



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 *

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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*

ef7f6dc8ce6e2229d21565a515770e42

3. Reporter File No.*

CN-1063074

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:

2020-01-22 (YYYY-MM-DD)

6. Date Submitted *

2021-02-04

(YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address		
8. Health Canada assigned company identification number (if known):		
9. Establishment License Number (if applicable):		

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)

5. Details of Incident

2. Date of Incident

(YYYY-MM-DD)

3. Reporter's Awareness Date

(YYYY-MM-DD)

73b6ce9500f783c59b1b739f2fb33ca7

4. Patient Consequences

8a6dc1812a25b99f97fff672597f07f9

C. MEDICAL DEVICE INFORMATION		E. INVESTIGATION INFORMATION
<p>1. Trade/Brand Name * OmniPod Insulin Management System</p> <p>2. Control/Lot/Serial No.</p> <p>3. Expiration Date (YYYY-MM-DD)</p> <p>4. i. Device Classification <input checked="" type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV </p> <p>ii. Device License No.</p> <p>iii. Device Identification No</p> <p>iv. Manufacturer's Medical Device (catalogue/model no.)</p>		<p>1. Investigative Actions and Timeline</p> <p>65ce05df0b90aa04f70bdb8480465f83</p> <p>5. Software Version</p> <p>6. Age of Device</p> <p>7. How long was the device in use?</p> <p>8. Was the device labelled as sterile? <input checked="" type="radio"/> Yes <input type="radio"/> No </p> <p>9. Availability of device for evaluation <input checked="" type="radio"/> Destroyed <input type="radio"/> Returned to Manufacturer/Importer <input type="radio"/> Neither (with explanation) </p>
<p>D. COMPLAINANT INFORMATION</p> <p>1. Complainant is a: <input checked="" type="radio"/> Consumer <input type="radio"/> Health Professional <input type="radio"/> Other </p> <p>2. Name of Complainant 618101b89ccfd9d27e767413458250cd</p> <p>3. Name of Health Care Facility (if applicable) 07ba5b638edecd54a618a2d0d8df4e06</p> <p>4. Address 4585e56bc31d98d9368a6537600613c1</p> <p>5. Telephone No. and/or E-mail Address 56f967ec451e678de8d477f6922ec540</p> <p>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</p>		
<p>This section only applies for preliminary and final, and final reports</p> <p>2. Root Cause of Problem</p> <p>b30de22efe522389239780831f516309</p> <p>3. Corrective Actions taken as a result of the</p> <p>bc4594e0bab621c1fe62bebc4903d779</p>		