Trial Neurostimulator
Model MN0100
Draft Physician Manual

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Explanation of Symbols on Product or Package Labeling

REF	Model Number
SN	Serial Number
	Read the Instructions for Use
	Consult the Instructions for Use
NON STERILE	Contents of Package are Non-Sterile
	Manufacturing Date
	Manufacturer
	Warning. Pay attention.
	Turns all stimulation off on the TNS.
	Protected against Electric Shock
	Device is a Radio Transmitter
IP 22	Limited Waterproof

50°C −10°C	Store between –10°C and 50°C
93 % 0	Store between 0 and 93% humidity
	Keep Dry

Symbols, cont.

Diathermy – High energy heat: used to cut or cauterize during surgery, or a type of therapy.

Electromagnetic Interference (EMI) – Electrical signals that interfere with the device function.

MRI (Magnetic Resonance Imaging) – Medical imaging: produces electronic images of tissues and organs.

Paresthesia – Tingling sensation felt during therapy delivery: produced by spinal cord stimulation.

Precaution – Situations of which the patient should be aware in order to avoid uncomfortable stimulation and possible damage to the TNS device.

Program – Instructions or changes to stimulation settings that are programmed into the Programmer and transmitted to the TNS device.

Spinal Cord Stimulation – Electrical pulses applied to the spinal cord to block pain signals to the brain.

Stimulation – A pain therapy reference to small electrical pulses felt as a tingling sensation that replaces pain signals.

Stimulation Level – Measure of stimulation: can be increased or decreased within a range specified by the clinician.

Warning – Potentially serious hazard to be aware of to avoid situations that could cause injury or death.

Introduction

This manual describes the care and use of the Trial Neurostimulator (MN0100).

Indications For Use

The Spinal Modulation Trial Neurostimulator System is intended as an aid in the management of chronic pain.

Contraindications

Patients contraindicated for the Spinal Modulation Trial Neurostimulator System are those who:

- Have an active implantable medical device including but not limited to cardiac pacemakers and cardiac defibrillators
- Are unable to operate the system
- Are poor surgical risks
- Are pregnant
- Are under the age of 18

Description

The Trial Neurostimulator (TNS) attaches to the Connector Cable and delivers energy to the trial leads. The TNS has a female locking connector that attaches to the Connector Cable, a standby button that disables stimulation and a clip for the patient to attach the TNS to their belt or waistband.

The output ranges for the system are:

Parameter	Range
Frequency (Hz)	4 – 100
Pulse Width (μs)	40 – 720
Amplitude (μA)	50 – 6000

FREQUENCY BAND: The TNS device uses the one frequency band designated specifically for implanted medical devices; the Medical Implant Communications Service (MICS) to communicate with the Programmers. The MICS band operates from 402 MHz to 405 MHz. The Listen Before Talk (LBT) protocol allows multiple pieces of equipment in the location to communicate at the same time without interference.

The Clinical and Patient Programmers are used to communicate with the Trial Neurostimulator.

The Clinical Programmer is used to program the stimulation parameters in the TNS, as determined by the physician. The TNS device delivers the programmed stimulation parameters (energy) to the Leads.

The Patient Programmer is easy to use and allows the patient to adjust the stimulation level within limits preset by the physician. It allows the patient to turn stimulation off.

The Clinical and Patient Programmers are portable, hand-held devices powered by internal batteries. The batteries are rechargeable using Programmer Charger MN3400 (provided) and a power outlet.

Both Programmers come with a carrying case and should be kept dry. Images depicting the components of the Spinal Modulation TNS System are shown in Figure 1.

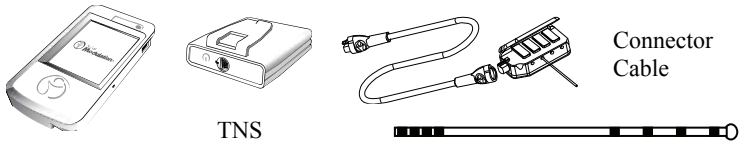


Figure 1: The Trial Neurostimulator System

⚠ **WARNINGS**

- The patient must be trained by their doctor before using the Patient Programmer and the NS device.
- The patient must not use their Patient Programmer until their doctor has set up the NS System.
- The patient must not undergo any elective magnetic resonance imaging (MRI). If MRI is necessary, the doctor should remove any lead(s) and disconnect the NS device. Use of MRI near the lead(s) may dislodge the lead(s) or damage the NS device. If a voltage is induced through the lead, it may cause uncomfortable ("jolting" or "shocking") levels of stimulation.

