Medtronic

Communicator
Instructions for use

TM91

! USA Rx only

CE 0123
2018

M966423A001 Rev D 2018-04-30

Label Symbols

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

Consult instructions for use

CE0123

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123).

Class II equipment

ON-OFF (Stand-by)

REF

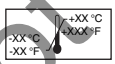
Reorder number

EC REP

Authorized Representative in the European Community

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.

Label Symbols

! USA	For USA audiences only
Rx only	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of manufacture
	Use by
	IEC60601-1/EN60601-1, Type BF equipment
	Direct Current
	Magnetic Resonance (MR) Unsafe
SN	Serial number
PIN	PIN number
	Keep dry
	Temperature limitation
	The Technical Conformity mark signifies that this device complies with Japan Radio Law.

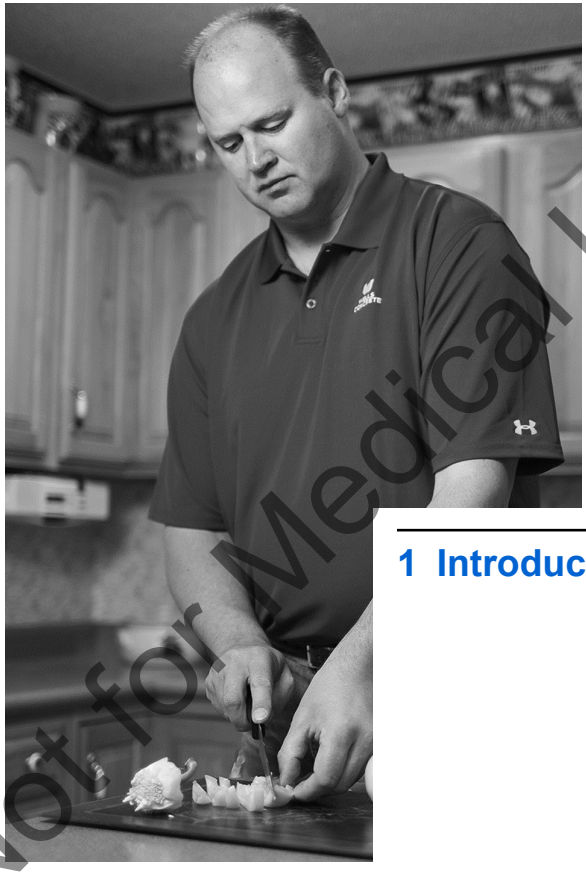
The RCM Certification mark signifies that this device complies with Australia/NewZealand EMC requirements for electrical and electronic equipment.

Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The "e" in this logo signifies none of the restricted substances are present above permitted levels.)

The KCC Certification mark signifies that this device complies with South Korea's radio requirements for telecommunication equipment.

Label Symbols

Table of contents



1 Introduction

How to use this manual

This manual contains information for patients and clinicians about the communicator device. Please read the entire manual before using the device.

- Chapter 1 “Introduction” explains how to use this manual, and provides patient information. This chapter describes the device and its purpose, and provides warnings, precautions, and Medtronic contact information.
- Chapter 2 “Using the communicator” lists items in the product package, and gives instructions for using the device.
- Chapter 3 “Troubleshooting and device care” provides information on electromagnetic interference (EMI), troubleshooting, and tips on caring for the device. This chapter also provides specifications, and information on who to call for assistance.

Patient information

You should have received additional manuals specific to your therapy. Review these materials, and keep them in a convenient location.

Purpose and description

The Medtronic Model TM91 Communicator is intended for patient or clinician use, to connect the app installed on the Model HH90 handset to the implanted medical device.

The app on the handset interacts with the implanted medical device through the communicator.

The communicator contains a lithium-ion battery that will need to be regularly charged. The communicator can be used in a home or health care setting.

For complete information, refer to the therapy manuals associated with your medical device.

Warnings

Sterile field—Avoid using the device in a sterile field. If it is necessary, place the device into a sterile bag or use a sterile barrier. The device is not sterile and cannot be sterilized. Failure to use a sterile bag or barrier may cause an infection.

Wound contact—Do not use the device on an unhealed wound. Place a sterile bandage or barrier between the wound and device. The device is not sterile. Contact with the wound without a sterile bandage or barrier may cause an infection.

Precautions

Disposal—Dispose of the communicator according to local regulations, or consult http://recycling.medtronic.com. Failure to dispose of the device correctly may lead to environmental damage.

How to contact Medtronic

! USA For assistance in the US, call +1 800 510 6735. Outside the US, call the phone numbers found at the back of the manual.

2 Using the communicator

Package contents

The Medtronic Model TM91 Communicator package contains the following parts:

- Model TM91 Communicator
- Product literature

The USB charging cable and AC adaptor are included in the handset package. Use this cable or another USB 2.0 compliant cable to charge the device.

