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Medtronic – Recall of MiniMed™ Insulin Pumps

- On June 27, 2019, the FDA announced that certain Medtronic MiniMed insulin pumps are being recalled due to potential cybersecurity risks and recommends that patients using these models switch their insulin pump to models that are better equipped to protect against these potential risks.
    - The FDA provided an additional safety communication highlighting patient, caregiver and healthcare provider recommendations.
- The recalled pumps are Medtronic's MiniMed 508 insulin pump and MiniMed Paradigm series insulin pumps.

Product Description	Software Version
MiniMed™ 508	All versions
MiniMed™ Paradigm™ 511	All versions
MiniMed™ Paradigm™ 512/712	All versions
MiniMed™ Paradigm™ 515/715	All version
MiniMed™ Paradigm™ 522/722	All versions
MiniMed™ Paradigm™ 522K/722K	All versions
MiniMed™ Paradigm™ 523/723	Version 2.4A or lower
MiniMed™ Paradigm™ 523K/723K	Version 2.4A or lower
MiniMed™ Paradigm™ 712E*	All versions
MiniMed™ Paradigm™ Veo 554CM/754CM*	Version 2.7A or lower
MiniMed™ Paradigm™ Veo 554/754*	Version 2.6A or lower

*Available outside the U.S. only

- Insulin pumps are small computerized devices that deliver insulin to a patient throughout the day through a catheter implanted under the skin. They are often used instead of periodic insulin injections. People with type 1 or type 2 diabetes may need an insulin pump when they require insulin to maintain acceptable blood glucose levels.
- The potential cybersecurity risks are related to the wireless communication between Medtronic's MiniMed insulin pumps and other devices such as blood glucose meters, continuous glucose monitoring systems, the remote controller and CareLink USB device used with these pumps.
    - The affected devices wirelessly connect to both the patients' blood glucose meter and continuous glucose monitoring system.
    - The remote controller and CareLink USB, a thumb-sized wireless device that plugs into a computer, are used with the affected insulin pumps. A patient can use the remote controller to send insulin bolus (dosing) commands to the insulin pump remotely and can use the CareLink USB to download data about their glucose levels from their insulin pump to monitor their own progress and share it with their healthcare provider.

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- The FDA is concerned that, due to cybersecurity vulnerabilities identified in the recalled devices, someone other than a patient, caregiver or healthcare provider could potentially connect wirelessly to a nearby MiniMed insulin pump and change the pump's settings. This could allow a person to over deliver insulin to a patient, leading to hypoglycemia, or to stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis.

- Medtronic is unable to adequately update the MiniMed 508 and Paradigm insulin pumps with any software or patch to address the devices' vulnerabilities. The FDA is working to assure that Medtronic addresses this cybersecurity issue, including helping patients with affected insulin pumps switch to newer models with better cybersecurity controls.

- The FDA recommends that patients and their caregivers check to see if the model and software version of their insulin pump is affected. Medtronic has provided a patient letter to assist identifying a pump's software version.

- Patients and their caregivers should do the following while waiting for a replacement pump:

    — Keep the insulin pump and devices that are connected to the pump within their control at all times whenever possible.
    — The pump serial number should not be shared.
    — Be attentive to pump notifications, alarms, and alerts.
    — Monitor blood glucose levels closely and act appropriately.
    — Immediately cancel any unintended boluses.
    — Connect the Medtronic insulin pump to other Medtronic devices and software only.
    — The USB device should be disconnected from the computer when it is not being used to download data from the pump.

- Patients should seek medical help right away if symptoms of hypoglycemia or diabetic ketoacidosis occur, or if the insulin pump settings or insulin delivery changes unexpectedly.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Medtronic MiniMed insulin pump.

- For more information regarding this recall, contact Medtronic at **1-866-222-2584**.

- For more information see:

    — Department of Homeland Security ICS-Cert
    — Medtronic Security Bulletin