

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a Class 1 recall by Medtronic of MiniMed Model 500 Remote Controls (MMT-500) and 503 Remote Transmitters (MMT-503) distributed August 6, 1999 to July 24, 2018 for use with MiniMed Insulin Pumps. The MiniMed Paradigm and 530G Insulin Pumps were recalled in a FDA Safety notice on June 27, 2019 due to potential cybersecurity risks identified with the programs used in these pumps.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-minimed-insulin-pumps-potential-cybersecurity-risks?utm_campaign=FDA%20MedWatch%20-%20MiniMed%20Insulin%20Pumps%20by%20Medtronic%3A%20Class%20I%20Recall&utm_medium=email&utm_source=Eloqua
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by:
 - o Faxing information—To: 919-792-6718 Attn: Quality Department

Thank you for your prompt attention and cooperation in this matter.