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 *

86fdbacde29076bbe3a039ae22035ff4

3. Reporter File No. *

0701020221

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:

2016-01-20 (YYYY-MM-DD)

6. Date Submitted *

2020-12-18 (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

3. Reporter's Awareness Date

2015-07-23

4. Patient Consequences

6dc88a257eff4fcf8a4557d47b200cb7

5. Details of Incident

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255eeeef1a34a803f3b7ad3dc8f752a0

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C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

ADVISA DR MRI SURESCAN

2. Control/Lot/Serial No.

PZK746817S

3. Expiration Date

2016-08-28

4. i. Device Classification

☐ I ☐ II ☐ III ☒ IV

ii. Device License No.

84909

iii. Device Identification No

56b34cb2d4027651737b241a20a84a5c

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

A3DR01

5. Software Version

Not Applicable

6. Age of Device

Manufacturing Date:2015-03-05

7. How long was the device in use?

Implant date not available.

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

c010f45d33171cfbc11e6a52776628de

3. Name of Health Care Facility (if applicable)

55a0637cc1d7a444316f15158d93b2ca

4. Address

49179d9d5dc5c8c9cb3cc6cff5903e79

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

1af747da26f36e440d77cc2c987fbbc8

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

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

2. Root Cause of Problem

a56485e02f6e47a01b6e512fd23de21e

3. Corrective Actions taken as a result of the investigation

f4f6b0a28dff0919413e2b30562bb29a