Medtronic	NEUROMODULATION CONFIDENTIAL	DOCUMENT/RECORD

This document/record is electronically controlled, printed copies are considered uncontrolled.

Identifier	Version	Author
NDHF1245-121586	4.0	Monica Tuy

Title: 97745 User Manual DRAFT for Agency and Summative Testing	**Pages:** 257 (including this page)

APPROVALS

Signed By	Responsibility	Date/Time (GMT)
Monica Tuy	Technical Communications Approver	7/12/2012 5:42:48 PM

Medtronic

CONTROLLER 97745

Pain therapy user manual for Intellis™ Model 97715 and Model 97725 Wireless External Neurostimulation Systems

! USA Rx only

CE 0123 2013

M948515A001 Rev X 2013-04

! USA FCC Information

The following is communications regulation information on the Model 97745 Controller.

FCC ID: LF597745

This device complies with Part 15 Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Label Symbols

Explanation of symbols on products and packaging. Refer to the appropriate product to see symbols that apply.

CE 0123	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.
	Consult instructions for use
MR	Magnetic Resonance (MR) Unsafe
	Manufacturer
SN	Serial number
PIN No.	PIN number
EC REP	Authorized representative in the European community
-XX °C -XX °F +XX °C +XXX °F	Temperature limitation
	Non-ionizing electromagnetic radiation
	IEC 60601-1/EN60601-1, Type BF Equipment

System meets the applicable Canadian (CAN/CSA-C22.2 No. 60601-1) and US (UL 60601-1:2003) electrical safety standard requirements.

Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

! USA

For USA audiences only

Label Symbols

Table of contents

Glossary

Caution - A statement describing actions that could result in damage to or improper functioning of a device.

Clinician - A healthcare professional such as a doctor or nurse.

Clinician programmer - A device used by a clinician to send instructions to a neurostimulator.

Contraindication - A condition or circumstance when a person should not have a neurostimulation system.

Controller - A hand-held device that allows you to turn your neurostimulator on and off and check your neurostimulator battery. It is also used to adjust some of the stimulation settings.

Diathermy - A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

Discharged battery - The rechargeable battery is depleted and should be charged as soon as possible. When the battery is in a discharged state, therapy is not available.

Elective replacement indicator (ERI) - Notification that the INS is nearing or has reached its recommended replacement date.

Electrode - A metal piece near the tip of the lead. Electrodes deliver electrical pulses to the area where your pain signals will be blocked.

Electromagnetic interference (EMI) - A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly.

End of service (EOS) - Condition of an ENS at the time it is no longer able to operate successfully.

External neurostimulator (ENS) - See Neurostimulator.

Group - Collection of programs that work together for a particular effect or area.

Implanted neurostimulator (INS) - See Neurostimulator.

Indication - The purpose of the neurostimulation system and the medical condition for which it may be implanted.

Intensity - The strength of an electrical pulse.

Neurostimulation system - The implanted and external components of the stimulation system that delivers electrical pulses to block pain signals as they move to the brain.

Neurostimulator - The power source of a neurostimulation system. It contains the battery and electronics that control the stimulation you feel. An external neurostimulator is carried outside the body. During test stimulation, it is used to determine whether or not stimulation is effective. An implanted neurostimulator is placed inside the body. If stimulation is effective during test stimulation, the neurostimulator is implanted.

Out-of-regulation (OOR) - The neurostimulator battery is unable to produce the levels of energy required for the current stimulation settings.

Pain areas - An area of the body where a patient feels pain.

Parameter - One of three stimulation settings that adjust the electrical pulse: intensity, pulse width, and rate.

Precaution - See Caution.

Program - Stimulation directed to a specific pain site.

Pulse width - The length or duration of an electrical pulse.

Recharger - The component of the neurostimulation system that is used to recharge your neurostimulator battery.

SoftStart/Stop - This feature is programmed by your clinician. When the neurostimulator is turned on, stimulation will slowly increase to the programmed intensity. When the neurostimulator is turned off, stimulation will slowly decrease.

Spinal cord - This is your body's information center. Nerve signals from the entire body travel to your spinal cord, and then to your brain.

Stimulation - The delivery of electrical pulses to the area where pain signals are blocked as they move to the brain. Stimulation blocks some pain signals from reaching the brain.

Stimulation settings - Refers to all the features assembled to define the stimulation you feel. The clinician programs all stimulation. You can adjust some stimulation settings within clinician-defined limits.

Test stimulation - The period of time when an external neurostimulator is used to determine if stimulation blocks the pain signals effectively.

Therapy - Treatment of a disease or condition. When neurostimulation therapy is prescribed, a neurostimulation system is used to deliver stimulation to one or more pain sites.

Therapy settings - A specific combination of intensity, rate, and pulse width parameters used to control the stimulation delivered by a neurostimulator.

