TEST STIMULATOR

Test Stimulator for Deep Brain Stimulation

Operator Manual

Rx only
Test Stimulator
Operator Manual

Model 3625
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Overview of Manual

The Medtronic Model 3625 Test Stimulator is used with the Activa System for deep brain stimulation. The test stimulator helps determine whether a particular patient can benefit from stimulation and should receive an implanted neurostimulator.

This operator’s manual describes the Model 3625 Test Stimulator’s controls, features, and cable connections and provides detailed instructions for using the Model 3625. The manual contains the following sections:

- Introduction
- Test Stimulator Description
- Test Stimulator Instructions for Use
- Patient Counseling Information
- Troubleshooting Guidelines
- Care and Service
- Specifications
- Package Contents
- Appendix: Interoperative Testing, Patient Counseling Information
Introduction

Description
The Medtronic Model 3625 Test Stimulator (Figure 1) is designed to provide output characteristics similar to Medtronic Neurological Stimulation Systems (amplitude, pulse width, and rate). This enables you to evaluate the efficacy of neurostimulation for your patient, particularly in relation to lead position, during intraoperative testing.

Figure 1. Model 3625 Test Stimulator.
The test stimulator kit is used with a lead implant kit to provide intraoperative and interoperative (if necessary) test stimulation. Each lead kit contains the applicable screening cable(s) for connecting the lead to the Model 3625 Test Stimulator. There are no cables in the test stimulator kit. When the test stimulator is used intraoperatively, the alligator clip screening cable is typically used; it connects directly to the implanted lead. If conducting interoperative testing, the twist-lock screening cable is used; it connects to the percutaneous extension that is included in the lead kit.

**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 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 the MRI guidelines manual packaged with this product for comprehensive safety information and instructions.

- Patients for whom test stimulation is unsuccessful.

- Patients who are unable to properly operate the brain stimulator.
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: Test Stimulation – A survey of literature regarding electrical stimulation of nervous tissue suggests that potential neural damage may occur above 30 microcoulombs/cm²/phase. The 3625 Test Stimulator, when used with a DBS lead, is capable of producing charge densities in excess of 30 microcoulombs/cm²/phase. For information on charge densities for the implanted deep brain stimulation system, refer to “Programming Stimulation Parameters” on page 58.

Avoid Excessive Stimulation: Implanted Components – 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 (Model 7426 and Model 7424 neurostimulators) described in “Programming Stimulation Parameters” on page 58. 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.
Warnings

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” in the Model 3387/3389 Lead manual 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 the MRI guidelines manual packaged with this product for comprehensive safety information and instructions.
Test Stimulation Warnings

Amplitude Adjustment – The voltage applied to the lead during test stimulation may cause uncomfortable stimulation. Higher amplitude levels have been described by some patients as “jolting” or “shocking.”

Cables – Always disconnect the test stimulator from the patient before checking test stimulator output.

External Amplitude Control – Always turn the A–amplitude OFF before selecting electrodes, changing polarities or Internal Controls, connecting or disconnecting the screening cable, or changing alligator clip connections.

Internal Controls – If testing interoperatorically, advise your patient not to attempt to change or adjust any of the Internal Controls. Explain that any changes he/she makes can cause uncomfortable levels of stimulation.

Precautions

Physician Training

Implanting Physicians – Implanting physicians should be experienced in stereotactic and functional neurosurgery. Refer to “Physician Training Information” in the Model 3387/3389 Lead manual for more 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.

Storage and Sterilization

Resterilization Considerations – For information on the resterilization of the system components, refer to the “Resterilization” section in the appropriate technical manual.
Precautions

Storage Temperature – Store the DBS Lead between -30° F (-34° C) and 135° F (57° C). Temperatures outside this range can damage components. Store the test stimulator kit between -40° F (-40° C) and 149° F (65° C).

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 Subthalmic 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 will return to his/her preoperative state 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.
Precautions

Magnet-Controlled Amplitude (Model 7424 Itrel II Neurostimulator\(^1\) 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.

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.

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

- Bilateral VIM stimulation
- Patients with neurological disease origins other than idiopathic Parkinson’s disease or Essential Tremor
- 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

\(^1\) The Itrel II Neurostimulator is used for Tremor Control Therapy only.
Precautions

Implantation/Explantation

**Body Fluids** – Do not resterilize any system component after exposure to body fluids.

**Component Disposal** – If explanting an Activa System component, please remember the following guidelines:
- Do not incinerate or cremate the neurostimulator; explosion can result if a neurostimulator is subjected to incineration or cremation temperatures.
- Return all explanted components to Medtronic for analysis and safe disposal.

**Connections** – Before connecting the lead/percutaneous extension to the screening cable, wipe off any body fluids from the lead/percutaneous extension connector contacts and screening cable contacts. Contamination of connections can affect stimulation.

