

MEDICAL DEVICE FIELD CORRECTIVE ACTION NOTIFICATION FORM

This form is to be used by establishment to notify the Authority any field corrective action of medical device. This form and other related attachments shall be completed and submitted to Medical Device Authority (MDA). It is recommended to submit the completed form via email.

MEDICAL DEVICE AUTHORITY


Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II, Block 3547, Persiaran APEC, Cyberjaya, Selangor, MALAYSIA.
Email : Notice_FCA@mda.gov.my
Tel: 03-8230 0300
Fax: 03-8230 0200

FIELD CORRECTIVE ACTION NOTIFICATION FORM

Type of Field Corrective Action (FCA)	<input type="checkbox"/> Return	<input type="checkbox"/> Exchange	<input checked="" type="checkbox"/> Specific Advice
	<input type="checkbox"/> Modification	<input type="checkbox"/> Destruction	
Establishment Particulars			
Name of company	Medtronic Malaysia Sdn Bhd		
Company address	B-23-1, Level 23, The Ascent, Paradigm, No 1 Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia		
Contact person name	Athirah Abu Bakar		
Job title	Regulatory Affairs Specialist		
Tel No.	+603-78838034	Fax No.	+603-78860474
Email Address	athirah.abu.bakar@medtronic.com		
Medical Device Details			
Medical device name	MiniMed Paradigm Insulin Pump and Accessories		
Medical device intended use	The Medtronic Minimed Paradigm Insulin Pumpa are intended for continuous delivery of insulin, at set and variable rates, for management of diabetes mellitus in persons requiring insulin.		
MDA Registration No. (if device is registered)	D72-20160201-43766/ GC83875229017		
Model No.	MMT-715NAP MMT-754CAP MMT-722CAH MMT-522CAS MMT-522CAH MMT-754CAB MMT-715NAL MMT-754CAL MMT-754CAH MMT-554CAS		
Serial No.	To be provided		
Lot/Batch No.	Not applicable		
Accessories/Associated medical devices affected (if any)	Not applicable		
Manufacturer name	Medtronic MiniMed		
Manufacturer address	18000 Devonshire Street, Northridge, CA 91325, USA		
AR/Distributor/Importer and contact details	Medtronic Malaysia Sdn. Bhd. B-23-1, Level 23, The Ascent, Paradigm, No 1 Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia		
FCA Proposed Plan and Action			
FCA planned by establishment	Medtronic will contact all customers that have been shipped the MiniMed Paradigm 515/715, 522/722 and 554/754 insulin pumps and notify them about this issue.		
FCA Information			
Did the FCA arise due to an incident? (Please select only one)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
If yes, what is the category of incident? (Please select all if applicable)	<input type="checkbox"/> Serious Public Health Threat	<input type="checkbox"/> Serious Injury	<input type="checkbox"/> Non-serious Injury
	<input type="checkbox"/> Death	<input checked="" type="checkbox"/> Not applicable	

Did this incident occur in Malaysia?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has the incident been reported to MDA? (Please select only one)	<input type="checkbox"/> Yes (incident ref. no.:) <input type="checkbox"/> No <input checked="" type="checkbox"/> Not applicable
Evaluation of the risk associated with affected medical device (Health Hazard Evaluation Report)	Please refer to attached Issue Impact Assessment (IIA)
Background information, root cause and reason for the FCA	The MiniMed Paradigm 515/715, 522/722 and 554/754 insulin pumps are designed to communicate using a wireless radio frequency (RF) with other devices such as a blood glucose meters, glucose sensor transmitters, and CareLink USB devices and remote programmers. Security researchers have identified potential cybersecurity vulnerabilities related to these insulin pumps. An unauthorized person with special technical skills and equipment could potentially connect wirelessly to a nearby insulin pump to change settings and control insulin delivery. This could lead to hypoglycemia (if additional insulin is delivered) or hyperglycemia and diabetic ketoacidosis (if not enough insulin is delivered).
FCA plan and action to be taken (corrective action)	Medtronic will contact all customers that have been shipped the MiniMed Paradigm 515/715, 522/722 and 554/754 insulin pumps and notify them about this issue.
Advice on actions to be taken by the distributor and the user	Same as above
Has the FCA been communicated to all consignees?	<input type="checkbox"/> Yes (Date sent:) <input checked="" type="checkbox"/> No (Expected date to be sent: 28 July 2021)
Number and name of affected units supplied to each consignee	To be provided
No. of affected units and the period that affected units are manufactured/imported/supplied in Malaysia	Manufactured in Malaysia: N/A Period: (mm/yyyy) to (mm/yyyy) Imported into Malaysia: To be provided Period (mm/yyyy) to (mm/yyyy) Supplied in Malaysia: To be provided Period (mm/yyyy) to (mm/yyyy) Expected shipments to Malaysia: N/A Expected date of arrival (mm/yyyy)
Date of commencement of FCA by manufacturer	21 July 2021
Date of commencement of FCA in Malaysia	21 July 2021
Proposed date of completion of FCA in Malaysia	To be provided
Follow Up / Final report	
FCA completed?	<input type="checkbox"/> Yes, Date: _____ (dd/mm/yyyy) <input type="checkbox"/> No
Progress of FCA, together with reconciliation status and/or effectiveness check and its method	
Proposed action to prevent recurrence of the problem (preventive action)	
Other Information	

I attest that the information submitted is true and correct.

Signature : 
Name of Reporting Person : Athirah Abu Bakar
Date of this report : 27 July 2021
Company stamp :

Medtronic Malaysia Sdn. Bhd. (611761-M)
(Formerly known as Covidien Sendirian Berhad)
B-23-01, The Ascent, Paradigm
No. 1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya, Selangor, Malaysia
Tel: 603-7883 8000 Fax: 603-7886 0474 / 4702