

Urgent Field Safety Notice

Restore™ Clinician Programmer Application - Device Reset Message

Model A71100, GTIN 00763000273668

Software Update

November 2025

Medtronic Reference: FA1458

Dear Healthcare Provider/Risk Manager,

This letter is to notify you that Medtronic has released a new version, v1.0.4489, of the Model A71100 Restore™ Clinician Programmer Application (CP App) that addresses a software issue that may occur when attempting to clear a Device Reset message. The A71100 CP App is used to program the Restore family of Spinal Cord Stimulation implantable neurostimulators (INS).

Issue Description

Up until 14-Oct-2025, Medtronic has identified 2 reports (occurrence rate of 0.003%) where a Device Reset message that was displayed on the A71100 CP App was unable to be cleared. This issue can occur in software versions prior to 1.0.4489.

A Device Reset can occur for a variety of reasons, including when the INS has an overdischarged battery, which is normally cleared during a programming session. In rare cases, the Device Reset message cannot be cleared and may result in the inability to resume therapy resulting in the patient experiencing a recurrence of underlying pain symptoms. Resolution would require surgical replacement of the INS to resume therapy.

Correction

Medtronic has developed a new version of the A71100 CP App, v1.0.4489 or later, that contains a fix for this issue by ensuring the ability to clear a Device Reset message by pressing "OK" if the message appears.

Customer Actions



Download A71100 CP App v1.0.4489 or any later version at your earliest convenience and contact your local Medtronic representative if you have any questions related to the update.

Complete the enclosed Customer Acknowledgement Form. When complete please return the form to rs.mdtafricareg-fca@medtronic.com. Retain a copy of this letter and completed Customer Acknowledgement Form for your records.

Additional Information

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

We sincerely regret any inconvenience this may have caused you or your patients. 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 sales representative.

Sincerely,

A handwritten signature in blue ink, appearing to read "Dirk Gey Van Pittius". The signature is stylized with a large, looping initial "D" and a smaller, more complex signature to the right.

Dirk Gey Van Pittius

Medtronic Africa: Quality and Regulatory Affairs

Enclosure: Customer Acknowledgement Form