Medtronic

Wireless External Neurostimulator 97725

User manual

! USA Rx only

CE 0123

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.


Consult instructions for use


Do not reuse


Use by

Sterilized using ethylene oxide

Do not resterilize


Manufacturer


Date of manufacture

Temperature limitation

Magnetic Resonance (MR) Unsafe


Non-ionizing electromagnetic radiation

Serial number

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.)

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


IEC60601-1/EN60601-1, Type BF equipment

Conformité Européenne (European Conformity). This symbol means that the device fully complies with MDD 93/42/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

EC REP

Authorized Representative in the European Community

! USA

For USA audiences only

Do not use of the package is damaged.

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 **FCC Information**

The following is communications regulation information on the Model 97725 Wireless External Neurostimulator.

FCC ID: LF597725

This device complies with Part 15 of the FCC 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.

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.**

Purpose of the device

The Medtronic Model 97725 Wireless External Neurostimulator (ENS) is used to evaluate a Medtronic Neurostimulation System during lead placement or test stimulation.

Description

The Medtronic Model 97725 Wireless External Neurostimulator is a disposable, sterile, single-use device equipped with Bluetooth wireless technology, and is part of a neurostimulation system.

Package contents

- Wireless external neurostimulator with batteries inserted
- Spare AAA alkaline batteries (2)
- Product literature
- ! USA Warranty card

Accessories

- Wireless external neurostimulator boot (packaged separately)

Device specifications

The Model 97725 Wireless External Neurostimulator (Figure 1 and Figure 2) is a multi-programmable device that delivers stimulation through 1 or more leads. The stimulation settings are stored in programs to target pain areas. A program is a specific combination of pulse width, rate, and intensity settings acting on a specific electrode combination (up to 16 electrodes per program). Up to 4 pain areas can be targeted by programs. When stimulating more than one pain area, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program.

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

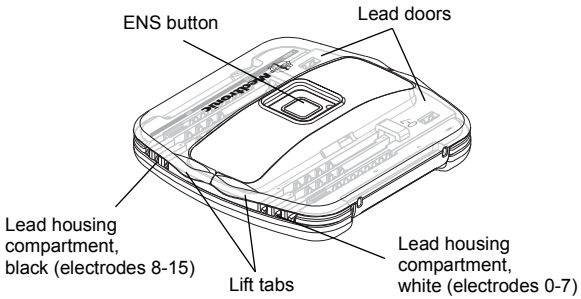

Figure 1. *Model 97725 Wireless External Neurostimulator (doors closed).*

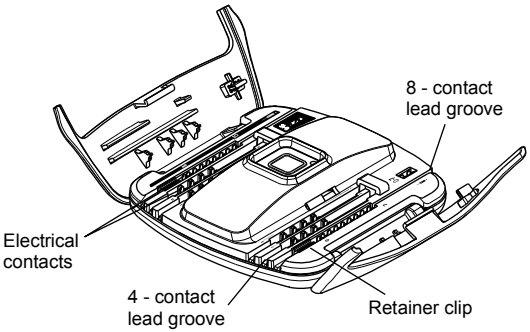

Figure 2. *Model 97725 Wireless Exernal Neurostimulator (doors open).*

Table 1. Operating values for the Model 97725 Wireless External Neurostimulator

Programmable parameter	Operating values and ranges[a]
Number of defined groups	1-3 (optional)
Number of programs per pain area	1-3
Number of programs	12

Table 1. Operating values for the Model 97725 Wireless External Neurostimulator (continued)

Programmable parameter	Operating values and ranges[a]
Number of pain areas	1-4
Electrode configuration	2 to 16 electrodes as anode, cathode, or off
Maximum intensity per electrode	0-25.5 mA (0.1-mA increment)
Program intensity	0-100 mA
Intensity – limits	Enabled or disabled at maximum 25.5 mA per electrode
Pulse width	60 to 1000 µs (10-µs increment)
Pulse width – limits	Enabled or disabled at maximum 1000 µs
Rate	10 to 1200 Hz[b] (1-Hz increment between 10 and 30 Hz; 5-Hz increment between 30 and 250 Hz; 10-Hz increment between 250 and 500 Hz; 20-Hz increment between 500 and 1000 Hz; 50-Hz increment between 1000 and 1200 Hz.)
Rate ratio	A fraction of the master rate (1/1, 1/2, 1/3, 1/4, 1/5)
Rate - limits	Enabled or disabled at maximum 1200 Hz
SoftStart/Stop	Off, on: 1, 2, 4, or 8 second ramp duration
Cycling	Off: 0.1 s to 30 min; on: 5 s-30 min (increment: 0.1 s from 0.1-1 s, 1 s from 1 s-1 min, 1 min from 1-30 min)

[a] Interlocks and out-of-regulation detection will prevent the use of some parameter combinations.

