INSTRUCTIONS ON COMPLETING THE MANDATORY MEDICAL DEVICE PROBLEM REPORTING FORM

A. REPORTER INFORMATION

This section contains information about the reporter, who is submitting the report to Canada Vigilance – Medical Devices Problem Reporting Program (CV-MD) to fulfil their obligations under sections 59, 60, 61 and 61.1 of the Medical Devices Regulations. It also includes details about the manufacturer and importer of the medical device that are responsible to submit the report to CV-MD.

A1. Reporter Type:
i. Indicate if the reporter submitting this report to CV-MD is the manufacturer or the importer.
ii. Indicates if the importer submitting this report to CV-MD has also submitted reported this problem to the manufacturer of the device.
iii. Indicates if the importer is submitting on behalf of the manufacturer.

A2. Reporter Contact Information: Includes the name of the individual,

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submitted by the manufacturer/importer to CV-MD.

A7. Name and Address: Indicates the name and address of the manufacturer and importer of the medical device.

A8. Health Canada assigned company identification number (if known): The company identification number can be found either on the medical device licence or on the medical device establishment licence, as appropriate.

A9. Establishment Licence Number (if applicable): Indicates the establishment licence (MDEL) number of the manufacturer and importer of the medical device in Canada.

B. INCIDENT INFORMATION

This section contains information about the incident that occurred with the medical device requiring a mandatory problem report to be submitted to CV-MD. It includes details about the incident and the patient consequences that occurred/could have occurred. In the context of mandatory problem reporting, information on the incident refers to the circumstances requiring reporting under section 59 of the Medical Devices Regulations.

B1. Classification of Incident:
i. Indicates if the report is a 10 day or 30 day report, based on the seriousness of the incident associated with the medical device ii. whether the incident occurred inside or outside Canada iii. whether the incident occurred during investigational testing, or was caused by a medical device available only through the special access program or is a radiation emitting device (RED).

B2. Date of Incident:
Indicates the date at which the incident with the medical device occurred.

B3. Reporter's Awareness Date:
Indicates the date at which the manufacturer/importer of the medical device became aware of the potential problem associated with the device.

B4. Patient Consequences:

C. MEDICAL DEVICE INFORMATION

This section contains details about the medical device involved in the incident, including its brand name and licence number.

C1. Trade/Brand Name: Indicates the trade/brand name of the device and reported on the label.

C2. Control/Lot/Serial #: Indicates the control number, lot number and/or serial number for the device.

C3. Expiration Date: Indicates the expiration date issued to the medical device(if applicable).

C4. i. Device Classification: Indicates the class of the device (I-IV).
ii. Device Licence Number: Indicates the medical device licence number issued by the Medical Devices Bureau on behalf of the Minister for Class II, III and IV medical devices sold in Canada.
iii. Device Identification No: Indicates the device identification number assigned by Health Canada in the license issued for the device.
iv. Manufacturer's Medical Device Identifier: Indicates the unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a catalogue, model or part number.

C5. Software Version: Indicates the version of the software contained within the device, if applicable for the device.

C6. Age of Device: Indicates the number of years since the manufacturing date of the device.

C7. How long was the device in use? Indicates how long the device was used.

C8. Was the device labelled as sterile? Indicates if the device sold was manufactured and packaged in sterile conditions.

C9. Availability of Device: Indicates if the device has been destroyed, or is available for the company/Health Canada for further evaluation to determine the root cause of the failure associated with the device.

D. COMPLAINANT INFORMATION

This section contains information about the complainant that contacted the reporter to inform them about the incident.

D1. Complainant is a: Indicates if the complainant reporting to the manufacturer/importer was a consumer, a health professional etc.

D2. Name of Complainant: Indicates the name of the person who informed the reporter about the incident

D3. Name of Health Care Facility: This section indicates the name of the health care facility where the problem occurred.

D4. Address: Indicates the complete address of the complainant, including the postal code.

D5. Contact Information: Indicates the telephone number and/or email address of the complainant.

E. INVESTIGATION INFORMATION

This section contains information about the investigation being carried out by the manufacturer/importer of the medical device to determine if there's any problem with the medical device, and if any corrective actions are necessary.

E1. Investigative Actions and Timeline: Includes the rationale for the course of action taken to investigate the incident, the details of the action to be completed, and the timeline for its completion. If no investigation is to be done, a rational needs to be provided here.

E2. Root Cause of Problem: To be completed once the investigation of the incident is complete, and the root cause of the incident identified. The root cause would ascertain the most likely reason why the problem occurred with the medical device. This section only applies for final reports.

E3. Corrective actions taken as a result of the investigation: Includes information on actions taken to correct the problem, including any

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*

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3. Reporter File No.*

18849193

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:

2019/12/23

te Submitted *

/07/27

	Manufacturer	Importer
7. Name and Address	Abbott Diabetes Care LTD. Range Road Witney, OX, GB OX290YL	Abbott Laboratories LTD 7115 Millcreek DR Mississauga, Ont L5N
8. Health Canada assigned company identification number (if known):	134918	
9. Establishment License Number (if applicable):		208

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

2019/11/25

3. Reporter's Awareness Date

2019/11/25

4. Patient Consequences

cb414391e2a1b4b1d5f68a8ad5495c47

5. Details of Incident

r

t

0a0fcca820a0c325df8a1d7bad52c5c2

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
FreeStyle Libre

2. Control/Lot/Serial No
0M0060LD5F0

3. Expiration Date
2019/11/25

4. i. Device Classification

○ I ○ II ◉ III ○ IV

ii. Device License No.
99351

iii. Device Identification No
799431

iv. Manufacturer's Medical Device Identifier(catalogue/model no.)
71534-01

5. Software Version
NA

6. Age of Device
Unknown

7. How long was the device in use?
1 Day

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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d41d8cd98f00b204e9800998ecf8427e

73b6ce9500f783c59b1b739f2fb33ca7

d41d8cd98f00b204e9800998ecf8427e

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

16ec7ab600d1d8ba431764d94c183b0a

3. Corrective Actions taken as a result of the investigation

b634b3b37c1b2df7e93d71f75cb6d751

Joey Larrowe

Alameda 09Jul2020