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Urgent Field Safety Notice

Vanta™ Clinician Programmer Application (CP App) A71200, v2.0.2455

"Unexpected Device Error Code 1502" CP App Message

Software Update

January 2023

Medtronic Reference: FA1266
EU Manufacturer Single Registration Number (SRN): US-MF-000019977.

Dear Health Care Professional,

This letter is to inform you that the Vanta™ Clinician Programmer Application (CP App) A71200 has been updated to version 2.0.2465. This new CP App version corrects the rare instances (0.085%) in which the Vanta Clinician Programmer Application (CP App) A71200 v2.0.2455 will display an "Unexpected Device Error Code 1502" Message, and the user will be unable to perform programming of the Vanta Implantable Neurostimulator (INS) Model 977006.

As of the date of this letter, Medtronic has developed a new software version for the Vanta CP App A71200 (v2.0.2465) to address this issue.

Issue Description:
As previously communicated by Medtronic, in July 2022, in these rare occurrences during initial programming, the Vanta CP App will display the Error Code 1502 message because the Vanta INS Reset Block ID log is full. Once the log is full, all subsequent interrogations with the affected device will not be possible.

If the Error Code 1502 message occurs, it will display during the next interrogation after the Vanta INS usage is started. Should this present at initial programming:

- Surgery may be delayed to obtain an alternative INS, or surgery may be cancelled if an alternative INS is unavailable and the affected INS is not implanted.

- It will not be possible to program the INS with the Vanta CP App so therapy cannot be initiated for newly implanted patients and patients receiving a replacement device may experience a return of underlying pain symptoms.
- If the recommended troubleshooting (see below) cannot be performed, an unanticipated surgical intervention may be needed to explant and replace the INS.

The issue is related to the Vanta CP App. If the Vanta INS has been previously implanted and programmed, it will continue to provide therapy to the patient within programmed parameters.

Since the launch of the Vanta INS in July 2021 through November 03, 2022, Medtronic has received two (2) reports of this issue. In both instances, the INSs were unable to be interrogated so Medtronic performed an INS diagnostic and log reset, which enabled the Vanta INSs to be interrogated by the Vanta CP App and complete programming.

Required Action:

- Update the Vanta CP App A71200 per the enclosed instructions.

Troubleshooting:

We recommend you install the latest Vanta CP App and confirm that the new software version (v2.0.2465) for the Vanta CP App A71200 was successfully installed. If you have been unable to install the update, continue to follow these troubleshooting steps as previously communicated by Medtronic, in July 2022:

- To determine if the issue is present before the implant procedure, it is recommended to ensure the Vanta INS is interrogated twice as follows:
    - Perform an initial interrogation of the Vanta INS and tap "start usage," tap "implant device" workflow, click "start," and on the next screen exit the session.
    - Initiate a second interrogation and if there is no "Unexpected Device Error Code 1502" displayed on the Vanta CP App, the INS may be used and will perform as intended.
- If the INS cannot be interrogated, contact your Medtronic Representative. If needed, Medtronic will schedule an in-field service appointment with the managing SCS physician and the patient to diagnose and reset the INS.

Additional Information:

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

We regret any difficulties this issue 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 directly or via Tel No: 01 511 1400.

Sincerely,

Keith Taverner. Regulatory Affairs Manager UK & Ireland

Enclosed: Instructions: Software download brochure