Medtronic

SOLETRA™

MemoryMod® Software Cartridge for
Deep Brain Stimulation

Software Cartridge Application Manual

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Device Description

The Medtronic Model 7460 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 7426 Soletra and the Model 7424 Itrel II Neurostimulators.¹,²

⚠️ Warning: The Medtronic Model 7432 Physician Programmer and the installed Medtronic Model 7460 MemoryMod Software Cartridge should not be used to attempt to program any neurostimulators other than the Model 7424 and 7426.

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 7426 Soletra and Model 7424 Itrel II programmable functions, refer to Table 1. Note that not all programmable parameters are used for Activa therapy. Detailed information on programming of Model 7426 and Model 7424 neurostimulators is in “General Programming Information” on page 18 and “Detailed Device Description” on page 39 of this manual.

¹ The term neurostimulator and IPG (implantable pulse generator) are used interchangeably in this manual.
² The Itrel II Neurostimulator is used for Tremor Control Therapy only.
**Device Description**

**Table 1. Model 7426 Soletra and Model 7424 Itrel II Neurostimulator Programmable Functions.**

<table>
<thead>
<tr>
<th>Controlling Device</th>
<th>Function</th>
<th>Programmable Parameters</th>
</tr>
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<tbody>
<tr>
<td>Model 7432 Physician Programmer with Model 7460 MemoryMod</td>
<td>Switches Neurostimulator Output ON/OFF Programs Stimulation Parameters</td>
<td>Rate Amplitude Pulse Width SoftStart/Stop Dose On Time Dose Lockout Time Output Polarity Special Ramp Feature</td>
</tr>
<tr>
<td>Programs System Mode</td>
<td>Continuous</td>
<td>SoftStart/Stop Continuous SoftStart/Stop Cycling Modulation Continuous Modulation Cycling Modulation SoftStart/Stop Cycling</td>
</tr>
<tr>
<td>Special Features</td>
<td>Hard Copy Printout IPG Battery Check Load Impedance Check Patient Compliance Data Nominal Programming Magnet-Controlled Low Amplitude (Model 7424 only) Telemetry Bypass (Model 7424 only)</td>
<td></td>
</tr>
</tbody>
</table>

⚠️ **Warning:** Do not use these parameters for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.
Indications

Medtronic Activa Therapy includes Activa Parkinson's Control Therapy and Activa Tremor Control Therapy.

Parkinson's Control Therapy

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.

Tremor Control Therapy

Unilateral thalamic stimulation by the Medtronic Activa Tremor Control System is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.
**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 radio-frequency (RF) coil or a head transmit coil that extends over the chest area. Refer to “Appendix: MRI and Activa Therapy” on page 62 for comprehensive safety information.

- Patients for whom test stimulation is unsuccessful.

- Patients who are unable to properly operate the brain stimulator.
Warnings

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.

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 µsec, 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 18.

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. CONSULT TECH MANUAL. PRESS CLEAR TO CONTINUE.

If a lead is implanted in the thalamus, 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 when the lead is implanted in the thalamus.
Precautions

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 OFF. 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 59 for more information.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to “Physician Training Information” on page 58 section in this manual 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.

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.

Magnet-Controlled Amplitude (Model 7424 Itrel II Neurostimulator only) – For Activa Therapy, always program Mag Amp, or Magnet-Controlled Amplitude, to the same value as the normal amplitude setting. If no Mag Amp value is programmed, the amplitude will decrease to zero when Mag Amp is activated, resulting in no stimulation whether the device is ON or OFF.
Precautions

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 Physician and Hospital Staff Manual. Refer to the physician manual for details of neurostimulator operation and complete indications, contraindications, warnings, and precautions.

Programming Different Neurostimulator Models – The Model 7432 Physician Programmer must be turned off and turned back on before attempting to program a different neurostimulator model (for example, if programming a Soletra Model 7426 neurostimulator immediately after programming an Itrel II Model 7424 neurostimulator). If the programmer is not turned off and on, the programmer will display NO TELEMETRY, POSITION HEAD AND TRY AGAIN and the software will not allow the different neurostimulator to be programmed.

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 or Essential Tremor.
Precautions

- 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.

Magnetic Resonance Imaging

Based on tests to date, some MRI procedures can be performed safely with an implanted Activa System. MRI systems used to safely perform MRI include MRI systems operating at 1.5 Tesla (specific MRI machines include Siemens Magnetom 1.5T VISION, Picker International 1.5T Edge, and GE Signa 1.5T Echospeed). The safety of other MRI machines used with implanted Activa Systems is not known.
Precautions

- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.
- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.
- Carefully weigh any decision to perform magnetic resonance imaging (MRI) scans on patients who require the neurostimulator to control tremor. Image quality during MRI scans may be reduced, because the tremor may return when the brain stimulator is turned off.

Use of MRI could possibly result in movement, heating, or damage to the implanted Activa System. The MRI image around the implanted lead may be distorted and shadowed. Induced voltages in the neurostimulator and/or lead may occur, possibly causing uncomfortable ("jolting" or "shocking") levels of stimulation. Clinicians should carefully weigh the decision to use MRI in patients with an implanted Activa System, and should refer to "Appendix: MRI and Activa Therapy" on page 62 for comprehensive safety information.

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.
Precautions

**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 lithotriptor, 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...
Precautions

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) 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 1-800-707-0933.
Adverse Events

**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.

Adverse Events

For a complete list of adverse events reported during the Parkinson’s disease and tremor clinical trials, refer to the *Activa Clinical Summary* packaged with the implanted components of the Activa System.

Clinical Studies

For results of the Parkinson’s disease and tremor clinical trials, refer to the *Activa Clinical Summary* packaged with the implanted components of the Activa System.