How the communicator works

The communicator acts as a wireless "bridge" between the app installed on the handset, and the implanted medical device. The implanted device only accepts communications from the app through the communicator.

Sending information between the app and implanted device, through the communicator, will only occur after the app and communicator have been "paired". Pairing will take place before first use of the app.

For a new communicator that has not been paired with the app, or for any other reason the communicator is not paired with the app, refer to the app user guide for pairing instructions or troubleshooting.

Instructions for use

This section provides instructions for turning the communicator on and off, connecting it to the handset, and charging the communicator.

For instructions on connecting the communicator and app with the implanted device, refer to the appropriate app user guide that is included in the communicator package.

Notes:

- Allow 15 minutes for the communicator to warm up before use, after being stored at the minimum storage temperature.
- Allow 15 minutes for the communicator to cool down before use, after being stored at the maximum storage temperature.

During a therapy session, hold the communicator over the implanted device, no more than 4 cm away from the body.

If the communicator warms during a therapy session, and this is uncomfortable against your skin, place a thin layer of clothing between the communicator and skin.

For additional guidance on how and where to place the communicator, refer to the app user guide that is included in the communicator package.

Declaration of conformity

Medtronic declares that the Medtronic Model TM91 Communicator is in conformity with the essential requirements of Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, call the appropriate phone number found at the back of this manual.

Communicator overview

The Medtronic Restorative Therapy Ultra Low Power Active Medical Implant Peripheral (UP-AMI-P), model TM91, communicates with the Medtronic Ultra Low Power Active Medical (ULP-AMI) Implant by means of short range radio communication with the generic parameters presented in the tables below.

Figure 2.1 Communicator

The communicator includes a power button and USB charging port. A battery indicator light shows when the battery is low (yellow), charging (orange), or fully charged (green).

The BLUETOOTH® technology indicator light (blue) shows if the communicator is connected to the handset.

Turning on the device

Figure 2.2 Turn the power on

The ON-OFF (Stand-by) symbol ( ) on the power button lights up when the device is on.

Connecting to the handset

Figure 2.3 BLUETOOTH® technology indicator

The blue light provides information on connection status between the communicator and the app on the handset.

Turning off the device

Figure 2.4 Turn the power off

The power button and indicator lights turn off.

Charging the device

Figure 2.5 Low battery

A yellow battery indicator light means that it is time to charge the communicator.

Use the USB charging cable and AC adaptor included in the handset package, or another USB 2.0 compliant cable.

For best results, charge the communicator overnight, so it is fully charged and ready for use at the beginning of the day.

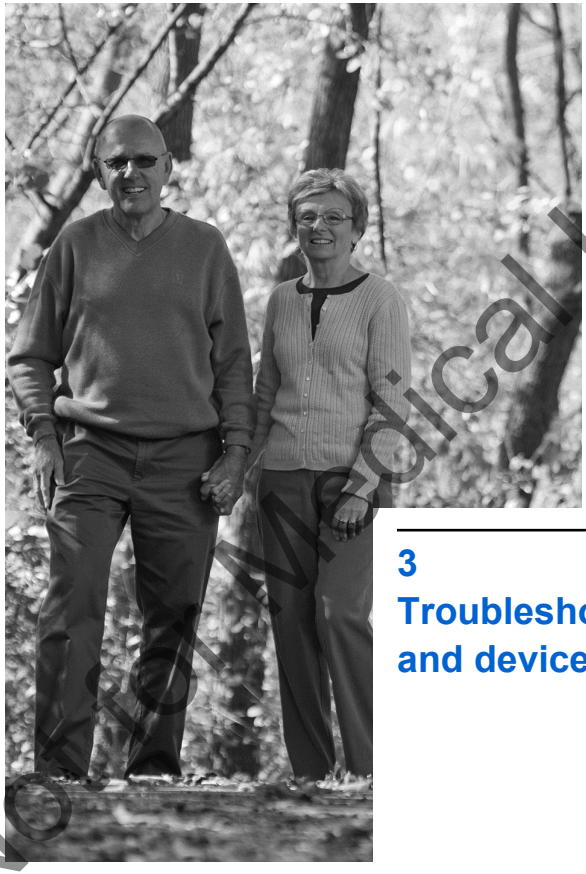
Figure 2.6 Charging the battery

While charging, the device will turn off after 3 minutes, if it is not communicating with the handset. The communicator will continue to charge.
Press the power button to turn off the communicator immediately. It will continue to charge while off.

A green battery indicator light means that the communicator is fully charged, and ready for use.

Figure 2.7 Fully charged battery

When the device is disconnected from the power source, the battery indicator light and power light will turn off.



