

Urgent Field Safety Notice

Vanta™ Implantable Neurostimulator (INS) Model 977006

Unable to be Interrogated

Notification

March 2022

Medtronic Reference: FA1240

Dear Healthcare Professional,

The purpose of this letter is to inform you that the Vanta™ Implantable Neurostimulator (INS) Model 977006, may be susceptible to not communicating with the clinician programmer and/or the patient programmer system (HH90 Handset and TM91 Communicator). Although there have been no complaints received related to this issue, we wanted to inform you of this potential issue and provide additional information.

Issue Description:

The INS will continue to provide therapy to the patient within programmed parameters. The below details describe what can be expected should the inability to communicating with the INS occur:

- If the clinician programmer will not be able to communicate with the INS, the clinician programmer will display "No Device Found" and will not connect to the INS.
- If the patient programmer system was paired to the INS, it will continue to communicate with the INS and therapy adjustments and group changes can be made within the clinician set limits as well as turn therapy on and off.
- If there is no communication with the INS during the implant procedure, troubleshooting may delay the surgical procedure, and may require a replacement INS.
- If there is no communication with the INS post procedure, it may not be possible to adjust therapy parameters and may cause the patient to experience inadequate therapy (i.e., return of underlying pain). If communication cannot be restored to the INS (refer to recommended mitigation below), an unanticipated surgical intervention may be needed to explant and replace the INS.

Since the launch of Vanta in July 2021, there have been no reported events related to the issue; however, we have seen this issue in devices using the same communication technology and therefore are pro-actively communicating this to implanting and managing SCS physicians. Medtronic can perform an INS diagnostic and communication reset should this issue occur and is investigating changes to prevent the occurrence.

Medtronic

Recommended Mitigation:

If the INS cannot communicate with the clinician programmer and/or patient programmer system, 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.

This diagnostic and communication reset is possible only if the patient's programming system is set up and working. If the communicator is not working, lost, or was never provided to the patient, the INS cannot be reset and would need to be explanted.

Required Actions:

- At the patient's initial programming session, ensure the patient programmer system is paired with the patient's INS.
- If a patient's INS cannot communicate with the clinician programmer and/or patient programmer system, and it is not possible to make therapy adjustments, contact your Medtronic Representative.

Additional Information:

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

We regret any difficulties this 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 at <XXXX>.

Sincerely,

Local / BU Manager