be displayed in place of the serial number.

Programming Overview

To:	Do the Following:
1. Install Model 7459 Cartridge.	Refer to page 17.
2. Turn ON physician programmer.	Press [ON/OFF] key ON.
3. Review current parameters.	Position programming head over neurostimulator. Press [REVIEW].

To:	Do the Following:
4. Turn ON the neurostimulator (continuous mode).	Press [IPG ON]. Position head. Press [PROGRAM].
5. Select Lead 1 (Program 1) or Lead 2 (Program 2 ^a).	Press [VIEW CH1] for Lead 1 or Press [VIEW CH2] for Lead 2.
6. Program polarity for selected lead.	Press [ELECTRODE]. Select desired polarity settings. Position head. Press [PROGRAM].
7. Select a parameter for programming.	Example: Press [AMPL].
8. Select an option displayed.	Example: Select numerical value.
9. Program neurostimulator with new settings.	Position head. Press [PROGRAM].
10. Repeat steps 7 through 9, until all parameters for the selected lead are programmed.	
11. Program other lead (program). ^b	Repeat steps 5 through 10 for other lead (program).
12. Program Access Model 7436 Therapy Controller limits for amplitude, pulse width, and rate (if desired). ^b	Press [SPECIAL]. Press [LIMIT]. Example: Select a parameter and value. Position head. Press [PROGRAM].
13. Using the therapy controller, confirm the programmed parameters and limits are appropriate for your patient.	Check the upper and lower limits for amplitude, rate, and pulse width. Refer to therapy controller manual for instructions.
14. If desired, program an additional special function.	Example: Press [SPECIAL]. Press [MAGSW]. Select ON or OFF. Position head. Press [PROGRAM].
15. Do a final review and print parameter and mode settings for patient records ^c .	Position programming head over neurostimulator. Press [PRINTER ON/OFF] key. Press [REVIEW] to print.

^a For information on selecting programs, refer to “Programming Stimulation Settings” on page 21.

^b The same rate value is programmed for both Program 1 and Program 2.

^c Review and print Day Cycling parameter settings before ending a programming session. Day Cycling start and end times are not stored in the neurostimulator and cannot be retrieved after the programming session.

Reviewing Neurostimulator Parameters

The programming session always begins with the review function. Pressing the [REVIEW] key automatically loads the programmer with the actual parameter settings of the neurostimulator you are programming. When you turn the programmer ON ([ON/OFF] key), after a brief programmer self-test, the upper display shows the software revision number and the lower display shows the message: PRESS REVIEW KEY.



Caution: Patients with extremely high sensitivity to stimulation may sense the transmission of the review signal.

Note: Except for [PRINTER ON/OFF] or [IPG OFF] keystrokes, parameter [REVIEW] must be the first keystroke after turning the programmer ON.

After you have reviewed the parameters during a programming session, you do not need to review them again unless the programmer is turned OFF. The parameters must be reviewed again whenever the programmer is turned ON. They also must be reviewed if the “home” screen message indicates invalid parameters. If telemetry cannot be established for review, adjust the programming head gain switch and try again. The review function does not change the mode or parameter values stored in the neurostimulator.

Power-On-Reset (POR)

Strong levels of electromagnetic interference (from cautery, for example) can result in a Power-On-Reset (POR). If this occurs, the programmer will notify you that a POR has occurred, the neurostimulator serial number is lost, and patient use data will be reset to zero. Any subsequent reviews of the neurostimulator will continue to display ??? for the neurostimulator serial number, but patient use data will remain accurate for the period following the POR.

Turning ON the Neurostimulator

Following a successful review, press the [CLEAR] key. Next, turn the neurostimulator ON by pressing the [IPG ON] key, then the [PROGRAM] key. The neurostimulator will turn ON at the programmed settings.

Initiating a Programming Transmission

After you have selected a parameter or mode for programming, the selection is listed on the upper display and the lower display shows the message, PRESS PROGRAM KEY. A programming transmission may be initiated as follows:

1. Hold the programming head steady in position over the neurostimulator.
2. Press [PROGRAM] key.

Note: If an unconfirmed transmission occurs (programmed value does not display), you can repeat simply by pressing [PROGRAM] again.



Caution: Patients with extremely high sensitivity to stimulation may sense the transmission of the programming signal.

Following successful programming, the programming head may be lifted from the neurostimulator. The newly programmed parameter value or stimulation mode will show on the upper display within the outlined area for that parameter.

Whenever rate, pulse width, amplitude, ON time, or OFF time are programmed and the neurostimulator is in cycling mode, the neurostimulator automatically switches to continuous mode for 15 seconds to allow evaluation of the programmed change. At the end of 15 seconds, if no further adjustments have been made, the neurostimulator output remains ON and starts an ON cycle period.

Using the Clear Function

The [CLEAR] key can be used to clear keyboard entries as follows:

1. The last keyboard entry, whether a numerical value, function, mode, or parameter entry, may be cleared by pressing the [CLEAR] key.
2. For most programming sequences, previous keyboard entries can be cleared in reverse order of entry by consecutively pressing the [CLEAR] key. The programmer display is updated to show the status of the parameters as the entries are cleared.

The [CLEAR] key does not change or clear parameters already programmed into a neurostimulator.

Programming Stimulation Settings

Overview

The Kinetra Model 7428 Neurostimulator can be programmed with independent amplitudes, pulse widths, and electrode polarities for each implanted lead. A typical sequence for programming stimulation settings consists of the following steps:

- Select Lead 1 (CH1) for programming
- Program electrode polarity for Lead 1
- Program rate, amplitude, and pulse width, for Lead 1
- Select Lead 2 (CH2) for programming
- Program electrode polarity for Lead 2
- Program amplitude and pulse width for Lead 2¹

¹ The same rate value is programmed for both Program 1 and Program 2.

Programs

The stimulation pulses delivered to each lead are determined by a parameter called a program. A program is a specific combination of amplitude, pulse width, and rate parameters acting on a specific electrode set. The Kinetra Model 7428 Neurostimulator has two available programs (CH1 and CH2). Program 1 corresponds to Lead 1 (Electrodes 0-3 and the case), and Program 2 corresponds to Lead 2 (Electrodes 4-7 and the case). Rate is not independently programmed; one programmed setting determines the rate for both programs.

Dual-Program Stimulation

Dual-program pulses are delivered alternately rather than simultaneously to each lead. Program 1 delivers an output pulse at its programmed amplitude and pulse width parameters, followed by the Program 2 output pulse at its programmed amplitude and pulse width parameters. This sequence is repeated, with single output pulses alternately delivered.

Figure 3 provides two examples of dual-lead stimulation. In example A, the programs corresponding to Leads 1 and 2 are programmed with different amplitude and pulse width settings, at a frequency of 180 Hz. In example B, the two leads are programmed with the same amplitude and pulse width settings, at a lower frequency of 120 Hz.

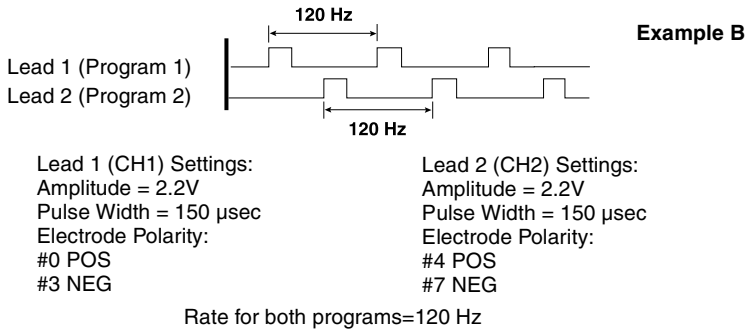
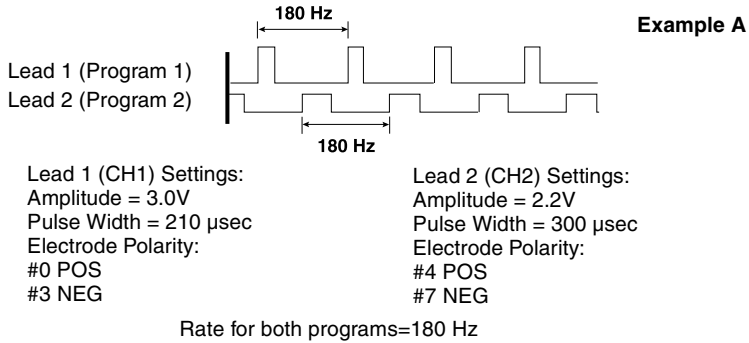


Figure 3. Dual-lead waveforms.

Typically amplitude, pulse width, and electrode polarity are programmed for Lead 1 (CH1) before programming Lead 2 (CH2). The selected program is shown in the upper display, while the unselected program is shown in the lower display. For example, if Program 1 is the selected program, CH1 will show in the upper display and VIEW CH2 will show in the lower display. Verify that the desired program is selected to avoid programming the wrong program and ensure that each program is programmed with the desired values.

Selecting a Lead for Programming

1. To select Lead 1 for programming, press the key below VIEW CH1.
2. To select Lead 2 for programming, press the key below VIEW CH2.

Programming Electrode Polarity

When the ELECTRODE parameter is selected, the programmer displays the present and new electrode polarity settings for the selected program in the upper display.

