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*

3. Reporter File No.*

CN-1224676

4. Health Canada File No. (if applicable) *

5. Type of Report*

( ) Preliminary ( ) Update (•) Final ( ) Preliminary and Final

If "preliminary" only, anticipated date for the final report:

If "update/final", date the previous report was submitted to Health Canada:

2020/05/11

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te Submitted *

/07/29

	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)

2. Date of Incident

3. Reporter's Awareness Date

4. Patient Consequences

5. Details of Incident

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C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *

OmniPod Insulin Management System

2. Control/Lot/Serial No

3. Expiration Date

4. i. Device Classification

I II III IV

ii. Device License No.

iii. Device Identification No

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

5. Software Version

6. Age of Device

7. How long was the device in use?

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

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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: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

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

2. Root Cause of Problem

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3. Corrective Actions taken as a result of the investigation

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