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Urgent Field Safety Notice

Wireless Recharger Kits, Models RS6230 and RS7230

Used with Neurostimulator Models 977119 and B35300

Recall

September 2024

Medtronic Reference: FA1441
EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Risk Manager/Healthcare professional,

Medtronic is recalling a limited number of Wireless Recharger Kits, Models RS6230 and RS7230, because they contain a Wireless Recharger (WR) that may not be functional upon initial use. Our records indicate that you have received a WR Kit that is part of this recall. See list of serial numbers affected in the Scope Section below. This WR is used with both the Inceptiv™ INS, Model 977119, as part of the Spinal Cord Stimulation (SCS) system, and Percept™ RC INS, Model B35300, as part of the Deep Brain Stimulation (DBS) system.

Issue Description:
The specific WRs noted below went through a certain manufacturing step that may have compromised their ability to communicate with the INS and establish a recharge session. Whether a WR is compromised or not will manifest the first time the WR is used. If the WR is compromised, then the WR will not establish a recharge session with the INS. If the WR is not compromised, then the WR will establish a recharge session with the INS and will continue to work as expected.

If you have any of these WR Kits still unused, please follow the actions outlined below. However, if the WRs in those kits were able to establish a recharge session with the INS, then those WRs are not compromised and will continue to work as expected. For those functional WR Kits, no further action is needed.

This issue only impacts the WR. The INS will continue to function as long as the battery is not depleted. However, there is risk of a loss of therapy and return of disease symptoms if the recharger, upon first use, does not function and the INS battery depletes before a recharge occurs. If the battery depletes before recharge occurs, contact your Medtronic Representative to obtain a replacement WR Kit.

As of 19-Aug-2024, Medtronic is aware of 17 WRs that were unable to function upon first use due to this issue, which is roughly 0.26% of total global sales of WR Kits. In one (1) case, a patient's INS reached full battery depletion requiring assistance to resume therapy. No serious injuries have been reported.

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Product Scope (Distributed to the Nordics):

Medtronic records indicate the following WR Kits may have this issue:

Product Name	Model Number	GTIN/UDI	Serial Number
RECHARGE SYSTEM RS7230	RS7230	00763000827540	NRA010646N; NRA010660N; NRA010664N; NRA011393N; NRA011853N; NRA012897N; NRA013635N

Customer Actions:

- Identify and quarantine all unused affected WR Kits. See attachment A for guidance on identifying potentially affected devices.
- Return all unused affected WR Kits and contact your Medtronic Representative to obtain a replacement WR Kit. Reach out to your Medtronic representative for any assistance.
- Share this notice with all those who need to be aware of this issue within or outside your organization or to any organization where the potentially affected product has been transferred or distributed and maintain a copy of this notice in your records.

Additional Information:

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

We regret any inconvenience this may cause. 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

Enclosures:

- Attachment A – Identifying Affected Devices.

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Attachment A:

IDENTIFYING POTENTIALLY AFFECTED DEVICES

Locate product information on product labels in your inventory.