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 *

b14dde04b3f7a2fa36eb61358fc5d20b

3. Reporter File No. *

INF-US-2020-030081 (412569)

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 *

2020-10-28 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	CareFusion 303, INC. 10020 Pacific Mesa Blvd. San Diego, California United States 92121-2733	Becton Dickinson Canada Inc. 2100 Derry Road, Suite 100, Mississauga, ON L5N 0B3
8. Health Canada assigned company identification number (if known):	105302	101291
9. Establishment License Number (if applicable):	Not Applicable	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

(YYYY-MM-DD)

3. Reporter's Awareness Date

2020-10-08 (YYYY-MM-DD)

4. Patient Consequences

7190b6c821819839ffe19bdb9134c377

5. Details of Incident

6c5020b74665eac7722ddcdac3132fbc

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Alaris Pump Module

2. Control/Lot/Serial No.
14119327

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
6 years 4 months

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)

No device will be returned per customer.

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
48b239629bc164f80ce9e4743abbba96

3. Name of Health Care Facility (if applicable)
8c38451bb924e902c54de84ae6d1b13d

4. Address
a473a21c276f8bbc60bee16d3398baf1

5. Telephone No. and/or E-mail Address
+1(604)851-4700 x642281
callum.macnicoll@fraserhealth.ca

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

1e2cbb60891b01fce560876e39ce09c4

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

2. Root Cause of Problem

46f888652f8b8c05cfa1723a83312709

3. Corrective Actions taken as a result of the investigation

274f3ca6caf473d9cd088b186114e888
