

Safety Communication

Certain MiniMed Insulin Pumps Have Potential Cybersecurity Risks

Device/ Product Description:	MiniMed Paradigm Series and MiniMed 508 Insulin Pumps
Brand Name:	Medtronic
Lot numbers/Serials:	<p>Pump Model: Software Version</p> <p>MiniMed 508 All versions</p> <p>MiniMed Paradigm 511 All versions</p> <p>MiniMed Paradigm 512/712 All versions</p> <p>MiniMed Paradigm 515/715 All versions</p> <p>MiniMed Paradigm 522/722 All versions</p> <p>MiniMed Paradigm 522K/722K All versions</p> <p>MiniMed Paradigm 523/723 Version 2.4A or lower</p> <p>MiniMed Paradigm 523K/723K Version 2.4A or lower</p> <p>MiniMed Paradigm 712E All versions</p> <p>MiniMed Paradigm Veo 554CM/754CM Version 2.7A or lower</p> <p>MiniMed Paradigm Veo 554/754* Version 2.6A or lower</p>
Manufacturer:	Medtronic SA
Problem:	<p>The MiniMed Paradigm and MiniMed 508 insulin pumps are designed to communicate using a wireless radio frequency (RF) with other devices such as a blood glucose meter, glucose sensor transmitters, CareLink USB devices, and remote programmers.</p> <p>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. This could lead to hypoglycaemia (if additional insulin is delivered) or hyperglycaemia and diabetic ketoacidosis (If not enough insulin is delivered).</p>

**Recommendation/
Actions:**

CYBERSECURITY PRECAUTIONS RECOMMENDED FOR ALL PATIENTS:

- Keep your insulin pump and the devices that are connected to your pump within your control at all times.
- Do not share your pump serial number.
- Be attentive to pump notifications, alarms, and alerts.
- Immediately cancel any unintended boluses.
- Monitor your blood glucose levels closely and act as appropriate.
- Do not connect to any third-party devices or use any software not authorized by Medtronic.
- Disconnect your CareLink USB device from your computer when it is not being used to download data from your pump.
- Get medical help right away if you experience symptoms of severe hypoglycemia or diabetic ketoacidosis, or suspect that your insulin pump settings, or insulin delivery changed unexpectedly

You can find more information and recommendations from ([HERE](#)).

**Devices/Products
photo:**



You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245

Or

Saudi Vigilance

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Sincerely,
NCMDR Team