[b] The maximum rate available for the external neurostimulator is limited to 600 Hz when two pain areas are simultaneously active, 400 Hz when three pain areas are simultaneously active, and to 300 Hz when four pain areas are simultaneously active.

Table 2. Physical characteristics of the Model 97725 Wireless External Neurostimulator[a]

Description	Value
Capacity	
Leads	4 quadripolar; 2 octapolar
Electrodes	32 electrodes, supporting 16 active
Length	79 mm (3.1 in)
Height	79 mm (3.1 in)

Table 2. Physical characteristics of the Model 97725 Wireless External Neurostimulator[a] (continued)

Description	Value
Width	74 mm (2.9 in)
Thickness	20 mm (0.8 in)
Weight (with batteries)	71 g (2.5 oz)
Battery life	7 days minimum for alkaline batteries[b]
Power source	AAA alkaline batteries (2)
Operating type	Continuous
Degree of protection against electrical shock	Type BF
Automatic shut off[c]	Lead door(s) open
Temperature limitation[d]	-20 °C to 54 °C (-4 °F to 130 °F)
Identification code	NLJ

[a] All measurements are approximate.

[b] Battery life is based on a 7-day trial using two active programs, 20-90 second controller Bluetooth sessions, and a 180-minute clinician Bluetooth session. For program 1: impedance = 620 Ω, Amp = 10.6 mA, PW = 330 µs, Rate = 60 Hz. For program 2: impedance = 560 Ω, Amp = 10.5 mA, PW = 330 µs, Rate = 60 Hz.

[c] Use the clinician programmer or controller to turn on the external neurostimulator once the condition is resolved.

[d] Store the external neurostimulator at room temperature.

Table 3. Material of components in the Model 97725 Wireless External Neurostimulator and boot accessory packages

Component	Material	Material contacts human tissue
Housing		
Base	Polycarbonate	Yes
Lead doors	Polycarbonate	Yes
Hinge pin	Stainless steel	No
Contacts	Gold- and nickel-plated beryllium copper	No
Retainer clip	Thermoplastic elastomer (TPE)	Yes

Table 3. Material of components in the Model 97725 Wireless External Neurostimulator and boot accessory packages (continued)

Component	Material	Material contacts human tissue
External neurostimulator boot		
Boot	Silicone	Yes
Adhesive	Medical acrylic microporous-coated adhesive	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 93/42/EEC on Medical Devices.

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

Instructions for use

The wireless external neurostimulator is used to evaluate lead placement and stimulation settings.

⚠ **Warning:** This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

⚠ **Caution:** The device is not certified for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the device near flammable atmospheres are unknown.

⚠ **Caution:** Do not modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.

⚠ **Caution:** Do not use the device in the proximity of equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in device function. Examples of common medical sources of EMI are magnetic resonance imaging (MRI) and lithotripsy. Powerful computer monitors, cell phones, x-ray equipment, and other monitoring equipment may also generate EMI.

Notes:

- Before placing the external neurostimulator into operation, ensure the external neurostimulator has had time to equalize to the current temperature and environment.
- For more information on EMI and x-ray use with the external neurostimulator, refer to the *Information for Prescribers Booklet*.
- Turn off and dispose of the external neurostimulator after defibrillation. For more information on the effects of defibrillation on the neurostimulator, refer to the *Information for Prescribers Booklet*.

Pairing the wireless external neurostimulator to a programmer or controller

For instructions on pairing the external neurostimulator to the clinician programmer, refer to the appropriate programming guide. For instructions on pairing the external neurostimulator to the controller, refer to the appropriate controller patient guide.

Using the wireless external neurostimulator during test stimulation

When programming during test stimulation, keep the clinician programmer within 3 meters (10 feet) of the external neurostimulator. The external neurostimulator does not attach to the programmer.

Using the ENS button

The **ENS** button is used to place the external neurostimulator into discovery mode to establish communication with a clinician programmer or controller. It can also be used when you need to immediately turn off the external neurostimulator. The **ENS** button is not an on/off control.

You must use either the clinician programmer or controller to turn on the external neurostimulator.

- Press and hold the **ENS** button for at least 3 seconds to turn off the external neurostimulator.

Understanding the LED light on the wireless external neurostimulator

When the external neurostimulator is turned on for the first time, the light-emitting diode (LED) shines continuously for a few seconds. When the LED begins to blink, the external neurostimulator has completed initiation, has entered discovery mode, and can be paired to a clinician programmer or controller.

