
Canada

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
callum.macnicoll@fraserhealth.ca

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 <CANDQualityCanada@bd.com>
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

Melissa.Sanz@bd.com
Complaints: TOR-ComplaintsCA@bd.com

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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