

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 *

				Page 1	_ of 2
A. REPORTER INFORM	IATION				
1. i. Reporter Type Manufacturer Importer		3. Reporter File No. COM-685058	*		
In the case where the reporter is the importer:		4. Health Canada File No. (if applicable) *			
ii. Did the importer report the incident to the manufacturer?					
O Yes O No iii. Is the importer also submitting the report on behalf of the		5. Type of Report * OPreliminary OUpdate OFinal OPreliminary & Final			
manufacturer?		Strommary at the			
O Yes O No		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)			
2. Reporter Contact Information *					
Tandem Diabetes Care 11075 Roselle Street San Diego, CA 92121, USA					
+1(850)366-6900		6. Date Submitted * 2020-09-21			
	'		(YYYY-MM-DD)		
7. Name and Address	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 INFORMA	ATION				
1. Classification of Incident *	5. Details of Inciden	t			
 i. O10-Day ii. OCanadian iii. OInvestigational testing OSpecial Access Program ORadiation emitting device (if applicable) 		It was reported that the pump overheated while charging. Reportedly, customer reverted to using another pump for insulin therapy.			
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 mmc deterioration in state of health.					



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 O I O II O III O 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? O Yes No
9. Availability of device for evaluation O Destroyed Returned to Manufacturer/Importer O Neither (with explanation)
D. COMPLAINANT INFORMATION
1. Complainant is a: O Consumer O Health professional O Other
2. Name of Complainant Stephanie Boragina
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

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

government-employee-information.html#a25

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



11075 ROSELLE STREET, SAN DIEGO, CA 92121

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