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 *

c6561edd1710da76dfdafdde6bcdf83c

3. Reporter File No. *

5947-2019-00019

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:

2019-11-08 (YYYY-MM-DD)

6. Date Submitted *

2020-12-02 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Umano Medical Inc 230 boulevard Nilus-Leclerc L'Islet (QC), GOR 2C0	
8. Health Canada assigned company identification number (if known):	137428	
9. Establishment License Number (if applicable):	5947	

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

2019-10-11 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-10-11 (YYYY-MM-DD)

4. Patient Consequences

50125db8161588e42325f4486c72a3d7

5. Details of Incident

91402ba53dcd6f27969623c24894ac00

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
ook snow

2. Control/Lot/Serial No.
FL3610777A

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
(•) I ( ) II ( ) III ( ) IV

ii. Device License No.

iii. Device Identification No

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
FL36

5. Software Version
2.1

6. Age of Device
14 months

7. How long was the device in use?
about 14 months

8. Was the device labelled as sterile?
( ) Yes (•) No

9. Availability of device for evaluation
( ) Destroyed ( ) Returned to Manufacturer/Importer
(•) Neither (with explanation)

In use at customer site

D. COMPLAINANT INFORMATION

1. Complainant is a:
( ) Consumer (•) Health professional ( ) Other

2. Name of Complainant
d0a89ff29bd491f2f6fe1a09eabad524

3. Name of Health Care Facility (if applicable)
32cfb6bbc7199dede4c58a38419b850f

4. Address
8ad147a65e79f2d32b2b1d20cca82410

5. Telephone No. and/or E-mail Address
3c769fface04ce20f51dfa96d4eb384d

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

de3f7507ae7e1fa5b1cf738fd26efde8

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

2. Root Cause of Problem

76588a37c2353c1e5c3678417ee23a0c

3. Corrective Actions taken as a result of the investigation

29a1c23936431a62a5d114e1144a7967