**NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY**

**Brief Summary:** Product manuals must be reviewed prior to use for detailed disclosure.

**Indications**

**Implantable neurostimulation systems** - A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system as an aid in the management of chronic, intractable pain of the trunk and/or limbs—excluding unilateral or bilateral pain associated with the following conditions:

- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postanteriority pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

**Contraindications**

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

**Warnings**

Sources of strong electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

**Precautions**

The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. To properly assess test stimulation, patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging.

**Adverse Events**

Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, gastrointestinal symptoms (diarrhea, constipation, and leakage of stool), bladder symptoms (urinary retention and frequency and leakage of urine) and surgical risks. For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic’s website at www.medtronic.com.

USA Rx Only  Rev 0817

**TAKE CONTROL OF YOUR FUTURE**

Pain and Activity Diary with Trial Quick Guide

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Personalized therapy to meet your needs

Your Intellis™ trialing system offers personalized therapy for pain relief and improvement in your day-to-day activity goals.

BEFORE THE TRIAL

TRACK YOUR PAIN

It’s important to keep track of your pain and progress on functional goals before and during the trial in order to best assess your response to spinal cord stimulation.

When does your pain occur? What kind of pain is it? Does it move from one place to another?

Patient Name ________________________________

Physician Contact Name ________________________________ Physician/Clinic Contact Phone _____________

Medtronic Contact Name _____________________________ Medtronic Contact Phone __________________

Average Daily Pain Score*: 

<table>
<thead>
<tr>
<th>No Pain</th>
<th>Moderate Pain</th>
<th>Worst Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Average Daily Pain Score ranges from 0 to 10, with 0 representing no pain and 10 representing worst pain.
In the area below, list up to five activities and related goals you would like to achieve if your pain were managed better. Rank them in order, with #1 being the highest rank.

**Activities**

- Walking
- Reclining

**Goals**

1. ___________ ___________ ___________
   - Walk to the back of the grocery store without resting
   - Watch a movie while sitting comfortably on the couch

2. ___________ ___________ ___________

3. ___________ ___________ ___________

4. ___________ ___________ ___________

5. ___________ ___________ ___________
EVALUATING YOUR EXPERIENCE

There is a lot to consider when making a decision to proceed with long-term therapy.

One way to think about your experience with spinal cord stimulation is to look back on your Pain Diary pages and compare your ability to do things before and during the trial. If you are not receiving adequate relief, tell your doctor. Your doctor and the Medtronic representative can adjust your settings. By simply having your settings changed, you may have better pain relief during your trial.
Use the space below to track your top two function and activity goals, and then share with your doctor.

For each of your goals, please answer the following: Have you tried one of your goals? How is that going? *(List them below)*

<table>
<thead>
<tr>
<th>Days 1 of Trial</th>
<th>Days 5 of Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ex., Yes, I was able to walk farther than I used to:</td>
<td>Goal 1.</td>
</tr>
<tr>
<td>Goal 2.</td>
<td></td>
</tr>
<tr>
<td>Pain Score (0-10):</td>
<td>Pain Score (0-10):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day 2 of Trial</th>
<th>Day 6 of Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 2.</td>
<td>Goal 2.</td>
</tr>
<tr>
<td>Pain Score (0-10):</td>
<td>Pain Score (0-10):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day 3 of Trial</th>
<th>Day 7 of Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 2.</td>
<td>Goal 2.</td>
</tr>
<tr>
<td>Pain Score (0-10):</td>
<td>Pain Score (0-10):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day 4 of Trial</th>
<th>Days 8-10 of Trial (if needed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 2.</td>
<td>Goal 2.</td>
</tr>
<tr>
<td>Pain Score (0-10):</td>
<td>Pain Score (0-10):</td>
</tr>
</tbody>
</table>
**PROGRAMMER QUICK GUIDE FOR TRIAL**

**PROGRAMMER KEYS**

1. **Stimulation On/Off**
   - Turns stimulation on or off

2. **Recharging Light***
   - Indicates battery charging status
   - (used with rechargeable neurostimulators)

3. **Touchscreen**
   - Screen reacts to your touch and allows you to press buttons and functions that are displayed on the screen

4. **Increase/Decrease Key**
   - Wakes up the programmer
   - Adjusts stimulation
   - Selects and navigates settings displayed on the screen

5. **Charging Port***
   - (used with rechargeable neurostimulators)
   - Connects to the recharger cord
   - Used to recharge the programmer
   - Used to recharge the neurostimulator

*Note: To perform most functions on the programmer, you must first press the Increase/Decrease key to wake up the programmer.

