Medtronic

RestoreSensor™ 37714

Multi-program rechargeable neurostimulator

Implant manual

! USA Rx only

CE 0123 2010

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

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.

Caution, consult accompanying documents

Consult instructions for use

Do not reuse

Date of manufacture

Manufacturer

Open here

Use by

SN

Serial number

STERILE | EO

Sterilized using ethylene oxide

EC | REP

Authorized representative in the European community

! USA

For USA audiences only

Temperature limitation

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.)

Table of contents

Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

! USA **Refer to the clinical summary booklet for information on the clinical study results of the neurostimulation system and individualization of treatment.**

Description

The Medtronic RestoreSensor Model 37714 Neurostimulator is part of a neurostimulation system for pain therapy.

Package contents

- Neurostimulator
- Torque wrench
- Product literature
- Warranty card (USA only)
- Registration form
- Patient identification card

Patient identification card

A patient identification card is packaged with this device. Advise the patient to carry the identification card at all times.

! USA The patient identification card packaged with the device is temporary; a permanent card will be mailed to the patient when Medtronic receives the registration form.

The implant registration form registers the device warranties and creates a record of the device in Medtronic's implant data system.

Device specifications

The neurostimulator is a multi-programmable, rechargeable device that delivers stimulation through 1 or more leads. The stimulation settings are stored in programs. A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode combination (up to 16 electrodes per program). Up to 4 programs can be combined into a group. When using more than 1 program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program.

Pulse width, amplitude, and electrode polarity for each program within the group can have different values. Rate, rate limits, ramping, and cycling for each program within the group have the same values.

Table 1. Operating values for the RestoreSensor Model 37714 Neurostimulator

Programmable parameter	Operating range and resolution[a]
Number of defined groups	1 to 8[b]
Number of programs per group	1 to 4[b]
Electrode configuration	2 to 16 electrodes as anode, cathode, or OFF
Amplitude	0 to 10.5 V with 0.05 V- or 0.1 V-resolution
Amplitude – upper patient limit	Tracking limit: programmed value +0 to +4 V (0.5 V-resolution) Custom limit: programmed value to 10.5 V (same resolution as amplitude)
Amplitude – lower patient limit	Custom limit: 0 V to the programmed value (same resolution as amplitude)
Pulse width	60 to 1000 µs (10-µs resolution)
Pulse width – upper patient limit[c]	Tracking limit: programmed value +0 to +300 µs (60-µs resolution) Custom limit: programmed value to 1000 µs (10-µs resolution)
Pulse width – lower patient limit[c]	Custom limit: 60 µs to the programmed value (10-µs resolution)
Rate	2 to 1200 Hz (resolution: 1 Hz from 2 Hz to 10 Hz, 5 Hz from 10 Hz to 250 Hz, 10 Hz from 250 Hz to 500 Hz, 20 Hz from 500 Hz to 1000 Hz, 50 Hz from 1000 Hz to 1200 Hz)[d]
Rate – upper patient limit	Tracking limit: programmed value +0, +10, +20, +50, +100 Hz Custom limit: programmed value to 1200 Hz (same resolution as rate)
Rate – lower patient limit	Custom limit: 2 to the programmed value (same resolution as rate)
SoftStart/Stop	OFF, ON: 1, 2, 4, or 8 second ramp duration
Cycling	OFF, ON: 0.1 s to 30 min (resolution: 0.1 s from 0.1 s to 1 s, 1 s from 1 s to 1 min, 1 min from 1 min to 30 min)
AdaptiveStim	OFF, ON: 6 positions

[a] Interlocks will prevent the use of some parameter combinations.

[b] No more than 16 programs may be defined within the 8 groups.

[c] Pulse width and rate limits not available for groups with AdaptiveStim enabled.

[d] Rate limited to 600 Hz when 2 programs per group are active, 400 Hz when 3 programs per group are active and 300 Hz when 4 programs per group are active.

