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 *

ecc122dda5dadea3e49c4c3ad5d76bda

3. Reporter File No. *

INF-US-2019-028494 (324068)

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:

(YYYY-MM-DD)

6. Date Submitted *

2019-10-16 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	CAREFUSION 303, INC. 10020 Pacific Mesa Blvd. San Diego, CA 92121-2733	Becton Dickinson Canada Inc. 2100 Derry Road, Suite 100, Mississauga, ON L5N 0B3 Canada
8. Health Canada assigned company identification number (if known):	105302	101291
9. Establishment License Number (if applicable):	N/A	204

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

2019-09-12 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-09-18 (YYYY-MM-DD)

4. Patient Consequences

1ab2b9a9d312b7a21c73d746c0d959a7

5. Details of Incident

464edf7baf0b0c9e8907c5c3f7324fb4

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Alaris® Pump Module

2. Control/Lot/Serial No.
14241685

3. Expiration Date
(YYYY-MM-DD)

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

ii. Device License No.
12364

iii. Device Identification No
563999

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
8100

5. Software Version
9.1.17.7

6. Age of Device
unknown

7. How long was the device in use?
unknown

8. Was the device labelled as sterile?
○ Yes ◉ No

9. Availability of device for evaluation
○ Destroyed ○ Returned to Manufacturer/Importer
◉ Neither (with explanation)

Although requested, product has not been received.

D. COMPLAINANT INFORMATION

1. Complainant is a:
○ Consumer ○ Health professional ◉ Other

2. Name of Complainant
59efe4b53d662d8e67d00ba3bbbe5c03

3. Name of Health Care Facility (if applicable)
6c6b5074d18d335f308bf75cfebd8aed

4. Address
f5ddeba545884fb12d4ad9ce5d4ce725

5. Telephone No. and/or E-mail Address
2c7895797fba473cdf9dace6068c9a18

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
7d2cd70a52b8f07c198272095594e17e

2. Root Cause of Problem
cc09933f28c4ccf940eabd0da7a683d8

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