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 *

37baf35e664783674ddc843bc2322ca7

3. Reporter File No. *

COM-535581

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:

2019-12-02 (YYYY-MM-DD)

6. Date Submitted *

2020-07-13 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	Tandem Diabetes Care 11075 Roselle Street San Diego, CA 92121, USA	
8. Health Canada assigned company identification number (if known):	146459	
9. Establishment License Number (if applicable):	8886	

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

2019-12-01 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-12-01 (YYYY-MM-DD)

4. Patient Consequences

e3ca1a262cb997eafc9a806a2fc72792

5. Details of Incident

2126577d3fd295054be946051b6ffe4a

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
t:slim X2 Insulin Pump

2. Control/Lot/Serial No.
590690

3. Expiration Date
2023-06-19 (YYYY-MM-DD)

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

ii. Device License No.
100992

iii. Device Identification No
834824

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
1002684/1002717

5. Software Version
5.2.2

6. Age of Device
6 months 17 days

7. How long was the device in use?
6 months 16 days

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

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

Device Not Returned

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
ac0f19947a51382a72c4de310cf6cf12

3. Name of Health Care Facility (if applicable)
3fe304703de99adb6b7321b993a86f7b

4. Address
2b7382b1fedfb41f1b07313327ef7c1d

5. Telephone No. and/or E-mail Address
1f6d00c6102b5fb62f0a344a1aded49b

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E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
aa0e260becc45451f050be28110d909b

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

2. Root Cause of Problem
620ce1c8130708c4c0d673287d9a7b34

3. Corrective Actions taken as a result of the investigation
dbda7cb958eeadacfebce14079c5648e