**Connector Block Setscrews** – Limit counter-clockwise rotations of neurostimulator setscrews. Rotate enough to provide an unobstructed pathway for the extension connector pins. Too many counter-clockwise rotations may disengage the setscrew from the connector block.

**Etched Identification** – Place the neurostimulator away from bony structures and with the etched identification side facing outward, away from muscle tissue to minimize pain at the neurostimulator site. This also helps to minimize the possibility of skeletal muscle stimulation, which may be perceived by the patient as twitching or burning.

**Excess Extension Wire** – Do not place any excess extension wire on top of the neurostimulator’s front side (printed side). Wrap any excess extension wire around the perimeter (Figure 2 and Figure 3). This avoids any increase in subcutaneous pocket depth, helps minimize potential damage during neurostimulator replacement surgery, and helps minimize potential kinking of the extension wire.
Precautions

Figure 2. Wrap excess wire around the perimeter of the Kinetra Model 7428 Neurostimulator.

Figure 3. Wrap excess wire around the perimeter of the Soletra Model 7426 or Itrel II Model 7424 Neurostimulator.
Precautions

Handling Components – Handle the implanted components of this system with extreme care. These components may be nicked, cut, or damaged by excessive traction or sharp instruments and may require surgical replacement.

- Do not bend, kink, or stretch the lead body whether or not the stylet is in place. Do not bend or kink the tungsten stylet.
- Do not tie a suture directly to the extension or the lead body. Use the burr hole cap and ring provided by Medtronic to secure the lead in place.
- When handling the lead with forceps, use only a rubber-tipped bayonet forceps.

Handling the Test Stimulator – The Model 3625 has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. Precautions should be taken to avoid damage to the unit, including, but not limited to, those listed in this section.

- Do not drop the unit or mishandle it in a way that might physically damage the device.
- Do not submerge the unit in water or any other liquid.

Hex Wrench – Do not overtighten setscrews when using the hex wrench. Excessive torque on setscrews may damage lead contacts. Verify that the sealing grommet has closed on the neurostimulator.

Implant Considerations – Do not implant a component of the system when:

- The storage package has been pierced or altered; or if the component shows signs of damage; or
- The “Use By” date has expired, because this can adversely affect storage package sterility.

Multiple Implants – The long-term safety associated with leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.
Precautions

Percutaneous Extension Setscrew Connector – If resistance is still felt when removing lead from the percutaneous extension setscrew connector, loosen the setscrews slightly to ensure that they clear the lead contacts. Avoid disengaging the setscrews. Inspect the lead contacts for damage (flattening or stretching of the lead) if resistance was felt prior to removal.

Percutaneous Extension Severing – When severing the percutaneous extension, use gentle traction on the extension to avoid dislodging the lead.

Percutaneous Extension Suture Removal – Do not cut near the lead when removing sutures from the percutaneous extension. Cutting the lead’s insulation can result in loss of stimulation and the lead’s failure.

Sutures – Do not draw the suture too tightly because damage may occur to the connector boot or to the extension or the lead.

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.
Precautions

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.
Precautions

- 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 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.
Precautions

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 4 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.
Test Stimulator Description

This section provides an overview of the Model 3625 Test Stimulator. The test stimulator provides two sets of controls—the Internal Controls and External Controls.

- The Internal Controls allow you to select the desired channel configuration, lead electrode polarities, and stimulation values for the test stimulation or trial screening.
- The External Controls allow you to adjust the stimulation values within the limits you set.

This section provides the following information:

- Internal Controls
- External Controls
- Cable Connections
- Attachment Clip

Internal Controls

There are two removable covers on the back of the test stimulator. The Internal Controls are under the top cover and the battery is under the bottom cover (Figure 4). The Internal Controls include:

- Amplitude Limit (AMP LIMIT) control
- Pulse Width control
- Rate and Pulse Width Select switch (for range selection)
- Electrode Select switches
Amplitude Limit (AMP LIMIT) Control

The Amplitude Limit (AMP LIMIT) control (Figure 5) allows you to limit the maximum output voltage that can be used with the external A–Amplitude control. For example, if AMP LIMIT is set at the maximum of 10 V, an external A–Amplitude setting of 10 will result in an actual output of 10 V (a 1:1 ratio). If AMP LIMIT is set at 5 V, an external A–Amplitude setting of 10 will result in an actual output of only 5 V (a 1:2 ratio). Refer to “Intraoperative Stimulation Test” on page 43 for the suggested starting parameters.
Test Stimulator Description

Figure 5. Amplitude Limit (AMP LIMIT) control. When AMP LIMIT is at the maximum setting, the external Amplitude will be accurate to within ± 0.5 V. The amplitude of the test stimulator closely correlates to the amplitude of the implantable stimulation system when the pulse widths of both devices are at the same setting.
Test Stimulator Description

Pulse Width Control
The PULSE WIDTH (PW) control allows you to select the desired pulse width (Figure 6). The dial is color coded to correspond with the RATE AND PULSE WIDTH SELECT switch and with the external R–Rate control on top of the test stimulator.

