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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

Notification

July 2022

Medtronic Reference: FA1260

For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000019977.

Dear Health Care Professional,

This letter is to inform you 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 when a patient is implanted with more than one (1) neurostimulator.

Issue Description:

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 us 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 May 19, 2022, Medtronic is estimating that globally there are a total of 23 patients implanted with two Vanta INSs. Medtronic has received four (4) reports of this issue (~17% double implants have encountered this issue), of which three (3) reported events were resolved with troubleshooting; however, one (1) reported event did result in explant and replacement of the INS.

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

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:

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Until Medtronic communicates the availability of a software update, Medtronic does not recommend implanting more than one (1) Vanta INS in a patient.

- While not recommended, 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, and ensure each is configured with the CP App before implanting in a patient.

Troubleshooting:

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.
- 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.
- 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.

Required Actions:

- 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.

Sincerely,

Local / BU Manager