Notes:

- The external neurostimulator will remain in discovery mode for 90 seconds, or until it successfully pairs with a programmer or controller, at which point the LED will stop blinking and turn off.
- The LED blinks whenever the external neurostimulator is in discovery mode, or when it receives data from a clinician programmer or controller.
- Refer to the appropriate programming guide or controller patient manual for more information.

Replacing the wireless external neurostimulator batteries

The external neurostimulator includes batteries inserted in the device, which should last the length of test stimulation (see Table 2 for more information on battery longevity). Replace the external neurostimulator batteries when the batteries are low or depleted. The battery level is shown on the clinician programmer and controller screens. For instructions on checking the external neurostimulator batteries, refer to the appropriate programming guide or the controller patient manual.

△ **Cautions:**

- When replacing batteries during test stimulation, save the programming settings before removing the batteries. If programming settings are not saved, stimulation history may no longer be available, and the stimulation settings may not reflect recent programming settings.
- Do not leave depleted batteries in the external neurostimulator. The batteries may corrode and cause damage to the electronic components.

Notes:

- Before inserting batteries, check for signs of battery leakage. If any residue is present, do not use.
- When replacing batteries outside the sterile field, use the spare alkaline batteries provided in the external neurostimulator package. The spare batteries are not sterile.

Changing the batteries during test stimulation

1. If the external neurostimulator is on, use the clinician programmer or controller to turn the external neurostimulator off.

2. Remove the tape or external neurostimulator boot from the external neurostimulator, keeping lead assembly and lead exit site secure. For instructions on removing the external neurostimulator boot from the external neurostimulator, refer to the boot's instructions for use.
3. Remove the leads from the external neurostimulator.
   a. Lift the lift tabs to open the lead doors.
   b. Gently lift each lead from the electrical contacts in the lead groove.
4. Proceed to step 2 in "Changing the batteries before test stimulation".

Changing the batteries before test stimulation

1. If the external neurostimulator is on, use the clinician programmer or controller to turn the external neurostimulator off.
2. Press back lightly on the latch of battery compartment cover, swing the cover open, then remove the cover (Figure 3).

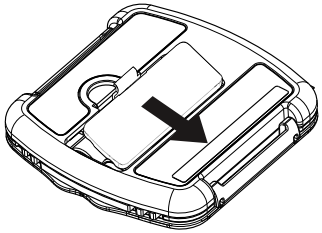

Figure 3. *Removing battery cover.*

3. Remove the depleted batteries, and insert new, Medtronic-supplied AAA alkaline batteries. Correct battery polarity is indicated inside the battery compartment (Figure 4).

Note: For optimal performance, use the same AAA alkaline batteries as those supplied by Medtronic.

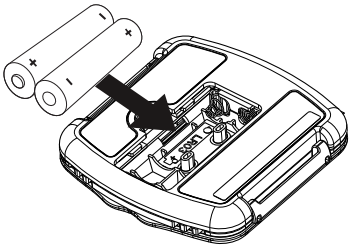

Figure 4. *Inserting new batteries.*

4. Replace the battery compartment cover, then press the cover until it snaps into place (Figure 5).

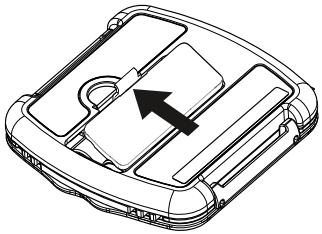

Figure 5. *Replace battery cover.*

Notes:

- After the batteries are installed and the battery compartment cover is closed, the external neurostimulator may take up to 6 seconds for device initiation. Stimulation is not available until device initiation is complete.
- Dispose of depleted batteries according to local requirements.

5. Place the leads in the external neurostimulator. Refer to "Connecting the wireless external neurostimulator to the 4-contact lead(s)" on page 14 or "Connecting the wireless external neurostimulator to the 8-contact lead(s)" on page 16 for instructions in placing the leads in the external neurostimulator.

Note: If replacing batteries during test stimulation, ensure identical seating of the leads inside the lead grooves.

6. Use the programmer to turn stimulation on.
7. Test lead insertion to confirm that the leads have been fully inserted into the lead grooves. For instructions on testing lead insertion, refer to the appropriate programming guide.
8. Secure the external neurostimulator to the patient. Refer to "Preparing the wireless external neurostimulator for test stimulation" on page 18 for instructions on securing the external neurostimulator to the patient.

Connecting the wireless external neurostimulator to the leads

The external neurostimulator has two lead housing compartments that each fit two 4-contact leads and one 8-contact lead. The leads are placed in lead grooves, which are numbered 0-7 on the white side and 8-15 on the black side (Figure 1). Leads are placed in both of the lead housing compartments.

