Health Canada / Santé Canada

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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 reported 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 Infomation*

9f0ea4da439c108b4fb390bb294150cf

3. Reporter File No*

2043994

4. Health Canada File No (if applicable)*

N/A

5. Type of Report*

☐ Preliminary ☐ Update ☒ Final ☐ Preliminary & Final

If "preliminary" only, anticipated date for final report:

2019-09-28 (YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:

2019-03-28 (YYYY-MM-DD)

6. Date Submitted *

2019-04-24 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Physio-Control, Inc. - 3015876 11811 Willows Road NE Redmond WA 98052 US todd.bandy@stryker.com	Stryker Canada 2 Medicorum Place Ontario Waterdown CA L8B 1W2 CARAQA@stryker.com
8. Health Canada assigned company identification number (if known):	108236	104767
9. Establishment License Number (if applicable):	N/A	130

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

2019-03-01 (YYYY-MM-DD)

3. Reporter's Awareness Date:

2019-03-07 (YYYY-MM-DD)

4. Patient Consequences

5. Details of Incident

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7d4803ca69cc12e80c79b1c48720f4e7

16d50d31292736ad620445f348a87cc7

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
LP15,EN,SPO2,12L,EX,NIBP,CO2,TR,VR,BT,V2

2. Control/Lot/Serial No.
42039284

3. Expiration Date:
(YYYY-MM-DD)

4. i. Device Classification
☐ I ☐ II ☐ III ☒ IV

ii. Device License No.
80574

iii. Device Identification No
259256

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
99577-001256

5. Software Version

6. Age of Device

7. How long was the device in use?

8. Was the device labelled as sterile?
☐ Yes ☐ No

9. Availability of device for evaluation
☐ Destroyed ☐ Returned to Manufacturer/Importer
☒ Neither (with explanation)
Device assessed in the field

D. COMPLAINANT INFORMATION

1. Complainant is a:
☐ Consumer ☐ Health Professional ☒ Other

2. Name of Complainant
f6336ce60594a7e2cac0b23725db8614

3. Name of Health Care Facility (if applicable)
1970295f38a87af33b332e10b15f4278

4. Address
f22afdc82c719d3d3d88ae8bdaa04458

5. Telephone No. and/or E-mail Address
2d43153a314dc00a9e7985bb914374de

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: Info Sources of Federal Government and Employee Information 2010

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
70b18c6838939e8b3a9bb57bf24b3d1d

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

2. Root Cause of Problem
8b207fb9ba5312d8d60813076eb58fe1

3. Corrective Actions taken as a result of the investigation
1f8a7270cad70e3a6e159f23429a5332