3 Troubleshooting and device care

This chapter provides information on troubleshooting, electromagnetic interference (EMI), and care for the communicator device. This chapter also provides specifications, and information on who to call for assistance.

Troubleshooting

While charging, the communicator will not connect to the implanted medical device.

Use of the communicator is specific to the medical device. Refer to the app user guide to troubleshoot possible issues while using the communicator with the app.

Software updates are sent to the communicator if needed.

For assistance or questions, refer to "How to contact Medtronic" on page 13.

Electromagnetic interference

Electromagnetic interference (EMI) is a field of energy made by equipment found in the home, work, medical, or public environments. EMI may be strong enough to interfere with

the connection between the handset and implanted device.

Refer to the app user guide included in the communicator package, for more information on EMI.

The therapy manuals associated with your medical device will also provide information about sources of EMI and advice on how to avoid this type of interference.

Safety and technical checks

Safety checks are not required for the Model TM91 Communicator. Maintenance is not necessary, because the communicator does not contain serviceable components.

If the communicator or handset was lost or damaged, call Medtronic for further assistance.

Refer to "How to contact Medtronic" on page 13 or refer to the back cover of the manual.

Device care

Follow these guidelines to ensure that the communicator operates properly.

- Charge the communicator at least every 6 months, even if it is not in use, to ensure the battery maintains power.
- Clean the communicator with a damp cloth or sponge. Mild household or medical cleaners will not damage the device.
- Clinicians should clean the device between uses on different patients.
- Keep the device and USB charging cable out of the reach of children and pets.
- Follow all warnings and the precaution in this manual.
- Handle the device with care. Do not drop, strike, or step on it.
- Do not dismantle or tamper with the device.

- The communicator is not waterproof. Do not allow moisture to get inside of the device.

Specifications

Table 3.1 Communicator

Item	Specification
Power source	Rechargeable battery, USB 2.0 compliant cable with external power supply
Battery life - Clinician use	2 hours per day with power on
Battery life - Patient use	30 minutes per day with power on
Service life	2 years minimum[a]
Operating temperature	5°C to 40°C[bc] (41°F to 104°F)
Storage temperature	-25°C to 70°C[d] (-13°F to 158°F)

Table 3.1 Communicator (continued)

Item	Specification
Mode of operation	Continuous
Classification	Internally powered
Case material	Polycarbonate/ABS blend plastic resin

[a] Communicator can continue to be used after the minimum service life has elapsed.
[b] A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and an atmospheric pressure range of 700 hPa to 1060 hPa.
[c] At the upper range of operating temperature, the communicator may reach 43°C (109°F).
[d] 5°C to 35°C at a relative humidity up to 90%, non-condensing; and >35°C to 70°C at a water vapour pressure up to 50 hPa.

Table 3.2 Charger

Item	Specification
Rated Input	100-240V ~ 50-60Hz, 0.15A
Rated Output	5.0V ⎓ 1.0A[a]
Isolation Mark	Class II equipment

Table 3.2 Charger (continued)

Item	Specification
Certification	Agency certified
Charging Cord	Micro USB 2.0 standard compliant

[a] Minimum

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Contacts:

Asia: Medtronic International Ltd.
Tel. 02919-1300

Australia: Medtronic Australasia P/L
Tel. +61-2-9857-9000
Toll-free 1-800-668-670

Austria: Medtronic Österreich GmbH
Tel. 01-240440

Belgium: Medtronic Belgium S.A.
Tel. 02-456-0900

Canada: Medtronic of Canada Ltd.
Tel. (1-905)-460-3800

Czech Republic: Medtronic Czechia s.r.o.
Tel. 2-330-591-11

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

Finland: Medtronic Finland Oy/LTD
Tel. (09) 207-281-210

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

Germany: Medtronic GmbH
Tel. (02159)-81490

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

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

Ireland: Medtronic Ireland Ltd.
Tel. (01) 511-1400

Italy: Medtronic Italia SpA
Tel. 02-241371

Japan: Medtronic Japan
Tel. 03-6776-0017

Latin America: Medtronic, Inc.
Tel. (1305)-500-9328

Norway: Medtronic Norge AS
Tel. 67-10-32-00

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

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

Russia: Medtronic Russia
Tel. (7495) 580-7377

Slovakia: Medtronic Slovakia, o.z.
Tel. 0268 206 911

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

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

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

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

Turkey: Medtronic Turkey
Tel. +90 216 636 1000

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

USA: Medtronic, Inc.
Tel. (1-763)-505-5000
Toll-free: (1-800)-328-0810

Medtronic

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Contacts for specific countries are listed inside this cover.

Taiwan : NCC Warning message in Chinese:

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