The lower display prompts you to select electrodes or case. The polarities of the electrodes and the case may be changed as often as desired before programming. When the desired electrode polarities are selected, press the [PROGRAM] key.

Note: Amplitude is automatically reduced to 0 volts when changes are made to electrode polarity.

To change the polarity settings:

1. Choose a lead to program by selecting VIEW CH1 (Lead 1) or VIEW CH2 (Lead 2).
2. Select ELECTRODE.
3. For each electrode, press the applicable key below CASE, #3, #2, #1, #0.
4. Select NEG, POS, or OFF.

Note: CASE cannot be programmed negative.

5. Hold the programming head steady in position over the neurostimulator.
6. Press the [PROGRAM] key.

The programmer will inform you if an invalid selection of electrode polarities has been made. For example, the case can be only positive or OFF, not negative. At least one electrode or the case must be positive and at least one electrode must be negative to complete the electrical circuit.

Programming Rate

The rate parameter is not independently programmable between Program 1 and Program 2 with Kinetra. To program rate, first program the rate at a value between 130-160 Hz for the lead and electrodes controlling the side of your patient's body where symptoms are the most obvious or intense. Then, program the amplitude and pulse width for that lead. Use the amplitude and pulse width that you programmed for the first lead as a baseline for programming amplitude and pulse width for the second lead.

Note: Remember that if you change the rate on one lead the rate on the second lead automatically changes to match the revised rate.

1. Press the key above RATE on the upper display.
2. Press the key below the desired value on the lower display.

Note: Press the key below NEXT to display additional values.

3. Press the [PROGRAM] key.

4. When electrode polarity, amplitude, pulse width, and rate are programmed for Lead 1 (CH1), select Lead 2 (CH2) and program electrode polarity, amplitude, and pulse width.

Note: Rate is not independently programmable. Changes to rate affect both leads.

Programming Amplitude

1. Press the key above AMPL on the upper display.
2. Press the key below the desired value on the lower display.
Note: Press the key below NEXT to display additional values.
3. Press the [PROGRAM] key.

Programming Amplitude with the [INCREASE] / [DECREASE] Keys

1. Press the key above AMPL on the upper display.
2. Press the [INCREASE] or [DECREASE] key. If either key is held down, the programming signals will continue to be sent, one step per second.

Note: Each keystroke sends a programming transmission, so it is not necessary to press the [PROGRAM] key when using the [INCREASE] / [DECREASE] keys.

Programming Pulse Width

1. Press the key above PULSE WIDTH on the upper display.
2. Press the key below the desired value on the lower display.
Note: Press the key below NEXT to display additional values.
3. Press the [PROGRAM] key.

Programming Restrictions: Stimulation Settings

When programming stimulation parameters, give consideration to the following recommendations regarding high output interlocks and charge density.

High Output Interlocks – Certain combinations of high amplitude, pulse width, and rate stimulation settings are not allowed by the clinician programmer. The desired parameter value can only be achieved by reducing one of the other parameter values. The programmer will prompt you on the proper steps to resolve the situation.

Refer to Table 2 for information on limited amplitudes at high programmed rate and pulse width combinations.

Note: If the upper limit for amplitude, pulse width, or rate is programmed to a higher value than the programmed value, the programmer will use the higher value when determining a high output interlock.

Table 2. Maximum Programmable Amplitude at High Rate/Pulse Width Combinations.

Programmed PW (µsec)	Limited Amplitude at High Rates (Hz)					
	130	150	175	200	220	250
90	10.5 V	10.5 V	10.4 V	9.9 V	9.5 V	9.1 V
120	10.4 V	10.0 V	9.5 V	9.0 V	8.6 V	8.1 V
180	9.2 V	8.7 V	8.1 V	7.6 V	7.0 V	6.4 V
240	8.3 V	7.7 V	7.1 V	6.6 V	6.0 V	5.5 V
300	7.3 V	6.8 V	6.2 V	5.7 V	5.4 V	5.0 V
360	6.8 V	6.2 V	5.6 V	5.0 V	4.7 V	4.3 V
420	6.4 V	5.9 V	5.3 V	4.8 V	4.5 V	4.1 V
450	6.0 V	5.5 V	4.8 V	4.2 V	3.8 V	3.4 V

Charge Densities – A survey of literature regarding electrical stimulation of neural tissue suggests that damage may occur above 30 microcoulombs/cm²/phase. The Activa System is capable of producing charge densities in excess of 30 microcoulombs/cm²/phase (Figure 4).

The device's maximum amplitude is 10.5 V, and maximum pulse width is 450 microseconds. The curved lines in Figure 4 represent a charge density of 30 microcoulombs/cm²/phase at various impedance measurements, calculated for the electrode surface area of the Model 3387/3389 DBS leads. Mean resistance found in the clinical studies were as follows.

- Parkinson's disease clinical studies (all targets): 1294 Ohms (range: 415-1999 Ohms).
- Parkinson's disease clinical studies (GPi): 1161 Ohms (range: 415-1967 Ohms).
- Parkinson's disease clinical studies (STN): 1177 Ohms (range: 628-1926 Ohms).

Charge density is determined by plotting a point corresponding to the pulse width setting (x-axis), and the amplitude setting (y-axis). If this point is below the appropriate resistance curve, then the charge density is below 30 microcoulombs/cm²/phase. Points above the curve indicate a charge density above 30 microcoulombs/cm²/phase.

The shaded area of Figure 4 indicates a charge density above 30 microcoulombs/cm²/phase at the conservative impedance estimate of 500 Ohms. If stimulation parameters are selected that fall into the shaded area of the graph, the following programmer warning appears: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE.** Programming may continue at the desired values by pressing the [CLEAR] key. See "Charge Density Programming Procedures" on page 27 for more information.

Figure 4 includes two examples of charge density calculated for the Activa System. In Example A, the Kinetra Model 7428 Neurostimulator is set to typical parameter settings for symptom suppression: amplitude = 3.0 V and pulse width = 90 μsec . The charge density for Example A is below the shaded warning zone, thus indicating a charge density below 30 microcoulombs/cm²/phase at the most conservative impedance of 500 Ohms.

In Example B, neurostimulator stimulation parameters are set to: amplitude = 6.1 V and pulse width = 210 μsec . The charge density at these settings is in the shaded area indicating it may be high enough to cause tissue damage at an impedance of 500 Ohms. However, as shown in Figure 4, if the impedance in this case is at the clinical mean from the Parkinson’s disease clinical study, the charge density would be below 30 microcoulombs/cm²/phase.

DBS Amplitude and Pulse Width Limits

Computed for Resistances ranging from 500 to 2,000 Ohms

DBS Lead Surface Area = 0.06 cm²,

Charge Density Threshold = 30 Microcoulombs/cm²/phase

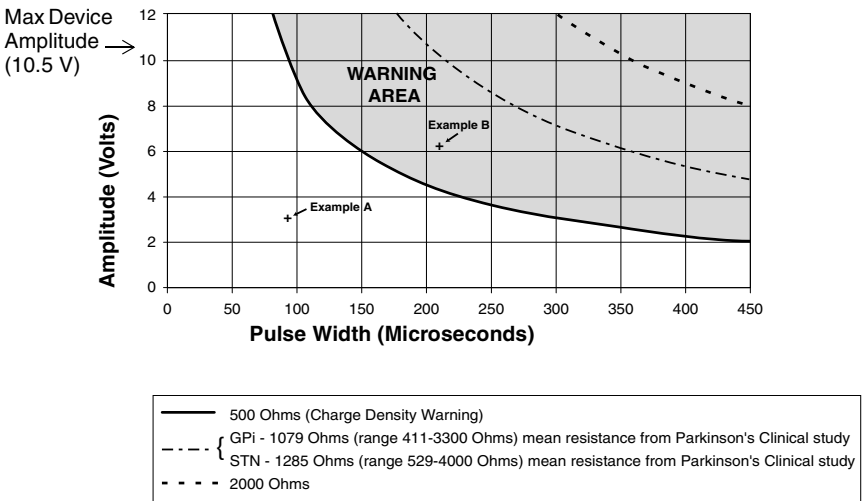


Figure 4. Charge density with Parkinson’s disease clinical mean resistance.

Charge Density Programming Procedures

If a programming attempt elicits the “Charge Density” warning, the following three options are available.

To Program a New Setting for the Selected Parameter

1. At the warning notification screen, press the [CLEAR] key.
2. Select the desired parameter setting from the value selection bar on the lower screen.

Note: The warning notification will appear again if the criteria for it are met by any subsequent programming attempt. If this value is not desired, return to Step 1.

3. Press the [PROGRAM] key.

To Select Another Parameter for Programming

1. At the warning notification screen, press the [CLEAR] key until you reach the parameter selection screen.
2. Select the desired parameter from the upper screen.
3. Select the desired parameter setting from the value selection bar on the lower screen.

Note: The warning notification will appear again if the criteria for it are met by any subsequent programming attempt. If this value is not desired, return to Step 1.

4. Press the [PROGRAM] key.

To Program the Selected Setting for the Selected Parameter



Warning: There is a potential for tissue damage if stimulation parameters are programmed that elicit the charge density warning.

If a selected parameter or parameter value elicits the “Charge Density” warning and is desired, follow this procedure:

1. At the warning notification screen, press the [CLEAR] key.
2. Press the [PROGRAM] key or select desired value.

Unconfirmed Stimulation Settings

If either pulse width or amplitude is unconfirmed (designated by ????) on the upper display of the programmer, the programmer will default to the highest setting for the parameter when calculating Charge Density. Therefore, if an unconfirmed value for pulse width or amplitude is either suspected or appears, follow this procedure:

1. Press the [CLEAR] key until the SELECT PARAMETER message is displayed on the lower screen of the programmer.
2. Press the [REVIEW] key.
3. If amplitude or pulse width is unconfirmed, reprogram the appropriate parameter.

Programming Stimulation Modes

Programming Continuous Mode with or without SoftStart/Stop

1. Press the key above MODE on the upper display.
2. Press the key below CONT on the lower display.
3. To program with SoftStart/Stop, press the key below the desired SoftStart/Stop Time.
4. Press the [PROGRAM] key.

Programming Cycling Mode with or without SoftStart/Stop

1. Press the key above MODE on the upper display.
2. Press the key below CYC on the lower display.
3. Select Cycle On Time by pressing the key below ON on the lower display.
4. Select the key below SEC, MIN, or HRS on the lower display.
5. Select a value in seconds, minutes, or hours.
Note: Press the key below NEXT to display additional values.
6. Press the [PROGRAM] key.
7. Select Cycle Off Time by pressing the key below OFF on the lower display.
8. Repeat steps 4 through 6 to select a value for Cycle Off Time.
9. Press the key below the desired SoftStart/Stop time (OFF, 1, 2, 4, 8), if available.
10. Press the [PROGRAM] key.

Day Cycling Feature

Day Cycling is a patient convenience that provides a method of synchronizing a patient's therapy schedule to the 24-hour clock. For example, if a patient needs stimulation during the day and no stimulation while sleeping, the neurostimulator could be programmed to turn ON at 7:30 a.m. and turn OFF at 10:00 p.m. each day. When the clinician enters the current time (Time Now), Start Time, and End Time, the physician programmer software is able to synchronize the neurostimulator timer with the time of day. Day Cycling will then be synchronized with the 24-hour clock. When the Day Cycling feature is active, the neurostimulator will automatically turn ON at Start Time, even if the neurostimulator has been intentionally turned OFF. The neurostimulator may be programmed ON or OFF at any time without erasing the programmed cycle times.

Note: The clinician should review and print Day Cycling parameter settings before ending a programming session.

Programming Day Cycling

1. Press the key above SPECIAL on the upper display.
2. Press the key below DAY-CYC on the lower display.
3. Turn Day Cycling ON or OFF by pressing the key below ON or OFF on the lower display.
4. Select a value for TIME NOW (the current time).
5. Select a value for START TIME (the time of day when the neurostimulator will turn ON).
6. Select a value for END TIME (the time of day when the neurostimulator turns OFF).
7. Press the printer's [ON] key and press the programmer console's [PRINTER ON/OFF] key to turn the printer ON.
8. The programmer will ask if these are the correct values. If the values are correct, press the [PROGRAM] key.
9. Press the [REVIEW] key, and then press the [PRINTER ON/OFF] key to print.
10. Store a printed record of Day Cycling parameter settings in the patient file.

Note: Day Cycling On and Off Times cannot be retrieved once the programmer is turned OFF. If Day Cycling parameter settings are reviewed after the programmer has been turned OFF (e.g., at a later patient session), question marks (????) will appear for Time Now, Start Time, and End Time. The operation of Day Cycling is not affected; it will still operate at the previously programmed settings. The neurostimulator may be programmed ON or OFF at any time without erasing the programmed Day Cycling ON or OFF times.

Using Measurement Functions

In addition to mode and parameter programming described above, the programmer with the Model 7459 MemoryMod Software Cartridge has a number of additional functions for programming the Model 7428 Kinetra Neurostimulator.

Checking Battery Status

The battery status is always indicated on the upper display on the “home screen” underneath IPG BATT. It is updated each time the neurostimulator is programmed or the battery status is reviewed. The battery status is defined by one of the following messages:

Battery Status Indicators	Battery Voltage Level
OK	Battery voltage is OK
Low	Battery voltage is approaching EOL ^a (5-15% remaining capacity)
EOL (End-of-Life)	Battery voltage is near depletion ^a (<5% remaining capacity)

^a Schedule replacement surgery immediately.

Checking Stimulation Current

The stimulation current measurement provides an indication of the current being delivered to the tissue. The neurostimulator's battery use can be optimized by comparing the stimulation current for your patient's various therapy settings. You can use the lowest settings to help extend battery life.

To check stimulation current:

1. Verify that the neurostimulator is ON.
2. Select the desired lead (CH1 or CH2) for stimulation current measurement.
3. Press the key above IPG BATT on the upper display.
4. Press a key below BATTERY CURRENT on the lower display.
5. Record the stimulation current value shown on the lower display for future reference.

Note: If the following message is displayed, it may be necessary to adjust Pulse Width and Amplitude: MEASUREMENT CANNOT BE MADE AT PRESENT SETTINGS. If the settings are high, decrease them. If the settings are low, increase them. Increase or decrease Pulse Width first, then Amplitude.

6. Press the [CLEAR] key to exit.

Checking Battery Capacity

The battery capacity measurement calculates the voltage of the neurostimulator battery and the percentage of battery capacity consumed.

Note: The neurostimulator must be OFF to perform this measurement.

To check battery capacity:

1. Press the key above IPG BATT on the upper display.
2. Press a key below BATTERY CAPACITY on the lower display.
3. Record the battery capacity and voltage shown on the upper and lower displays for future reference.
4. Press the [CLEAR] key to exit.

Checking Load Impedance

Neurostimulator load impedance consists of the combined impedance of the extensions, leads, and body tissue for an implanted stimulation system. Measurement of load impedance may help provide information on what happens to an implanted stimulation system, particularly the stimulating lead, over time.

Impedance values that are much higher or lower than those seen in clinical experience can indicate a system problem. Mean load impedance found in the clinical studies was as follows:

- Parkinson's disease clinical studies (all targets): 1294 Ohms (range: 415-1999 Ohms).
- Parkinson's disease clinical studies (GPi): 1161 Ohms (range: 415-1967 Ohms).
- Parkinson's disease clinical studies (STN): 1177 Ohms (range: 628-1926 Ohms).

To check load impedance:

1. Verify that the neurostimulator is ON.
2. Press the key above IPG OUTPUT on the upper display.

Note: At lower parameter settings, the neurostimulator's accuracy for impedance may vary.

3. Press the key below IMP on the lower display.
4. Record the load impedance value for future reference.

Note: If the following message is displayed, it may be necessary to adjust Pulse Width and Amplitude: MEASUREMENT CANNOT BE MADE AT PRESENT SETTINGS. If the settings are high, decrease them. If the settings are low, increase them. Increase or decrease Pulse Width first, then Amplitude. The amplitude setting must be greater than 0.0 V to take a load impedance measurement.

5. Press the [CLEAR] key to exit.

Note: Refer to "Electrode Impedance and Stimulation Current Measurements for the Kinetra Neurostimulator" on page 47 for additional information.

During the measurement sequence, the neurostimulator output is switched ON at the programmed amplitude for one pulse. The patient may feel the pulse.

Patient Use Data

Patient use data is checked by selecting the key above the word [IPG OUTPUT] on the upper display and then selecting [USE] on the lower display.

The total stimulating time and the elapsed time data are used to calculate the average daily stimulation time or a percentage of stimulation time. The number of activations, that is, the number of times the neurostimulator was turned ON by the magnet or therapy controller, is also counted and reported.

The programmer displays patient use data from the neurostimulator in 60 minute increments for total stimulating time and for elapsed time. Patient use data, therefore, is not displayed until at least 60 minutes (neurostimulator output ON time) after the counters have been reset.

To review patient use data:

1. Press the key above IPG OUTPUT on the upper display.
2. Press the key below USE on the lower display.
3. Read the patient use data from the upper display.
4. Exit or perform the counter reset.
5. To exit, press the key below NO or press the [CLEAR] key.
6. To perform the counter reset:
 - a. Press the key below YES, or turn the printer ON and press the key below YES.
 - b. Press the [PROGRAM] key.

Using Special Functions

Amplitude Resolution

There are two programmable Amplitude Resolutions:

- Normal Resolution (NORMAL): the programmable amplitude range is from 0 to 10.5 V in 0.1 V steps.
- Fine Resolution (FINE): the programmable amplitude range is from 0 to 6.35 V in 0.05 V steps (useful for patients who are highly sensitive to small changes in stimulation).

Note: The neurostimulator should be ON when you adjust the amplitude. In order to program FINE Resolution, the amplitude must be less than or equal to 6.35 V.

1. Reduce the amplitude to 0.0 volts.
2. Press the key below ARES (Amplitude Resolution) on the lower display.
3. Press the key under FINE.
4. Press the [PROGRAM] key.
5. From the Home Screen, select the desired program by pressing the key below VIEW CH1 or VIEW CH2 on the lower display.
6. Press the key above AMPL on the upper display.
7. Select the desired amplitude or use the [INCREASE] / [DECREASE] keys to adjust the amplitude.
8. Press the [PROGRAM] key.
Note: If the [INCREASE] / [DECREASE] keys are used to select Amplitude, the [PROGRAM] key does not have to be pressed.
9. Select the other program and repeat steps 6 through 8.
10. Press the [CLEAR] key to exit.

Telemetry Beeper

The Telemetry Beeper function provides audible feedback during programming to confirm successful or unsuccessful telemetry. Successful telemetry is confirmed with one audible beep. Unsuccessful telemetry is confirmed with three audible beeps and is accompanied by a NO TELEMETRY message, an INTERFERENCE message or a PROGRAMMING INVALID message.

Note: The default setting for the Telemetry Beeper is OFF.

Programming for Patient Control

Overview

Two Kinetra Neurostimulation System components allow the patient to control the implanted Kinetra Model 7428 Neurostimulator:

- The Access Model 7436 Therapy Controller allows the patient to turn the neurostimulator ON and OFF and check the neurostimulator battery status (device shipped with these features active). In addition, the Kinetra Neurostimulator can be programmed with upper and lower limits for amplitude, pulse width, and rate. The Kinetra Neurostimulator is shipped with these optional limits set to ± 0 . When these optional limits are enabled by the physician, patients can adjust their stimulation within the prescribed limits using the therapy controller.
- The Model 7452 Control Magnet allows the patient to turn the neurostimulator ON and OFF. A magnet-actuated reed switch in the neurostimulator is programmed to enable or disable the control magnet. The magnet-actuated reed switch status has no effect on the patient's ability to turn the neurostimulator ON or OFF with the Access Model 7436 Therapy Controller.

Adjustable Parameter Control

Patient selection – Adjustable parameter control may not be appropriate for all patients. Physician discretion will need to be exercised to determine whether an individual patient and/or caregiver is capable of managing parameter control that adjusts therapy. Patients may be eligible for adjustable parameter control if they:

- do not exhibit symptoms of dementia.
- have the cognitive ability to understand and operate the therapy controller.
- have the physical ability to operate the therapy controller (or the patient's caregiver is physically able to operate it).
- may benefit from having the ability to adjust parameters.
- have the ability and willingness to maintain contact with the programming clinician.

Programming recommendations – If you decide to give your patient adjustable parameter control, please note the following recommendations:

- Give only amplitude control to patients who have never adjusted their stimulation before.
- Use a step approach when allowing additional parameter control. Give your patient control of one additional parameter at a time.
- Program limits to allow the patient or caregiver to easily return to the programmed baseline when needed (see step 4 in “Programming Limits” on page 39). The therapeutic baseline is the clinician-programmed value for amplitude, pulse width, or rate.
- Always check the programmed changes prior to the patient leaving the office.
- Schedule follow-up visits with the patient. Giving the patient adjustable parameter control is not intended to replace follow-up visits.

The Therapy Controller and Limits

The user manual patients receive with their Model 7436 therapy controller explains that patients adjust a stimulation parameter by pressing the Increase or Decrease key for the selected program. For each successful adjustment (increase or decrease) of a stimulation parameter the therapy controller beeps once. Three beeps indicate the patient has tried to adjust a stimulation parameter beyond the programmed limit.

Number and size of adjustments – Explain to your patients how many adjustments it takes to reach their upper limit and lower limit from their programmed baseline for each parameter. In programming patient control limits, the number of patient adjustments for a parameter equals the number of programmable values between the limit value and programmed value. See the table below for the programmable values for each stimulation parameter.

Table 3. Stimulation Parameter Values

Stimulation Parameters	Values
Amplitude	Normal resolution: 0 to 10.5 V in 0.1 V steps Fine resolution: 0 to 6.35 V in 0.5 V steps
Pulse Width	60, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390, 420, 450 μ sec
Rate	3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 102, 105, 107, 110, 115, 117, 120, 125, 127, 130, 132, 135, 137, 140, 142, 145, 147, 150, 152, 155, 157, 160, 165, 167, 170, 175, 180, 182, 185, 190, 195, 200, 205, 210, 215, 220, 230, 235, 240, 250 pps

Programmable Limits for the Therapy Controller

The Kinetra Model 7428 neurostimulator offers two types of programmable limits:

- Custom Limits are higher and lower values independent of the programmed values. Custom Limits offer a much greater range of programmable limit settings, with the drawback that any programmed change to amplitude, pulse width, or rate may require a change to the Custom Limits for that parameter.



Caution: If Custom Limits are programmed, they should always be set as a last step in programming, prior to printing a final review. The limits often change when using the physician programmer to program new settings for amplitude, amplitude resolution, pulse width, or rate. By programming Custom Limits last, you ensure accuracy and save time otherwise required to reprogram.

Notes:

- You must always evaluate both upper and lower custom limits with any change to programmed values.
- If you program a value for amplitude, pulse width, or rate above or below the programmed custom upper and lower limit values, the programmer will adjust the custom value to equal the programmed value.
- Tracking Limits track at a value that is automatically adjusted with respect to the programmed value. For example, if amplitude is programmed to 3 V, and the Tracking Limit is programmed to ± 0.4 V, the range of amplitudes available to the patient is 2.6 V – 3.4 V. If the programmed amplitude is changed to 3.5 V, the range of amplitudes available to the patient would shift with the new amplitude to 3.1 V – 3.9 V. This automatic “tracking” function conveniently ensures that a change to amplitude, pulse width, or rate does not require reprogramming of the limits.

Table 4. Custom Limits for Kinetra 7428 Neurostimulator.

Parameter (Range)	Programmable Lower Limits	Programmable Upper Limits
Amplitude		
Normal Resolution (0 to 10.5 V)	0 V to programmed value	Programmed value to 10.5 V
Fine Resolution (0 to 6.35 V)	0 V to programmed value	Programmed value to 6.35 V
Pulse Width (60 to 450 μ sec)	60 μ sec to programmed value	Programmed value to 450 μ sec
Rate (3 to 250 Hz)	3 Hz to programmed value	Programmed value to 250 Hz

Table 5. Tracking Limits for Kinetra Model 7428 Neurostimulator.

Parameter (Range)	Programmable Tracking Limit
Amplitude	
Normal Resolution (0 to 10.5 V)	± 0 V, ± 0.4 V, ± 1.0 V, ± 2.0 V, ± 3.0 V
Fine Resolution (0 to 6.35 V)	± 0 V, ± 0.4 V, ± 1.0 V, ± 2.0 V, ± 3.0 V
Pulse Width	
(60 to 450 μ sec)	± 0 μ sec
Rate	
(3.0 to 250 Hz)	± 0 Hz

Programming Restrictions: Limits

- Program 1 and Program 2 must be set to the same programmable option, either custom limits or tracking limits.
- Tracking Limits are not independently programmable between programs (leads). If a Tracking Limit for amplitude, pulse width, or rate is programmed for one program, the other program is automatically programmed to the same Tracking Limit.
- Custom Limits for amplitude and pulse width are independently programmable, and can be different for each program.
- If the parameter limit for the selected program is switched from a Tracking Limit to a Custom Limit, the parameter limit for the unselected program will also change to a Custom Limit. This new Custom Limit is calculated by adding the programmed parameter value for the unselected lead to the old Tracking Limit value.
- When Tracking Limits are used, and Fine Amplitude Resolution is programmed, the upper limit value for amplitude will never exceed 6.35 V.
- If the upper limit for amplitude or pulse width is programmed to a higher value than the programmed value, the physician programmer will use the higher value when calculating charge density.
- When you are programming patient control limits, the physician programmer will warn you if the combination of programmed parameters plus the patient control limits exceed the safe charge density values. You should not override this charge density warning when programming patient limits. Reduce the allowed programmability so that the maximum settings that the patient could program do not exceed the safe charge density values. The patient does not receive the charge density warning.

Programming Limits

Note: When programming patient limits, take into consideration the patient's use of medications.

1. Select the desired program by pressing the key below VIEW CH1 or VIEW CH2 on the lower display.
2. Press the key above SPECIAL on the upper display.
3. Press the key below LIMIT on the lower display.
4. Review the upper display. Note that AMPL, PULSE WIDTH, and RATE are displayed with two rows of numbers below them. The upper row is the upper limit (HIGH LIMIT) and the lower row is the lower limit (LOW LIMIT). The current lead (program) is also indicated.

Note: When programming patient limits, ensure that patients can return to their therapeutic baseline by programming one of the following options:

- Set the lower limit to the baseline value so patients can only increase their stimulation but can return to their baseline by simply decreasing stimulation.
 - Set the upper limit to the baseline value so patients can only decrease their stimulation but can return to their baseline by simply increasing stimulation.
 - Set the lower and upper limits as desired around the baseline. Inform patients of the number of steps between the therapeutic baseline and the upper and lower limits (See "Number and size of adjustments" on page 36).
5. Set the amplitude limits:
 - a. To program a Tracking Limit, press the AMPL key and select an amplitude limit; then press the [PROGRAM] key. If a Custom Limit is desired, select CUSTOM, then proceed to step 5b.

