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 *

02472129b3fab52dbf212d0e88217855

3. Reporter File No. *

PC-000031030

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:

2020-01-30 (YYYY-MM-DD)

6. Date Submitted *

2020-04-24 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address:	VYAIRE MEDICAL, INC. ALSO TRADING AS CAREFUSION 26125 N. Riverwoods Blvd. Mettawa, IL, US, 60045	CARDINAL HEALTH CANADA 1000 Tesma Way Vaughan, ON, CA, L4K 5R8
8. Health Canada assigned company identification number (if known):	144700	104924
9. Establishment Licence Number (if applicable):		

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

2019-10-30 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-11-26 (YYYY-MM-DD)

4. Patient Consequences

5. Details of Incident

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t

04162f6b8dfa6d5618df61f606a00dd6

d2ae4b5b9d0b4f39a77d668d6882780f

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

AIRLIFE U/ADAPIT EXHALATION MANIFOLD BODY

2. Control/Lot/Serial No.

0000318408, 0000353988

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

○ I ◉ II ○ III ○ IV

ii. Device License No.

8086

iii. Device Identification No

004379

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

004379/AIRLIFE U/ADAPIT EXHALATION MANIFOLD BODY

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)

D. COMPLAINANT INFORMATION

1. Complainant is a:

○ Consumer ○ Health Professional ◉ other

2. Name of Complainant

d6b7e81b4e2020f0b5e1a5323be11cae

3. Name of Health Care Facility (if applicable)

7dc74984979b6626e016cf053452f177

db2bf6c0a164a6269e6810230594b05e

132ebf2ecb6625117d7f01c483357629

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

f713eaa2180d280ec48eff2128790f0e

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

2. Root Cause of Problem

e51ca50cf9d8e9ea1c1cc4ce5b695bf0

3. Corrective Actions taken as a result of the investigation

e361b66255e633d5be504ecbada10676