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.
General Programming Information

General Programming Information

Setting Up the System

The Model 7460 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 1).
   
   **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 1. Insert software cartridge.](image)

   **Figure 1. Insert software cartridge.**
General Programming Information

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 7460 Software Cartridge. The specific parameters and values entered will be determined by the therapy you prescribe for your patient. To obtain patient feedback, programming should be done with the neurostimulator output on. To help ensure an optimum therapy for your patient, 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.

If programming errors occur, it may be necessary to reposition the programmer head or move to a new location.

Amplitude programming is best done with the neurostimulator output on to allow patient feedback. This helps avoid “shocking” or “jolting” the patient when the system is turned on. If attempting to program the amplitude with the neurostimulator output off, the display message suggests turning the output on before continuing. To deliberately program amplitude with the neurostimulator output off, press [PROGRAM].
General Programming Information

⚠️ **Caution:** The Model 7432 Physician Programmer must be turned off and turned back on before attempting to program a different neurostimulator model (for example, if programming a Soletra Model 7426 neurostimulator immediately after programming an Itrel II Model 7424 neurostimulator). If the programmer is not turned off and on, the programmer will display **NO TELEMETRY, POSITION HEAD AND TRY AGAIN** and the software will not allow the different neurostimulator to be programmed.

The basic steps for programming the Model 7426 or 7424 neurostimulators are shown in page 22.
General Programming Information

Warnings:

- When using the programming head in a sterile field, place it into 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 (electromagnetic interference)(e.g., electrocautery, defibrillatory discharge, MRI) can permanently erase the neurostimulator serial number, causing ??? to be displayed in place of the serial number.

Note: 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.
General Programming Information

Programming Overview

<table>
<thead>
<tr>
<th>To:</th>
<th>Do the Following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Install Model 7460 Cartridge.</td>
<td>Refer to page 18.</td>
</tr>
<tr>
<td>2. Turn on Physician Programmer.</td>
<td>Press [ON/OFF] key ON.</td>
</tr>
<tr>
<td>5. Select a parameter for programming.</td>
<td>Example: Press [AMPL].</td>
</tr>
<tr>
<td>8. Repeat steps 5 through 7, until all parameters are programmed.</td>
<td></td>
</tr>
</tbody>
</table>

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.
General Programming Information

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

**Note:** Except for [PRINTER ON/OFF], [TELEMETRY BYPASS] 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.

**“Home” Messages**

Review of parameters when programming the Model 7426 or 7424 neurostimulators does not include the neurostimulator battery status.

The first “home” status message that appears when you program the neurostimulator is the following: SELECT PARAMETER OR MEASURE IPG BATTERY. After you check the neurostimulator battery status, the “home” message changes to read: SELECT PARAMETER.

**Neurostimulator Memory Effects**

Mode or parameter values stored in the neurostimulator memory are not changed or altered when you use the [REVIEW] key function from the “home” message. Under certain rare conditions, however, the memory can be changed or altered. 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 permanently lost, and patient compliance data will show PATIENT COMPLIANCE...
General Programming Information

DATA MEMORY LOST on the [REVIEW] printout and on the patient [USE] test display and printout.

Any subsequent reviews of the neurostimulator will continue to display ??? for the neurostimulator serial number, but patient compliance data will remain accurate for the period following the POR.

Selecting Mode and Parameters

After reviewing parameters, a stimulation mode or parameter may be selected for programming as follows:

1. Press the key above the word [MODE] or one of the parameter options (e.g., [AMPL], [RATE], [PULSE WIDTH]) shown on the upper display.
   
   **Note:** The stimulation mode or parameter value options appear on the lower display and, if the printer is on, it prints a list of selection options.

2. Select continuous mode or parameter value or other selection choice by pressing the appropriate key below the lower display.

   **Notes:**
   - This keystroke registers the selection on the lower line of the upper display. The lower display shows PRESS PROGRAM KEY if a programming transmission is allowed.
   - To view additional selection options, press the key below the word [NEXT].
   - Some selections will allow several parameters to be programmed at once. For example, when programming electrode polarity, all electrodes and the case polarity can be selected before you press [PROGRAM]. In other cases, only one stimulation mode or parameter value may be programmed at a time. The newly programmed mode or parameter value remains on the upper display after a successful programming transmission.
General Programming Information

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.
   
   **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,¹ 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.

¹ Do not use Cycling Mode for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.
General Programming Information

Programming Stimulation Parameters

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

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 2).

The device’s maximum amplitude is 10.5 V, and maximum pulse width is 450 microseconds. The curved lines in Figure 2 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): 1226 ohms (range: 411-4000 ohms).
- Parkinson’s disease clinical studies (STN): 1285 ohms (range: 529-4000 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 2 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. CONSULT TECH MANUAL. PRESS CLEAR TO CONTINUE.** Programming may continue at the desired values by pressing the [CLEAR] key.

Figure 2 and Figure 3 include two examples of charge density calculated for the Activa System. In Example A in each figure, the Soletra Model 7426 Neurostimulator is set to: 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 in each figure, 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 2 and Figure 3, if the impedance in this case is at the clinical mean from either the tremor clinical study or Parkinson's disease clinical studies, the charge density would be below 30 microcoulombs/cm²/phase.
General Programming Information

**Figure 2.** Charge density with tremor clinical mean resistance.
Figure 3. Charge density with Parkinson’s disease clinical mean resistance.

