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 *

Tandem Diabetes Care
11075 Roselle Street
San Diego, CA 92121, USA
+1(850)366-6900

3. Reporter File No. *

COM-685058

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:

2020-06-02 (YYYY-MM-DD)

6. Date Submitted *

2020-09-21 (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

2020-05-14 (YYYY-MM-DD)

3. Reporter's Awareness Date

2020-05-14 (YYYY-MM-DD)

4. Patient Consequences

Customer's blood glucose was 7.3 mmol/L. There was no serious deterioration in state of health.

5. Details of Incident

It was reported that the pump overheated while charging. Reportedly, customer reverted to using another pump for insulin therapy.

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
t:slim X2, Basal-IQ, mmol/L

2. Control/Lot/Serial No.
568392

3. Expiration Date
2024-03-27 (YYYY-MM-DD)

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

ii. Device License No.
103869

iii. Device Identification No
1014006

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

5. Software Version
6.3.0.1

6. Age of Device
1 year, 3 months, 30 days

7. How long was the device in use?
1 year, 3 months, 18 days

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

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

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
Stephanie Boragina

3. Name of Health Care Facility (if applicable)
Not Applicable

4. Address
106 Regina St N
Waterloo, ON, N2J 3A9, CA

5. Telephone No. and/or E-mail Address
+1(647)988-4139/stephanieboragina@gmail.com

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

The failure investigation was completed on 2020-08-27.

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

2. Root Cause of Problem

Duplication testing was performed and the pump performed as intended. No failure was identified.

3. Corrective Actions taken as a result of the investigation

None taken. The risk to the user has been mitigated.

Quality Engineer reviewed manufacturing device history records and there were no non-conformance, deviation or labeling issues associated with the reported issue.

Salazar, Glenda (HC/SC)

From: Jane Thompson <JThompson@tandemdiabetes.com>
Sent: 2020-09-21 1:48 PM
To: mdpr / dimm (HC/SC)
Cc: QA Complaint Mgmt; Customer Technical Support - International
Subject: MDPR Final COM-685058
Attachments: MDPR Final COM-685058.pdf

Hello,

Please find the attached Final Report. If you have any questions please do not hesitate to contact us. If possible, please reply with confirmation that this Report was received.

Thank you,

Jane Thompson
Sr. Global Post Market Surveillance Specialist

TANDEM DIABETES CARE

11075 ROSELLE STREET, SAN DIEGO, CA 92121
WWW.TANDEMDIABETES.COM