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 *

Peter Sparacio
peter.sparacio@vyaire.com
Phone-(833) 327-3284

3. Reporter File No. *

PC-000036763

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:

2020-08-14 (YYYY-MM-DD)

6. Date Submitted *

2020-08-26 (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

2020-03-30 (YYYY-MM-DD)

3. Reporter's Awareness Date

2020-03-30 (YYYY-MM-DD)

4. Patient Consequences

The customer confirmed that there is no patient harm associated with this reported event.

5. Details of Incident

The customer reported that the patient used the nebulizer after an hemodialysis run. However, it did not mist, and a new one was used which worked properly.

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

AIRLIFE MISTY-NEB MEDICATION NEBULIZERS

2. Control/Lot/Serial No.

0004103399

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

○ I ◉ II ○ III ○ IV

ii. Device License No.

7926

iii. Device Identification No

002438

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

002438/AIRLIFE MISTY-NEB MEDICATION NEBULIZERS

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

Yuyan Li

3. Name of Health Care Facility (if applicable)

CHR - Northeast Calgary Hemodialysis Centre

4. Address

200, 2580 - 32nd St., Ne c/o Sunridge Medical, Calgary, AB, T1Y 7M8, Canada

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

Phone –(403) 955-9823
Email –yuyan.li@albertahealthserv

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

Review of device history record of the lot number revealed no anomalies, and a sample had been received by the manufacturer for evaluation. Unfortunately, that sample was discarded by mistake. However, technical team indicated that a CAPA has been initiated based on a similar problem, and the manufacturing date of the product reported on this complaint is covered by that CAPA. Therefore, technical team is confirming the reported failure. There has been no previous report made to the Minister with respect to the device for the past 24 months.

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

2. Root Cause of Problem

Technical team determined that the defect is related to method of Jet height measurement (altimeter loses calibration frequently and throwing assembled piece to container can produce failure) and equipment (wear in the area of the locks related to the mold/flash in the thread area can cause incorrect measurement reading and assembly fixture design allowing the piece to be removed at certain angle can cause disassembly).

3. Corrective Actions taken as a result of the investigation

Corrective/preventive actions have been implemented to address the reported failure and are detailed under CAPA 567.

Perras, Eryn (HC/SC)

From: Shadley, Susan <Susan.Shadley@vyaire.com>
Sent: 2020-08-26 11:28 AM
To: mdpr / dimm (HC/SC)
Cc: Bonilla, Erika
Subject: Vyaire Final MDPR Report- PC-000036763
Attachments: PC-000036763 FINAL REPORT _CVMDReportPDF 08-26-2020.pdf

To whom it may concern,

This is notification that we are submitting our Final MDPR for Manufacturer Reference #: PC-000036763. Please see the attached PDF file and confirm receipt.

If there are any questions, please feel free to contact me directly.

Many Thanks,

Susie Shadley
Complaint Analyst, Complaint Management Group

714.919.3628 Direct
susan.shadley@vyaire.com

Mailing Address:
Vyaire Medical
510 Technology Drive
Irvine, CA 92618
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please relay to the sender by reply email and delete this email. Thank you
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