



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 *

Page 1 of 2

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 *

dafa617f9c6c2cf047c14cc9f2a958f3

3. Reporter File No. *

2019-7141-QA-ST

4. Health Canada File No. (If applicable) *

N/A

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:

2019-12-13

(YYYY-MM-DD)

6. Date Submitted *

2020-02-24

(YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel Switzerland	Accuristix 6090 White Hart Lane, Mississauga, Ontario, L5R 3Y4 Canada
8. Health Canada assigned company identification number (if known):	141952	119556
9. Establishment License Number (if applicable):	N/A	1923

B. INCIDENT INFORMATION

1. Classification of Incident *

10-Day 30-Day

Canadian Foreign

Investigational testing Special Access Program

Radiation emitting device (if applicable)

2. Date of Incident

2019-11-29 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-11-29 (YYYY-MM-DD)

4. Patient Consequences

573ed5e6bcf4433a020979d7624608ee

5. Details of Incident

0fa62079e6811aa8193885f5a5332d33

C. MEDICAL DEVICE INFORMATION**1. Trade/Brand Name ***

Contour Next One Meter

2. Control/Lot/Serial No.

1129542

3. Expiration Date

(YYYY-MM-DD)

4. i. Device Classification

I II III IV

ii. Device License No.

98283

iii. Device Identification No

817063

iv. Manufacturer's Medical Device Identifier

(catalogue/model no.)

9764

5. Software Version**6. Age of Device**

2017-04-06

7. How long was the device in use?

2 Year 7 Months

8. Was the device labelled as sterile?

Yes No

9. Availability of device for evaluation

Destroyed Returned to Manufacturer/Importer
 Neither (with explanation)

See section E.

D. COMPLAINANT INFORMATION**1. Complainant is a:**

Consumer Health professional Other

2. Name of Complainant

06bf9fcc88219dfac2e7cb6b3800636e

3. Name of Health Care Facility (if applicable)

745fa8b5edda1bbe30ac53f72647b022

4. Address

af7af00c92b9e70a6e26ae892e49a1c5

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

16635c3a36a4a9b589c1c74bf4166abe

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E. INVESTIGATION INFORMATION**1. Investigative Actions and Timeline**

dd10d275c4137abd3127dc79a2306aa3

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

2. Root Cause of Problem

8877c0d937ec69ee39d4f84966ad095d

3. Corrective Actions taken as a result of the investigation

862fdbd98247164931fb91ec2769bbf7a