![Figure 6. 50–450 µsec pulse width range.](image)

Rate and Pulse Width Select Switch
The RATE AND PULSE WIDTH SELECT switch (Figure 7) allows you to choose between two rate and pulse width ranges, labeled A and B. The switch is color coded to correspond with the PULSE WIDTH control in the Internal Controls area and the external R–Rate control on top of the test stimulator.

While each patient requires a different set of stimulation parameters, the majority of deep brain stimulation patients will utilize the high frequency parameters available when the switch is in position B.
Test Stimulator Description

Figure 7. Rate and Pulse Width Select switch.

When the switch is in position A (Low Rate, High Pulse Width):

- Rate = 5–120 pulses per second (pps)
- PW = 50–1000 microseconds (µsec)

When the switch is in position B (High Rate, Low Pulse Width):

- Rate = 60–1400 pps
- PW = 50–250 µsec
Test Stimulator Description

Refer to Table 1 for typical parameter ranges by brain target.

<table>
<thead>
<tr>
<th></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>

Electrode Select Switches

The ELECTRODE SELECT switches (Figure 8) function when the appropriate screening cable is connected to the test stimulator. When a switch is in the up position, the electrode is programmed positive (+). When a switch is in the middle position, the electrode is OFF. And when a switch is in the down position, the electrode is programmed negative (−). At least one electrode must be programmed positive and one electrode negative to allow stimulation.

Caution: If using the alligator clip screening cable, the switches on the 3625 Test Stimulator corresponding to electrodes 0 and 3 must be manually set to establish a circuit. One switch must be positive and the other switch negative. If the 0 and 3 electrode switches are not set accordingly, no stimulation will result.
Test Stimulator Description

Twist-Lock Screening Cable – The twist-lock screening cable is quadripolar. When connected to the Model 3625 Test Stimulator, all four electrode switches are active. For more information on the differences between these cables, refer to “Cable Connections” on page 32.

Warning: The external A–Amplitude control should be turned OFF prior to changing electrode settings.

External Controls
Two External Controls are located on the top of the test stimulator case (Figure 9).

Amplitude Control (A)
The control labeled A–Amplitude functions as an ON/OFF switch and output voltage control. It allows you to adjust the intensity of stimulation, within preset limits, to achieve optimum results.
Test Stimulator Description

Rate Control (R)
The control labeled R–Rate allows you to vary the stimulating frequency in one of two selected ranges. The first range is from 5 to 120 pulses per second. The second range is from 60 to 1400 pulses per second.

⚠️ Warning: The A–Amplitude control must be turned OFF when electrodes are selected, polarities are changed, Internal Controls are changed, or the screening cable is being connected or disconnected.

Figure 9. External Controls.
The top of the test stimulator also has two lights that blink when the power is on (green light labeled ON) or when the battery is low (yellow light labeled BAT).
Test Stimulator Description

Cable Connections

There is one cable receptacle on the Model 3625 Test Stimulator. It is keyed so that the applicable screening cable correctly connects to it. There are two types of screening cables used with the test stimulator: the alligator clip connector screening cable (Figure 10) and the twist-lock connector screening cable (Figure 11).

The cable connections are made by first attaching the screening cable to the lead or percutaneous extension. Then, with the test stimulator OFF, the plug end of the cable is connected to the test stimulator—it is designed so that it will only fit one way into the receptacle jack. The ELECTRODE SELECT switches control the test stimulator's output polarity to the receptacle.

Refer to the applicable lead implant manual for detailed instructions on connecting the screening cable to the Model 3387 or the Model 3389 DBS Lead.

Warnings:

- Keep the lead stationary while connecting or disconnecting the alligator clip screening cable. Movement may cause lead dislodgement.
- Always turn the A–Amplitude OFF before connecting cables or making changes to the electrodes.
Test Stimulator Description

Figure 10. Typical alligator clip screening cable connection to test stimulator.

Warnings:

- Keep the lead or percutaneous extension stationary while connecting or disconnecting the twist-lock screening cable. Movement may cause lead dislodgement.

- Always turn the A–Amplitude OFF before connecting cables or making changes to the electrodes.
Test Stimulator Description

Attachment Clip

This section provides the following test stimulator attachment clip information:

- Attaching the Clip
- Locking the Clip
- Removing the Clip

An attachment clip is provided for the Model 3625 Test Stimulator. The clip can be attached to the test stimulator in either a rotating or locked position.

- The position of the clip can be adjusted when the clip is in the rotating position. When the clip is in this position it is easy to remove from the test stimulator.

Figure 11. Typical twist-lock screening cable connection to test stimulator.
Test Stimulator Description

- The locked position allows you to secure the clip in the desired position and also prevents the test stimulator from easily detaching from the clip. Removal of a locked clip may require moderate force.

The attachment clip has two mounting holes on each attachment arm: one is used to attach the clip in the rotating position and the other is used for the locked position (Figure 12).

Figure 12. Attachment clip and mounting holes.
Test Stimulator Description

Attaching the Clip

1. Position the clip as in Figure 13.

![Figure 13. Position the clip.](image)

2. Slide the edges of the clip attachment arms over the small pins protruding from each side of the top of the test stimulator. Note that the clip can be attached or removed only when it is in the position shown in Figure 13.

3. Rotate the clip to the desired position (Figure 14).
Locking the Clip

1. Position the clip in the down or the up position (Figure 15).

2. Hold the test stimulator and attachment clip with both hands so that thumbs are pressed against the base of each attachment arm (Figure 15a).

3. Using the thumb and index finger of left hand, press left attachment arm and test stimulator together until the left test stimulator pin snaps from the first mounting hole into the second mounting hole (Figure 15b).

4. Repeat steps 2 and 3 to secure the right attachment arm.

Note: Do not try to rotate the clip when in the locked position; this can damage the clip or test stimulator.

Figure 14. Rotate the clip as desired.
Figure 15. Lock the clip into the “down” position.

Removing the Attachment Clip from the Locked Position

1. Hold the test stimulator and attached clip with both hands.
2. Place the right index finger over the center of the clip to hold it stable.
3. Place the left thumb on the inside of the left attachment arm, wedged between the arm and the test stimulator.
4. Press outward, prying the attachment arm off the test stimulator pin, so that the left pin is in the first (rotating) mounting hole on the attachment arm.
5. Repeat steps 1 through 4 for the right attachment arm. The attachment clip should be in the rotating position.
Test Stimulator Description

Removing the Attachment Clip from the Rotating Position
1. Rotate the attachment clip to the position shown in Figure 16.
2. Pull the clip away from the test stimulator (Figure 16).

Figure 16. Pull the clip away from the test stimulator.
Test Stimulator Instructions for Use

Test Stimulator Instructions for Use

This section provides the following test stimulator operation instructions:

- Replace Battery
- Remove Internal Controls Cover
- Set Internal Controls
- Set External Controls
- Connect Cable and Test Stimulate

⚠️ Warning: Always turn the A-Amplitude OFF before connecting the implanted lead or the percutaneous extension to the test stimulator.

>Note: Before using the test stimulator, it is recommended that you replace the 9-volt battery with a fresh one if you have not very recently done so.
Replace Battery

1. Remove the battery compartment cover from the back of the test stimulator by lifting at the tab at the left side of the cover (Figure 17).

![Figure 17. Remove battery cover.](image)

2. Place a fresh battery into the battery compartment. Match the positive and negative poles of the battery with the positive (+) and negative (−) markings on the test stimulator (Figure 18).
3. Replace the battery compartment cover by lining up the two hinges with the holes in the test stimulator (Figure 19). Press down on the cover to close it.
Remove Internal Controls Cover

Remove the Internal Controls cover from the back of the test stimulator by lifting the tab at the left side of the cover (Figure 20).

![Figure 20. Remove internal controls cover.](image)

Intraoperative Stimulation Test

To ensure patient eligibility for the Activa Therapy, verify that the screening parameters using the Model 3625 Test Stimulator are within the parameter range available with the neurostimulator. Refer to the appropriate neurostimulator manual.

This section outlines the intraoperative stimulation test that helps confirm the desired lead position for optimum symptom suppression and minimization of side effects. This test requires the following components:

- A Model 3625 Test Stimulator and
- An alligator clip or twist-lock screening cable (provided with the lead).

**Note:** A spare 9V battery is recommended.
Test Stimulator Instructions for Use

The procedures outlined in this section provide instructions for test stimulation with the alligator clip or twist-lock screening cable and the Model 3625 Test Stimulator.

To ensure patient eligibility for Activa Therapy, verify that the screening parameters using the Model 3625 Test Stimulator are within the parameter range available with these neurostimulators: Kinetra Model 7428, Soletra Model 7426, or Itrel II Model 7424. Refer to Table 2 and Table 3.

Table 2. Programmable Stimulation Parameter Values for Model 7428.

