

Safety Notice

Medical Devices

MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps

Priority 2 – Warning

HPRA Safety Notice: SN2019(26)

Issue Date: 16th July 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic	V40568

ISSUE

The HPRA is issuing this Safety Notice for information and to raise awareness of a potential security vulnerability related to the use of the MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps.

The manufacturer, Medtronic, has confirmed that an unauthorized person with special technical skills and equipment could potentially send radio frequency (RF) signals to a nearby insulin pump to change settings and control insulin delivery. This could lead to hypoglycaemia (if additional insulin is delivered) or hyperglycaemia and diabetic ketoacidosis (if not enough insulin is delivered).

Further information, including details of the affected pump models, is provided in the accompanying field safety notice (FSN) and letter to pump users.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Refer to the accompanying pump user letter, and follow the instructions provided by the manufacturer.
- 2 Report any concerns regarding this device to the manufacturer and the HPRA as soon as possible.
- 3 Contact your healthcare professional with any concerns.

The HPRA advises that healthcare professionals:

- 4 Refer to the accompanying FSN and follow the instructions provided by the manufacturer.
- 5 Inform all pump users of this issue using the accompanying pump user letter.
- 6 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
- 7 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Carers	Medical directors
Clinical engineers	Nursing homes
Community care managers	Outpatient clinics
Community nurses	Paediatricians
Community therapists	Pharmacists
Diabetes clinics	Practice nurses
Diabetes nurse specialists	Private medical practitioners
Endocrinologists	Risk managers
Endocrinology units	School nurses
General practitioners	Supplies managers
Hospital managers / CEOs	

BACKGROUND

The MiniMed™ Paradigm™ and MiniMed™ 508 insulin pumps are designed to communicate using a wireless RF with other devices such as a blood glucose meter, glucose sensor transmitters, 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 send RF signals to a nearby insulin pump to change settings and control insulin delivery.

Medtronic has advised that they have not received any reports of unauthorized people changing settings or controlling insulin delivery.

The manufacturer has confirmed that this vulnerability is not applicable to the MiniMed 600 series pump platforms or the Paradigm Veo pump with software versions 2.7 or higher.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Medtronic Limited
Building 9, Hatters Lane
Croxley Park, Watford
United Kingdom

Telephone: +353-1-5111444
E-mail: vigilance.eu@medtronic.com
Website:

Enquiries to the **distributor** should be addressed to:

PharmMed Ltd
Unit 3 Clonmore Business Park
Mullingar,
Co Westmeath

Telephone: +353 44 939 6188
E-mail: customerservice@pharmed.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie