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 *

ce85eedc55a4b2463a06a1c32b82748b

3. Reporter File No. *

INF-US-2019-035686 (335826)

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:

2019-12-18 (YYYY-MM-DD)

6. Date Submitted *

2020-03-25 (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

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**
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5. **Telephone No. and/or E-mail Address**
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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**
5312beb1a842c7a90ab26b6fdb9466bb

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

2. **Root Cause of Problem**
717a5a0e15c6ead3e6cea7888f2d9d89

3. **Corrective Actions taken as a result of the investigation**
5f2b578072c8ff84dc7c130eb1a31fde