Table 2. Physical characteristics of the RestoreSensor Model 37714 Neurostimulator[a]

Description	Value
Connector type	Octapolar, in-line 2.8-mm (0.110-in) spacing
Height	54.0 mm (2.1 in)
Length	54.0 mm (2.1 in)
Thickness	
case	9.0 mm (0.4 in)
connector	11.0 mm (0.4 in)
Weight	45.0 g (1.6 oz)
Volume	22.0 cm^3
Battery life	9 years
Power source	Lithium ion rechargeable battery
Storage temperature	–18° to +52°C (0° to +126°F)
Serial number model designator[b]	NKS
Radiopaque identification (ID) code	NKD

[a] All measurements are approximate.

[b] The serial number is the model designator followed by a number. The clinician programmer displays the entire serial number beginning with the model designator.

Table 3. Material of components in the RestoreSensor Model 37714 package

Components	Material	Material contacts human tissue
Neurostimulator		
Case	Titanium	Yes
Connector block	Polysulfone, silicone rubber, silicone medical adhesive	Yes
Grommets, seals	Silicone rubber	Yes
Setscrews	Titanium alloy	Yes
Adhesive	Silicone medical adhesive	Yes
Torque wrench		
Handle	Ultem	Yes
Shaft	Stainless steel	Yes

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact the appropriate Medtronic representative listed on the inside back cover of this manual.

Instructions for use

Implanting physicians should be experienced in epidural-access procedures and should be thoroughly familiar with all product labeling.

⚠ **Warning:** DO NOT use the recharger on an unhealed wound. The recharger, antenna, and holder are not sterile, and contact with the wound can cause an infection.

⚠ **Caution:** Advise patients to charge the neurostimulator when a **Low battery** () screen is displayed on the patient programmer or recharger; this prevents the battery from overdischarging. If the neurostimulator battery is allowed to overdischarge, the patient cannot charge the neurostimulator; however, the clinician may be able to restore the battery function using the Physician Recharge Mode on the recharger (refer to the troubleshooting section of the software manual).

Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.
- Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored when:
  - the neurostimulator battery is permanently damaged.
  - the neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

⚠ **Cautions:**

- When using sharp instruments near the neurostimulator, be extremely careful to avoid nicking or damaging the case, the insulation, or the connector block. Damaging the neurostimulator may require surgical replacement.
- Do not use saline or other ionic fluids at connections, which could result in a short circuit.

Charging the neurostimulator battery

Charge the neurostimulator battery before opening the package. For charging instructions, refer to the charging system user manual.

Verifying neurostimulator operation

Before opening the sterile neurostimulator package, verify that the neurostimulator is operable by using the clinician programmer to interrogate the neurostimulator and read the neurostimulator battery charge level. (Refer to the software manual for instructions on how to read the battery charge level.)

Caution: Do not implant a neurostimulator if it was dropped onto a hard surface from a height of 30 cm (12 in) or more, because the neurostimulator may be damaged and fail to operate properly.

Note: The neurostimulator pocket may be flushed with an antibiotic solution; do not submerge the neurostimulator in fluid.

Connecting the extension or lead to the neurostimulator

Caution: Before connecting components, wipe off any body fluids and dry all connections. Fluids in the connection may result in stimulation at the connection site, intermittent stimulation, or loss of stimulation.

1. Wipe the extension or lead connector pins with sterile gauze. If necessary, use sterile (United States Pharmacopeia [USP]) water or a nonionic antibiotic solution.
2. Make sure the connector block receptacles are dry and clean.
3. Insert the appropriate extension or lead connector pins into the appropriate neurostimulator socket until they are seated fully within the connector block (Figure 1).

   Notes:

   - During insertion, some resistance is typical.
   - To retract the setscrews, insert the torque wrench into the self-sealing grommet and rotate the setscrews counterclockwise; however, do not remove the setscrews from the connector block.

     Caution: Do not insert the extension or lead connector into the connector block if the setscrews are not sufficiently retracted. If the setscrews are not retracted, the setscrews may damage the extension or lead and the extension or lead will not be seated fully into the connector block.

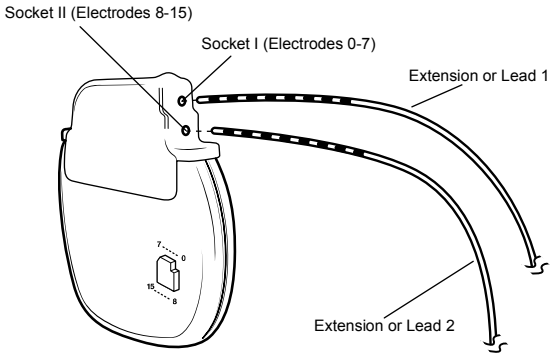

Figure 1. *Insert the extension or lead connector pins fully into the neurostimulator.*

Note: Insert a connector plug (from an accessory kit) into any unused neurostimulator socket.

