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 *

245a74bde09dcacf8faa14caa6095c40

3. Reporter File No. *

INF-US-2019-037814 (339150)

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:

2020-01-07 (YYYY-MM-DD)

6. Date Submitted *

2020-03-02 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address		
8. Health Canada assigned company identification number (if known):		
9. Establishment License Number (if applicable):		

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

(YYYY-MM-DD)

3. Reporter's Awareness Date

(YYYY-MM-DD)

4. Patient Consequences

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5. Details of Incident

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C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Alaris Pump Module Administration Set

2. Control/Lot/Serial No.

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
○ I ○ II ○ III ○ IV

ii. Device License No.

iii. Device Identification No

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

5. Software Version

6. Age of Device

7. How long was the device in use?

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
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3. Name of Health Care Facility (if applicable)
d41d8cd98f00b204e9800998ecf8427e

4. Address
d41d8cd98f00b204e9800998ecf8427e

5. Telephone No. and/or E-mail Address
d41d8cd98f00b204e9800998ecf8427e

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*, and 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
2997810528289a4a837f7e27243788d4

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

2. Root Cause of Problem
4d0cfb4aab1be6af7e7fa773c021a700

3. Corrective Actions taken as a result of the investigation
c07b374441f9eb7daae2942d851c0fb6