Charge Imbalance Condition – For certain neurostimulator stimulation parameter settings this device can produce a CHARGE IMBALANCE CONDITION. Charge imbalance may occur when the circuit does not recover the total negative charge that is produced by the On activations. If the charge imbalance (net DC current) exceeds 1.5 µamps average current, tissue damage may occur. When programming the neurostimulator the following operating conditions should be observed to remain below the 1.5 µamps average current.
General Programming Information

- Cycling Mode. **DO NOT PROGRAM** the Solatra Model 7426 Neurostimulator or the Itrel II Neurostimulator to cycling mode for Activa Therapy. This warning **INCLUDES** the “Special Ramp Stimulation Mode.”

- SoftStart/Stop. In this feature, when the device is initially turned ON, the voltage is incremental until it reaches the patient’s programmed voltage. Each increment is considered an ON activation. When programming the neurostimulator using the SoftStart/Stop feature, refer to Table 2 for aid in programming therapy stimulation. Check the amplitude setting and the pulse width setting. The neurostimulator should **not** exceed the number of activations listed for the selected parameters. An activation occurs when the neurostimulator is turned ON and OFF by either the patient magnet or the programmer.

More than 50,000 activations in a 24-hour period would be required to generate a charge imbalance condition using typical settings for symptom suppression (frequency = 185 pps, amplitude = 3.0 V, and pulse width = 90 µsec). A patient typically turns their neurostimulator On in the morning, and Off at night; this counts as one device activation.
### Table 2. Maximum Allowable Device Activations

**Per 24-Hour Period.**

<table>
<thead>
<tr>
<th>Programmed Amplitude (volts)</th>
<th>Device Activation Per 24-Hour Period Programmed Pulse Width 60 µsec</th>
<th>Device Activation Per 24-Hour Period Programmed Pulse Width 90 µsec</th>
<th>Device Activation Per 24-Hour Period Programmed Pulse Width 120 µsec</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0-0.1</td>
<td>135,000</td>
<td>135,000</td>
<td>135,000</td>
</tr>
<tr>
<td>0.2-1.0</td>
<td>101,000</td>
<td>73,000</td>
<td>73,000</td>
</tr>
<tr>
<td>1.1-2.0</td>
<td>81,000</td>
<td>50,000</td>
<td>50,000</td>
</tr>
<tr>
<td>2.1-3.0</td>
<td>54,000</td>
<td>50,000</td>
<td>32,000</td>
</tr>
<tr>
<td>3.1-3.6</td>
<td>54,000</td>
<td>30,000</td>
<td>19,000</td>
</tr>
<tr>
<td>3.7-4.0</td>
<td>29,000</td>
<td>16,000</td>
<td>12,000</td>
</tr>
<tr>
<td>4.1-5.0</td>
<td>22,000</td>
<td>13,000</td>
<td>8,300</td>
</tr>
<tr>
<td>5.2-6.0</td>
<td>16,000</td>
<td>8,900</td>
<td>5,500</td>
</tr>
<tr>
<td>6.1-6.5</td>
<td>14,000</td>
<td>7,800</td>
<td>5,000</td>
</tr>
<tr>
<td>6.7-7.2</td>
<td>12,000</td>
<td>6,600</td>
<td>3,500</td>
</tr>
<tr>
<td>7.4-8.0</td>
<td>10,000</td>
<td>6,200</td>
<td>3,200</td>
</tr>
<tr>
<td>8.2-9.0</td>
<td>8,800</td>
<td>4,600</td>
<td>2,500</td>
</tr>
<tr>
<td>9.1-9.5</td>
<td>7,900</td>
<td>4,000</td>
<td>2,100</td>
</tr>
<tr>
<td>9.7-10.0</td>
<td>7,600</td>
<td>3,500</td>
<td>1,800</td>
</tr>
<tr>
<td>10.1-10.5</td>
<td>6,700</td>
<td>3,100</td>
<td>1,500</td>
</tr>
</tbody>
</table>
**General Programming Information**

**Table 2. Maximum Allowable Device Activations**

*Per 24-Hour Period.*

<table>
<thead>
<tr>
<th>Programmed Amplitude (volts)</th>
<th>Device Activation Per 24-Hour Period Programmed Pulse Width 150-210 µsec</th>
<th>Device Activation Per 24-Hour Period Programmed Pulse Width 270-330 µsec</th>
<th>Device Activation Per 24-Hour Period Programmed Pulse Width 400-450 µsec</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0-0.1</td>
<td>135,000</td>
<td>135,000</td>
<td>81,000</td>
</tr>
<tr>
<td>0.2-1.0</td>
<td>32,000</td>
<td>23,000</td>
<td>13,000</td>
</tr>
<tr>
<td>1.1-2.0</td>
<td>17,000</td>
<td>6,500</td>
<td>4,200</td>
</tr>
<tr>
<td>2.1-3.0</td>
<td>7,600</td>
<td>3,200</td>
<td>1,800</td>
</tr>
<tr>
<td>3.1-3.6</td>
<td>5,600</td>
<td>2,200</td>
<td>1,000</td>
</tr>
<tr>
<td>3.7-4.0</td>
<td>5,000</td>
<td>2,200</td>
<td>1,000</td>
</tr>
<tr>
<td>4.1-5.0</td>
<td>2,500</td>
<td>1,100</td>
<td>600</td>
</tr>
<tr>
<td>5.2-6.0</td>
<td>1,600</td>
<td>580</td>
<td>300</td>
</tr>
<tr>
<td>6.1-6.5</td>
<td>1,200</td>
<td>380</td>
<td>200</td>
</tr>
<tr>
<td>6.7-7.2</td>
<td>840</td>
<td>240</td>
<td>140</td>
</tr>
<tr>
<td>7.4-8.0</td>
<td>840</td>
<td>240</td>
<td>140</td>
</tr>
<tr>
<td>8.2-9.0</td>
<td>570</td>
<td>200</td>
<td>120</td>
</tr>
<tr>
<td>9.1-9.5</td>
<td>430</td>
<td>160</td>
<td>110</td>
</tr>
<tr>
<td>9.7-10.0</td>
<td>330</td>
<td>130</td>
<td>100</td>
</tr>
<tr>
<td>10.1-10.5</td>
<td>260</td>
<td>110</td>
<td>90</td>
</tr>
</tbody>
</table>

