Medtronic

Field Safety Notice

MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps

Notification

January 2023

Medtronic Reference: FA875

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000023100>

Dear Distribution Partner / Service Provider,

You are receiving this letter because our records indicate that one or more of your patients may be using a MiniMed™ 508 insulin pump or a MiniMed™ Paradigm™ series insulin pump.
In June 2019, Medtronic issued a communication letter for MiniMed™ 508 insulin pump and MiniMed™ Paradigm™ series insulin pump due to a potential cyber security issue. Medtronic has made the decision to notify customers using insulin pumps that were affected by the field action.
We would like to ensure you and your patients and customers are aware of the information and precautions associated with using these products.

Medtronic asks that you inform impacted patients and customers using the enclosed letter.

Potential Cybersecurity Issue Description:

The MiniMed™ 508 insulin pump and the MiniMed™ Paradigm™ series insulin pumps (see chart below to see all model numbers) are designed to communicate using a wireless radio frequency (RF) with other devices such as blood glucose meters, glucose sensor transmitters, and CareLink™ USB devices.

Security researchers 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).

IMPORTANT NOTE: At this time, we have received no confirmed reports of unauthorized persons changing settings or controlling insulin delivery.

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The following pump models ARE vulnerable to this potential issue:

Product Information	
Insulin Pump	Software Versions
MiniMed™ 508 pump	All
MiniMed™ Paradigm™ 511 pump	All
MiniMed™ Paradigm™ 512/712 pumps	All
MiniMed™ Paradigm™ 515/715 pumps	All
MiniMed™ Paradigm™ 522/722 pumps	All
MiniMed™ Paradigm™ Veo™ 554/754 pumps	Software Versions 2.6A or lower*

*To find the software version for the MiniMed™ Paradigm™ pumps, go to the STATUS screen:

- To open the STATUS screen, press ESC until the STATUS screen appears.
- To view more text on the STATUS screen, press the up or down arrow to scroll and view all the information.
- To exit the STATUS screen, press ESC until the STATUS screen disappears.

ACTIONS REQUIRED:

Complete and return the attached Field Action Confirmation Form to acknowledge that:

1. Impacted patients are informed about the Field Safety Notice using the enclosed pump user letter.
2. This notice is passed on to all those who need to be aware within your organization.

<The Competent Authority of your country has been notified of this action.>

As always, we are here to support you. If you have further questions or need assistance, please call <our Helpline / your Medtronic contact at < XXXXX >
We apologize for any inconvenience this may cause. Your safety and satisfaction are our top priorities. We appreciate your time and attention in reading this important notification.

Sincerely,

Local/OU Manager

Enclosure:

- Pump User Letter
- HCP Letter