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 *

Kwang Ju (Grace) Nam, QA Associate
Accuristix
121 Stone Ridge Road, Vaughan, ON, L4H 0A5
KNam@accuristix.com
Phone: 416-637-3273 EXT 5032

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-D

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

2019-12-13 (YYYY-MM-

6. Date Submitted *

2020-02-24 (YYYY-MM-

	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 *

i. ○ 10-Day ◉ 30-Day
ii. ◉ Canadian ○ Foreign
iii. ○ 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

The customer was not feeling sick, did not self-medicate, he did not change his diet and he did not seek medical attention.

5. Details of Incident

A customer called to report that he obtained variable blood glucose results on his Contour Next One Meter. The results in question were 21.9 mmol/L and 5.8 mmol/L, which were received within one minute of each other.

LAST 5 RESULTS:
5.8 mmol/L 07:56 PM 29/11/2019
21.9 mmol/L 07:55 PM 29/11/2019
5.2 mmol/L 07:52 PM 28/11/2019
6.1 mmol/L 12:10 PM 27/11/2019
5.7 mmol/L 07:48 PM 27/11/2019
Compared blood results fall within Zone "C" of the Parkes Error Grid being outside of the fitness-to-use limits.

This incident was flagged as a Mandatory Problem Report due to the fact that the comparison between two blood results taken within 1 minute of each other landed in Zone "C" of the Parkes Error Grid.

MEDICAL DEVICE INFORMATION

1. Trade/Brand Name
Contour Next One Meter

2. Control/Lot/Serial No.
1 295-2

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
○ I ○ II ◉ III ○ IV

ii. Device Licence 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?
1 Year 7 Months

8. Was the device labelled as sterile?
○ Yes ◉ No

9. Availability of device for evaluation
○ Destroyed ◉ Returned to Manufacturer/Importer
○ Neither (w... explain)

See section E

D. COMPLAINANT INFORMATION

1. Complainant is a:
◉ Consumer ○ Health professional ○ Other

2. Name of Complainant
R... T...r

3. Name of Health Care Facility (if applicable)
N/A

4. Address
896 CH DE SAINTE-FLORE
SHAWINIGAN, QC
G... 5K...

5. Telephone No. and/or E-mail Address
(819)533-5648

Privacy Notice Statement: For the purposes of the Canada Vigilance Medical Device Problem Reporting Program, information related to the identity of the complainant and 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 ...088 https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a2...

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

The meter and strips were returned by the customer and examined by our specialized department. A search in our complaint database indicates that there were no previous reports associated with these particular devices.

C1... - The device either functioned as intended or a problem was not found.

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

2. Root Cause of Problem

The returned Contour Next One meter and Contour Next test strips were tested with blood spiked with glucose at 22.0 mmol/L and 7.5 mmol/L, in 5 replicates each. All results recovered were within the fitness-for-use limits. The event is not confirmed for erratic blood glucose results or any performance problems.

3. Corrective actions taken as a result of the investigation

No corrective actions were taken due to the fact that the event was not confirmed by the investigation.

Crisan, Simona (HC/SC)

From: Kwang Ju Nam <KNam@accuristix.com>
Sent: 2020-02-24 4:50 PM
To: mdpr / dimm (HC/SC)
Cc: Kevin Chin; Gordon Rockett; Cuong Nguyen; Kwang Ju Nam; QA Summerlea
Subject: MDPR_2020-7182-QA-ST_689506_F
Attach ments: MDPR_2020-7182-QA-ST_689506_F.pdf

Hello,

Please find attached Final MDPR.

Thank you ,

Kwang Ju Grace Nam
Quality Assurance Associate

ACCURISTIX
ADVANCING HEALTHCARE LOGISTICS

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