Warning - A statement describing an action or situation that could harm the patient.

1 Introduction

How to use this manual

Use this manual during test stimulation and after receiving an implanted neurostimulator. Ask your clinician to explain anything that is unclear.

- A glossary is provided at the beginning of this manual.
- Chapter 1 "Introduction", describes how to use this manual, patient guides you should receive, and information about the patient identification card.
- Chapter 2 "Important therapy information", describes when you should and should not use a neurostimulation system, the neurostimulation system components, and the risks, benefits, warnings, precautions, and patient activities related to your neurostimulation system.
- Chapter 3 "Recovery and care after surgery", provides information about recovering from surgery, activity and care

information, and when to contact your clinician.

- Chapter 4 "Using your controller", describes the controller and how to perform specific tasks.
- Chapter 5 "Adjusting your stimulation", describes how to adjust your stimulation using your controller.
- Chapter 6 "MRI examinations", provides important information about what you should do if you have an MRI examination.
- Chapter 7 "Using the recharging system with the implanted neurostimulator", describes how to use the recharging system to recharge your implanted neurostimulator battery.
- Chapter 8 "Troubleshooting", describes controller warning, alert, and information screens and how to solve problems.
- Chapter 9 "Additional information", describes how stimulation works, possible

adverse effects, changes in therapy, and possible system complications.

- Chapter 10 "Maintenance and assistance", describes how to set up a new controller, care for your controller, and instructions on using accessories. This chapter also provides controller specifications and information about who to call for assistance.
- Chapter 11 "Appendix A: Electromagnetic interference (EMI)", provides information about electromagnetic interference and how it may affect your neurostimulation system.

Patient guides

Table 1.1 on page 23 describes the documents you should receive during test stimulation and after a neurostimulator is implanted.

Table 1.1 Patient guides for test stimulation and implanted neurostimulation systems

Document	ENS[a]	INS[b]
Medtronic Model 97725 Wireless External Neurostimulator: Test Stimulation Patient Guide Describes the goals, activities, components, and instructions for test stimulation.	X	
Medtronic Model 97745 Controller: Quick Reference Guide: Provides instructions for common controller tasks.	X	X

Table 1.1 Patient guides for test stimulation and implanted neurostimulation systems (continued)

Document	ENS[a]	INS[b]
Medtronic Model 97755 Recharger: Recharging System User Manual: Describes the components of the recharging system, including the rechargeable battery pack and power supply.		X
Patient Identification Card: Provides information about you, your implanted neurostimulator, and your doctor.		X

[a] External neurostimulator
[b] Implanted neurostimulator

Patient identification card

When you leave the hospital, your doctor will give you a patient identification card. This card supplies information about you, your implanted device, and your doctor. Your identification card may allow you to bypass security devices. Carry this card with you at all times and bring this card with you to all MRI appointments (see Chapter 6 "MRI examinations").

If you move, change doctors, or lose your card, contact Medtronic for a replacement card. Refer to the Medtronic contacts at the end of this manual.

! USA A temporary identification card will be provided at the hospital. After Medtronic receives your implant registration from the hospital, you will receive a permanent identification card.

2 Important therapy information

Purpose of the device

The Medtronic Model 97745 Controller is designed to program the following Medtronic neurostimulators:

Rechargeable

- Intellis Model 97715 Implanted Neurostimulator

Nonrechargeable

- Model 97725 Wireless External Neurostimulator

Refer to your patient identification card to determine the model number of your neurostimulator.

Purpose of the neurostimulation system (indications)

Refer to the indications sheet that is packaged with the controller for the purpose of the neurostimulation system and related information.

Description of your system

A typical neurostimulation system has implanted parts that deliver the electrical pulses to the area where your pain signals are blocked.

Typically the implanted parts of a neurostimulation system include (Figure 2.1): a neurostimulator, 1 or more leads, and 1 or more extensions (optional).

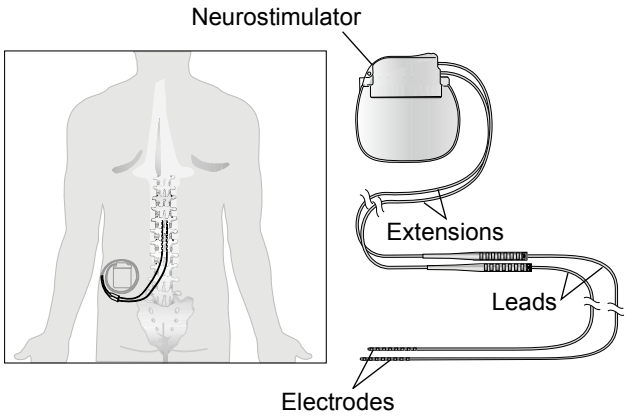

Figure 2.1 Implanted parts of a typical neurostimulation system (spinal cord stimulation shown).