4. For each extension, lead, or plug, fully insert the torque wrench (packaged with the rechargeable neurostimulation system) into each self-sealing grommet of the connector block and tighten each setscrew (Figure 2).

   Cautions:

   - Be sure the torque wrench is fully inserted into the self-sealing grommet. If the torque wrench is not fully inserted, the setscrew may be damaged, resulting in intermittent or loss of stimulation.
   - Before tightening setscrews, ensure that the extension or lead connector pins are inserted into the connector block to prevent damaging the lead or extension.
   - Verify that each leaf of the self-sealing grommet is closed after the torque wrench is withdrawn. If fluid leaks through a grommet seal that is not fully closed, the patient may experience shocking, burning, or irritation at the neurostimulator implant location, or intermittent stimulation, or loss of stimulation.

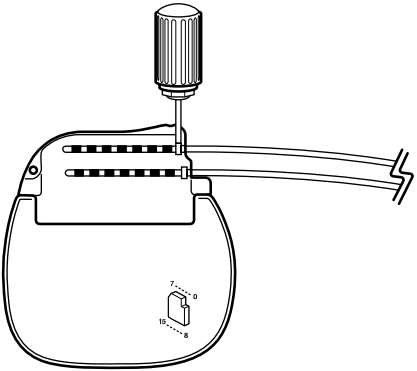

Figure 2. *Tightening the setscrews in the self-sealing grommet.*

Implanting the neurostimulator

1. Place the neurostimulator into the subcutaneous pocket with the Medtronic logo facing outward, away from muscle tissue, and ensure that the extension or lead is not bent sharply.

Cautions:

- Ensure that the neurostimulator is placed no deeper than 1 cm (0.4 in) below the skin and is parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, recharge may be inefficient or unsuccessful.
- Position the neurostimulator with the Medtronic logo facing outward. If implanted with the Medtronic logo facing inward, the neurostimulator cannot be charged.
- Do not coil excess extensions or leads in front of the neurostimulator. Wrap excess extensions or leads around the perimeter (Figure 3) or behind the neurostimulator to help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension or lead, and minimize interference with telemetry and recharge operation.

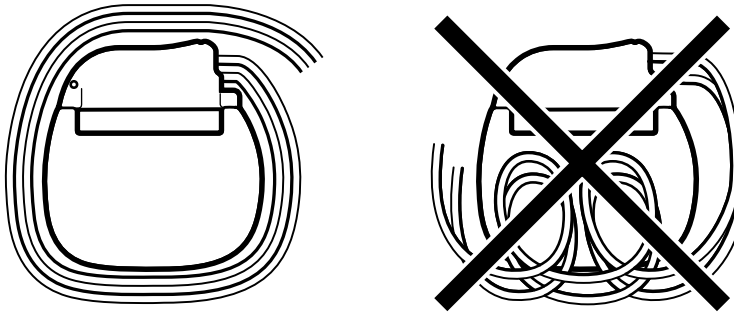

Figure 3. *Wrap excess extensions or leads around the perimeter (or behind) the neurostimulator.*

2. Use the suture holes in the connector block to secure the neurostimulator to the muscle fascia with nonabsorbable silk.

   Note: Secure the neurostimulator in the pocket to minimize movement or migration of the neurostimulator.

Checking system integrity

Caution: To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Note: The neurostimulator should be in the pocket during system interrogation for integrity to ensure proper readings.

1. To ensure proper connection of each extension or lead to the neurostimulator, use the clinician programmer to program the basic stimulation parameters, check the battery status, and check the electrode impedances to rule out a short or open circuit.
2. If the system integrity test results are not acceptable, refer to "Connecting the extension or lead to the neurostimulator" on page 10.
3. Complete the stimulation assessment form.

Completing the implant procedure

1. Close and dress all incisions.
2. Ensure that a patient control device is given to the patient.
3. Complete the device tracking and patient registration paperwork and return the documents to Medtronic.

