



Health  
Canada

Santé  
Canada



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**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

**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 &amp; 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)

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**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.

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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](mailto: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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Thank you.

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Corporate Headquarters Mailing Address: BD (Becton, Dickinson and Company) 1 Becton Drive Franklin Lakes, NJ 07417 U.S.A.