

Urgent Field Safety Notice

Vanta™ Clinician Programmer Application - Start Usage

Model A71200, GTIN 00763000520083

Notification

December 2025

Medtronic Reference: FA1512

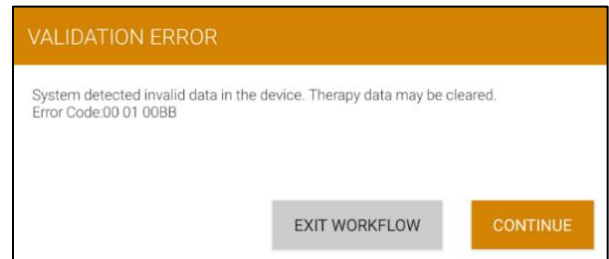
Dear Healthcare Provider:

This letter is to notify you of the potential for a software issue that may occur during the initial programming of a Model 977006 Vanta implantable neurostimulator (INS) using the Model A71200 Vanta™ Clinician Programmer Application (CP App).

Issue Description

As of 27-Oct-2025, Medtronic has identified 130 reports (occurrence rate of 0.75%) where during the initial programming of the Vanta INS, if the "Start Usage" button on the Current Device Status screen of the A71200 CP App is pressed more than once, a system error message is displayed prompting the user to restart the application. This issue can occur on software versions 2.0.2465 and 2.0.2683.

After restarting and interrogating, the A71200 CP App then displays a Validation Error message with two (2) options: Exit Workflow or Continue. If "Continue" is selected, the error is cleared, and the programming session can proceed. However, a software issue can occur if the Exit Workflow is selected, as the session will end without clearing the error and may result in a surgical delay for additional troubleshooting.



Mitigation

- During the initial programming of a Vanta INS, press the "Start Usage" button **only once**
- If you encounter this Validation Error, select **"Continue"**, which will clear the error and allow for the programming to continue.

Correction

Medtronic has developed a new version (v2.0.2684 or later) of the A71200 CP App that contains a fix for this issue. Medtronic will notify you once it has been approved for distribution in your region. If you encounter this issue, please contact your local Medtronic representative.

Customer Actions

Complete the enclosed Customer Acknowledgement Form. When complete please return the form to rs.mstfcasupportemea@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. Please contact your local Medtronic representative if you have any questions related to this issue.

Sincerely,

Local / OU Manager

Enclosure: Customer Acknowledgement Form