<table>
<thead>
<tr>
<th>Programmable Parameters&lt;sup&gt;a,b&lt;/sup&gt;</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Amplitude</td>
<td>Normal Resolution: 0 to 10.5 V</td>
</tr>
<tr>
<td></td>
<td>Fine Resolution: 0 to 6.35 V</td>
</tr>
<tr>
<td>Rate</td>
<td>66 values from 3 to 250</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>60, 90, 120, 150, 180, 210, 240, 270, 300, 330,</td>
</tr>
<tr>
<td></td>
<td>360, 390, 420, 450 µsec</td>
</tr>
</tbody>
</table>

<sup>a</sup> Certain combinations of amplitude, pulse width, and rate are not allowed. See the Kinetra Model 7428 neurostimulator manual for programming limits.

<sup>b</sup> Pulse amplitude and pulse width are independently programmable for Programs 1 and 2; the same value for rate is programmed for both Programs 1 and 2.

**Note:** High amplitude/pulse width combinations can result in excessive charge density. Refer to "Programming Stimulation Parameters" on page 58 for more information.
Table 3. Programmable Stimulation Parameter Values for Model 7426 and Model 7424.

<table>
<thead>
<tr>
<th>Programmable Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Amplitude (Peak Voltage)</td>
<td>0 to 10.5 V</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>
</tbody>
</table>

**Note:** High amplitude/pulse width combinations can result in excessive charge density. Refer to “Programming Stimulation Parameters” on page 58 for more information.
Test Stimulator Instructions for Use

Test Stimulation with the Alligator Clip Screening Cable

The alligator clip screening cable is bipolar. The polarity of the black alligator clip is controlled by Electrode Switch 0, and the red alligator clip is controlled by Electrode Switch 3. Electrode Switches 1 and 2 on the Model 3625 Test Stimulator are inactive. Use the alligator clips to select the lead contacts that correspond to the electrodes you want to test. For example, if you want to change the negative electrode from electrode 0 to electrode 1, attach the black alligator clip to the lead contact corresponding to electrode 1.

⚠️ Caution: The switches on the 3625 Test Stimulator corresponding to electrodes 0 and 3 must be manually set to establish a circuit. One switch must be positive and the other switch negative. If the 0 and 3 electrode switches are not set accordingly, no stimulation will result. Refer to Figure 24, page 49.

1. Check that the test stimulator External A–Amplitude Control (Figure 21) is turned Off.

![Figure 21. Model 3625 Test Stimulator External Controls.](image-url)
2. Attach the alligator clips to the applicable lead contacts that correspond to the desired electrodes. Figure 22 provides an example of the connection to the lead contacts for electrodes 0 and 3.

Warning: Always turn External A–Amplitude Control Off before connecting or disconnecting the screening cable from the test stimulator, or before changing alligator clip connections to the lead contacts to prevent possible uncomfortable patient stimulation.

![Figure 22. Connect clips to lead contacts.](image)
3. Verify that the test stimulator output (Amplitude) is turned to Off, then push the plug on the test stimulator end of the cable into the output jack of the test stimulator (Figure 23). Note the correct plug orientation, with the cord pointing up. The plug fits in one way only.

*Figure 23. Model 3625 Test Stimulator Internal Controls.*
4. Remove the Internal Control Cover and set the Internal Controls (Figure 23) as follows:
   a. Set the **ELECTRODE SELECT** switch polarities as shown (Figure 24).

   ![Figure 24. Set Electrode Select switches.](image)

   - **Non-functional**
   - **Black Clip’s Polarity-Negative**
   - **Red Clip’s Polarity-Positive**

   **Figure 24. Set Electrode Select switches.**

   b. Set the **RATE AND PULSE WIDTH SELECT** switch to B (Figure 25).

   **Note:** When the switch is in position B (High Rate, Low Pulse Width):
   - Rate = 60–1400 Hz
   - PW = 50–250 µsec
Test Stimulator Instructions for Use

Figure 25. Set Rate and Pulse Width Select to B Position.

c. Set the External Rate to 130 Hz or as desired (typical therapeutic range 130-185 Hz) (Figure 26).

Figure 26. Set External Rate Control to 130 Hz.

d. Set the PULSE WIDTH control to 60 µsec or as desired (typical therapeutic range 60-120 µsec) (Figure 27).
Figure 27. Set Pulse Width to 60 µsec.

e. Set the AMP LIMIT control to 10 V, or as desired (Figure 28).

Figure 28. Set Amp Limit to 10 V.

5. Turn the External A–Amplitude Control On and gradually increase it until the patient indicates an effect (typical therapeutic range 1.0 to 3.5 volts), or until a stimulation effect such as the suppression of symptoms is noted.
Test Stimulator Instructions for Use

If the Vim is the targeted nucleus, the desired stimulation effect is an obvious suppression of tremor. Other stimulation effects that may aid in placement of the lead, but may not be desirable, include paresthesia, especially in the hand and around the mouth.

