Medtronic

Activa® RC 37612

Multi-program rechargeable neurostimulator

Implant manual

! USA Rx only

CE 0123 2008

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Open here

Do not reuse

Sterilization: ethylene-oxide gas

Caution: consult accompanying documents

Date of manufacture

Manufacturer

Use by

Temperature limitation

Serial number

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.

Authorized representative in the European community

For USA audiences only

Table of contents

Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet and any other additional information packaged with the product for contraindications, warnings, precautions, component disposal, and other important device therapy information.

Refer to System Eligibility, Battery Longevity, Specifications reference manual packaged with the software application card for neurostimulator selection and battery longevity calculations.

! USA **Refer to the clinical summary booklet packaged with the neurostimulator for information on the clinical study results of the neurostimulation system.**

Description

The Medtronic Activa RC Model 37612 Neurostimulator is part of a neurostimulation system for deep brain stimulation.

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 2 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 four programs can be combined into a group, with a maximum of 2 programs per lead. When using more than one 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 Activa RC Model 37612 neurostimulator

Programmable parameter	Operating range and resolution[a]
Number of defined groups	1 to 4[b]
Number of programs per group	1 to 4[b]
Electrode configuration	Up to 4 electrodes as anode, cathode, or OFF Case defined as anode or OFF
Amplitude (voltage mode)	0 to 10.5 V with 0.05 V or 0.1-V resolution
Amplitude (current mode)	0 to 25.5 mA with 0.1-mA resolution
Amplitude – upper patient limit	By hemisphere: Tracking limit: +0 to +2 (0.2 resolution); +2 to +4.5 (0.5 resolution)
Amplitude – lower patient limit	By hemisphere: Tracking limit: -0 to -2 (0.2 resolution); -2 to -4.0 (0.5 resolution); full range[c]
Pulse width	60 to 450 µs (10-µs resolution)
Pulse width – upper patient limit	Tracking limit: +0 to +100 µs (10-µs resolution)
Pulse width – lower patient limit	Tracking limit: -0 to -100 µs (10-µs resolution)
Rate (voltage mode)	2 to 250 Hz (resolution: 1 Hz from 2 Hz to 10 Hz, 5 Hz from 10 Hz to 250 Hz)[d]
Rate (current mode)	30 to 250 Hz (5-Hz resolution)[d]
Rate – upper patient limit	Tracking limit: +0 to +50 Hz (10-Hz resolution)
Rate – lower patient limit	Tracking limit: -0 to -50 Hz (10-Hz resolution)
SoftStart/Stop	OFF, ON: 1-, 2-, 4-, or 8-second ramp duration
Cycling	OFF, ON: 0.1 s to 24 hr (resolution: 0.1 s from 0.1 s to 1 s, 1 s from 1 s to 59 s, 1 min from 1 min to 59 min, 1 hr from 1 hr to 24 hr)

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

[b] No more than 16 programs may be defined within the 4 groups.

[c] Full range = -10.5 V (voltage mode); -25.5 mA (current mode)

[d] Rate limited to 125 Hz when two programs are active on a single lead.

Table 2. Physical characteristics of the Activa RC Model 37612 neurostimulator[a]

Description	Value
Connector type	Octapolar, in-line 2.8-mm (0.110-in) spacing
Height	54 mm (2.1 in)
Length	54 mm (2.1 in)
Thickness	
case	9 mm (0.4 in)
connector	11 mm (0.4 in)
Weight	40 g (1.6 oz)
Volume	22 cm^3
Battery life	9 years
Power source[b]	Lithium ion rechargeable battery
Storage temperature	–18° to +52°C (0° to +126°F)
Serial number model designator[c]	NKG
Radiopaque Identification (ID) code	NKG

[a] All measurements are approximate.

[b] The neurostimulator is not shipped with a full battery charge. Refer to the charging system user manual for neurostimulator charging instructions.

[c] 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 Activa RC Model 37612 package

Components	Material	Material contacts human tissue
Neurostimulator		
Case	Titanium, parylene	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	Polyetherimide	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 stereotactic and functional neurosurgery and have expertise with functional stereotactic neurosurgical treatment of movement disorders and should be thoroughly familiar with all product labeling.

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

⚠ **Caution:** Advise patients to charge the neurostimulator on a regular basis, taking into consideration the therapeutic parameters and battery usage of the patient, to prevent 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 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 connectors 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 each extension connector into the appropriate neurostimulator socket until it is 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 connector into the connector block if the setscrews are not sufficiently retracted. If the setscrews are not retracted, the setscrews may damage the extension and the extension will not be seated fully into the connector block.

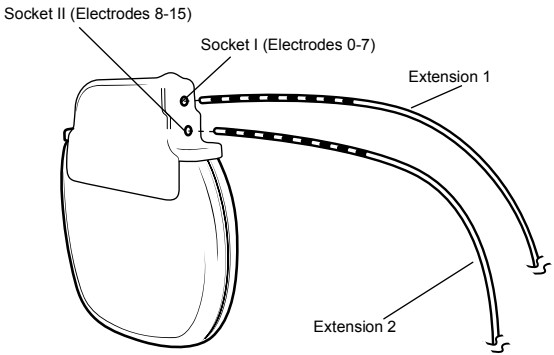

Figure 1. *Insert the extension connectors into the neurostimulator.*

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

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

   Cautions:

   - To prevent undertightening the neurostimulator setscrews, do not use the torque wrench from the extension kit. Undertightening may result in insufficient electrical contact within the connector block, which may cause intermittent stimulation.
   - 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 connector is inserted into the connector block to prevent damaging the 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.

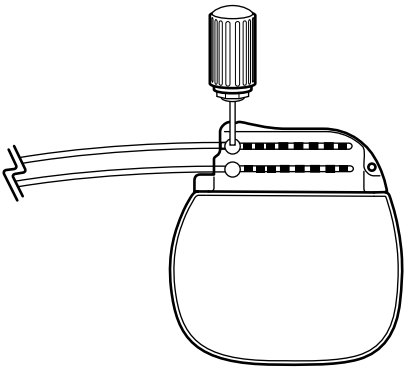

Figure 2. *Tightening the setscrews in the self-sealing grommet.*

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 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 will be difficult to charge.
   - Do not coil excess extension in front of the neurostimulator. Wrap excess extension around the perimeter (Figure 3) of the neurostimulator to minimize subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension, and minimize interference with telemetry and recharge operation. Excess extension should not exceed two wraps around the perimeter of the neurostimulator. Extension lengths requiring more than two wraps can interfere with telemetry.

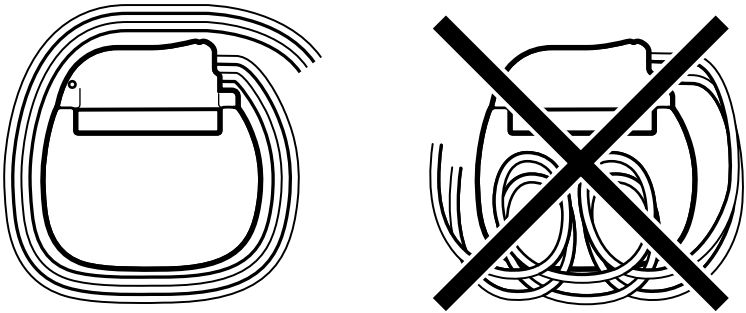

Figure 3. *Wrap excess extensions around the perimeter of the neurostimulator.*

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

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 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 to the neurostimulator" on page 10.

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.

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