*a* An activation occurs when the neurostimulator is turned On and Off by either the patient magnet or the programmer.
General Programming Information

Charge Density Programming Procedures

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

I. 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.

II. 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.

III. To Program the Selected Setting for the Selected Parameter

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.
General Programming Information

Charge Imbalance Programming Procedures

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

I. To Program a New Mode:
   1. At the warning notification screen, press the [CLEAR] key until you reach the parameter selection screen.
   2. Select the desired mode from the upper screen.
      Note: The warning notification will appear again if the criteria for it are met by any subsequent programming attempt. If this mode is not desired, return to Step 1.
   3. Select the desired stimulation mode parameter settings from the value selection bar on the lower screen.
   4. Press the [PROGRAM] key.

II. To Program the Selected Mode:
   1. At the warning notification screen, press the [CLEAR] key.
   2. Continue programming stimulation mode parameters; when finished, press [PROGRAM].

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.
General Programming Information

Programming Electrode Polarity

When the ELECTRODE parameter is selected, the programmer displays the current electrode polarity settings and indicates whether the configuration is unipolar or bipolar.

The new electrode selection(s) are displayed on the upper display. The polarities of all electrodes and the case may be changed as often as you wish before programming. When the electrode polarities are as desired, press the [PROGRAM] key.

⚠️ Warning: Always decrease the amplitude to zero before changing electrodes to prevent possible uncomfortable patient stimulation.

To change the polarity settings:

1. Select ELECTRODE.
2. For each electrode, press the applicable key below CASE, #3, #2, #1, #0.
3. Select NEG, POS, or OFF.
4. Hold the programming head steady in position over the neurostimulator.
5. 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.

⚠️ Warning: Always decrease the amplitude to zero before changing electrode polarities. After the change, slowly increase the amplitude to avoid causing unpleasant stimulation.
General Programming Information

Programming to Nominal Settings

Nominal command parameter settings are a set of default settings for stimulation. The settings are at a low amplitude to avoid the possibility of over-stimulation. By pressing [NOMINAL] and then [PROGRAM], the mode and all parameters are automatically programmed to their nominal values (Table 4). This is useful when an immediate change to low output is required.

For deep brain stimulation, the following parameter ranges are offered as a reference for settings that provide symptom suppression in many patients. These values, however, may require adjustment to achieve optimum results.

Table 3. Average Parameters for Activa Therapy by Target

<table>
<thead>
<tr>
<th>Parameter</th>
<th>STN</th>
<th>GPI</th>
<th>Vim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude</td>
<td>2.1-3.0 V</td>
<td>2.8-3.5 V</td>
<td>2.1-3.2 V</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>60-90 µsec</td>
<td>90-150 µsec</td>
<td>60-120 µsec</td>
</tr>
<tr>
<td>Rate</td>
<td>138-158 pps</td>
<td>145-160 pps</td>
<td>144-163 pps</td>
</tr>
</tbody>
</table>

Note: The [NOMINAL] key may be pressed whenever the SELECT PARAMETER message is displayed.

Table 4. Nominal Command Parameter Settings.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitude</td>
<td>0.0 V (Model 7426 only)</td>
</tr>
<tr>
<td></td>
<td>0.5 V (Model 7424 only)</td>
</tr>
<tr>
<td>Rate</td>
<td>30 pps</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>210 µsec</td>
</tr>
<tr>
<td>Dose Time</td>
<td>OFF</td>
</tr>
<tr>
<td>Lockout Time</td>
<td>OFF</td>
</tr>
<tr>
<td>Mode</td>
<td>Continuous</td>
</tr>
</tbody>
</table>
Programming SoftStart/Stop
To program SoftStart/Stop for the continuous stimulation mode:
1. Select [MODE]
2. At the Mode Selection prompt, select [CONT]
3. At the SoftStart Selection prompt, select [YES]
4. Press the [PROGRAM] key.

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 Modulation Modes
To program stimulation modes with modulation, press the [MODULATION] key. The programmer will prompt you to select: modulation off, pulse width modulation, rate modulation, or both rate and pulse width modulation. When selecting pulse width modulation or both rate and pulse width modulation, you must also select

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output Polarity</td>
<td>Remain as selected by clinician</td>
</tr>
<tr>
<td>Neurostimulator Output</td>
<td>OFF</td>
</tr>
</tbody>
</table>
General Programming Information

whether you wish to modulate at normal pulse widths (between 150 – 300 μsec) or Wide (between 300 – 450 μsec).

If pulse width modulation is selected, [RATE] is programmable, but [PULSE WIDTH] is not, and selecting it will result in an error message. If rate modulation is selected, [PULSE WIDTH] is programmable, but [RATE] is not, and selecting it will result in an error message.

Note: Modulation Modes are typically not used for Activa Therapy.

Telemetry Bypass: Model 7426

The [TELEMETRY BYPASS] key is not available for use with the Soletra Model 7426 Neurostimulator. If this key is pressed, the following message appears: TELEMETRY BYPASS IS NOT AVAILABLE WITH THE MODEL 7426 IPG. PRESS CLEAR TO CONTINUE.

