

**URGENT FIELD SAFETY NOTICE**

**Medtronic Wireless Recharger Model WR9220  
included in RS5200 Charging Systems**

Product Description	Product Number
RECHARGER KIT (InterStim Micro)	RS5200

November 2021

Medtronic Reference: FA1183

Dear Health Care Professional,

The purpose of this letter is to inform you of the potential for the Medtronic Wireless Recharger (WR) device WR9220 to become unresponsive if the charging steps indicated in the Recharger Patient User Guide are not followed. This issue can be prevented by adhering to the charging instructions for use. Below we provide more information on the issue and how to prevent it from occurring.

The Wireless Recharger device is used by the InterStim™ Micro (Model 97810) implantable neurostimulator.

**Issue Overview:**

Medtronic has identified through a complaint assessment that the Medtronic WR9220 recharger, contained within the Recharger Kit RS5200 have had occurrences where the WR device may become unresponsive. This issue may occur when the WR is fully depleted and the WR is placed on the dock and quickly removed within 20 seconds, interrupting the initialization routine. The Recharger Patient User Guide instructs the user to place the WR on the dock and charge to full before first use. When the WR becomes unresponsive, the WR will not respond to a button press, cannot pair with the recharger app, and will cause the recharger battery indicator to continuously flash when placed on the battery dock.

In the event of an unresponsive wireless recharger, the user will not be able to charge their implanted neurostimulator, until a replacement WR device is received and potentially lead to therapy disruption and return of symptoms if the battery of the neurostimulator would deplete prior receiving the replacement WR.

This issue only occurs if the specific sequence described above is followed. This issue can be prevented by adhering to the instructions outlined in the Recharger Patient User Guide. From January 2020 to June 22, 2021, Medtronic has received 73 complaints associated to this issue, of which there have been no reports of serious patient injury attributed to this issue.

**Requested Actions:**

- Enclosed is a Patient Quick User Guide, which provides guidelines to ensure proper care and maintenance of the Wireless Recharger. Please reinforce these instructions with your patients. Additional copies of the Patient Quick User Guide are available through your Medtronic Representative.
- If the WR device appears unresponsive, first attempt to reset the WR by holding the power button down (located at the top of your recharger device) until the battery lights begin to flash. This could take up to 45 seconds. If the problem is not resolved, contact your Medtronic Representative.

**Additional Information:**

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience that this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Local / BU Manager

# RECHARGER CARE AND MAINTENANCE GUIDE

for your InterStim™ Micro system

Welcome to Medtronic bladder or bowel control therapy delivered by the InterStim™ Micro system.

This user guide will help you understand how to care for and maintain your recharger.

## YOUR INTERSTIM MICRO SYSTEM RECHARGER

### Recharger

Recharges the neurostimulator in about 20 minutes during one weekly session\*

#### Battery Light

- Solid green: indicates recharger charge level
- Flashing green: indicates recharger is charging
- Flashing amber: indicates recharger battery is low



### Charging Dock and USB Power Cord

Supplies the recharger with power



## CHARGE YOUR RECHARGER



Charging



Fully Charged



- 1 Connect the USB cord to the blue charging dock.
- 2 Plug the USB cord into the power adapter. Plug the adapter into a wall outlet. The dock must rest on a flat surface while plugged in.
- 3 Place the recharger, button-side up, into the dock. Your recharger is now charging; the battery icon will display as shown in the figure to the left.
- 4 When your recharger is fully charged, the battery icon will display as shown in the figure to the left.
- 5 Leave your recharger on the blue charging dock plugged into the wall outlet. This will ensure that your recharger maintains its charge and is ready for the next use.

\*Under standard therapy settings and appropriate recharger placement

## RECHARGER CARE

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Clean the outside of your recharger with a damp cloth when necessary. Mild household cleaners will not damage the components.

## HELPFUL RESOURCES

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**Medtronic.com/RechargeBladder**  
**Medtronic.com/RechargeBowel**

Find information and more resources on Medtronic bladder and bowel control therapies.



**Medtronic Patient Services**

Get help for your device-related technical questions.  
Call 1-800-510-6735 Monday to Friday, 8 a.m. to 5 p.m. CT.

**Medtronic Bladder Control Therapy delivered by the InterStim™ system** treats urinary retention (inability to completely empty the bladder) and the symptoms of overactive bladder, including urinary urge incontinence (leakage) and significant symptoms of urgency-frequency. It should be used after you have tried other treatments such as medications and behavioral therapy and they have not worked, or you could not tolerate them. This therapy is not intended for patients with a urinary blockage.

Safety and effectiveness have not been established for pregnancy and delivery; patients under the age of 16; or for patients with neurological disease origins.

**Medtronic Bowel Control Therapy delivered by InterStim™ system** treats chronic fecal incontinence (an accident or leaking involving stool). It should be used after you have tried other treatments such as medications and dietary modifications and they have not worked, or if you are not a candidate for them.

Safety and effectiveness have not been established for pregnancy and delivery; patients under the age of 18; or for patients with progressive, systemic neurological diseases.

**Medtronic Bladder Control Therapy and Medtronic Bowel Control Therapy:** You must demonstrate an appropriate response to the evaluation to be a candidate. You cannot have diathermy (deep heat treatment from electromagnetic energy) if you have an InterStim™ device.

In addition to risks related to surgery, complications can include pain at the implant sites, new pain, infection, lead (thin wire) movement/migration, device problems, interactions with certain other devices or diagnostic equipment such as MRI, undesirable changes in urinary or bowel function, and uncomfortable stimulation (sometimes described as a jolting or shocking feeling).

This therapy is not for everyone. This treatment is prescribed by your doctor. Please talk to your doctor to decide whether this therapy is right for you. Your doctor should discuss all potential benefits and risks with you. Although many patients may benefit from the use of this treatment, results may vary. For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at [www.medtronic.com](http://www.medtronic.com).

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