Medtronic

Medtronic Ireland Limited
Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
www.medtronic.ie
Tel: 01 511 1400
Fax: 01 807 7220

Urgent Field Safety Notice

Model A610 DBS Clinician Programmer Application Versions 2.0.4584, 2.0.4594, 2.0.4605 and 3.0.1057

INS Replacement Cycling

Notification

March 2021

Medtronic Reference: FA968

Dear Healthcare Professional,

The purpose of this letter is to inform you of a potential issue with the stimulation cycling setting when using the INS replacement feature on the A610 clinician programmer application version 2.0.4584, 2.0.4594, 2.0.4605 (and 3.0.1057). When replacing an INS and using the A610 "REPLACEMENT" workflow to transfer existing neurostimulator settings to the new neurostimulator, cycling may appear to be enabled but cycling is actually disabled. This issue can only occur when using the A610 "REPLACEMENT" workflow. For all current patients who have a replacement Model B35200 Percept™ PC INS with cycling enabled, please follow the requested actions below.

Issue Description:
This issue only impacts Percept PC patients with cycling enabled. When using the replacement feature to transfer settings from an existing implanted device with cycling enabled to a newly implanted Percept device, cycling is not properly enabled, though it appears to be enabled in the clinician programmer screen and reports. As a result, the patient's stimulation is always on, and battery longevity may be significantly reduced. All Percept PC replacement patients previously implanted with Activa family of devices are at risk for premature battery depletion if they are configured with cycling using the A610 "REPLACEMENT" workflow. As a consequence, the estimated time remaining, as displayed on the A620 patient programmer, may be significantly lower than the predicted device longevity. If BrainSense is configured for a group, the lack of cycling can be observed on the stimulation graph while streaming.

This issue is a software anomaly that affects how the A610 transfers cycling settings between INSs. As of the date of this letter, Medtronic has received two complaints on this issue, one of which resulted in explant due to premature battery depletion.

Actions:
Due to the potential for battery depletion, please follow these steps immediately to restore cycling to function properly:

- For each group:
    1. Manually turn cycling off.
    2. Manually turn cycling back on.
    3. Adjust the cycling on/off durations (as needed).
    4. If BrainSense is configured for the group, click the "Start Streaming" button, and observe the stimulation is cycling properly.

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- After applying this mitigation to each group, confirm on the end-session screen that your changes are properly saved for each group.

- If using the A610 "REPLACEMENT" workflow on any new Percept PC implants, follow the above actions in steps 1-4 to ensure that cycling is enabled as intended.

As soon as possible, pending regulatory approvals, Medtronic intends to provide a software update to prevent the issue from impacting future patients. Medtronic will notify you upon availability of the software update to correct this issue. The software will be available for installation on the clinician programmer tablet.

Additional Information:
The Competent Authority of your country has been notified of this action.
We regret any difficulty that this issue may have caused. Medtronic is committed to patient safety and appreciates your prompt attention to this matter. If you have questions or require assistance, please contact your Medtronic Representative directly or via Tel No: 01 511 1400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland