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 *

Melissa Sanz, Quality Management Associate
Becton Dickinson Canada Inc.
2100 Derry Road, Suite 100,
Mississauga, ON L5N 0B3
tel: (905)288 -6148 / E-mail: [redacted]

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

There was no reported patient involvement.

5. Details of Incident

It was reported that allegedly fourth top right and bottom left segments were dim for three devices and fourth top right segments were dim for two devices. Reportedly, the display boards of five large volume pump modules will be replaced.

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
Callum MacNicoll, Biomed

3. Name of Health Care Facility (if applicable)
ABBOTSFORD REGIONAL HOSPITAL

4. Address
32900 MARSHALL RD
ABBOTSFORD, BC, V2S 0C2
Canada

5. Telephone No. and/or E-mail Address
+1(604)851-4700 x642281
[redacted]

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

The customer complaint could not be confirmed because the device was not returned for failure investigation.

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

2. Root Cause of Problem

The root cause of this failure was not identified.

3. Corrective Actions taken as a result of the investigation

This failure is being addressed through BD's corrective and preventive action processes.

Suthan, Thatpara (HC/SC)

From: CANDQualityCanada <[redacted]>
Sent: 2020-10-28 2:53 PM
To: CANDQualityCanada; mdpr / dimm (HC/SC)
Subject: MDPR Health Canada Reports / 411003,411006,411196,412569,413178,413177,413179,413947
Attachments: 413177 Combined MDPR_28Oct2020.pdf; 412569 Combined MDPR_28Oct2020.pdf; 411196 Combined MDPR_28Oct2020.pdf; 411006 Combined MDPR_28Oct2020.pdf; 411003 Combined MDPR_28Oct2020.pdf; 413179 Combined MDPR_28Oct2020.pdf; 413178 Combined MDPR_28Oct2020.pdf; 413947 Combined MDPR_28Oct2020.pdf

Mandatory Problem Reporting - Completed Medical Device Problem Report from Becton Dickinson Canada Inc.

Please find enclosed, completed Medical Devices Problem Report Form for the following complaints:

BD Internal PIR File	Mandatory Report Type	Completed Forms
411003	30 day	Combined MPR
411006	30 day	Combined MPR
411196	30 day	Combined MPR
412569	30 day	Combined MPR
413178	30 day	Combined MPR
413177	30 day	Combined MPR
413179	30 day	Combined MPR
413947	30 day	Combined MPR

Abbreviations: PIR = Product Incident Report (Complaint), Combined = Preliminary and Final

We trust that you will find the present package satisfactory; however should you have any questions or concerns, please do not hesitate to contact me.

In the event that an email message is sent, we respectfully request that all of the aforementioned individuals be “cc’d” on the communiqué.

Thank you,

Melissa Sanz
Quality Associate
Quality Assurance

[redacted]
Complaints: TOR-[redacted]

2100 Derry Rd W #100
Mississauga, ON L5N 0B3

CA

Please note my number has changed:
Direct: +1.905.288.6148
Toll free: +1.800.268.5430 ext. 6148

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