If the GPi or STN is the targeted nucleus, the desired stimulation effect is the obvious suppression of a predominant Parkinson's disease symptom, such as rigidity, bradykinesia, or tremor. Neurological assessments such as the passive movement of joints, finger tapping, hand movements, or holding and drinking from a ceramic cup can be administered to evaluate the effects of stimulation on Parkinson's disease symptoms. Other stimulation effects that may aid in placement of the lead in the STN, but are not desirable, include dystonia and choreic dyskinesias. Other stimulation effects that may aid in placement of the lead in the GPi, but are not desirable, include visual field effects and dystonia.

If test stimulation is unsuccessful or if parameter settings to achieve therapeutic benefit are within the charge density warning area (refer to “Programming Stimulation Parameters” on page 58) the system should not be implanted.

6. To reverse the output polarity:
   a. Set the External A-Amplitude Control to Off.
   b. Set the ELECTRODE SELECT switch polarities as shown (Figure 29).
Figure 29. Set Electrode Select switches to reverse polarity.

**Note:** The output polarity can also be reversed by switching the alligator clip-electrode contact connections.

**Warning:** Always turn the test stimulator External A–Amplitude Control to Off before changing ELECTRODE SELECT switches or other Internal Controls to prevent possible uncomfortable patient stimulation.

7. When the optimum stimulation mode and electrode configuration are determined, and the suppression of the movement disorder has been achieved with a minimum of side effects, turn the test stimulator's External A–Amplitude Control to Off.

8. When finished with the Internal Controls, replace the Internal Controls cover:
   a. Line up the two hinges with the holes in the test stimulator case.
   b. Press down on the cover to close it.

9. Disconnect the screening cable alligator clips from the lead contacts.
Test Stimulator Instructions for Use

Test Stimulation with the Twist-Lock Screening Cable

The twist-lock screening cable is quadripolar. When connected to the Model 3625 Test Stimulator, all four Electrode Switches are active.

⚠️ Caution: Before connecting the twist-lock screening cable to the stylet handle of the DBS Lead, secure the cable to the frame or another stable object. Otherwise, the weight of the twist-lock connector may cause lead movement.

1. Check that the test stimulator output (Amplitude) is Off.
2. Insert and lock the stylet handle on the lead into the twist-lock connector on the screening cable (refer to Figures 30-33).
   
   Note: The handle fits into cylindrical twist connector in only one way (Figure 30).

Figure 30. Insert the pin connector into the twist-lock cable.

   a. Place the stylet handle into the groove at a slight angle to secure the handle’s end (Figure 31).
Test Stimulator Instructions for Use

**Figure 31.** Secure stylet handle's end in groove.

**Figure 32.** Insert stylet handle into groove.

**Figure 33.** Lock the twist-lock connector.
Test Stimulator Instructions for Use

3. Verify that the test stimulator output (Amplitude) is turned to Off, then push the plug on the test stimulator end of the cable into the output jack of the test stimulator (Figure 34).

⚠️ Warning: Always adjust test stimulator output (Amplitude) to Off before connecting or disconnecting screening cable to prevent possible uncomfortable patient stimulation.

Note: The plug of the screening cable only fits one way into the test stimulator jack.

4. Proceed with the test stimulation. Refer to steps 4-6 of Test Stimulation with the Alligator Clip Screening Cable starting on page 49 for stimulation parameter recommendations. All four electrode switches are active with the twist-lock cable. Electrode selection and activation is controlled by the switches on the back of the Model 3625 Test Stimulator (refer to Figure 23 on page 48).

5. When finished with intraoperative test stimulation, turn the test stimulator Off.
6. When finished with the Internal Controls, replace the Internal Controls cover:
   a. Line up the two hinges with the holes in the test stimulator case.
   b. Press down on the cover to close it.

7. Unlock the cylindrical twist-lock connector and remove the connector handle.
   a. Hold the test stimulator end of the twist connector stationary in the left hand and turn the lead end of the twist connector clockwise with the right hand until the grooves on each side are lined up (Figure 35).

   ![Figure 35. Unlock the twist-lock connector.](image)

   b. Gently pull up on lead end of connector handle until it is free to remove it from the twist connector.

When the optimum stimulation mode and electrode configuration are determined, and the suppression of the movement disorder has been achieved with minimal side effects, record the settings.
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 36).