Note: The current limit setting is underlined on the lower display.
 - b. Press the left AMP key and select the lower limit, then press the [PROGRAM] key.
 - c. Press the right AMP key and select the upper limit, then press the [PROGRAM] key.

Notes:

 - For patients who have never adjusted their stimulation before, it is recommended that you provide only amplitude control (go to step 8 to finish the procedure).
 - If you decide to give your patient additional parameter control, use a step approach and give only one additional parameter at a time.
 6. Set the pulse width limits:

Programming for Patient Control

- a. To program a Tracking Limit, press the pulse width key and select ± 0 USEC; then press the [PROGRAM] key. If a Custom Limit is desired, select CUSTOM then proceed to step 6b.
 - b. Press the left PW key and select the lower pulse width limit, then press the [PROGRAM] key.
 - c. Press the right PW key and select the upper pulse width limit, then press the [PROGRAM] key.
7. Set the rate limits:
- a. To program a Tracking Limit, press the RATE key and select ± 0 PPS, then press the [PROGRAM] key. If a Custom Limit is desired, select CUSTOM, then proceed to step 7b.
 - b. Press the left RATE key and select the lower limit, then press the [PROGRAM] key.
 - c. Press the right AMP key and select the upper limit, then press the [PROGRAM] key.
8. Use the therapy controller to confirm that all programmed parameters and limit values are appropriate for your patient.
9. Select the other lead (program) and program amplitude and pulse width limits.
10. After setting the patient control limits, program the neurostimulator to the minimum and maximum amplitude, rate, and pulse width combinations to assure that each combination does not cause any undesired side effects.
- Note:** When testing patient limits, take into consideration the patient's use of medications as they may affect the patient's overall therapy outcomes.
11. Prior to the patient leaving the clinic:
- Explain to the patient or caregiver how to adjust stimulation parameters with the therapy controller, including how programmable limits affect parameter adjustment. Inform patients how to return to their therapeutic baseline (see step 4 in "Programming Limits" on page 39).
 - Tell the patient or caregiver which side of his or her body is controlled by the Program 1 Increase/Decrease keys and which side corresponds to the Program 2 Increase/Decrease keys on the Therapy Controller. Record this information in the program record section of the Access Model 7436 Therapy Controller patient manual.
 - Have the patient or caregiver use the therapy controller to demonstrate that he or she has the ability to implement therapy changes and return to the programmed therapeutic baseline.
 - Instruct the patient or caregiver to return to therapeutic baseline settings or turn the device off and call the prescribing physician if changing stimulation values results in uncomfortable stimulation or other unwanted effects.
 - Remind the patient or caregiver to schedule follow-up visits with the prescribing clinic.

Control Magnet Enable/Disable

The magnet-actuated reed switch may be turned ON and OFF to enable or disable the control magnet. Turning the magnet-actuated reed switch ON allows the patient to turn the neurostimulator ON and OFF with the Model 7452 Control Magnet. Turning the magnet-actuated reed switch OFF may be considered if, for example, the patient is experiencing unexpected ON/OFF switching due to exposure to magnets or strong electromagnetic fields. The magnet-actuated reed switch status will have no effect on the patient's ability to turn the neurostimulator ON or OFF with the Access Model 7436 Therapy Controller.



Caution: If the magnet-actuated reed switch is turned OFF, the patient must have an Access Model 7436 Therapy Controller to turn the neurostimulator ON or OFF.

Note: The default setting for the magnet-actuated reed switch is ON.

To enable or disable the control magnet:

1. Press the key above SPECIAL on the upper display.
2. Press the key below MAGSW (magnet switch) on the lower display.
3. Press OFF (to disable the control magnet) or ON (to enable to control magnet).
4. Press the [PROGRAM] key.
5. Press the [CLEAR] key to exit.

Specifications

Table 6. Kinetra Model 7428 Neurostimulator Programmable Parameter Values.

Programmable Parameters	Values^a
Pulse Amplitude ^b and Limits for Programs 1 and 2	Normal resolution: 0 to 10.5 V (0.1 V steps) Fine Resolution: 0 to 6.35 V (0.05 V steps)
Rate and Limits ^{b,c}	66 values from 3 to 250
Pulse Width and Limits for Programs 1 and 2 ^b	60, 90, 120, 150, 180, 210, 240, 270, 300, 330, 360, 390, 420, 450 μ sec
Cycle On Time	0.1 second to 24 hours
Cycle Off Time	0.1 second to 24 hours
Cycle On Time w/SoftStart	2 seconds to 24 hours
Cycle Off Time w/SoftStart	2 seconds to 24 hours
SoftStart/Stop	The values are 1, 2, 4, or 8 seconds.
Electrode Polarity for Program 1	0, 1, 2, 3, Electrodes: Off, Neg or Pos Case: Off or Pos
Electrode Polarity for Program 2	4, 5, 6, 7, Electrodes: Off, Neg or Pos Case: Off or Pos
Day Cycling ON Time	30 minutes to 24 hours
Day Cycling OFF Time	30 minutes to 24 hours
Magnet ON/OFF Control Circuit	Enabled or Disabled

^a All values are approximate.

^b Certain combinations of amplitude, pulse width, and rate are not allowed. Refer to “High Output Interlocks” on page 25.

^c The same values for rate and rate limits are programmed for both Program 1 and Program 2.

Physician Training Information

Prescribing physicians should have expertise in the medical treatment of patients with movement disorders. Implanting physicians should have expertise with functional stereotactic neurosurgical treatment of movement disorders. Such expertise should include knowledge of the anatomical and neurophysiological characteristics of the targeted nucleus, surgical and /or implantation techniques for the Activa System, operational and functional characteristics of the Activa System, and experience in the continued management of patients by stimulation parameter adjustment. Physicians may contact Medtronic before prescribing or implanting an Activa System for the first time and request a referral to a physician experienced in the use of Activa Therapy

All Activa System programming should be by or under the supervision of a physician or other experienced medical personnel familiar with the use of the programming software and equipment. Physicians should be thoroughly familiar with Activa System supporting material, including:

- All product labeling, and
- Education and training materials.

Patient Counseling Information

Before surgery, the patient and family 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. After the Activa System is implanted, the patient should also be advised to read the patient manual included in the neurostimulator package.

Theft Detectors and Screening Devices

Patients should be advised to use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores) because these devices can turn ON or turn OFF their neurostimulator. If an airport security wand is used, they should ask the security personnel to avoid placing the wand over the neurostimulator.

When approaching these devices, patients should do the following:

1. If security personnel are present, show them the neurostimulator identification card and request a hand search.
2. If patients must pass through the security device, they should approach the center of the device and walk normally (Figure 5).
 - 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.

How Supplied

3. Proceed through the security arch or gate. Do not touch, lean on or linger near the security arch or gate.

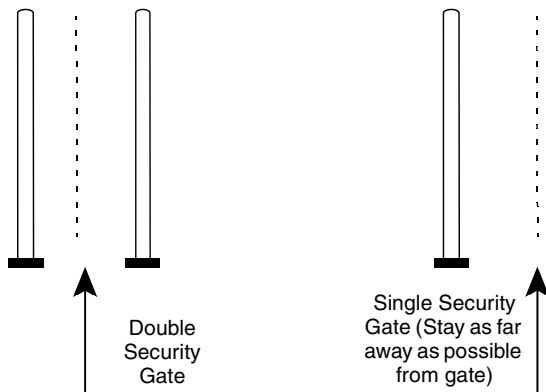


Figure 5. Approaching security gates.

4. If patients suspect that their neurostimulator was turned OFF, they should make sure someone is able to turn ON the system again. (This person could be the patient, if their medical condition allows it. It could also be a family member or clinician who has been taught how to use the system.)

Component Manipulation by Patient

Advise your patient to avoid manipulating the implanted system components (e.g., the neurostimulator, the burr hole site). This can result in component damage.

How Supplied

Package Contents

- One Model 7459 MemoryMod Software Cartridge
- One Software Application Manual

Appendix A: Troubleshooting

No Stimulation or Intermittent Stimulation

No stimulation or intermittent stimulation may be caused by any of the sources listed below. If you suspect one of these problems, perform Procedure 1.

Causes of No Stimulation or Intermittent Stimulation

- The patient is confused about the use of the therapy controller or control magnet.
- The patient has turned OFF the neurostimulator.
- Amplitude is too low to be effective.
- Stimulation is in the Cycling Mode (Cycling Off Time).
- There is a short circuit or open circuit in the lead or extension.
- The metal of the conductor wire or connection mechanism is exposed or uninsulated.
- The wound dressing is too thick to allow for successful telemetry.
- There is a connection problem (lead to extension or neurostimulator to extension).
- The neurostimulator battery is depleted.
- Neurostimulator component failure.
- The patient has come into contact with a magnet (telephone head, refrigerator door, stereo speakers, etc.) and the neurostimulator has turned OFF and ON.
- The neurostimulator is in Dose Lockout Mode (Soletra and Itrel II).

Procedure 1 – Noninvasive troubleshooting for no stimulation or intermittent stimulation

1. Ask the patient to describe the stimulation problem using the following questions:

Did the loss of stimulation occur suddenly or gradually?

- Sudden loss of stimulation may indicate that the neurostimulator has been turned OFF or that there is a hardware problem.
- Gradual loss of stimulation may indicate battery depletion or a physiologic cause such as sensory accommodation.

