Medtronic

Urgent Field Safety Notice

Vanta™ Implantable Neurostimulator (INS) Model 977006

Battery Life Expectations
Notification

August 2024

Medtronic Reference: FA1433

Dear Healthcare Professional,

The purpose of this letter is to emphasize the impact programming settings can have on the battery life of the Vanta™ Implantable Neurostimulator (INS) Model 977006. Additionally, this letter is intended to remind you of the tools that currently exist in both Models A71200 Vanta Clinician Programmer Application and A71300 Stimulation Trialing Clinician Programmer Application. These tools should be used to assist in selecting the appropriate INS model for the patient and to assess the longevity of the Vanta™ INS throughout the life of the implant.

Issue Description:

Medtronic has received reports from Health Care Professionals (HCP) and patients indicating that the Model 977006 Vanta™ INS has depleted faster than HCPs or patients expected leading to outpatient reprogramming or earlier than anticipated surgical replacements. Review of complaint data and analysis of returned devices confirmed that the Vanta System is working as designed and there were no performance issues. However, Medtronic is taking this field corrective action in order to re-iterate warnings and instructions contained in labeling regarding the impact of programming on INS battery longevity and the use of INS battery longevity estimator tools to assess the impact of programming on INS battery life.

Recommended Mitigation:

The battery life of the Vanta™ INS can last less than 6 months or up to 11 years based on the stimulation settings (e.g., amplitude, pulse width, pulse rate, and number of active electrodes or programs), system impedance, and hours per day of stimulation. High stimulation settings will increase power consumption of the INS battery and lead to a faster depletion. To assist HCPs in determining the impact of programming and impedance on battery longevity, Medtronic provides the following tools built into the Model A71200 and A71300 Clinician Programmer Applications to calculate INS battery life based on real usage. These tools should be used by the HCP to determine whether a non-

rechargeable or rechargeable INS is the best option for the patient, and also throughout the life of the INS to understand how programming changes can impact battery life.

Device Eligibility Screen:

The "Device Eligibility" screen, which is displayed in the A71300 Stimulation Trialing CP App, should be used during the trialing evaluation to assess the compatibility of the different INS models. The eligibility screen lists the compatible INSs (non-rechargeable and rechargeable) that will allow the same parameters as programmed in the External Neurostimulator (ENS) used for the trial evaluation. The eligibility screen automatically updates the list of INSs based on the current stimulation settings. If the patient is eligible for a Vanta™ INS, the Device Eligibility Screen displays an icon for the "Estimated Battery Longevity" tool, which should be used to estimate battery longevity based on the current stimulation settings. Use of the eligibility screen is explained in A71300 Trialing manual.

The "Device Eligibility Screen" can be accessed by the clinician by navigating to the side menu -> click on "Eligibility" or "End Evaluation" workflow -> "Eligibility."

NOTE: The following screenshots are samples of the tools as displayed on the clinician programmer (the results displayed in the samples are hypothetical and not based on actual patient settings).

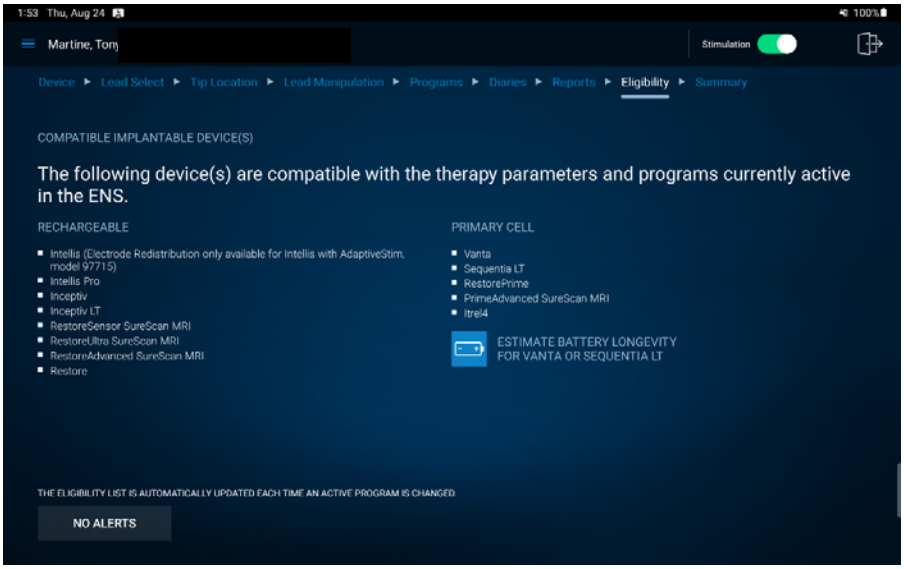

Figure 1: Device Eligibility Screen in A71300 Stimulation Trialing CP App

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Estimated Battery Longevity Tool:

The Estimated Battery Longevity tool, which is displayed in the A71200 Vanta CP App allows the clinician or field representative to estimate battery longevity based on the current program and group settings, along with the number of hours per day the patient might use each group. This tool uses the current battery level of the INS to calculate the estimated longevity. It also provides a battery life estimate for three ranges of impedance values. Refer to the A71200 Programming Guide manual, section "Estimating Battery Longevity" for the instructions on assessing and using the longevity tool.

The "Estimated Battery Longevity" can be accessed by the clinician under "Programs" -> Click on a program -> Navigate to "Energy Access" Sub-screen -> Under Battery Longevity, press "Estimate."