The neurostimulator’s maximum amplitude is 10.5 V, and maximum pulse width is 450 microseconds. (The test stimulator’s maximum amplitude is 10.0 V, and maximum pulse width is 1000 microseconds.) The curved lines in Figure 36 represent a charge density of 30 microcoulombs/cm²/phase at various impedance measurements, calculated for the electrode surface area of the DBS Model 3387/3389 Lead. 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 (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 in the shaded area in Figure 36 indicates a charge density above 30 microcoulombs/cm²/phase at the conservative impedance estimate of 500 ohms.
Figure 36 includes two examples of charge density calculated for the Activa System. In Example A in each figure, the neurostimulator parameters are 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 36, if the impedance in this case is at the clinical mean from either the tremor clinical study or the Parkinson's disease clinical studies, the charge density would be below 30 microcoulombs/cm²/phase.
Programming Stimulation Parameters

**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

![Graph showing DBS amplitude and pulse width limits with various resistance values.](image)

- **Example A**
- **Example B**

**Figure 36. Charge density with clinical studies resistance values.**
Patient Counseling Information

Physicians should use their medical and professional judgement as to what is meaningful and useful to each particular patient in his or her individual circumstances. However, it is suggested that you give the patient information about the following topics concerning the Medtronic Model 3625 Test Stimulator System and the implanted lead(s):

**Terminology** – Explain that the test stimulator is a temporary power source that provides output characteristics similar to an implantable neurostimulation system (amplitude, pulse width, and rate).

- **Amplitude** – Explain that amplitude is the strength or intensity of the stimulating pulse. Increasing the amplitude can increase the strength of the stimulation.
- **Pulse Width** – Explain that the pulse width is how long each stimulating pulse lasts, in microseconds.
- **Rate** – Explain that rate is the number of times per second an electrical pulse is delivered.

**Risks and Benefits** – Your patient should be advised of the known risks and potential benefits of the surgical procedure and the therapy, as discussed in the applicable lead and neurostimulator implant manuals.

**Patient Manual** – Your patient should be advised to read the patient manual packaged with the neurostimulator, which provides explanations of system components and their function, an overview of the implant procedure and the therapy, warnings and precautions, and answers to commonly asked questions.

**Note:** If a postoperative test stimulation period is desired, refer to “Appendix: Interoperative Testing” on page 67.
Troubleshooting Guidelines

Correcting Test Stimulator Shut-Off

- The output of the test stimulator will turn OFF if the output amplitude exceeds the External Amplitude setting by more than 1 volt. The green ON light on top of the test stimulator will shut OFF if this occurs. To reset the test stimulator, turn the A-Amplitude OFF for a second and then ON again.

- Stimulation will not occur if the battery is replaced while the A-Amplitude (power) switch is turned ON. The green ON light on top of the test stimulator will remain OFF if this occurs. To reset the test stimulator, turn the A-Amplitude (power) switch OFF for a second and then ON.

- The test stimulator will shut OFF if the RATE AND PULSE WIDTH SELECT switch is operated when power is on. To reset the test stimulator, turn the A-Amplitude (power) switch OFF for a second and then ON.

Verifying Test Stimulator Function

The function of the test stimulator can be verified as follows:

1. Check that the A-Amplitude is OFF.
2. Disconnect the test stimulator from patient and/or screening cable.

⚠️ Warning: Always disconnect the test stimulator from the patient before checking test stimulator output.

3. Place a fresh battery into the battery compartment and check for proper polarity of the battery.
4. Turn on an AM radio (a small transistor radio works the best) and tune it to the lowest setting on the dial (about 540 kHz, but not on a station). Adjust the volume to its loudest setting.
5. Turn the **AMP LIMIT** control to the maximum setting. Hold the test stimulator against the radio. Turn the test stimulator ON and increase the **A–Amplitude**. The radio should emit a strong buzzing sound.

   **Note:** The volume of the buzzing sound will not change.

6. If no sound is produced despite the use of a good battery, return the test stimulator with the battery to Medtronic (refer to “Care and Service” on page 63 for the address).

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**Care and Service**

The Model 3625 Test Stimulator has been carefully designed and tested to ensure reliability during normal use. However, precautions should be taken to avoid damage to the unit, including, but not limited to the following:

- Do not expose the test stimulator kit to storage temperatures above 149° F (65° C) or below -40° F (-40° C).
- Do not drop the unit or mishandle it in a way that might physically damage the device.
- Do not submerge the unit in water or any other liquid.
- When not using the test stimulator for more than 4 weeks, remove the 9-volt battery to prevent possible corrosive damage.
- The test stimulator may be cleaned with a cloth moistened with a mild soap and water solution. The test stimulator is moisture resistant but not waterproof. Do not immerse the test stimulator in any cleaning solution.

Safety and technical checks should be carried out on the Model 3625 Test Stimulator at least once every 12 months and after any malfunction or accident. Medtronic recommends that the checks be carried out by qualified engineers and technicians trained in the use of Medtronic products. A brief outline of necessary checks is listed on the next page. For service and training, contact your Medtronic sales representative.
Care and Service

or service representative. Medtronic does not recommend field repair of the test stimulator kit.

