Report Form
Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? Agency for medicinal products and medical devices (HALMED) Ksaverska cesta 4 10000 Zagreb Croatia	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 05 March 2025	
Reference number assigned by the manufacturer FA1468	
FSCA reference number assigned by NCA	
Incidence reference number assigned by NCA	
Name of the co-ordinating national competent authority (if applicable) IGJ (Dutch) Health and Youth Care Inspectorate – ref: IT2105542	
2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☒ Authorised representative within EEA, Switzerland and Turkey ☐ Others (identify the role):	
3 Manufacturer information	
Name Medtronic, Inc.	
Contact name -	
Address 710 Medtronic Parkway	
Postcode MN 55432	City Minneapolis
Phone -	Fax -
E-mail -	Country US
4 Authorised representative information	
Name Medtronic B.V	
Contact name Inge Vandenbussche	

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Phone -	Fax -
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5 National contact point information	
National contact point name Medtronic Adriatic doo	
Name of the contact person Vedran Biondic	
Address Folnegoviceva 1c	
Postal code 10000	City Zagreb
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6 Medical device information	
Class ☐ AIMD Active implants ☒ MDD Class III ☐ MDD Class IIb ☐ MDD Class IIa ☐ MDD Class I ☐ IVD Annex II List A ☐ IVD Annex II List B ☐ IVD Devices for self-testing ☐ IVD General	
Nomenclature system (preferable GMDN) EMDN	Nomenclature code J020782
Nomenclature text NEUROSTIMULATORS PROGRAMMERS – SOFTWARE ACCESSORIES	
Commercial name/ brand name/make Stimulation RC Clinician Programmer Application	
Model number A71400	Catalogue number N/A
Serial number(s) N/A	lot/batch number(s) N/A
Device Manufacturing date N/A	Expiry date N/A
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number 0123	
7 Description of FSCA	

Background information and reason for the FSCA

Device description:
The clinician programmer application is intended for use by clinicians in the programming of Medtronic neurostimulators for pain therapy.

Description of Issue:
The wireless external neurostimulator (WENS) can be used for intraoperative testing during lead placement and for trial stimulation outside of the operating room. When the WENS is used intraoperatively, there is an optional Switch Device feature that allows transfer of certain patient and lead information that was entered on the A71300 Stimulation Trialing Application to the newly implanted neurostimulator without having to enter it again in the A71400 CP App. Performing this Switch Device operation from the WENS using the A71300 SCS Trialing App to transfer data to a newly implanted Inceptiv or Intellis Pro implantable neurostimulator (INS), results in the A71400 Inceptiv Clinician Programmer Application (CP App) crashing and the INS becoming unusable when the transfer involves legacy lead options in the App using the forward slash character "/" (i.e. 3777/3877/3873). During the Switch Device process, a forward slash "/" character, otherwise known as a special character, in a legacy lead model name (e.g., 3777/) is replaced with an "X" (e.g., 3777X) by the A71400 CP App. The A71400 CP App does not support any leads transferred with a "/" character in the lead model name selection. This anomaly causes the CP App to not recognize the lead selection. Because the lead is not recognized, the impedance check command that is issued to the INS during the interrogation sequence is called with '0' valid electrodes. This causes the firmware to issue a reject code because it cannot do an impedance check with 0 electrodes. The CP App responds by issuing a System Error (code 0x5d4bae06) and forces the app to quit. Because the interrogation is required to start a session, and the impedance check occurs during the interrogation, the INS cannot be programmed.
The Switch Device feature is optional, and the information transferred using the switch device feature can also be directly entered using the A71400 CP App. Legacy leads remain compatible with the Inceptiv and Intellis Pro systems as long as the Switch Device feature is not used to transfer information to the A71400 CP App. Use of the WENS is not impacted by this issue and can still be used intraoperatively for lead positioning and impedance checks.

Risk Analysis Summary:
When this scenario occurs, the INS becomes unusable. During the implant the patient is exposed to the issue, resulting in a prolonged or rescheduled surgical procedure. The issue causes the INS to become unstable so it cannot be programmed and a backup INS must be obtained. If a backup INS is not available at the time of surgery, or if the issue with the impacted INS is not recognized and the INS is implanted, an additional surgical procedure to replace the INS will be required.
Up until 27-Jan-2025, a total of four (4) events (02 Spain, 02 United States) have been identified as related to this anomaly. In 3 of the 4 known events, a backup INS was used to complete the procedure, and communication was successful with the INS. In the fourth remaining event, the patient underwent a revision surgery to implant a working INS.
The safety risk is in Zone 2 (Medium) and the assessed risk herein exceeds the existing risk in the published hazard analysis.

Description and justification of the action (corrective/preventive)
An FSN will be delivered to affected implanting/managing Physicians to inform them of the issue with the Model A71400 CP App and to give recommendations until a permanent solution can be implemented. Until the permanent solution is available, Medtronic will monitor for new customers and will inform them of this issue.

Advice on actions to be taken by the distributor and the user:

- 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.

Progress of FSCA, together with reconciliation data (Mandatory for a Final FSCA)

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English ☒ FSN in national language ☒ Others (please specify): Customer List in your country	☐ Draft ☒ Final

Time schedule for the implementation of the different actions

This FSCA will be initiated 05 March 2025 and notification of initially identified customers is planned to be completed by 09 July 2025.

Medtronic will be monitoring for new customers until permanent solution is in place.

These countries within the EEA and Switzerland and Turkey are affected by this FSCA

- within the EEA, Switzerland and Turkey:

☒ AT	☒ BE	☐ BG	☒ CH	☐ CY	☒ CZ	☒ DE	☒ DK	☐ EE	☒ ES
☒ FI	☒ FR	☒ GB	☒ GR	☒ HU	☒ IE	☒ IS	☒ IT	☐ LI	☐ LT
☐ LU	☐ LV	☐ MT	☒ NL	☒ NO	☒ PL	☒ PT	☐ RO	☒ SE	☒ SI
☒ SK	☐ TR	☒ HR							

☐ All EEA, Candidate Countries, Switzerland and Turkey

- Others:

Comments:
EU-MDR Risk Class: Class III. Classification Rule: Rule 9 / active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices.
Basic UDI-DI: 0763000B00008798V

In Croatia, 1 distributor is in scope of this FSCA.

I affirm that the information given above is correct to the best of my knowledge.

i.a. 

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Signature

Inge Vandenbussche	Heerlen	05 March 2025
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.