Telemetry Bypass: Model 7424

In an electrically “noisy” environment it may be difficult to establish a telemetry link with the neurostimulator. The [TELEMETRY BYPASS] key delivers programming commands to the neurostimulator, but invalid telemetry is ignored. Note that without telemetry the programmer cannot determine the neurostimulator model or the present parameters. Therefore, this feature should be only used when absolutely necessary.

When you review parameters, the values displayed are not necessarily coming directly from the neurostimulator, but may be values from the programmer memory. The POSITION HEAD indicators extinguish as soon as values from the programmer memory begin to be transmitted.

To re-enable telemetry, press the [TELEMETRY BYPASS] key again. This key alternately bypasses or enables telemetry each time it is pressed. Each time the physician programmer is turned On,
**Detailed Device Description**

Telemetry is automatically enabled. **Note:** [IPG BATT], and [IPG OUTPUT] cannot be selected when telemetry has been bypassed.

**Detailed Device Description**

The Medtronic 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 4). 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.

![Programmer keyboard and display panel.](image)

**Figure 4.** Programmer keyboard and display panel.
Detailed Device Description

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 — SELECT PARAMETER message is shown.

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. 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.
Detailed Device Description

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 or during Telemetry Bypass 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 3 2 1 0 (electrode polarity)
- DOSE
- MODULATION
- 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.

**Note:** Some parameter choices are available only for certain neurostimulator models. Use the Model 7460 MemoryMod Cartridge only with the Model 7426 or 7424 neurostimulator.
Detailed Device Description

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 — 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.

NOMINAL

Use the [NOMINAL] key in conjunction with the [PROGRAM] key to program all parameters and the stimulation mode to their nominal values (refer to Table 4 on page 36). Press [NOMINAL] first and then [PROGRAM] to send the transmission — with the programming head over the neurostimulator.

Nominal programming is intended as a safety or convenience feature. It allows you to immediately return to no output (7426) or low output (7424) parameter settings. The [NOMINAL] key may be pressed whenever the programmer is in the “home” state — SELECT PARAMETER message shown on the lower display. For a list of nominal values, refer to Table 4 on page 36.

INCREASE

To increase 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 when you press and hold the key. (Note: Amplitude programming requires that the programming head be held in position over the neurostimulator.)
Detailed Device Description

DECREASE To decrease 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 when you press and hold the key. (Note: Amplitude programming requires that the programming head be held in position over the neurostimulator.)

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.
Programmable Modes

The physician programmer offers a choice of six stimulation modes for the Model 7426 Soletra neurostimulator, each with specific waveform characteristics (Figure 5).

⚠️ Warning: Only use Continuous Mode for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.
Detailed Device Description

Figure 5. Stimulation waveform diagram.
Continuous Mode
In this mode, stimulation is continuous or unchanging. Output is determined by programmed selections of:
- Amplitude
- Pulse Width
- Rate

Cycling Mode
Do not use Cycling Mode for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.

SoftStart/Stop Option
With programmed SoftStart, the amplitude is increased gradually from zero to its selected value at the onset of stimulation. This feature is intended to increase patient comfort by providing a gentle or “soft” start as stimulation begins. The SoftStop feature causes the output to ramp gradually down to zero when the stimulation is turned off. It is recommended to use the SoftStart/Stop feature when possible to avoid any unpleasant sensation at the onset of stimulation.

SoftStart/Stop Cycling Mode
Do not use SoftStart/Stop Cycling Mode for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.
Detailed Device Description

**Modulated Modes**  The selection of Modulation increases the number of stimulation modes from three to six since it is used in conjunction with the Continuous, Cycling, and SoftStart/Stop Cycling. Either Rate or Pulse Width modulation or a combination of both can be selected cycling through a 5.5 second modulation period (Figure 6).


**Modulated Pulse Width** – Pulse width can be selected to modulate between 300 µsec and 150 µsec (Normal) or 450 µsec (Wide). Pulse width decreases from the top value of the range to the bottom in six equal increments and then increases again to the top value in six equal increments. Rate and Amplitude are fully adjustable.

**Modulated Rate** – Pulse rate increases from 30 pps to 85 pps in twelve equal increments, and then returns to 30 pps in twelve equal increments. Pulse width and amplitude are fully adjustable.

**Combination Modulation** – Combination modulation consists of alternating modulated pulse width and modulated rate so that one parameter is always decreasing while the other is increasing and vice versa. Amplitude is fully adjustable.
Measurement Functions

In addition to mode and parameter programming described above, the Physician Programmer with the Model 7460 Soletra MemoryMod Software Cartridge has a number of additional functions for programming the Model 7426 Soletra or Model 7424 Itrel II neurostimulator.

Because of specific parameter interactions, some of the parameters available for programming may change. Only those parameters and values that can be selected for programming are displayed.

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.

Figure 6. Modulation mode waveforms.
Detailed Device Description

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:

- Tremor clinical studies (Vim): 1348 ohms (range: 610-2000 ohms)
- Parkinson’s disease clinical studies (all targets): 1226 ohms (range: 411-4000 ohms)
- Parkinson’s disease clinical studies (GPI): 1079 ohms (range: 411-3300 ohms)
- Parkinson’s disease clinical studies (STN): 1285 ohms (range: 529-4000 ohms)

Troubleshooting High Impedance Measurements – An impedance value over 2000 ohms (the maximum value for the Soletra neurostimulator) 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:

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.
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 10 uamps, then an x-ray should be obtained to verify a possible lead fracture.