- The patient must not undergo any diathermy (high energy heat) procedures. Diathermy could injure the patient or damage the NS device.
- The patient must not remove the lead(s) or Connector Cable from their body. Removal of the lead (s) or Connector Cable may result in an infection.
- Changes in body position can affect the amount of stimulation felt, causing increased feelings of pain or uncomfortable stimulation. The patient should use the Patient Programmer to adjust stimulation levels or to turn stimulation off, if needed.
- Under certain conditions, strong electromagnetic fields may affect the NS device, possibly affecting the level of stimulation and causing discomfort. The patient should avoid theft detection devices at store and library exits and security screeners at airports. The patient must not stand near the screening equipment.
- Other equipment that may cause interference includes, but is not limited to: power generators, arc welders and large magnetized speakers

PRECAUTIONS — DEVICES

The following precautions should be taken to avoid damage to and assure proper function of the Patient Programmer and TNS device.

- The patient should not drop or mishandle the Patient Programmer or TNS device. Physical damage to the units may impair their function.
- The patient should not wash or get the Patient Programmer or TNS device wet.
- The patient should not shower or bathe with the TNS device. (A sponge bath is acceptable as long as the TNS device does not get wet.).

- The patient should not use abrasive or caustic cleaning products on the Patient Programmer or TNS device.
- The patient should not open the cases of the Patient Programmer or TNS device. Attempts to open the cases may expose the units to elements that alter their function.
- The patient should not place the Patient Programmer close to credit cards or other cards with magnetic strips, as the Patient Programmer contains a magnet and may demagnetize your cards. Also, the patient should keep the Patient Programmer away from computer hard drives or magnetic storage devices.
- The patient should not operate the Patient Programmer or TNS device outside the temperature range of -5°C to 45°C. Rapid temperature changes may affect device operation.
- The patient should not store the Patient Programmer outside the temperature range of -10°C to 50°C.
- The patient should not leave the Patient Programmer in a car or other places where temperatures can exceed 50°C.
- Failure of your NS System, although unlikely, is possible due to random component failure. If any part of the TNS System stops working, contact your doctor during normal business hours.
- The Patient Programmer and the TNS device must be returned at the end of the trial period. The patient must not discard or burn the TNS device or Patient Programmer. Fire may cause its internal battery to explode.
- The patient should not try to replace the TNS device battery, even if the TNS device does not function. The internal battery for the TNS device must be replaced by Spinal Modulation personnel only.

- The patient should not allow unauthorized use of your Patient Programmer. This may cause unwanted changes in the programming.
- The patient should not use the Patient Programmer or NS in the presence of explosive or flammable gases as this may cause serious injury.

PRECAUTIONS –THERAPY

The patient should be instructed to take the following precautions to maintain appropriate therapy during this study:

- Follow proper wound care techniques as instructed by their doctor.
- Do not rub or exert pressure at the implant site as it may dislodge the leads or cause skin erosion.
- Avoid excessive bending, twisting and stretching, and do not lift objects over ten pounds. These activities may result in lead movement producing either understimulation or overstimulation.
- Avoid driving a car or operating other potentially dangerous machinery while stimulation is turned on. If sudden changes in stimulation were to occur, the patient may be distracted from vehicle or device operation.
- It is possible that the NS System may affect the operation of other implantable devices such as pacemakers or implantable cardiac defibrillators. The physician should be aware of any other implantable devices the patient may have or are scheduled to get.

- The patient's other healthcare providers should be aware of their NS. They should not undergo any elective medical procedures during the trial stimulation period. Some medical devices or therapies, such as those listed below, may produce interference with the TNS System:
    - Electrocautery – Electric probe: to cauterize blood vessels and stop bleeding during surgery.
    - Lithotripsy – High-output shock waves: breaks up gallstones and kidney stones.
    - Therapeutic Radiation – Ionizing radiation: to destroy cancer cells.
    - High-output ultrasound – High frequency sound waves: to treat bone and muscle injuries, or to stimulate muscle or improve blood flow.
    - RF Ablation – Radio frequency energy: causes controlled tissue damage.
    - Microwave Ablation – High speed alternating electric field: causes controlled tissue damage.
    - Dental procedures, electrolysis, static field therapeutic magnets and diagnostic X-ray.
- The patient should designate a representative (family member or friend) to notify emergency medical personnel of their trial stimulator, in case they require emergency care. The patient will be provided with a Medical Alert Card to carry with them that will inform emergency medical personnel that they have an NS.

