Health Canada Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry

CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets

Fields required to be completed for updates/final reports are indicated by an *

A. REPORTER INFORMATION

1. i. Reporter Type

☐ Manufacturer ☒ Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?

☒ Yes ☐ No

iii. Is the importer also submitting the report on behalf of the manufacturer?

☒ Yes ☐ No

2. Reporter Contact Information *

Laura Pascal - RA/QA Dept.
Medtronic Canada
Phone: 514-693-7146
Fax: 514-693-7278
Laura.d.pascal@medtronic.com

3. Reporter File No. *

0703667127

4. Health Canada File No. (if applicable) *

5. Type of Report *

☐ Preliminary ☒ Update ☐ Final ☐ Preliminary & Final

If "preliminary" only, anticipated date for the final report:

(YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

2020-07-06 (YYYY-MM-DD)

6. Date Submitted *

2020-10-27 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	MEDTRONIC NAVIGATION, INC. 826 COAL CREEK CIRCLE, LOUISVILLE, CO, US Postcode:80027 Tel:(+1-720)8903200 Fax:(+1-720)8903500	MEDTRONIC CANADA ULC 99 HEREFORD STREET, BRAMPTON, ON, CANADA Postcode:L6Y 0R3 Tel:(800)268-5346 Fax:(905) 460-3992
8. Health Canada assigned company identification number (if	114892	106916
9. Establishment License Number (if applicable):	NA	35

B. INCIDENT INFORMATION

1. Classification of Incident *

i. ☐ 10-Day ☒ 30-Day

ii. ☒ Canadian ☐ Foreign

iii. ☐ Investigational testing ☐ Special Access Program

☐ Radiation emitting device (if applicable)

2. Date of Incident

2020-03-13

3. Reporter's Awareness Date

2020-03-13

4. Patient Consequences

No patient consequences were reported

5. Details of Incident

Medtronic received information regarding a navigation system being used in a cranial biopsy. It was reported that the site couldn't get the system to recognize the emitter box. The system could still be used Clinically as optical was working, but was tagged as such until the box could be tested/replaced. No patient was present at the time of the event.

Concomitant Medical Products:
Product ID: 9733597, Product Type: CABLE 9733597 EXTERNAL AXIEM PWR/DATA.

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

STEALTHSTATION® S7´

2. Control/Lot/Serial No.

4501123545

3. Expiration Date

4. i. Device Classification

☐ I ☐ II ☒ III ☐ IV

ii. Device License No.

79099

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)

9733857

5. Software Version

Not Applicable

6. Age of Device

UNKNOWN

7. How long was the device in use?

UNKNOWN

8. Was the device labelled as sterile?

☐ Yes ☒ No

9. Availability of device for evaluation

☐ Destroyed ☐ Returned to Manufacturer/Importer

☒ Neither (with explanation)

Still in Use

Product ID: 9733597, Product Type: CABLE 9733597 EXTERNAL AXIEM

D. COMPLAINANT INFORMATION

1. Complainant is a:

☐ Consumer ☒ Health professional ☐ Other

2. Name of Complainant

Unknown Healthcare Professional

3. Name of Health Care Facility (if applicable)

Foothills Medical Centre

4. Address

1403-29th Street NW Calgary AB T2N 2T9

5. Telephone No. and/or E-mail Address

Tel#: +1UNKNOWN#

Privacy Notice Statement: For the purposes of the Canada Vigilance - Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System;HC PPU 088 at: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

Text for this section follows on the subsequent page(s)

This section only applies for preliminary & final, and final reports

2. Root Cause of Problem

The lemo connector on the returned cable had been previously opened and the alignment sleeve is missing. Without the sleeve, the pin block is not set will not connect correctly. The cable is not usable as is.

3. Corrective Actions taken as a result of the investigation

No corrective actions have been taken as a result of this event. We will continue to monitor for trends as more definitive data is collected.

Disclaimer

Medtronic, Inc. (Medtronic) is submitting this report to comply with regulatory reporting requirements. This report is based upon information obtained by Medtronic,which the company may not have been able to fully investigate or verify prior to the date the report was required to be submitted.Medtronic has made reasonable efforts to obtain more complete information in the time allotted and has provided as much information as is available to the company as of the submission date of this report. This report does not constitute an admission or a conclusion by the regulatory authority,Medtronic, or its employees that the device, Medtronic or its employees caused or contributed to the event described in the report. In particular, this report does not constitute an admission by anyone that the product described in this report has any "defects" or has "malfunctioned". Medtronic objects to the use of thesewords and others like it because of the lack of definition and the connotations implied by these terms. This statement should be included with any information or report disclosed to the public under applicable disclosure laws.

E. 1. Investigative Actions and Timeline

The CABLE 9733597 has been received at the USA Global Business Unit and investigation was re-opened.

Investigation Summary - It was reported that the site couldn't get the system to recognize the emitter box. The system could still be used Clinically as optical was working but was tagged as such until the box could be tested/replaced. No patient was present at the time of the event. As the event was reportable to a regulatory authority and indicated a possible failure of a device, labeling, or packaging to meet any of its specifications, an investigation was required. The event was investigated to determine cause. The system was serviced in the field and the external axiem cable was replaced.

Hardware analysis determined that the lemo connector on the returned cable had been previously opened and the alignment sleeve is missing. Without the sleeve, the pin block is not set will not connect correctly. The cable is not usable as is. As the reported issue was unrelated to a software issue, a software analysis was not performed. There was no indication that the event was related to a possible manufacturing issue, so a Device History Record review was not performed. The investigation determined that this event was similar to an event that had already been investigated, and another investigation is not necessary. See Test Track Number 2257. the in-house analysis indicates the event is similar to events investigated per Test Track # 2257.

Aijaz, Naeem (HC/SC)

From: Pascal, Laura <laura.d.pascal@medtronic.com>
Sent: 2020-10-27 11:42 AM
To: mdpr / dimm (HC/SC)
Subject: MDPR - UPDATE - Medtronic file #703667127 - Date of submission: 27-Oct-2020
Attachments: 703667127 - MDR.pdf

Please find attached an Update – *30 DAY* – MDPR. Medtronic File no. 703667127

Best regards,

Laura Pascal
Compliance/Audit Specialist CANADA

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