A typical neurostimulation system also includes an external controller for controlling your system. If you have a rechargeable neurostimulator, your system also includes a recharging system (Figure 2.2).

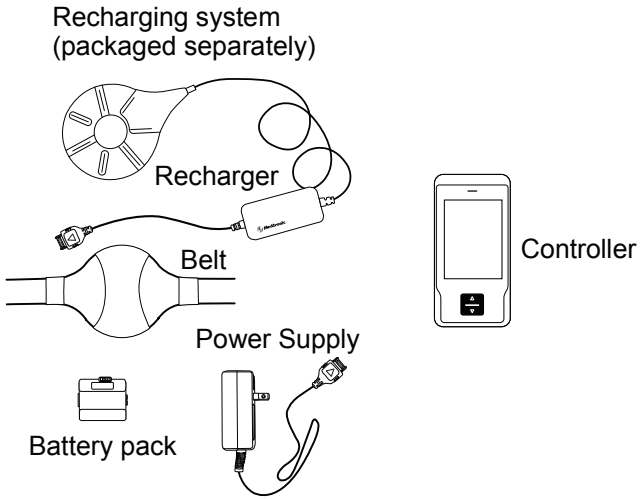

Figure 2.2 Recharging components of a rechargeable neurostimulation system.

Neurostimulator – The neurostimulator is the power source (battery) for your neurostimulation system. It contains electronics that generate the electrical pulses. During test stimulation, an external neurostimulator is used to determine whether an implanted neurostimulator is the right choice for you.

Note: Your controller refers to the neurostimulator as the device.

Lead(s) – A lead is a set of thin wires, covered with a protective coating. A lead has small metal electrodes near the tip. The electrodes transmit electrical pulses to the area where your pain signals are blocked.

Extension(s) – An extension is a set of thin wires, covered with a protective coating, that connects the neurostimulator to a lead. Not all neurostimulation systems include an extension.

Controller – A controller is a hand-held device that you use to select and adjust your stimulation.

Recharging system – The recharging system is used to charge the implanted rechargeable neurostimulator battery. Components included in the recharging system are: recharger, belt, battery pack, power supply, and system carrying case. Refer to the manual packaged with the recharging system for more

information about the recharging system components.

Therapies that may not be used with the neurostimulation system (contraindications)

Diathermy—Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, and can cause tissue damage, resulting in severe injury or death.

Risks and benefits

Stimulation has helped thousands of patients manage their pain and improve their quality of life. Your neurostimulation system may be used with other pain treatments. Stimulation

will not cure your pain. It can, however, reduce your pain to a tolerable level and allow you to resume many of your daily activities.

Risks of surgery

Implanting a neurostimulation system has risks similar to spinal procedures, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis.

If you are on anticoagulation therapy you might be at greater risk for postoperative complications such as hematomas that could result in paralysis.

For information about possible adverse effects, refer to "Possible adverse effects" on page 200.

Warnings

Wound contact—DO NOT use the recharger on an unhealed wound. The recharging system is not sterile, and contact with the wound may cause an infection.

Trial systems (neurostimulation systems that are not fully implanted)—MRI should not be prescribed for patients undergoing trial (test) stimulation or who have any neurostimulation system components that are not fully implanted. If an MRI scan is required, the clinician must explant all trial (test) stimulation components. MRI has not been tested on trial (test) stimulation components and may cause heating of the lead electrodes, resulting in tissue damage or serious patient injury.

Electromagnetic interference—
Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, sources of strong EMI can result in the following:

- **Serious patient injury or death,** resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue.
- **System damage,** resulting in a loss of or change in symptom control and requiring additional surgery.
- **Operational changes to the neurostimulator,** that can cause it to turn on or off, resulting in loss of neurostimulation and the return of underlying symptoms.
- **Unexpected changes in stimulation,** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure a patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.

Refer to the following table for information on the effect of EMI on you and your neurostimulation system. Additional information and instructions on how to reduce the risk from EMI are located in Appendix A of this manual.

Table 2.1 Potential effects of EMI from devices or procedures

Device or procedure	Serious patient injury	Device damage	Device turns off/on	Momentary increase in stimulation	Intermittent stimulation
Bone growth stimulators		X		X	X
CT scans				X	
Defibrillation/ cardioversion	X	X		X	X
Dental drills and ultrasonic probes		X			
Diathermy, therapeutic	X	X			X
Electrocautery	X	X			
Electrolysis		X			X

Table 2.1 Potential effects of EMI from devices or procedures (continued)

Device or procedure	Serious patient injury	Device damage	Device turns off/on	Momentary increase in stimulation	Intermittent stimulation
Electromagnetic field devices (eg, arc welding, power stations)			X	X	X
High-output ultrasonics / lithotripsy		X			
Household items			X	X	
Laser procedures		X			