Describe the feeling of stimulation that you are experiencing at this time.

Note: Encourage the patient to accurately and completely describe the feeling of stimulation.

- No feeling may indicate a hardware problem, battery depletion, or a physiologic cause as described above.

Appendix A: Troubleshooting

- A burning sensation, somewhere along the system pathway from the neurostimulator to the lead, that comes and goes when the neurostimulator is turned ON and OFF may indicate a problem with leads, extensions, or connectors.
 - A burning sensation that is constant may indicate a physiologic cause such as infection.
 - A change in the therapy results may indicate lead migration.
 - In a unipolar configuration (case is positive) the patient may experience skeletal muscle stimulation around the site of the neurostimulator, particularly at high amplitude settings. Consider using bipolar configurations when possible to resolve skeletal muscle stimulation.
2. If the source of the problem is revealed in Step 1, perform the relevant test listed below and resolve the problem. Otherwise, perform the following tests in succession until the problem is uncovered or resolved.
- Programming Review
 - Battery Depletion Check
 - Electrode Impedance and Stimulation Current Measurements
 - Component Palpation
 - X-ray Examination

Programming Review

1. Ensure the patient is using the device(s) correctly.
2. Review all program settings, electrode selections, parameters, and modes to ensure that all settings are correctly programmed.
3. Set stimulation to the continuous mode and eliminate the SoftStart/Stop feature while ensuring that the neurostimulator is ON.
4. Slowly increase the amplitude to determine therapy response. In some cases, the patient has simply “accommodated” to a certain voltage level and may require a slight increase to obtain adequate control.

Battery Depletion Check

Battery depletion is one potential cause of system problems, particularly with a neurostimulator. Check the neurostimulator battery status. Refer to the appropriate programming guide and neurostimulator technical manual for additional information.

Component Palpation

1. Turn the amplitude to the previously programmed, comfortable voltage level.
2. Try a palpation test to further interrogate the system:
 - a. Firmly palpate or massage the skin over the implanted system components, beginning at the neurostimulator pocket.

- b. Continue to palpate the skin along the pathway to the lead-extension connection near the neck, ensuring that all components and connections are firmly palpated.
- c. Watch for these results:
 - Stimulation recurs when implanted components are palpated, indicating a possible loose connection that must be surgically repaired (refer to Procedure 2).
 - Patient feels a burning sensation, particularly at a connection or along the extension pathway, indicating a possible exposed wire or connection that must be surgically repaired (refer to Procedure 2).

Note: If the burning sensation continues when the neurostimulator is OFF, a physiological cause, such as infection, may be the cause.

X-ray Examination

Obtain an x-ray to investigate lead position, loose connections, and possible broken wires.

- Because an x-ray detects metal, a continuous path of metal should be seen from the neurostimulator to the stimulating electrodes.
- An opening or “blank spot” in the path may indicate a broken wire or an open connection.
- Confirm that no connections have been pulled apart.

Lead migration, loose connections, and broken lead wires all require surgical intervention (refer to Procedure 2).

Note: Lack of visualization of the metal conductors of the extension may not indicate discontinuity. Contact Medtronic for more information.

Electrode Impedance and Stimulation Current Measurements for the Kinetra Neurostimulator

Electrode impedance and stimulation current are electrical values that can be interrogated with the programmer. These values may help to further define the system problem.

Look for the expected measurement values for short circuit (low impedance, high stimulation current), or open circuit (high impedance, low stimulation current):

Impedance values indicating potential short circuit	Impedance values indicating potential open circuit
Impedance < 100 Ohms	Impedance > 4000 Ohms

Accuracy of impedance measurement for the Model 7428 Kinetra

Neurostimulator – At typical stimulation settings for Parkinson’s disease patients (1-3.5 V, 60-120 μ sec), the impedance measurement may not accurately reflect the actual lead impedance. In general, the accuracy of the impedance measurement increases at higher amplitudes and wider pulse widths. Refer to Table 7 for a listing of stimulation parameter settings, measured impedance, and corresponding actual impedance.

Caution: Do not rely solely on the results of impedance testing for troubleshooting. Accuracy of the data generated during impedance tests can fluctuate based on the neurostimulator that is being tested and on the programmed settings.

Table 7. Accuracy of Load Impedance Measurement.^a

Stimulation Parameter Settings (Amplitude and Pulse Width)	Measured Impedance (Ohm)	Actual Impedance (Ohm)
1 V, 60 μ sec	0-200	0-700
	200-400	700-2000
	400-4000	2000-Open
3 V, 120 μ sec	0-500	0-500
	500-1000	500-1400
	1000-2000	1400-4000
	2000-4000	4000-Open
4 V, 210 μ sec	0-500	0-500
	500-1000	500-1000
	1000-1600	1000-1900
	1600-2400	1900-3400
	2400-4000	3400-Open

^a All values are approximate.

Troubleshooting High Impedance Measurements – An impedance value over 2000 Ohms may indicate a fractured lead wire or problem with the integrity of the component connections. If a patient is receiving no therapeutic benefit from stimulation, and impedance measures greater than 2000 Ohms, follow this procedure to help localize the potential problem:

For Lead 1:

1. Program the amplitude to 1.0 V
2. Program the neurostimulator to unipolar mode, with the neurostimulator case positive, electrode 0 negative, and other electrodes OFF.
3. Measure and record impedance.
4. Program electrode 0 OFF, and electrode 1 negative, and repeat impedance measurement.

5. Program electrode 1 OFF, and electrode 2 negative, and repeat impedance measurement.
6. Program electrode 2 OFF, and electrode 3 negative, and repeat impedance measurement.

For Lead 2:

1. Program the amplitude to 1.0 V
2. Program the neurostimulator to unipolar mode, with the neurostimulator case positive, electrode 4 negative, and other electrodes OFF.
3. Measure and record impedance.
4. Program electrode 4 OFF, and electrode 5 negative, and repeat impedance measurement.
5. Program electrode 5 OFF, and electrode 6 negative, and repeat impedance measurement.
6. Program electrode 6 OFF, and electrode 7 negative, and repeat impedance measurement.

Impedance values within the clinical ranges found above should indicate a viable electrode configuration. A value exceeding 2000 Ohms for one configuration may indicate a problem. The electrode polarity should then be reprogrammed with the suspect electrode OFF. If values exceed 2000 Ohms for all electrode combinations and battery current is less than 15 μ amps, then an x-ray should be obtained to verify a possible lead fracture.

Troubleshooting Low Impedance Measurements – An impedance value of less than 50 Ohms may indicate a shorted lead wire. If a patient is receiving no therapeutic benefit from stimulation, and impedance measures less than 50 Ohms, follow this procedure to help localize the potential problem:

For Lead 1:

1. Program the amplitude to 1.0 V
2. Program the neurostimulator to bipolar mode, with electrode 0 positive, electrode 1 negative, and other electrodes OFF.
3. Measure and record impedance.
4. Program electrode 1 OFF, and electrode 2 negative, and repeat impedance measurement.
5. Program electrode 2 OFF, and electrode 3 negative, and repeat impedance measurement.
6. Program electrode 0 OFF, electrode 1 positive, and electrode 2 negative and repeat impedance measurement.
7. Program electrode 2 OFF, and electrode 3 negative, and repeat impedance measurement.

Appendix A: Troubleshooting

8. Program electrode 1 OFF, electrode 2 positive, and electrode 3 negative and repeat impedance measurement.

For Lead 2:

1. Program the amplitude to 1.0 V
2. Program the neurostimulator to bipolar mode, with electrode 4 positive, electrode 5 negative, and other electrodes OFF.
3. Measure and record impedance.
4. Program electrode 5 OFF, and electrode 6 negative, and repeat impedance measurement.
5. Program electrode 6 OFF, and electrode 7 negative, and repeat impedance measurement.
6. Program electrode 4 OFF, electrode 5 positive, and electrode 6 negative and repeat impedance measurement.
7. Program electrode 6 OFF, and electrode 7 negative and repeat impedance measurement.
8. Program electrode 5 OFF, electrode 6 positive, and electrode 7 negative and repeat impedance measurement.

Impedance values within the clinical ranges found above should indicate a viable electrode configuration. A value less than 50 Ohms for one configuration may indicate a problem. The electrode polarity should then be reprogrammed with the suspect electrodes off.

Procedure 2 - Invasive troubleshooting for no stimulation or intermittent stimulation

If none of the noninvasive troubleshooting tests have identified the problem or if these tests have demonstrated that the problem is with an implanted component, contact Medtronic Technical Services for additional information before proceeding with the invasive procedure (surgery).

Supplies needed for invasive troubleshooting include the following:

- Alligator clip cable
- Test Stimulation (Screener)
- Backup system components (lead, extension, neurostimulator)
- Programmer
- Accessories (hex wrenches, boots, medical adhesive, stylets, anchors)
- Other supplies as needed

Note: All supplies must be sterile except the test stimulator and programmer.

If you have identified specific component problems, perform the corresponding troubleshooting procedure from the following:

- Exposed wire or connection
- Connection problem
- Lead migration

Exposed Wire or Connection

If the patient presents with a “burning” sensation that is only present when the neurostimulator is ON, perform the initial surgical incision over the site of the reported burning. Be careful not to damage any insulation.