Contacts:

Asia:
Medtronic International Ltd.
Tel. 02891-4068
Fax 02591-0313

Medtronic Asia Ltd.
Tel. (02)-548-1148
Fax (02)-518-4786

Australia:
Medtronic Australasia Pty. Ltd.
97 Waterloo Road
North Ryde, NSW 2113
Australia
Tel. +61-2-9857-9000
Fax +61-2-9878-5100
Toll free 1-800-668-6700

Austria:
Medtronic Österreich GmbH
Tel. 01-240440
Fax 01-24044-100

Belgium:
Medtronic Belgium S.A.
Tel. 02-456-0900
Fax 02-460-2667

Canada:
Medtronic of Canada Ltd.
Tel. (1905)-826-6020
Fax (1905)-826-6620

Czech Republic:
Medtronic Czechia s.r.o.
Tel. 2-965-795-80
Fax 2-965-795-89

Denmark:
Medtronic Danmark A/S
Tel. 45-32-48-18-00
Fax 45-32-48-18-01

Finland:
Medtronic Finland Oy/LTD
Tel. (09)-755-2500
Fax (09)-755-25018

France:
Medtronic France S.A.S.
Tel. 01-5538-1700
Fax 01-5538-1800

Germany:
Medtronic GmbH
Tel. (02159)-81490
Fax (02159)-8149100

Greece:
Medtronic Hellas S.A.
Tel. 210-67-79-099
Fax 210-67-79-399

Hungary:
Medtronic Hungária Kft.
Tel. 1-889-06-00
Fax 1-889-06-99

Ireland:
Medtronic Ireland Ltd.
Tel. (01)-890-6522
Fax (01)-890-7220

Italy:
Medtronic Italia SpA
Tel. 02-241371
Fax 02-241381
Tel. 06-328141
Fax 06-3215812

Japan:
Medtronic Japan
Tel. 3-6430-2011
Fax 3-6430-7140

Latin America:
Medtronic, Inc.
Tel. (1305)-500-9328
Fax (1786)-709-4244

Norway:
Medtronic Norge AS
Tel. 067-10-32-00
Fax 067-10-32-10

Poland:
Medtronic Poland Sp. z.o.o.
Tel. (022)-465-69-00
Fax (022)-465-69-17

Portugal:
Medtronic Portugal, Lda.
Tel. 21-724-5100
Fax 21-724-5199

Russia:
Medtronic Russia
Tel. (8495) 580-7377
Fax (8495) 580-7378

Slovakia
Medtronic Slovakia, o.z.
Tel. 0268 206 911
Fax 0268 206 999

Spain:
Medtronic Ibérica, S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden:
Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01

Switzerland:
Medtronic (Schweiz) AG
Tel. 031-868-0100
Fax 031-868-0199

The Netherlands:
Medtronic B.V.
Tel. (045)-566-8000
Fax (045)-566-8668

U.K.:
Medtronic U.K. Ltd.
Tel. 01923-212213
Fax 01923-241004

USA:
Medtronic, Inc.
Tel. (1763)-505-5000
Fax (1763)-505-1000
Toll-free: (1-800)-328-0810

Medtronic

Alleviating Pain · Restoring Health · Extending Life

Manufacturer
Medtronic, Inc.
710 Medtronic Parkway,
Minneapolis, MN 55432-5604,
USA.
Internet: www.medtronic.com
Tel. +1-763-505-5000
Fax +1-763-505-1000

Authorized Representative in the European Community EC REP
Medtronic B.V.
Earl Bakkenstraat 10,
6422 PJ Heerlen,
The Netherlands
Internet: www.medtronic.com
Tel. +31-45-566-8000
Fax +31-45-566-8668

Europe/Africa/Middle East Headquarters
Medtronic International Trading Sàrl
Route du Molliau 31,
Case Postale 84
CH-1131 Tolochenaz,
Switzerland
Internet: www.medtronic.com
Tel. +41-21-802-7000
Fax +41-21-802-7900

Asia-Pacific
Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza,
The Lee Gardens, 33 Hysan Avenue,
Causeway Bay,
Hong Kong
Tel. +852-2891-4068
Fax +852-2591-0313

Contacts for specific countries are listed inside this cover.

M934840A001

M934840A001