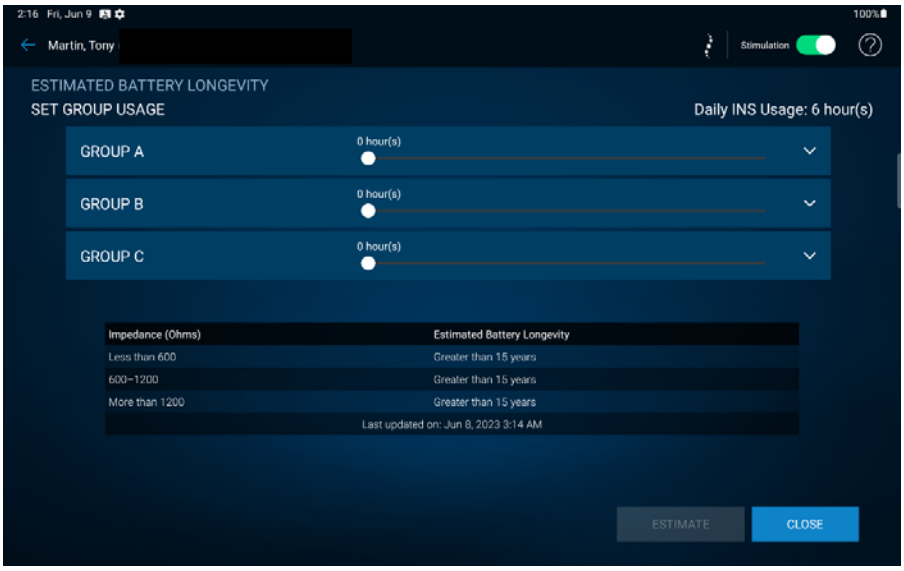

Figure 2: Estimate Battery Longevity Tool screenshot in A71200 Vanta CP App

Estimated Battery Remaining Screen:

The Estimated Battery Remaining displays the estimated time remaining for the INS battery based on actual usage over the past 7 days in the A71200 Vanta CP App. This calculation is automatically displayed on the first screen that appears after starting a follow-up session with the INS. Use of both the Estimated Battery Longevity and Estimated Battery Remaining tools is explained in the A71200 Programming Guide manual.

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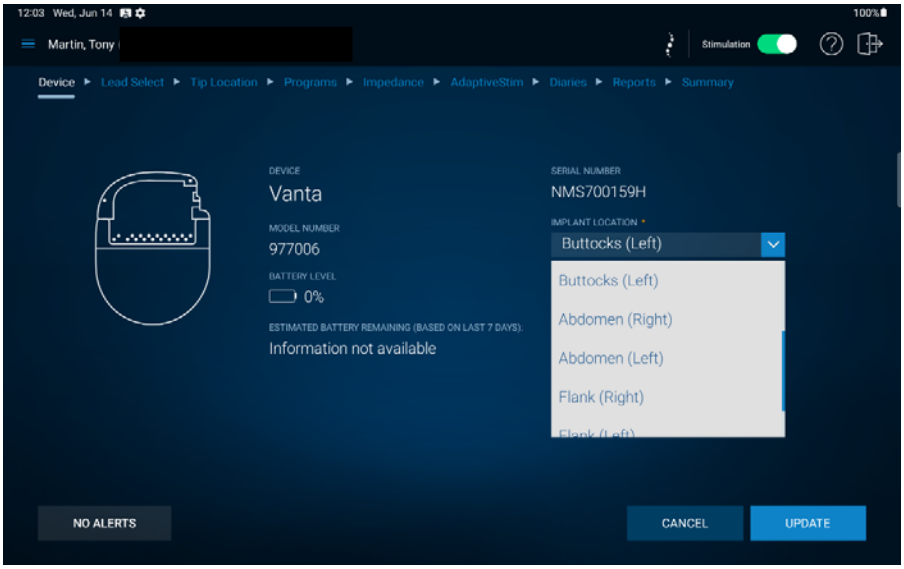

Figure 3: Estimated Battery Remaining Tool in A71200 Vanta CP App

Additionally, Medtronic also provides instructions to optimize the battery longevity in the System Eligibility Battery Longevity manual, including the following tips:

- Place the leads in the optimal location to achieve paresthesia.
- Use fewer programs.
- Use the minimum number of electrodes necessary for effective stimulation.
- Use the lowest effective settings for amplitude, rate, and pulse width.
- Instruct the patient to use the neurostimulator only when needed.
- Consider implanting low-impedance leads and extensions.

The manuals referenced above are available at the Medtronic website: https://manuals.medtronic.com/manuals/main/region

Required Actions:

- Ensure that the Device Eligibility screen in the Model A71300 Clinician Programmer application is used during the trialing evaluation to review compatible INSs that will allow the same parameters used during the trial evaluation.
- Ensure that the battery longevity tools in the Model A71200 Clinician Programmer application are used during each patient visit, to keep track of the estimated longevity of the Vanta INS.
- Ensure that the patient understands the impact of therapy changes on the battery life of the Vanta INS.
- Please complete and return the Customer Acknowledgement Form enclosed in this letter acknowledging that you have received this information.

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Additional Information:

Medtronic has notified the Competent Authority of your country 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 at: esther.okello@medtronic.com

Sincerely,

Digitally signed by
Dirk Gey Van Pittius
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Dirk Gey Van Pittius
Senior Regulatory and Quality affairs Manager
Enclosure:
Customer Acknowledgment Form