Note: A constant burning that continues when the neurostimulator is OFF may indicate a physiologic cause such as infection.

If the burning is at a connection site, redo the connection using a new insulation boot, then:

- Inspect for lead full insertion into the extension connector.
- Inspect connection for any damage.
- Inspect setscrews for proper tightness.
- Place the newly redone connection back into the incision and retest the system prior to wound closure.

If the burning is at the neurostimulator site, be certain that:

- The etched identification side of the neurostimulator is facing towards the skin, not towards the muscle.
- The rubber grommets remain in all four screw holes on the neurostimulator connector block and that no leaf within a rubber grommet is stuck open.
- The extension is fully seated in the connector block and that there are no nicks or cuts on the underside of the neurostimulator or anywhere that might result in bare metal exposure.

Note: If the rubber grommets appear to be damaged or open to fluid infiltration, use a small amount of medical adhesive on the surface to seal. Do not force adhesive into the setscrews.

Connection Problem

If there is a connection problem, perform the surgical incision over the connection site. Redo connection, testing for system integrity prior to wound closure.

Note: Do not overtighten connections. Tighten each setscrew clockwise until it touches the extension connector pin—continue tightening for a maximum of 1/4 turn only. After you remove the hex wrench, check that the rubber grommet has closed.

Lead Migration

If the lead has migrated, perform the incision over the lead-extension connection.

1. Expose and bring the connection outside the incision. Disconnect the lead extension.
2. If the lead is anchored, carefully dissect down to the anchoring site and remove the anchor.
3. Attempt to guide the lead to a location that yields appropriate therapy response. Conduct screening tests to confirm proper lead location.
4. Carefully redo the lead-extension connection, internalize the system, and close the wound.

If you have not identified specific component problems, perform the troubleshooting procedure below.

1. Position the patient on the operating table so that the lead-extension site and neurostimulator pocket are accessible.
2. Identify the lead-extension connection by palpation or fluoroscopy and perform an incision to expose the connection, being careful not to damage the system components with the scalpel. Carefully bring the connection outside the incision.
3. Remove the protective boot from the connection, undo the connection and separate the lead and extension.
4. Connect the screening cable to the lead. Connect the screening cable to the test stimulator and screen the patient to determine the electrode combination last used by the patient.
 - a. If stimulation occurs, proceed to step 5.
 - b. If stimulation does not occur, the lead may need to be replaced or repositioned.
5. Reconnect the lead and extension and turn the system ON.
 - a. If stimulation occurs, put the protective boot back on and carefully redo the connection, retesting prior to internalizing the system.
 - b. If stimulation does not occur, proceed with step 6.
6. Perform an incision and bring the neurostimulator outside. Exercise extreme care with the scalpel to avoid damaging the components. Undo the extension-neurostimulator connection and separate the components. Attach the alligator clip screening cable to the end of the extension. Connect the cable to the test stimulator and test the patient for stimulation response.
 - a. If stimulation occurs, proceed with step 7.
 - b. If stimulation does not occur, the problem may be with the extension. Replace it with a new extension. Reconnect system components and screen prior to internalization.
7. Reconnect the neurostimulator to the extension. Turn the neurostimulator ON.

- a. If stimulation occurs, inspect the connection to ensure that it is secure and carefully place the neurostimulator back in the pocket. Turn the neurostimulator ON once more and verify system integrity prior to wound closure.
- b. If stimulation does not occur, contact a Medtronic representative. For possible causes of no stimulation, refer to “No Stimulation or Intermittent Stimulation” on page 45.

Changes in Symptom Suppression

Changes in symptom suppression may be caused by any of the sources listed below. If you suspect one of these problems, perform Procedure 3.

Causes of Change in Therapy Response

- There is lead migration.
- There is a short or open circuit resulting in reduced current delivered to the stimulating electrodes.
- There is medication interference.

Procedure 3 – Noninvasive troubleshooting for change in therapy response

1. Try different electrode combinations. Be certain to have at least one electrode negative and one electrode positive.
2. Palpate along the extension-lead connection; the patient should feel a change in stimulation if there is an insulation break or a loose connection. If found, an insulation break or loose connection must be invasively repaired.
3. Obtain an x-ray to determine if the lead has migrated.
4. If the patient feels a burning in the neurostimulator pocket, there may be a short or open circuit (e.g., exposed wire). Short or open circuits must be invasively repaired. Refer to Procedure 4.

Procedure 4 – Invasive troubleshooting for change in therapy response

If none of the noninvasive troubleshooting tests are able to recapture appropriate stimulation, contact Medtronic Technical Services for additional information before proceeding with the invasive procedure (surgery).

1. Make an incision at the lead-extension connection. Expose and bring the connection outside the incision. Disconnect the lead and extension.
2. If the lead is anchored, carefully dissect down to the anchoring site and remove the anchor.
3. Attempt to guide the lead to a location that yields appropriate therapy response. Conduct screening tests to confirm proper lead location.
4. Carefully redo the lead-extension connection, internalize the system, and close the wound.

Ineffective Stimulation

Ineffective stimulation (i.e., stimulation that is in the appropriate areas, but not strong enough to meet therapy needs) may be caused by patient-related or etiology-related causes as described below. If you suspect one of these problems, see the corresponding troubleshooting procedure.

Patient-related Causes for Ineffective Stimulation

- Changes in family circumstances or dynamics
- Psychological changes

Procedure 5 – Troubleshooting for patient-related causes for ineffective stimulation

1. Review recent changes in patient's life.
2. Initiate psychotherapy/family counseling, if necessary.

Etiology-related Causes for Ineffective Stimulation

- Accommodation to stimulation
- Disease progression resulting in original parameter settings being ineffective.

Appendix B: MRI and Activa Therapy

Introduction

It is important to read this appendix in its entirety before conducting an MRI examination on a patient with any implanted Activa System component. Contact Medtronic at 1-800-707-0933 if you have any questions.

Due to the number and variability of parameters that affect MRI compatibility, the safety of patients or continued functioning of Activa Systems exposed to MRI cannot be absolutely ensured. MRI systems generate powerful electromagnetic fields that can produce a number of interactions with implanted components of the Activa neurostimulation system. Some of these interactions, especially heating, are potentially hazardous and can lead to serious injury or death. However, with appropriate control measures, particularly with respect to the selection of MRI parameters and RF coils, it is generally possible to safely perform an MRI head scan on an Activa patient. In addition, Activa System components can affect the MRI image, potentially impacting the diagnostic use of this modality. The following information describes the potential interactions and control measures that should be taken to minimize the risks from these interactions.



Contraindication: Implantation of an Activa Brain Stimulation System is contraindicated for patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area. Performing MRI with this equipment can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death.



Warnings:

- Do not conduct an MRI examination on a patient with any implanted Activa System component until you read and fully understand all the information in this manual. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.
- In-vitro testing has shown that exposure of the Activa neurostimulator system to MRI at parameters other than those described in this guideline can induce significant heating at the lead electrodes or at breaks in the lead. Excessive heating may occur even if the lead and/or extension are the only part of the Activa System that is implanted. Excessive heating can result in serious and permanent injury including coma, paralysis, or death.
- MRI examinations of patients with an implanted Activa System should only be done if absolutely needed and then only if these guidelines are followed. MRI should not be considered for Activa patients if other potentially safer diagnostic methods such as CT, X-ray, ultrasound, or other methods will provide adequate diagnostic information.
- A responsible individual with expert knowledge about MRI, such as an MRI radiologist or MRI physicist, must assure all procedures in this guideline are followed and that the MRI scan parameters, especially RF specific absorption rate (SAR) and gradient dB/dt parameters, comply with the recommended settings, both for the pre-scan (tuning) and during the actual MRI examination. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this appendix.
- Do not conduct an MRI examination if the patient has any other implants or limiting factors that would prohibit or contraindicate an MRI examination.



Cautions:

- The neurostimulator, especially those without filtered feedthroughs such as the Itrel II Model 7424, may be reset or potentially damaged when subjected to an MRI examination. If reset, the neurostimulator must be reprogrammed. If damaged, the neurostimulator must be replaced.
- MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted Activa System components, especially near the neurostimulator. If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator to obtain an image, or use alternate imaging techniques. Do not remove the neurostimulator and leave the lead system implanted as this can result in higher than expected lead heating.
- Carefully weigh any decision to perform magnetic resonance imaging (MRI) examinations on patients who require the neurostimulator to control tremor. Image quality during MRI examinations may be reduced, because the tremor may return when the neurostimulator is turned off.
- If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.
- Monitor the patient during the MRI examination. Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations/uncomfortable stimulation, or unusual sensations.

Note: The MRI guidelines provided here may significantly extend the MRI examination time or prevent some types of MRI examinations from being conducted on Activa patients.