- If using four 4-contact leads, two are placed in each housing compartment.
- If using two 8-contact leads, one is placed in each housing compartment.
- If using two 4-contact leads and one 8-contact lead, the 4-contact leads are placed in one housing compartment and the 8-contact lead must be placed in the other.

Notes:

- The 4-contact leads and the 8-contact leads enter the external neurostimulator in the same direction.
- The procedure for connecting the external neurostimulator is the same for leads and extensions.

Connecting the wireless external neurostimulator to the 4-contact lead(s)

Check battery status before connecting the external neurostimulator to the leads. Refer to the appropriate programming guide for information on checking battery status.

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

1. Wipe the lead contacts with dry sterile gauze.
2. Lift the lift tab on the appropriate lead housing compartment to open the clear lead door (Figure 6a).
3. Disconnect the long stylet handle from the 4-contact lead and withdraw the long stylet from the 4-contact lead.
4. Insert the short stylet into the 4-contact lead and connect the short stylet handle to the 4-contact lead.
5. Make sure the lead contacts and the electrical contacts inside the lead grooves are dry and clean.

6. Align the short stylet and proximal end of the lead against the inside end of a 4-contact lead groove of the connector (Figure 6a).

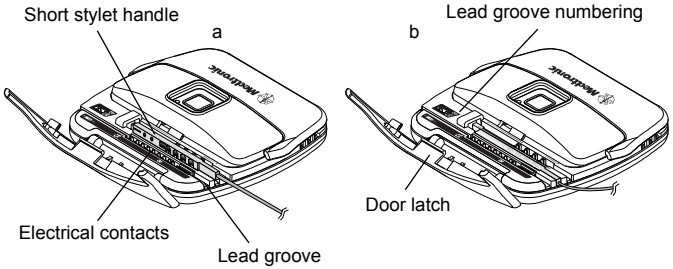

Figure 6. *External neurostimulator with a 4-contact lead.*

7. Check that the lead contacts align with the electrical contacts inside the lead groove and that the short stylet handle aligns with the stylet-shaped portion of the lead groove (Figure 7).

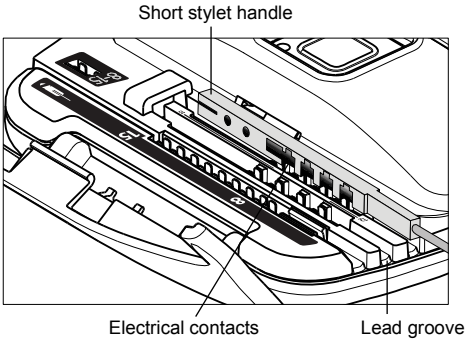

Figure 7. *Align the lead contacts with the electrical contacts in the lead groove.*

Note: The lead and short stylet fit only one way into the external neurostimulator lead housing.

8. Press the lead and short stylet gently into the lead groove (Figure 6b). If an additional 4-contact lead is used, repeat step 1 and steps 3 to 8.
9. Push the door(s) closed until the latch snaps firmly into place.

   Note: Do not force the doors closed; they should close easily. If they do not, disassemble the components and repeat steps 2 to 9.
10. Confirm correct seating by viewing the leads through the closed doors.
11. Refer to the appropriate programming guide and lead manual to reestablish communication with the external neurostimulator and the clinician programmer, verify proper connection, and identify optimal stimulation parameters.

Connecting the wireless external neurostimulator to the 8-contact lead(s)

Check battery status before connecting the external neurostimulator to the leads. Refer to the appropriate programming guide for information on checking battery status.

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

1. Wipe the lead contacts with dry sterile gauze.
2. Lift the lift tab on the appropriate lead housing compartment to open the clear lead door (Figure 8a).
3. Make sure the lead contacts and the electrical contacts inside the lead grooves are dry and clean.
4. While holding the 8-contact lead, disconnect the stylet handle from the lead (proximal end), and partially withdraw the stylet.

   Note: If connecting an extension or a lead without a stylet, proceed to step 5.
5. Align the proximal end of the lead against the inside end of an 8-contact lead groove of the connector (Figure 8a).

