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 ULC
Phone: 514-693-7146
Fax: 514-693-7278
Laura.d.pascal@medtronic.com

3. Reporter File No. *

0703703023

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:

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

6. Date Submitted *

2020-09-23 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	MEDTRONIC INC. 710 MEDTRONIC PARKWAY NE, MINNEAPOLIS, MN, US Postcode:55432 Tel:(+1-763)5144000 Fax:(+1-763)5144879	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	114663	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

2020-04-07

3. Reporter's Awareness Date

2020-04-08

4. Patient Consequences

There were no reported patient symptoms.

5. Details of Incident

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

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

SYNCHROMED II

2. Control/Lot/Serial No.

NGV477565H

3. Expiration Date

2014-10-28

4. i. Device Classification

☐ I ☐ II ☒ III ☐ IV

ii. Device License No.

63074

iii. Device Identification No

426043

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

8637-40

5. Software Version

Not Applicable

6. Age of Device

Manufacture Date:2013-05-02

7. How long was the device in use?

Implant Date:2014-02-24

8. Was the device labelled as sterile?

☒ Yes ☐ No

9. Availability of device for evaluation

☐ Destroyed ☒ Returned to Manufacturer/Importer

☐ Neither (with explanation)

D. COMPLAINANT INFORMATION

1. Complainant is a:

☐ Consumer ☒ Health professional ☐ Other

2. Name of Complainant

Femir Nesib

3. Name of Health Care Facility (if applicable)

Health Sciences Centre Winnipeg

4. Address

820 Sherbrook St, Winnipeg, MB R3A 1R9, Canada

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

12047872365

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 root cause of the motor stall was determined to be related to residue on the gear shaft of the motor gear train.

3. Corrective Actions taken as a result of the investigation

No corrective actions have been taken as a result of this event. This failure mode will continue to be monitored and trended.

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.

B. 5. Details of Incident

It was reported that the patient heard their alarm on 2020-APR-07 and went into the clinic to investigate the alarm. Upon interrogation, it read motor stall occurred on 2020-APR-07 at 8:40 PM and recovered on 2020-APR-08 at 11:59 AM. The patient did not have an MRI, and it was unsure if the patient had any EMI exposure. There were no reported patient symptoms. Additional information was received in response to a request for follow-up. It was reported interrogating the pump a few times helped to resolve the issue and it was confirmed by the pump message "motor stall recovery" had occurred. It was confirmed that the patient denied going for any diagnostic testing such as an MRI, but was noted that the patient worked with computers and digital technologies. The HCP had given the patient a prescription for oral baclofen in case the issue occurred again and the patient was encouraged to call the clinic with any concerns. Additional information was received. No replacement was planned at this time.

Additional information was received on 2020-APR-27. It was indicated the pump stalled again and had not recovered. There was no EMI or magnetic interaction (MRI).

Further information received indicated the pump was replaced on 2020-MAY-05 and the patient had recovered and was doing well.

Further information received on 2020-AUG-14 indicated that logs showed tube set occurred.

E. 1. Investigative Actions and Timeline

It was reported that multiple motor stalls occurred, resulting in tube set. 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. Additional information was required to investigate the event and/or determine the cause of the event. The healthcare provider (HCP) was contacted via a manufacturer representative to investigate contributing factors. The HCP's response via the manufacturer representative indicated that the patient denied going for any diagnostic testing i.e. MRI. However, the patient said he works with computers, and digital technologies. The device was returned as part of this investigation. Analysis found residue in the motor gear train. Analysis identified wearing on the upper shaft of gear number two. 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 PUMP MOTOR CORROSION AND WEAR. Analysis found residue in the motor gear train. Analysis identified wearing on the upper shaft of gear number two. The root cause, if available, is documented in the referenced investigation record.

Salazar, Glenda (HC/SC)

From: Pascal, Laura <laura.d.pascal@medtronic.com>
Sent: 2020-09-23 10:47 AM
To: mdpr / dimm (HC/SC)
Subject: MDPR - FINAL - Medtronic file # 703703023 - Date of submission: 23-Sep-2020
Attachments: 703703023 - MDR.pdf

Please find attached a *FINAL – 30 DAY* – MDPR. Medtronic File no. 703703023

Best regards,

Laura Pascal
Compliance/Audit Specialist CANADA

Medtronic
16720 Transcanadienne, Suite 200
Kirkland, Québec H9H 4M7
Bureau/Office: 514-693-7146 | Fax: 514-693-7278
laura.d.pascal@medtronic.com