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 *

Kristen Hall
Medtronic Canada ULC
99 Hereford Street Brampton ON L6Y 0R3
Telephone: (905) 460-3567
Email: kristen.hall@medtronic.com

3. Reporter File No. *

0703493418

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:

2020-01-16 (YYYY-MM-DD)

6. Date Submitted *

2020-09-29 (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

2019-11-28

3. Reporter's Awareness Date

2019-11-29

4. Patient Consequences

No Injury - No patient complications have been reported as a result of this event.

5. Details of Incident

It was reported that the patient's Implantable Cardioverter Defibrillator (ICD) was showing unexpected battery depletion. The ICD had previously been prepped for implant; however, it was not used at that time. The ICD was then implanted approximately seven months later. One day after implant the ICD was showing less than two years of remaining longevity. The ICD remains in use.

2020-09-25 It was later determined that the shorter than expected longevity estimate was due to a programmer software estimator error.

Concomitant devices:
Trade Name: 2090 PROGRAMMER // Serial No. UNKNOWN // MDAL: 36425 // Model No. 2090

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

Evera MRI XT DR SureScan

2. Control/Lot/Serial No.

PGZ634702S

3. Expiration Date

2020-07-28

4. i. Device Classification

☐ I ☐ II ☐ III ☒ IV

ii. Device License No.

92108

iii. Device Identification No

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

DDMB2D4

5. Software Version

Not Applicable

6. Age of Device

Manufacture Date: 2019-01-28

7. How long was the device in use?

Implant Date: 2019-11-28

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

D. COMPLAINANT INFORMATION

1. Complainant is a:

☐ Consumer ☒ Health professional ☐ Other

2. Name of Complainant

Stephen Buffet

3. Name of Health Care Facility (if applicable)

Not Available

4. Address

Not Available

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

Not Available

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

The device was not returned for analysis. However, performance data collected from the device was received and analyzed. Analysis of the device memory had an observation relating to the battery longevity estimator.

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

2. Root Cause of Problem

No conclusion can be drawn. Should additional information become available the file will be updated

3. Corrective Actions taken as a result of the investigation

The clinical experience with this model has been incorporated into our database used to identify performance trends. The case is deemed closed, with no further action or reports to follow. If new information becomes available, the file will be re-assessed.

Upon further review, analysis confirmed this event to be related to a known advisory issue for Medtronic programmers.

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.

Aijaz, Naeem (HC/SC)

From: Hall, Kristen <kristen.hall@medtronic.com>
Sent: 2020-09-29 12:29 PM
To: mdpr / dimm (HC/SC)
Subject: MDPR_PE0703493418_Preliminary&Update_2020-09-29
Attachments: MDPR_PE0703493418_Preliminary&Update_2020-09-29.pdf

Hello,

Please see the attached Update MDPR.

Thank you,

Kristen Hall
Post-Market Vigilance & Compliance Specialist | CANADA

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LET'S TAKE HEALTHCARE FURTHER, TOGETHER