

## 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  $^{\star}\,$ 

A. REPORTER INFORMATION  1. I. Reporter Type				Page <u>1</u> of <u>3</u>
Manufacturer   Importer   In the case where the reporter is the importer: ii. Did the importer report the incident to the manufacturer?   Yes	A. REPORTER INFORMATI	ON		
### A. Health Canada File No. (if applicable) *  ### A. Health Canada File No. (if app	1. i. Reporter Type		3. Reporter File	No. *
In the importer report the incident to the manufacturer?	Manufacturer		0703493418	
Yes	In the case where the reporter is the importer:		4. Health Canada File No. (if applicable) *	
iii. Is the importer also submitting the report on behalf of the manufacturer?    Yes	ii. Did the importer report the incident to the manufacturer?			
Yes		☐ No	5. Type of Repo	rt *
Yes				
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    Manufacturer	manufacturer?		If "preliminary" only, anticipated date for the final report:	
Kristen Hall Meditronic Canada ULC 99 Hereford Street Brampton ON L6Y 0R3 Telephone: (905) 460-35667 Email: kristen.hall@meditronic.com    Manufacturer		☐ No		·
Meditronic Canada ULC 99 Hereford Street Brampton ON L6Y OR3 Telephone: (905) 460-3567 Email: kristen.hall@medtronic.com    Manufacturer				
99 Hereford Street Brampton ON L6Y 0R3 Telephone: (905) 460-3567 Email: kristen.hall@medtronic.com    Manufacturer				
Email: kristen-hall@medtronic.com    2020-09-29   (YYYY-MM-DD)	99 Hereford Street Brampton ON L6Y 0R3			
Manufacturer	• • •			
7. Name and Address  MEDTRONIC INC. 710 MEDTRONIC PARKWAY NE, MINNEAPOLIS, MN, US Postcode:55432 Tel:(+1-763)5144879  8. Health Canada assigned company identification number (if 9. Establishment License Number (if applicable):  B. INCIDENT INFORMATION  1. Classification of Incident *  i.		Manufacturer	2020-09-29	
## A Postcode:55432 Tel:(+1-763)5144879  ## B. Health Canada assigned company identification number (if  ## 9. Establishment License Number (if applicable):  ## B. INCIDENT INFORMATION  1. Classification of Incident    I	7. Name and Address			·
Postcode:55432 Tel:(+1-763)5144000 Fax:(+1-763)5144879  8. Health Canada assigned company identification number (if  9. Establishment License Number (if applicable):  B. INCIDENT INFORMATION  1. Classification of Incident *  i.			OLIS, MN, US	
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company identification number (if  9. Establishment License Number (if applicable):    B. INCIDENT INFORMATION		Fax:(+1-763)5144879		Fax:(905) 460-3992
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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
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
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

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

#### **Medtronic Canada**

99 Hereford St. | Brampton, ON L6Y 0R3 | CANADA Office 905.460.3567 | <a href="mailto:kristen.hall@medtronic.com">kristen.hall@medtronic.com</a>

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# LET'S TAKE HEALTHCARE FURTHER, TOGETHER

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