

Urgent Field Safety Notice

Vanta™ Clinician Programmer Application (CP App) A71200, v2.0.2455 “Unexpected Device Error Code 1502” CP App Message Notification

July 2022

Medtronic Reference: FA1266

Dear Health Care Professional,

This letter is to inform you that in rare instances (0.085%) at initial programming, 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.

Issue Description:

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.

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- It will not be possible to program the device 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 mitigation (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. The Vanta INS is performing as intended. If the INS has been previously programmed, it will continue to provide therapy to the patient within programmed parameters.

Since the launch of the Vanta INS in July 2021 through May 19, 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.

Medtronic is working on a Vanta CP App software update that will resolve this issue and will communicate additional information when it becomes available.

Recommended Mitigation:

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.

Requested Actions:

- 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 Code1502" displayed on the Vanta CP App, the INS may be used and will perform as intended.
- If a patient's INS cannot be interrogated with the Vanta CP App, contact your Medtronic Representative.

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.

Sincerely,

Medtronic GmbH