

UPDATE TO URGENT FIELD SAFETY NOTICE

RE: Percept™ PC Model B35200 Implantable Neurostimulator (INS)

INS Failure After Cardioversion - Software Update

January 2025

Medtronic Reference: FA1206

Dear Health Care Professional,

Distribution has begun for a new clinician tablet, model CT900F, and a software update for the clinician programmer application A610 version 5.0 (or later). The CT900F tablet with application A610 version 5.0 contains a mitigation to the previously identified issue: *Percept™ PC Model B35200 Implantable Neurostimulator (INS) Mitigations Reducing INS Failure After Cardioversion Procedure* (see enclosed copy dated January 2022). This mitigation ensures that if the Percept PC Model B35200 is turned off, it will automatically revert to the recommended DBS neurostimulator settings for cardioversion, as outlined in the product labeling.

This mitigation will be automatically applied to the INS when the A610 version 5.0 communicates with an affected device.

Customer actions:

- Please share this notice with all those within your organization who need to be aware of this issue/mitigation or to any organization where the identified clinician tablet(s) have been transferred and maintain a copy of this notice in your records.
- Your Medtronic Deep Brain Stimulation (DBS) sales representative will distribute the new tablet and/or assist with installation of the A610 version 5.0 as soon as those are available in your region. If you have any questions, please contact your Medtronic Sales Representative.
 - The A610 version 5.0 software will assess each Percept INS device at interrogation for whether an update to the implanted device's firmware is needed. The INS firmware update will be automatically installed. The user will see on-screen prompts that provide guidance throughout the update process. During this process the neurostimulator will restart, interrupting therapy for less than 30 seconds. When the neurostimulator restart is complete, you will be directed to the HOME screen, and a banner will display INFORMATION: NEUROSTIMULATOR UPDATE SUCCESSFUL at the bottom of the screen. In addition, device Instructions For Use (IFU) have been updated and can be found online at <http://manuals.medtronic.com>.

Medtronic

- Following review of this letter, sign and return the enclosed Customer Acknowledgement Form via email to rs.ranordic@medtronic.com.

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

We remain dedicated to ensuring the highest level of quality and will continue to monitor performance of our products to ensure we meet your needs and those of your patients. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Local / OU Manager

Enclosure(s):

- Urgent Field Safety Notice January 2022: Percept™ PC Model B35200 Implantable Neurostimulator (INS) Mitigations Regarding INS Failure After Cardioversion Procedure
- Customer Acknowledgment Form