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Urgent Field Safety Notice

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

"Too Many Devices Found" CP App Message

Software Update

January 2023

Medtronic Reference: FA1260
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 potential communication issue ("Too Many Devices Found") when a patient is implanted with more than one (1) neurostimulator.

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

Issue Description:

In July 2022, Medtronic notified customers of a potential communication issue in which the Vanta Clinician Programmer Application (CP App) A71200 v2.0.2455 may be unable to connect with a Vanta Implantable Neurostimulator (INS) Model 977006. The Vanta CP App might display the "Too Many Devices Found" message when trying to connect to a Vanta INS if the communicator detects more than one (1) Vanta INS that is implanted in the same patient. When this message is displayed:

- *Communication with the Vanta INS is not possible resulting in an inability to program or adjust therapy.*
- *Troubleshooting, as detailed below, is required which may include an additional clinic visit.*
- *If troubleshooting is unsuccessful, surgical replacement of the Vanta INS may be required.*
- *If the issue occurs intraoperatively, it may prolong the procedure.*

The issue affects only the Vanta CP App. A Vanta INS that has been previously programmed will continue to provide therapy to the patient within programmed parameters, and the patient's ability to use their patient programmer to make therapy adjustments will be maintained.

Since the launch of the Vanta INS in July 2021 through November 3, 2022, Medtronic is estimating that globally there are a total of 46 patients implanted with two Vanta INSs. Medtronic has received five (5) reports of this issue, of which four (4) reported events were resolved with troubleshooting; and, one (1) reported event resulted in explant and replacement of the INS.

While it is possible for the Vanta CP App to display this message when the communicator detects another implanted Medtronic neurostimulator, there have been no complaints received for this scenario.

Required Actions:

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

Please Note: After the Vanta CP App is updated, if implanting a patient with two (2) Vanta INSs, ensure the INSs are implanted on opposite sides of the body as noted in the Information for Prescribers labeling.

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:

If multiple neurostimulators have been implanted and the Vanta CP App displays the "Too Many Devices Found" message, the following troubleshooting steps should be attempted to resolve this message and connect with the Vanta INS(s):

- Move the clinician communicator away from the body, trying to create distance from the unintended INS while keeping it within communication range of the intended Vanta INS and tap the "retry" button on the Vanta CP App.
- Place a metal barrier (such as a metal tray) over the unintended INS, hover the communicator over the metal barrier, and attempt interrogating the intended Vanta INS using the Vanta CP App.
- When there are two (2) Vanta INSs, use the patient programmer to temporarily toggle stimulation up or down on one (1) Vanta INS, and within 30 seconds use the Vanta CP App and communicator to interrogate the other Vanta INS.
- *If troubleshooting does not resolve the issue, 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 directly or via Tel No: 01 511 1400

Keith Taverner Regulatory Affairs Manager UK & Ireland. Enclosed: Software download brochure