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Urgent Field Safety Notice

Model A71400 Stimulation RC Clinician Programmer Application Intraoperative Use of the Switch Device Feature Impacting Inceptiv™/Intellis™ Pro INS Functionality

Notification

March 2025

Medtronic Reference: FA1468

Model #	UDI/GTIN
Model A71400	00763000371463 0763000B00008798V

Dear Healthcare Professional,

We are writing to inform you of a software issue that can permanently disable communication with an implantable neurostimulator (INS) when a specific intraoperative programming sequence is used. This issue occurs during the initial setup of the Inceptiv (Model 977119) and Intellis Pro (Model 977118) neurostimulators.

This issue is triggered during intraoperative use of the Wireless External Neurostimulator (WENS) and the Stimulation Trialing Clinician Programmer Application (Model A71300 CP App) when the Switch Device feature is used in combination with a specific lead model selection. Once this issue occurs, the affected INS cannot be interrogated, requiring a replacement INS.

When This Issue Occurs:
This issue only occurs intraoperatively when all of the following conditions are met:

1. A Wireless External Neurostimulator (WENS) (Model 97725 or 9772501) is used.
2. The Stimulation Trialing CP App (Model A71300) is used for lead testing.
3. A specific lead model option (listed below) is selected in the Stimulation Trialing App.
4. The optional Switch Device feature is selected to transfer patient and lead data to the Stimulation RC (Rechargeable) CP App (Model A71400) otherwise referred to as the Inceptiv/Intellis Pro CP App.

If these conditions are met, the Inceptiv/Intellis Pro CP App (A71400) will fail to recognize the transferred lead selection, permanently disabling communication with the INS. The typical implant workflow includes additional checks after using the Switch Device feature, such as impedance checks, at which point this issue would be recognized, and the INS would need to be replaced with an alternative INS prior to implantation. However, if these checks are not performed, the issue may go undetected until after implantation, potentially requiring a revision procedure.

Medtronic is aware of four (4) events due to this issue, which is roughly 0.057% of the estimated total global implants of Inceptiv and Intellis Pro INS. In three (3) of the events, the issue was resolved by using a backup INS to complete the procedure. In the fourth event, the issue was discovered after the INS was implanted, and communication with the device was not possible. This event resulted in a revision surgery to replace the INS.

Affected Devices & Software

- INS Models:
  - Inceptiv (977119)
  - Intellis Pro (977118)
- Software Applications:
  - Stimulation Trialing CP App (A71300) – used intraoperatively with WENS
  - Inceptiv/Intellis Pro CP App (A71400) – used for INS programming
- Wireless External Neurostimulators (WENS):
  - Model 97725

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    - Model 9772501
- Lead Models Affected:
    - 3777/3877/3873 Standard
    - 3778/3878/3874 Compact
    - 3776/3876/3875 Subcompact
    - 3888/3892 Pisces Quad Plus
    - 3487A/3890 Pisces Quad Standard
    - 3887/3891 Pisces Quad Compact

Note: This issue only applies when any of the lead models listed above are selected. Newer leads, such as the Vectris™ SureScan™ and Specify™ SureScan™, are not affected.

Required Actions:

- When utilizing any of the lead options mentioned above, avoid using the Switch Device feature to transfer data from the Model A71300 Stimulation Trialing CP App to the Model A71400 Stimulation RC CP App. As an alternative, manually enter the patient and lead information using the Model A71400 Stimulation RC CP App, ensuring not to utilize the Switch Device feature.
- Inform relevant medical staff about the potential of this issue and the steps to mitigate it.
- Ensure that backup INS devices are readily available for scheduled surgeries.
- During the implant procedure, check the system integrity before securing the neurostimulator in place as described in the Inceptiv/Intellis Pro Implant Manual.
- Please complete and return the customer acknowledgment form enclosed in this letter acknowledging that you have received this information.

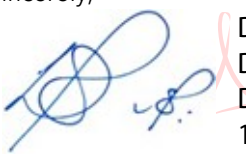
Additional Information:

Medtronic is actively working on a permanent solution and will inform you as soon as it becomes available.

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. Please contact your Medtronic Representative if you have any questions regarding this communication.

Sincerely,



Digitally signed by
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Dirk Gey Van Pittius
Medtronic Africa Quality and Regulatory Affairs

Enclosure:
Customer Acknowledgment Form