If there is any concern regarding the proper function of the NS System, they should discontinue use and contact their physician during normal business hours.

TNS Device Overview

The TNS device connects to the lead(s) via the Connector Cable. The TNS is worn by the patient for up to 30 days during the trial period. The TNS device has a clip to attach the device to clothing or a belt or the patient may choose to use a flexible, elastic bandage to secure the TNS device during the trial period.

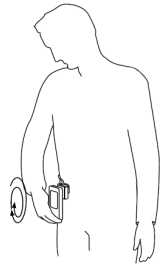
The TNS device must be programmed by the physician or company representative using a Clinical Programmer prior to use. The TNS device will periodically check for communication from the Patient Programmer. Using the Patient Programmer, stimulation can be started by selecting a body region to receive stimulation. The level of stimulation can be adjusted, and the stimulation can be turned OFF. For detailed instructions on the use of the Patient Programmer, see the Patient Programmer Manual.

STIMULATION OFF SWITCH

The TNS device has a button with a red marking located on the top of the TNS device. This button may be used to turn OFF stimulation on all leads, by pressing it for more than 2 seconds. A Programmer is required to turn

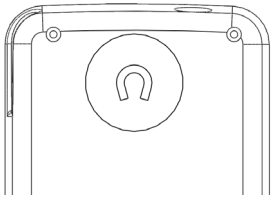
MAGNET ACTIVATION

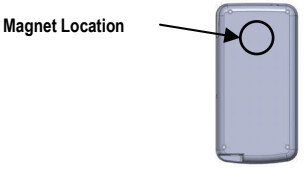
Move the magnet located in the Programmer in a circular motion over the top of the TNS to connect to the Patient Programmer or the Clinical Programmer.



TNS DEVICE CARE

Tell the patient <u>not</u> to immerse their TNS device in water or pour water over it. If cleaning is necessary, remove soil with a soft damp cloth.





RF Operating Frequencies. Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:
MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in

Europe: EN ETSI 301 839-2

USA FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219

FCC ID: Y8L-MN0100

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation.
This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Your Spinal Modulation Neurostimulator System complies with the following International Standards

• IEC 60601-1: 2005 • IEC 60601-1-11: 2010 • IEC 60601-1-2: 2007	• ISO 14708-1: 2000 • ISO 14708-3: 2008

AUTHORIZED EUROPEAN REPRESENTATIVE

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Appendix I: Troubleshooting

Issue	Potential Solutions
Unable to connect to the TNS using the programmer.	• Verify that the back side of the programmer and the magnet label was put over the "label" side of the TNS. This is the side without the belt clip. Hit "Connect" again. It should not take more the 30 seconds to connect. • The programmer may be too far away from the TNS, so bring the programmer closer to the TNS and wait for connection. You may have to activate the switch in the TNS using the magnet. • Verify that the patient has put the magnet of the programmer over the correct side of the TNS. The patient may need to use the stand alone magnet to activate the TNS instead. • Move to another location as there may be interference in your current location and reconnect. • The programmer battery may be low. Charge the programmer and then attempt to reconnect. • The battery of the TNS may need to be replaced. Call your physician during normal business hours.

Appendix I: Troubleshooting - continued

Issue	Potential Solutions
Understimulation or no stimulation	• Verify the patient has checked the connections of the connector cable to the TNS. They may have come loose and are no longer connected. The patient should connect to the stimulator and turn the stimulation levels down on each lead before reconnecting the cable. • The standby button may have been pressed. Connect to the stimulator and re-enable each lead to turn stimulation on. • The patient may have activated a new Group. The patient should reconnect to the stimulator and adjust the Group or stimulation levels on each lead appropriately. • The magnet may have been held in place too long over the switch and turned off stimulation. The patient should reconnect to the device and turn each lead back on individually. • If the leads cannot be re-enabled, call your physician during normal business hours.
Overstimulation	• Postural changes can affect stimulation. Before laying down or standing up, the patient may need to adjust the stimulation levels. • Stimulation levels can change due to interference from anti-theft devices, high power lines and large magnetized speakers. If this occurs, the patient should be instructed to use the Patient Programmer to adjust their stimulation setting.