**Troubleshooting Low Impedance Measurements** – An impedance value of less than 250 ohms may indicate a shorted lead wire. If a patient is receiving no therapeutic benefit from stimulation, and impedance measures less than 250 ohms, follow this procedure to help localize the potential problem:

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

Impedance values within the clinical ranges found above should indicate a viable electrode configuration. A value less than 250 ohms for one configuration may indicate a problem. The electrode polarity should then be reprogrammed with the suspect electrodes off.
Detailed Device Description

Using the programmer to check load impedance – Load impedance is checked by selecting the key above [IPG OUTPUT] on the upper display and then selecting [IMP] on the lower display. For maximum accuracy, load impedance should be measured only after the neurostimulator has been programmed to the following parameters: amplitude = 1.0 volt, pulse width = 210 µsec, rate = 30 pps. Accuracy of load impedance at other parameter values may vary significantly, particularly at voltage multiplier points (3.7 volts and 7.4 volts) where multiplier circuits are used to obtain higher output amplitude. The neurostimulator can be turned off for this measurement before setting these parameters.

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

Patient Compliance Data

Patient compliance data cannot be checked when telemetry has been bypassed. Patient compliance 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 patient activations, that is, the number of times the neurostimulator was turned on by the magnet, is also counted and reported.

Patient compliance data are updated by the neurostimulator in increments of 68 minutes for total stimulating time and 160 minutes for elapsed time. Patient use, therefore, is not displayed until at least 68 minutes (neurostimulator output on time) after the counters have been reset.
Reviewing Neurostimulator Battery Status

To check the battery status:
Press [IPG BATT] and [REVIEW]. The results of the test will be displayed and the status will register in the window below the words [IPG BATT]. To return to parameter, press [CLEAR].

In addition to neurostimulator battery status, you can determine the telemetry readout of the battery voltage level (in volts) and battery current drain can be obtained using the Physician Programmer measurement function. The value obtained for battery voltage level relates to battery status indicators as follows:

<table>
<thead>
<tr>
<th>Battery Voltage Levela</th>
<th>Battery Status Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;3.3 volts</td>
<td>OK</td>
</tr>
<tr>
<td>3.1 to 3.3 volts</td>
<td>Low</td>
</tr>
<tr>
<td>&lt;3.1 volts</td>
<td>EOL (End-of-Life)</td>
</tr>
</tbody>
</table>

a Battery voltage level measurements are accurate to ±5%.

The battery current drain measurement is included to provide additional information. This measurement can be used as a relative indication of the energy being drawn from the neurostimulator battery with different parameter and electrode polarity combinations, but it cannot be used to predict actual battery longevity for any given patient.

Refer to the appropriate neurostimulator manual for information on maximizing neurostimulator battery longevity.

A Note on Measurement Functions

Any measurement function, IPG Battery Status (voltage and current drain) or Load Impedance, is accomplished by a series of telemetry exchanges between the neurostimulator and Model 7432 programmer. Therefore, the battery status and load impedance
measurements cannot be performed when telemetry has been bypassed.

Rate, IPG Output, Mode, Dose and Lockout are reprogrammed during the measurement functions. Following the measurement, if the original values are not restored because of a telemetry error, the message IPG VALUES MAY HAVE CHANGED, PRESS REVIEW AND VERIFY VALUES is displayed.

If the measurement is successfully completed, the message MEASUREMENT COMPLETE appears on the lower display. Only measurements that are successfully completed with the display of MEASUREMENT COMPLETE are valid. Measurements should be repeated if the MEASUREMENT COMPLETE message is not displayed.

Special Functions

Dose and Dose Lockout

At times, you may wish to restrict a particular patient's use of the neurostimulator. To do this, program a dose of stimulation and a time of dosage lockout — a time when the patient cannot turn the neurostimulator output on. To program the dose and lockout, press the key above the word [DOSE] on the upper display. Select [DOSE] or [LOCK] on the lower display and the desired times for each. Then press [PROGRAM]. Repeat the process to program the lockout time.

During dose lockout, the amplitude cannot be programmed with patient feedback. The programmer warns that neurostimulator output is off when [AMPLITUDE] is selected. The amplitude must either be deliberately programmed without feedback (press [PROGRAM]) or program the lockout time to zero, turn the neurostimulator output on and proceed with amplitude programming.
Special Ramp Stimulation

Special Ramp Stimulation is a variation of the Cycling mode with SoftStart/Stop. Do not program Special Ramp Stimulation for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.

Special Functions: Model 7424 Only

Telemetry Bypass

To program the neurostimulator when there is too much interference for telemetry, you can first set the programming head [GAIN] control at its lowest setting (L). If this is not successful, you can use the [TELEMETRY BYPASS] key. Without telemetry, however, the physician programmer cannot determine the neurostimulator model or the current parameters. Therefore, this feature should be only used when absolutely necessary.

The programmer will prompt the selection of the neurostimulator model and review parameters before continuing. Question marks (?????) appear in the parameter locations on the upper display until they have been programmed during the session. When you use telemetry bypass, be sure to program all the desired parameters. Some parameter interactions can cause zero values to be programmed where a non-zero value had previously been programmed.

An asterisk (*) appears in the lower right corner of the upper display to indicate that telemetry has been bypassed. When the printer is ON, the * alternates with the P in that location. To return to normal operation (telemetry enabled), press the [TELEMETRY BYPASS] key again, or use the [ON/OFF] key to turn the programmer OFF then back ON.

Magnet-Controlled Amplitude

Mag Amp, or Magnet-Controlled Amplitude, is a lower amplitude setting than that programmed using the [AMPLITUDE] parameter key. Mag Amp is designed to allow the patient to lower the stimulating
Detailed Device Description

amplitude as desired without a programmer. Once Mag Amp has been established, the patient can switch the neurostimulator Amplitude from normal to Mag Amp using the control magnet. The amplitude value is displayed underlined when Mag Amp is in effect. If the amplitude value is not underlined, then normal Amplitude is in effect. To program Mag Amp, set the neurostimulator into magnet mode (6 second application of magnet) and select [SPECIAL] on the upper display. Then select [MAG AMP] and the desired amplitude setting. The only parameter selection options available are those amplitudes less than or equal to the currently programmed normal amplitude. If Mag Amp is in effect, press [SPECIAL] and select [MAG AMP] to determine the normal programmed amplitude value.

