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-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 *

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.

GN 24 FEB 2020

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