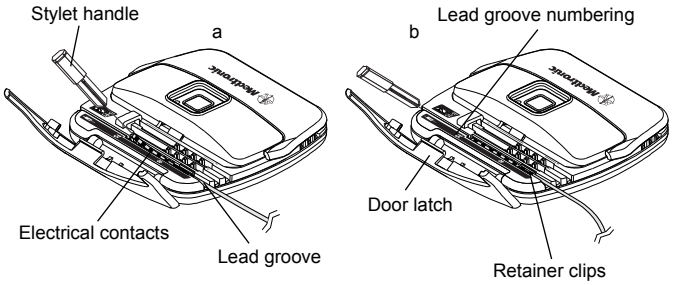

Figure 8. *External neurostimulator with an 8-contact lead with the stylet partially withdrawn.*

6. Check that the lead contacts align with the electrical contacts inside the lead groove (Figure 9).

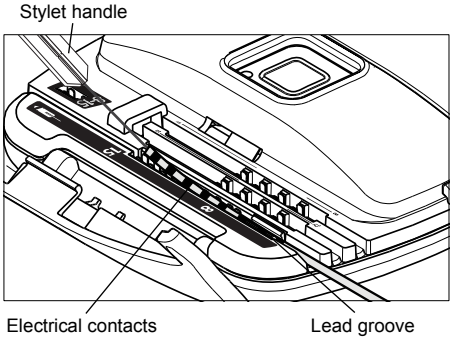

Figure 9. *Align the lead contacts with the electrical contacts in the lead groove.*

Note: The lead fits only one way into the external neurostimulator lead housing.

7. Press the lead gently into the lead groove and the retainer clip (Figure 8b). If an additional 8-contact lead is used, repeat step 1 and steps 3 to 7.

8. Push door(s) closed until the latch snaps firmly into place.

Note: Do not force the doors closed; they should close easily. If they do not, disassemble the components and repeat steps 2 to 8.

9. Confirm correct seating by viewing the leads through the closed doors.
10. Refer to the appropriate programming guide and lead manual to reestablish communication with the external neurostimulator and the clinician programmer, verify proper connection, and identify optimal stimulation parameters.

Preparing the wireless external neurostimulator for test stimulation

Check battery status and test lead insertion before attaching the external neurostimulator to the patient. Refer to the appropriate programming guide for information on checking battery status and testing lead insertion.

1. Place a gauze bandage on the skin where the lead and external neurostimulator will be placed on the patient.

   Note: If using the wireless external neurostimulator boot, refer to the boot's instructions for use.
2. Tape the lead and external neurostimulator separately to the skin.
3. Tape the entire assembly to the skin, allowing for strain relief.

   Notes:
   - Ensure that the **ENS** button faces away from the patient.
   - Avoid placing bandaging over the **ENS** button in a way that obstructs it from use.
4. Proceed with the trial evaluation.

Removing the wireless external neurostimulator after test stimulation

1. Verify that the external neurostimulator is off.
2. Remove all tape from the lead and external neurostimulator.
3. Lift the lift tabs to open the lead doors.
4. Gently lift each lead from the electrical contacts in the lead groove.
5. Dispose of the external neurostimulator according to environmental regulations.

Device care and storage

- Keep new AAA alkaline batteries available. For optimal performance, use the same batteries as those supplied by Medtronic.
- Use the clinician programmer or the controller to check the external neurostimulator battery level daily. For instructions on checking the external neurostimulator batteries, refer to the appropriate programming guide or the controller patient manual.
- Replace low or depleted batteries.
- Handle the device and system components with care. Do not drop, strike or step on the device or system components.
- Do not dismantle or tamper with the device.

- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- Store the external neurostimulator at room temperature. Avoid extreme hot or cold temperatures and direct sunlight.
- The device and system components are not waterproof. Do not allow moisture to get inside the device or system components.
- Dispose of depleted batteries and devices according to local requirements.

Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the external neurostimulator are not required.

The external neurostimulator contains no serviceable components. If the external neurostimulator requires repair or is nonfunctional, send it to the appropriate address.

USA

Medtronic, Inc.
Neurological Division
MS N600
PO Box 1250
Minneapolis, MN 55440-9087

Europe, Africa, Middle East, and Asia-Pacific countries

Medtronic EOC
Medical Equipment Service Europe
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. 31-455664880
Fax 31-455668028

Contacts:

Asia:
Medtronic International Ltd.
Tel. 02919-1362
Fax 02907-3998

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. (1-905)-460-3800
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. 03-6430-2016
Fax 03-6430-7110

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
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
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
www.medtronic.eu
Tel. 41-21-802-7000
Fax 41-21-802-7900

Asia-Pacific
Medtronic International Ltd.
Suite 1106-11, 11/F, Tower 1, The Gateway
25 Canton Road, Tsimshatsui
Kowloon
Hong Kong
Tel. 852-2891-4068
Fax 852-2591-0313

Contacts for specific countries are listed inside this cover.

M946491A001

M946491A001