General Information on MRI

An MRI system produces three types of electromagnetic fields that may interact with implanted neurostimulation systems. All three of these fields are necessary to produce an MRI image. Each of these fields can also produce specific but different types of interactions with implanted neurostimulator systems. These fields include:

- **Static Magnetic Field.** This is a steady state non-varying magnetic field that is normally always ON, even when no scan is underway. In a 1.5 Tesla MRI system, the static magnetic field is approximately 30,000 times greater than the magnetic field of the earth.
- **Gradient Magnetic Field.** This is a low-frequency pulsed magnetic field that is only present during a scan. The gradient magnetic field can induce voltages onto the lead system that may result in unintended stimulation or functional interactions with the neurostimulator.
- **RF Field.** This is a pulsed radio frequency (RF) field that is only present during a scan. It can be produced by a variety of transmission RF coils such as a whole body transmit coil or an extremity coil such as a transmit/receive head coil. Only a transmit/receive head coil should be used as the other RF coils can expose more of the lead system to RF energy, thereby increasing the risk of excessive heating and thermal lesions possibly resulting in coma, paralysis, or death.

MRI Interactions with Implanted Activa Systems

MRI/neurostimulation system interactions are various, and the risk to the patient can range from minimal to severe. These interactions include the following:

Heating – The MRI RF field induces voltages onto the lead system that can produce significant heating effects at the lead electrode-tissue interface or at the location of any breaks in the neurostimulator lead system. Component heating from the MRI RF field is the most serious risk from MRI exposure. Failure to follow these MRI recommendations can result in thermal lesions possibly resulting in coma, paralysis, or death.

Magnetic Field Interactions – Magnetic field interactions such as force and torque effects are produced by the static magnetic field. Any magnetic material will be attracted to the static magnetic field of the MRI. The force and torque effects may produce movement of the neurostimulator that can be uncomfortable to the patient, open a recent incision, or both. Activa System components are designed with minimal magnetic materials.

Induced Stimulation – Gradient magnetic fields may induce voltages onto the lead system that may cause unintended stimulation. The voltage of the induced stimulation pulses is proportional to the time rate of change (dB/dt) of the gradient pulses, the effective loop area created by the neurostimulator lead system, and the location of the lead system with respect to the gradient coils of the MRI.

Effects on Neurostimulator Function – The static, gradient, and RF fields of the MRI may affect the neurostimulator operation and programming. The static magnetic field may cause the neurostimulator to turn ON or OFF if the neurostimulator uses a magnetically controlled switch that allows the patient to control stimulation by the application of a handheld magnet. Additionally, the MRI RF, static, and gradient fields may temporarily affect or disable other functions, such as telemetry or stimulation pulses. Parameters will need to be reprogrammed if the MRI causes a POR (Power On Reset) of the neurostimulator.

Image Artifacts and Distortion – The neurostimulation system components, particularly the neurostimulator, can cause significant imaging artifacts and/or distortion of the MRI image, particularly if the neurostimulator components contain magnetic material. The neurostimulator can cause the MRI image to be completely blocked from view (i.e., signal loss or signal “void”) or severely distorted within several inches of the neurostimulator.

MRI Procedure

Scope

These MRI/neurostimulator exposure guidelines apply to Activa Systems comprising combinations of the following components:

- Neurostimulator Models: Itrel II 7424, Soletta 7426, Kinetra 7428
- Lead Extension Models: 7495, 7482
- Lead Models: DBS 3387, 3389

Supervision

A responsible individual such as an MRI radiologist or MRI physicist must assure these procedures are followed. If the MRI is operated by an MRI technician, it is strongly recommended the responsible individual verifies that the MRI recommendations are followed.

Preparation

Do the following prior to performing an MRI examination on an Activa patient:

1. Inform the patient of the risks of undergoing an MRI.
2. Check if the patient has any other implants or conditions that would prohibit or contraindicate an MRI examination. Do not conduct an MRI examination if any are found.
3. Verify that all proposed MRI examination parameters comply with the “MRI Operation Settings” on page 61. If not, the parameters must be modified to meet these requirements. If this cannot be done, do not perform an MRI.
4. If the patient has implanted leads but does not have an implanted neurostimulator, perform the following steps:
 - a. Wrap the external portion of the leads/percutaneous extensions with insulating material.

Appendix B: MRI and Activa Therapy

- b. Keep the external portion of the leads/percutaneous extensions out of contact with the patient.
 - c. Keep the external leads/percutaneous extensions straight, with no loops, and running down the center of the head coil.
5. If the patient has an implanted neurostimulator, perform the following steps:
- a. Review the neurostimulator with a clinician programmer and print out a copy of the programmed parameters for reference.
 - b. Test for possible open circuits by measuring impedance and battery current on all electrodes in unipolar mode (see Table 8). If an open circuit is suspected, obtain an x-ray to identify whether the open circuit is caused by a broken lead wire. If a broken lead wire is found, do not perform an MRI.

Table 8. Measurement Values Indicating Possible Open Circuits

Neurostimulator	Impedance	Battery Current
Itrel II Model 7424	>2000 Ω	<10 μ A
Soletra Model 7426	>2000 Ω	<10 μ A
Kinetra Model 7428	>4000 Ω	<15 μ A



Warning: An MRI procedure should not be performed in a patient with an Activa System that has a broken lead wire because higher than normal heating may occur at the break or the lead electrodes which can cause thermal lesions. These lesions may result in coma, paralysis, or death.

- c. If the Activa System is functioning properly and no broken lead wires are found, program the neurostimulator to the settings provided in Table 9.

Table 9. Recommended Neurostimulator Settings for MRI

Parameter	Setting
Stimulation output	OFF (all programs)
Stimulation mode	Bipolar (all programs)
Amplitude	0 Volts (all programs)
Magnetic (reed) switch	Disabled (Kinetra Model 7428 only)
Other parameters	Do not change

MRI Operation Settings

Prior to the MRI examination, a responsible individual such as an MRI radiologist or MRI physicist must assure the examination will be conducted according to the following MRI requirements. If standard MRI pulse sequences will be used, they must meet these requirements. If they do not, the pulse parameters must be adjusted so that they comply with these requirements:



Warning: In-vitro testing has shown that exposure of the Activa System to MRI under conditions other than described in this guideline can induce excessive heating at the lead electrodes or at breaks in the lead to cause lesions. These lesions may result in coma, paralysis, or death.

- Use only a 1.5 Tesla horizontal bore MRI (do not use open sided or other field strength MRI systems).
- Use only a transmit/receive head coil.



Contraindication: Implantation of an Activa Brain Stimulation System is contraindicated for patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area. Performing MRI with this equipment can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death.

- Enter the correct patient weight into the MRI console to assure the head SAR is estimated correctly.
- Use MRI examination parameters that limit the head SAR to 4/10 (0.4) W/kg or less for all RF pulse sequences.



Warnings:

- Ensure the SAR value is the value for head SAR. Some MRI systems may only display SAR, whole body SAR, or local body SAR. Make sure the value being limited to 4/10 (0.4) W/kg is for head SAR. Excessive heating may occur if the wrong SAR value is used.
- If MRI parameters must be manually adjusted after the initial automatic MRI prescan, do not make any adjustments that will increase the SAR value. Some MRI machines may not automatically update the displayed SAR value if manual adjustments are made. This may lead to higher than expected temperature increases in the Activa System, particularly at the lead electrodes.

Appendix B: MRI and Activa Therapy

- Limit the gradient dB/dt field to 20 Tesla/second or less.

Note: The recommendations provided are based on in-vitro testing and should result in a safe MRI examination of a patient with an implanted Medtronic Activa System. However, due to the many variables that affect safety, Medtronic cannot absolutely ensure safety or that the neurostimulator will not be damaged. The user of this information assumes full responsibility for the consequences of conducting an MRI examination on a patient with an implanted Activa System.

Prior to the MRI Examination

Prior to the scan examination, the responsible individual must verify the MRI examination parameters comply with these guidelines.

- Patients with implanted Activa Systems should be informed of the risks of undergoing an MRI.
- If possible, do not use sedation so the patient can inform the MRI operator of any heating, discomfort, or other problems.
- Instruct the patient to immediately inform the MRI operator if any discomfort, stimulation, shocking, or heating occurs during the examination.

During the MRI Examination

- Monitor the patient both visually and audibly. Check the patient between each imaging sequence. Discontinue the MRI examination immediately if the patient is unable to respond to questions or reports any problems.
- Conduct the examination using only the MRI pulse sequence that the MRI radiologist or physicist has confirmed meets the MRI requirements above.

Post MRI Examination Review

- Verify that the patient is feeling normal.
- Verify that the neurostimulator is functional.
- Reprogram the neurostimulator to pre-MRI settings.

Glossary

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

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

Mode – The type of stimulation that can be programmed.

Parameter, Programmable – A specific function with an operating range of selectable values (i.e., Rate, Pulse Width) that enables the tailoring of a neurostimulation therapy to a patient.

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

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

SoftStart/Stop Stimulation – A feature that allows stimulation to begin with a ramped output, i.e., prevents an unpleasant surge of stimulation when the neurostimulator turns ON. This is done by gradually increasing the amplitude of the stimulating pulses up to the programmed value. The SoftStart feature causes a gradual decrease of the stimulation amplitude back down to zero.

Telemetry – An RF (radio-frequency) type of reciprocal communication for the purpose of verifying neurostimulator parameter settings.

Test Stimulator – A type of stimulator that closely matches the neurostimulator output but is operated externally and allows the physician and staff to test for symptom suppression in patients prior to chronic implant.



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