Medtronic

Field Safety Notice

MiniMed™ 508 and MiniMed™ Paradigm™ Series 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 Healthcare Professional,

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 are aware of the information and precautions associated with using these products.

The purpose of this letter is to make you aware that Medtronic will be notifying all impacted patients by enclosed letter. There is no action to be taken by you.

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have further questions, please call <our Helpline / your Medtronic contact at <XXXXX>.

Sincerely,

Local/OU Manager

Enclosure:

- Pump User Letter