Table 2.1 Potential effects of EMI from devices or procedures (continued)

Device or procedure	Serious patient injury	Device damage	Device turns off/on	Momentary increase in stimulation	Intermittent stimulation
Magnetic resonance imaging (MRI)	X	X	X	X	X
Psychotherapeutic procedures		X	X	X	X
Radiation therapy		X			
Radio-frequency (RF) / microwave ablation	X	X			X

Table 2.1 Potential effects of EMI from devices or procedures (continued)

Device or procedure	Serious patient injury	Device damage	Device turns off/on	Momentary increase in stimulation	Intermittent stimulation
Theft detector or security device			X	X	X
Therapeutic ultrasound	X	X			X
Transcutaneous electrical nerve stimulation (TENS)			X	X	

Case damage—If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Neurostimulator interaction with implanted cardiac devices—When a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator) are required, the doctors involved with both devices (eg, neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. To minimize or prevent device damage or interactions, your doctors should place the devices on the opposite side of the body from one another.

- Defibrillation therapy from an implanted defibrillator can damage the neurostimulator.
- The electrical pulses from the neurostimulation system could affect with the sensing operation from the cardiac device and result in inappropriate responses from the cardiac device.Your

doctor should program your neurostimulator to a bipolar configuration and a minimum rate of 60 Hz. The cardiac device should be programmed to bipolar sensing.

Precautions

System and therapy

Battery charge level—Check battery status and charge the battery regularly. Battery capacity will continue to slowly drain, even when the neurostimulator is off. If the battery becomes completely discharged, therapy will be lost.

Clinician programmer interaction with a cochlear implant—If you have a cochlear implant, the external portion of the cochlear system should be kept as far away as possible from the clinician programmer or the cochlear implant should be turned off during programming to prevent unintended audible clicks.

Component compatibility—For proper therapy, use only Medtronic Neuromodulation components that are prescribed by your physician.

Equipment modification—Do not modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.

Patient control devices may affect other implanted devices—Do not place patient control devices (eg, patient programmer, controller, recharger) over another device (eg, pacemaker, defribrillator, another neurostimulator). The patient control device could accidently change the operation of another device.

Patient device handling—To avoid damaging the device, do not immerse it in liquid; do not clean it with bleach, nail polish remover, mineral oil, or similar substances; and do not drop it or mishandle it in a way that may damage it.

Patient device use—When operating a patient control device (eg, external neurostimulator, patient programmer, controller, recharging system), use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the device could occur. The consequences of using a battery-powered device near flammable or explosive atmospheres are unknown.

Programmer interaction with other active implanted devices—If you have a neurostimulator and another active implanted device the radio-frequency (RF) signal used to program either device can reset or reprogram the other device.

To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed settings before you are sent home from the hospital and after either device is programmed (or as soon as possible after these times).

Contact your doctor immediately if you notice symptoms that could be related to either device or to the medical condition treated by either device.

Patient activities

Activities requiring excessive twisting or stretching—Avoid activities that may put undue stress on the implanted components of your neurostimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause parts of your neurostimulation system to fracture or migrate. This can result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery. Spinal cord stimulation patients, in particular, should avoid excessive bending of the torso.

Component manipulation (twiddler's syndrome)—Do not manipulate or rub your neurostimulation system through the skin; this is sometimes called "twiddler's syndrome." Manipulation can cause damage to your

system, lead dislodgement, skin erosion, or stimulation at the implant site.

Scuba diving or hyperbaric chambers—Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) can damage the neurostimulation system. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

Skydiving, skiing, or hiking in the mountains—High altitudes should not affect the neurostimulator; however, you should consider the movements involved in any planned activity and take precaution to not put undue stress on your implanted system. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the lead, requiring additional surgery to repair or replace the lead.

Unexpected changes in stimulation—Electromagnetic interference, changes in

posture, and other activities can cause a perceived increase in stimulation, which some patients have described as uncomfortable stimulation (a jolting or shocking sensation). You should reduce your intensity to the lowest setting and turn off your neurostimulator before engaging in activities that could be unsafe for you or others if you received an unexpected jolt or shock (eg, driving, operating power tools). Discuss these activities with your doctor.

Individualization of Treatment

Patient management—Best results are achieved when you are fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the neurostimulation system require long-term postsurgical management.

Patient selection—The neurostimulation system should not be implanted if:

- your symptoms are not of physiological origin,

- you are not an appropriate candidate for surgery,
- you cannot properly operate the system, or
- you do not receive satisfactory results from test stimulation.

Use in specific populations—The safety and effectiveness of this therapy has not been established for the following:

- Pregnancy, unborn fetus, or delivery
- Pediatric use (patients under the age of 18)