⚠️ Caution: For Activa Therapy, always program Mag Amp, or Magnet-Controlled Amplitude, to the same value as the normal amplitude setting. If no Mag Amp value is programmed, the amplitude will decrease to zero when Mag Amp is activated.
Specifications

Table 5. Model 7426 Soletra and Model 7424 Itrel II Neurostimulator
Programmable Parameter Values.

<table>
<thead>
<tr>
<th>Programmable Parameters</th>
<th>Values&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Amplitude (Peak Voltage)</td>
<td>0 to 10.5 volts (Magnet-controlled Low Amplitude--Model 7424 Only)</td>
</tr>
<tr>
<td>Rate</td>
<td>2, 5, 10, 15, 20, 25, 30, 33, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 130, 135, 145, 160, 170, 185 pps</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>60, 90, 120, 150, 180, 210, 270, 330, 400, 450 µsec</td>
</tr>
<tr>
<td>Cycle ON Time</td>
<td>0.1 second to 24 hours</td>
</tr>
<tr>
<td>Cycle OFF Time</td>
<td>0.1 second to 24 hours</td>
</tr>
<tr>
<td>Cycle ON Time w/SoftStart</td>
<td>15 seconds to 24 hours</td>
</tr>
<tr>
<td>Cycle OFF Time w/SoftStart</td>
<td>15 seconds to 24 hours</td>
</tr>
<tr>
<td>Ramp</td>
<td>Allows selection of 15, 20, 25, or 30 seconds ramp increasing gradually from zero to the selected amplitude</td>
</tr>
<tr>
<td>Dose Time</td>
<td>15, 30, 45, 60, or 75 minute stimulation periods</td>
</tr>
<tr>
<td>Dose Lockout Time</td>
<td>1.0, 1.5, 2.0, 2.5, 3.0, 3.5, or 4.0 hours</td>
</tr>
</tbody>
</table>

<sup>a</sup> All values are nominal.

⚠️ Warning: Do not use these parameters for Activa Therapy. Refer to “Programming Stimulation Parameters” on page 26 for further information.
Physician Training Information

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 7).
   a. If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
   b. If one gate is present, they should walk as far away as possible from it.
   
   **Note:** Some theft detectors may not be visible.

3. Proceed through the security device. Do not linger near the device.
Patient Counseling Information

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.

Figure 7. Approaching security gates.
How Supplied

Package Contents
- One Model 7460 MemoryMod Software Cartridge
- One Software Applications Manual
Appendix: MRI and Activa Therapy

Appendix: MRI and Activa Therapy

Activa Therapy Clinical Experience

Due to the variability of clinical MRI systems, the safety of patients or the functioning of devices exposed to MRI systems cannot be unequivocally ensured. However, 39 patients in the Medtronic-sponsored clinical study with an implanted Activa System have safely undergone 1.5 Tesla MRI procedures. These patients were implanted with the Itrel II Model 7424 Neurostimulator, the Model 7495 Extension, and the Model 3387/3389 DBS Lead. For comparison purposes, the Activa System comprising the Soletra Model 7426 Neurostimulator, the 7495/7482 Extension, and the 3387/89 DBS lead is expected to have similar outcomes.

- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.
- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.

To validate the in-vitro information regarding safety and efficacy, patient medical records were reviewed at four North American centers that participated in the Medtronic-sponsored clinical investigations of Activa therapies. These centers had 39 patients who underwent a total of 55 MRI procedures with implanted components of the Activa System. At least one neurostimulator was in place for 27 of these procedures.

The MRI procedures were used to verify lead implant within the target (40 procedures); to assess other medical conditions (7 procedures); to localize the brain target contralateral to an implanted lead or to replace a lead (8 procedures). There were no reported adverse events associated with MRI procedures used in conjunction with the implanted Activa lead, regardless of implantation of extensions and neurostimulators.
Appendix: MRI and Activa Therapy

Risks of MRI and Activa Therapy Safety Results

The potential risks of performing MRI on patients with implanted neurostimulation systems and the specific safety information related to the Activa System include:

- Magnetic field interactions and mechanical forces
- Heating effects around the neurostimulator or lead electrodes from Electromagnetic Interference (EMI)
- Inadvertent reed switch activation from magnetic fields
- Neurostimulator damage
- Image distortion and artifacts

Magnetic Field Interactions and Mechanical Forces

Potential Risk: The neurostimulator may experience mechanical forces within or near the static magnetic field of the MRI system due to small amounts of magnetic material contained in the neurostimulator. This may cause the neurostimulator to move within the implant pocket and/or may place mechanical stress on tissues and/or the lead. Compromised tissues (such as recently sutured tissue) may be susceptible to further injury from these forces. Patients may feel a tugging sensation at the site of the neurostimulator implant.

Summary of Test Results: Implanted leads and extensions should not experience magnetic field related mechanical forces since they are made from nonmagnetic material. Based on MRI safety testing conducted using an MRI system with a static magnetic field of 1.5 Tesla, patient-equivalent phantoms and various device configurations, the magnetic forces acting on the Activa neurostimulator are less than the force of gravity.
Appendix: MRI and Activa Therapy

Heating Effects

Potential Risk: As with many biomedical implants (e.g. joint replacements, spinal fixation rods, etc.), heating associated with MRI may occur in the Activa System. Tissue damage is a risk because of the potential for temperature rise in the system.

