

Urgent Field Safety Notice

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

Application Crash After INS Interrogation Notification

March 2021

Medtronic Reference: FA969

Dear Healthcare Professional,

The purpose of this letter is to inform you of a potential software crash with the A610 clinician programmer application version 2.0.4584, 2.0.4594, 2.0.4605 (and 3.0.1057) when interrogating the Percept™ PC Implantable Neurostimulator (INS). Although the A610 clinician programmer may crash, the INS continues to provide programmed therapy. As soon as possible, pending regulatory approvals, Medtronic intends to provide a software update to correct this issue. In the meantime, please follow the mitigations outlined in this letter.

Issue Description:

When starting a programming session with the A610 clinician programmer application with a Percept PC INS, A610 software may crash approximately one minute after interrogation. The programming session can be restarted, and the INS can still be programmed, but only in short sessions, because the app will repeatedly crash approximately one minute after interrogation completes. This is a software anomaly that is related to how the A610 reads information logged in the INS. Medtronic has received three complaints on this issue. None has resulted in patient harm. The issue may lead to potential patient risk if programming changes are required and cannot be accomplished within multiple one-minute intervals due to the ongoing software crashes. Please note that this issue does not occur when using the A610 software with the Activa™ family of INSs.

Mitigations:

Medtronic intends to provide a software update to correct this issue. In the meantime, if the software crash is seen, please note the mitigations below:

- The Percept PC INS is delivering therapy as intended. Therapy adjustments can be made during the one-minute interval prior to the crash occurrence(s). If it is anticipated that multiple programming adjustments may be needed, consider pre-planning program parameter changes and patient assessments across multiple short sessions prior to interrogation.
- The patient programmer is not affected by this issue and can be used to make therapy adjustments within defined limits set by the clinician.

Requested Actions:

Medtronic will notify you upon availability of the software update to correct this issue. Once the software is available, please install the new version on the clinician programmer tablet.

Additional Information:

Medtronic

The Competent Authority of your country has been notified of this action.

We regret any inconvenience and difficulties 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,

A handwritten signature in black ink, appearing to read 'Keith Taverner', is positioned above the printed name.

Keith Taverner
Regulatory Affairs Manager UK & Ireland