* Only available with implanted devices

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**THERAPY SCREEN OVERVIEW**

1. **Battery status button**
   - Press to check battery status
   - Left icon on this button displays the programmer battery status
   - Right icon displays the neurostimulator battery status

2. **Lock Button**
   - Press to lock programmer

3. **Menu Button**
   - Press to access Menu screen

4. **Group Button**
   - Press to show current group name (indicated by A, B, or C)
   - Green highlighting indicates the group is active

*Note: The Group button will be gray when stimulation is off. An orange message will appear, alerting you that stimulation is off.
### Program Buttons

- **Press to show up to four programs, indicated by numbered boxes (1-4)**
- **After pressing the program button on the home screen, available settings for that program will appear:**

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="Intensity.png" alt="Intensity" /></td>
<td>Controls the strength of the stimulation</td>
</tr>
<tr>
<td><img src="Stimulation.png" alt="Stimulation" /></td>
<td>Turns stimulation on or off</td>
</tr>
<tr>
<td><img src="Rate.png" alt="Rate" /></td>
<td>Sets the speed of the stimulation pulses</td>
</tr>
<tr>
<td><img src="AdaptiveStim.png" alt="AdaptiveStim™" /></td>
<td>Turns AdaptiveStim™ on or off (this feature is only available with the Intellis™ with AdaptiveStim™ technology implanted neurostimulator)</td>
</tr>
<tr>
<td>![Pulse width](Pulse width.png)</td>
<td>Sets the length of the stimulation pulse (pulse width affects the strength and coverage area of the stimulation)</td>
</tr>
<tr>
<td><img src="Cycling.png" alt="Cycling" /></td>
<td>Turns stimulation on and off at regular intervals, as programmed by your clinician</td>
</tr>
<tr>
<td>![Up/Down buttons](Up/Down buttons.png)</td>
<td>Press to view additional parameter and stimulation settings for a program (these buttons may not appear, depending on how your clinician has programmed your neurostimulator)</td>
</tr>
</tbody>
</table>

### BASIC PROGRAMMER FUNCTIONS

#### Unlocking your programmer

1. **When the Increase/Decrease key is pressed to wake up the programmer, the Unlock screen appears.**
   - When the programmer is locked, you can press the Stimulation On/Off key to bypass the Unlock screen and to turn stimulation on or off.
2. **Press and hold the Lock button on the Unlock screen.**
   - As the Lock button is held, bars appear on the screen and move toward the Lock button.
   - Stop pressing the Lock button when the screen changes to a circle of dots. This indicates that the programmer is searching for your neurostimulator.

#### Turning stimulation On or Off for all programs within a group

1. **Press the Stimulation On or Off button, which is located on the top of your programmer, to turn the stimulation on or off.**
2. **Press the Go To Unlock button, if you wish to access the Home screen instead.**
3. **The Home screen will appear to confirm whether stimulation is on.**

**Note:** When stimulation is on, the active Group will be highlighted in green.
Adjusting stimulation
A. Press a Program button on the Home screen. The available setting for that program will display.
B. Use the increase/decrease keys to adjust desired program settings.
Note: Some settings may not be available, depending on what your clinician has programmed for your neurostimulator.

Changing a group
A. From the Home screen, select the group on the left side of the screen to access the other groups available, then select the circle next to the desired group. Only one group can be selected at a time.
B. Up to 3 groups may be available. Groups are viewed by letters A, B, and C.
C. Press the OK button. The Home screen will display showing the selected group.

Checking programmer battery level
A. From the Home screen, press the Battery status button. Two battery figures appear.
B. Press the Exit button at the top right corner of the touchscreen to exit.

Contact your doctor with any questions you may have about your programmer or spinal cord stimulation trial.

WARNING, ALERT, AND NOTIFICATION SCREENS
Warning screens indicate a problem with the programmer, recharger, or neurostimulator. See pages 166-173 of the controller (programmer) manual for more detailed explanation of each warning screen.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Screen Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Red triangle with an exclamation point" /></td>
<td>Warning screen</td>
<td><img src="image" alt="Orange triangle with an exclamation point" /></td>
</tr>
<tr>
<td><img src="image" alt="Blue circle with the letter “i”" /></td>
<td>Notification screen</td>
<td></td>
</tr>
</tbody>
</table>