Summary of Test Results: To date, no clinically significant heating has been reported in patients with Activa Systems in the Medtronic-sponsored clinical investigations. Clinically significant heating of up to 15°C was observed in a patient-equivalent phantom during testing in a 1.5 Tesla MRI. To minimize heating the recommendations in “MRI Operation/Settings” on page 66 must be followed.

Inadvertent Reed Switch Activation/Electromagnetic Interference (EMI)

Potential Risk: The magnetic fields of the MRI may activate the magnetic reed switch within the neurostimulator. This may cause the neurostimulator to switch between ON and OFF (in addition, the Model 7424 Itrel II Neurostimulator may also switch between normal and Mag Amp modes). The MRI gradient and/or RF fields could cause extraneous electrical current to be induced through the lead/extension that the patient may feel.

Summary of Test Results: MRI testing using a 1.5 Tesla MRI System and a patient-equivalent phantom show that the neurostimulator reed switch may be activated by the MRI resulting in on/off switching of the neurostimulator (or also for Itrel II, changing between Normal and Mag Amp modes). In the Medtronic-sponsored clinical trial, there were no reports of shocking or jolting resulting from induced voltages on the lead system.

Neurostimulator Damage

Potential Risk: Induced voltages on the lead/extension system could damage the electronic circuitry and result in a nonfunctioning neurostimulator, requiring replacement. Induced voltages could also cause the neurostimulator to lose its programmed parameter values,
Appendix: MRI and Activa Therapy

which would require subsequent reprogramming. In addition, the neurostimulator could lose its serial number, which cannot be reprogrammed by the physician programmer but does not affect therapeutic use of the neurostimulator.

Summary of Test Results: Medtronic-sponsored in-vitro testing using a 1.5 Tesla MRI system (GE Signa 1.5T) did not result in damage or reprogramming to the Activa neurostimulator or associated leads and extensions.

Image Distortion and Artifacts
Potential Risk: The neurostimulator and lead/extension may distort the MRI image or cause artifacts that may block viewing of tissue located near them.

Summary of Test Results: MRI testing using a 1.5 Tesla MRI System and a patient-equivalent phantom show that there may be substantial image distortion or artifacts near the DBS lead system and neurostimulator. Proper selection of various imaging parameters, while not exceeding the recommendations in “MRI Operation/Settings” on page 66, will help reduce image distortion or artifacts.

MRI Guidelines

Pre-MRI Preparation
- Because of the need to change the operating parameters for the Activa System, an appropriate health care professional with access to a Medtronic neurological physician programmer should assist and prepare the patient with this device for the MRI procedure.
- If the neurostimulator has already been implanted, record the patient’s current therapeutic settings, set the neurostimulator amplitude to 0 volts (normal and magnet amplitude for the Model 7424 neurostimulator) and turn the neurostimulator output to OFF.
Appendix: MRI and Activa Therapy

- Disconnect all external leads (screening cables) from any percutaneous extensions. Any parts of the percutaneous extensions that exit the body should be wrapped in a thermally and electrically insulating material of approximately 0.5-inch thickness or greater. These coils/leads should be kept out of contact with the patient’s skin to avoid the risk of thermal burns from RF energy.
- Instruct the patient to alert the MRI system operator of any problems (heating, shocks, etc.) so the operator can terminate the MRI procedure if needed.

⚠️ **Caution:** An MRI procedure should not be performed in a patient with an Activa System that has a broken lead wire because tissue damage may result from localized heating at the break. If a broken lead wire is suspected, lead impedance should be checked on all electrodes in unipolar mode. If any electrode impedance is > 2000 ohms and battery current is <10 µA, then an x-ray should be obtained prior to an MRI to verify the presence of a broken wire.

**Implant Recommendations**

- Implant the minimum length lead and extension possible to minimize induced RF voltage in the lead system.
- Avoid, if possible, implanting the neurostimulator in the abdomen. This requires the use of longer length leads/extensions that can increase the amplitude intensity of the induced RF voltage on the lead system.

**MRI Operation/Settings**

- Use only MRI systems operating at a static magnetic field strength of 1.5 Tesla.
- Use only a transmit and receive type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields. Do not use a whole body RF coil.
Appendix: MRI and Activa Therapy

- Select imaging parameters to perform MRI at a specific absorption rate (SAR) that does not exceed 0.4 W/kg in the head.
- Carefully perform continuous verbal and visual monitoring of the patient throughout the MRI procedure.
- Discontinue the MRI if the patient experiences any pain or discomfort, or if you observe heating or other problems with the implanted components.

Post-MRI Recommendations Operation/Settings

- Verify the neurostimulator is functional.
- Reprogram the stimulation parameters to pre-MRI values.
Glossary

Glossary

Amplitude – A measure of the electrical intensity delivered in a stimulating pulse, measured in volts. Low Amplitude is the same as Magnet-Controlled Amplitude or Mag Amp.

Dose – A single cycle of stimulation (15, 30, 45, 60, or 75 minutes), which is initiated by a brief application of the magnet (or by the On command from patient or physician programmer).

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

Mode – The condition of stimulation delivery, with or without rate and/or pulse width modulation. Stimulation can be delivered with or without a SoftStart ramp at onset and SoftStop ramp at the end of stimulation.

Modulation – Automatic cyclic changing of rate and/or pulse width to provide a constantly changing stimulation sensation.

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.
Glossary

**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.

**Voltage Multiplier Points** – In order to provide amplitudes greater than the 3.7-volt battery output, voltage multiplier circuits are used at strategic intervals called Voltage Multiplier Points (3.7 volts and 7.4 volts).