Units requiring service or repair should be returned to:

Medtronic Neurological
Repair Service
800 53rd Avenue, NE
Minneapolis, MN 55421
USA

Visual Inspection

- Technical Manual
- Inscriptions, information, and warning signs properly and completely fixed
- Mechanical damage to the test stimulator
- Inspection of the battery compartment and battery connection for corrosion and contamination

Functional Inspection

- Inspection of all connections and warnings
- Examination of warnings

Practical Measurements

- Amplitude
- Pulse Width
- Rate
- Output
Specifications

Table 4. Specifications.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Nominal Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Amplitude</td>
<td>0–10 V (peak)</td>
</tr>
<tr>
<td>Pulse Rate and Pulse Width</td>
<td><strong>Position A</strong></td>
</tr>
<tr>
<td></td>
<td>Rate = 5–120 pps(^a)</td>
</tr>
<tr>
<td></td>
<td>PW = 50–1000 µsec(^b)</td>
</tr>
<tr>
<td></td>
<td><strong>Position B</strong></td>
</tr>
<tr>
<td></td>
<td>Rate = 60–1400 pps</td>
</tr>
<tr>
<td></td>
<td>PW = 50–250 µsec</td>
</tr>
<tr>
<td>Waveform</td>
<td>Monophasic with net of 0 volt DC</td>
</tr>
<tr>
<td>Battery Type</td>
<td>9-volt alkaline battery (one supplied with unit) or 7.2- to 9-volt rechargeable if desired</td>
</tr>
<tr>
<td>Size</td>
<td>8.9 cm x 6.4 cm x 2.3 cm</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>0° C to 55° C</td>
</tr>
<tr>
<td>Storage Temperature</td>
<td>-40° C to 65° C</td>
</tr>
</tbody>
</table>

\(^a\) pps: pulses per second  
\(^b\) µsec: microsecond
Package Contents

The Model 3625 Test Stimulator Kit contains the following:

- One Model 3625 Test Stimulator
- One 9-volt battery
- One attachment clip
- Two operator manuals
Appendix: Interoperative Testing

In some cases, the physician may choose to conduct interoperative testing. The patient may use the test stimulator during this time to determine the effect of stimulation on his/her symptoms.

Patient Counseling Information

Explain that the trial screening period may last from 1 to 10 days with the purpose of seeing whether this therapy will provide adequate suppression of the patient's symptoms.

If deep brain stimulation is successful, a complete system will be implanted in a second surgery, with the test stimulator replaced by an implantable neurostimulator. The second surgery is normally done at the end of the trial screening period.

Warnings:

- Advise your patient not to attempt to change or adjust any of the Internal Controls. Explain that any changes they make can cause uncomfortable levels of stimulation.

- Since it is possible that your patient’s device may switch OFF unexpectedly, advise your patient about any activities that are potentially hazardous if his or her symptoms unexpectedly return.

Test Stimulator Operation – Explain how to turn the test stimulator ON and OFF and how to verify it is on when the green ON light blinks. Also explain how to adjust the A—Amplitude and R—Rate controls, and that any increase in amplitude should be made very slowly to avoid uncomfortably high stimulation.
Appendix: Interoperative Testing

**Test Stimulator Use** – Explain if and when the patients should turn OFF the test stimulator (e.g., when not experiencing their usual medical condition or when their medical condition is manageable). Indicate when to turn ON the test stimulator.

**Cable Connections** – Explain how to connect and disconnect the cable(s) from the test stimulator after turning OFF the test stimulator. A disconnected cable should be rolled up and taped to the patient’s body or clothing to prevent pulling on the lead.

**Battery Replacement** – Explain that a blinking green light, labeled ON, indicates a working battery, a blinking yellow light, labeled BAT, indicates a weak battery. Show the patient how to replace the battery.

**Troubleshooting Guidelines** – Explain what the patient can do if he/she doesn’t experience symptom control:

- Turn OFF test stimulator; wait 2 seconds and turn ON test stimulator.
- Turn OFF test stimulator; disconnect cables from test stimulator and check battery. Replace if necessary.
- Turn OFF test stimulator; check cable connections.

**Log Maintenance** – If desired or necessary, explain how your patient can keep a log to record the following information:

1. When and why the patient turned the test stimulator ON and OFF.
2. The intensity of symptoms when the patient turned the test stimulator ON and OFF using the scale given to him/her.
3. What activities they were involved in when they turned the test stimulator ON or OFF, or when they adjusted amplitude or rate.
4. Any additional adjustments made to the test stimulator (e.g., battery replacement).
Appendix: Interoperative Testing

Activities to Avoid – Explain that the patient should avoid any activities that may damage the implant site, implanted lead/percutaneous extension or test stimulator. They should be encouraged to consult their physician if they notice any unusual signs or symptoms.