

URGENT FIELD SAFETY NOTICE
Medtronic Wireless Recharger Model WR9200
included in Model RS6200 Charging System

Product Description	Product Number
RECHARGER KIT (ACTIVA RC)	RS6200

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) devices WR9200 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 Activa™ RC (Model 37612) implantable neurostimulator.

Issue Overview:

Medtronic has identified through a complaint assessment, that the Medtronic WR9200 recharger, contained within the Recharger Kit RS6200, have had occurrences where the WR device becomes 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 Wireless Recharger becomes unresponsive, the Wireless Recharger 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. The unresponsive state of the wireless recharger may lead to unanticipated implanted neurostimulator INS battery depletion. For the Activa INS, if the INS battery continues to deplete and the over-discharge state is reached three times, the INS battery cannot be recharged and will require surgical intervention.

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 ([WR9200 as of page 205](#)). From January 2020 to June 22, 2021, Medtronic has received 19 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 at <XXXX>.

Sincerely,

Local / BU Manager

Enclosure:

Patient Quick User Guide

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