Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in
Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No.29/Misc./03/2021-DC(355)

Date: 08th Nov2021

MEDICAL DEVICE ALERT

DEVICE

MMT-500 Remote Controller & MMT-503 Remote Controller used as an optional accessory with Ambulatory Insulin Infusion Pumps

BACKGROUND

- The Medtronic Minimed 508 pump and the 5xx and 7xx Series Paradigm Pump is an ambulatory, battery powered, rate-programmable infusion pump intended for continuous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.
- In addition to delivery of insulin, Paradigm pump is also designed to receive and display real-time glucose values received via a compatible transmitting device. Glucose values and pump history can be stored for subsequent download for further analysis of track patterns to improve diabetes management.

Reason for Recall

- Medtronic is recalling all remote controllers used with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps due to potential cybersecurity risks. An unauthorized person (someone other than a patient, patient caregiver, or health care provider) could potentially record and replay the wireless communication between the remote and the MiniMed insulin pump.
- Using specialized equipment, an unauthorized person could instruct the pump to either over-deliver insulin to a patient, leading to low blood sugar (hypoglycemia), or stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis, even death.

Who May Be Affected

- Any person who uses the remote controller feature with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps. The vulnerability is applicable to the MiniMed 508, MiniMed 511, MiniMed 512/712, MiniMed515/715,

MiniMed 522/722, MiniMed 523(K)/723(K), MiniMed 523/723 (Revel), MiniMed 554/754 (VEO), and MiniMed 551/751 (530G) pumps.

- Health care providers and caregivers who treat people with diabetes who use remote controllers associated with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps

Important Note: CDSCO have not received any complaintsfrom the market on this issue.

FURTHER DETAILS & CONTACTS

M/s India Medtronic Pvt. Ltd, Gurugram, Haryana had issued a Field SafetyNotice which is attached herewith this alert.

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Medtronic Recalls Remote Controllers Used with Paradigm and 508 MiniMed Insulin Pumps for Potential Cybersecurity Risks

October 5, 2021 Update: Medtronic has expanded this recall of remote controllers used with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps due to potential cybersecurity risks. Medtronic sent updated instructions to people who use these devices, including instructions to stop using and return the remote controller. If you have questions about this recall, call Medtronic's 24-Hour Technical Support line: 1-800-378-2292. For more details, see the **What to Do** section of this page.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- All MiniMed Remote Controllers (model MMT-500 and MMT-503) used with a Medtronic MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps
- Distribution Dates: August 1999 to July 2018
- Devices Recalled in the U.S.: 31,310
- Date Initiated by Firm: August 7, 2018

Device Use

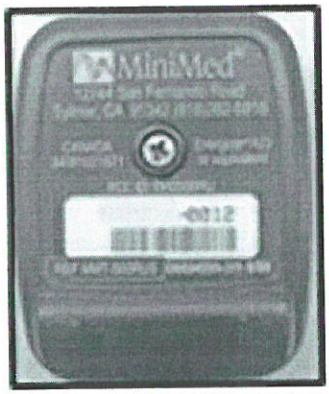
People who have diabetes may use the MiniMed insulin pump to deliver insulin for the management of their diabetes. The pump system includes an optional remote controller device which is designed to communicate wirelessly with the pump to deliver a specific amount of insulin to the person with diabetes.

The following table shows the recalled Medtronic remote controllers, used with the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps. The remote controllers impacted by this issue are older models that use previous-generation technology. As of July 2018, Medtronic is no longer manufacturing or distributing these remote controllers.

Remote Controller	Model Number Location	Serial Numbers

All

MiniMed remote controller MMT-500



The model # is behind the remote under the barcode

All

MiniMed remote controller MMT-503

The model # is behind the remote under the barcode

Reason for Recall

Medtronic is recalling all remote controllers used with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps due to potential cybersecurity risks. An unauthorized person (someone other than a patient, patient caregiver, or health care provider) could potentially record and replay the wireless communication between the remote and the MiniMed insulin pump. Using specialized equipment, an unauthorized person could instruct the pump to either over-deliver insulin to a patient, leading to low blood sugar (hypoglycemia), or stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis, even death.

If you have never programmed a remote controller ID into the pump and never programmed the easy bolus option, you are **not** impacted by this vulnerability.

To date, the FDA is not aware of any reports of patient harm related to these potential cybersecurity risks.

Who May Be Affected

- Any person who uses the remote controller feature with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps
- Health care providers and caregivers who treat people with diabetes who use remote controllers associated with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps

What to Do

On October 5, 2021, Medtronic began notifying anyone who may still be using the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps and have purchased a remote controller of the expanded recall. Medtronic provided the following instructions:

If you use a recalled remote controller:

- Stop using the remote controller.
- Turn off the easy bolus feature.
- Disconnect the remote controller from your insulin pump:
    - First, you must turn off the radio frequency function and delete all remote controller IDs that are programmed into your insulin pump.
    - Then, follow the instructions in the appendix attached to Medtronic's letter. The steps to disconnect the remote controller will vary by insulin pump model.
- Contact Medtronic to return the remote controller in one of three ways:
    - Visit medtronicdiabetes.com/RemoteControl (https://info.medtronicdiabetes.com/remote-controller-return) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
    - Call Medtronic's 24-Hour Technical Support line at 1-800-378-2292, or
    - Complete and return the Customer Confirmation Form.

Use the prepaid return packaging to return the recalled remote controller to Medtronic. Until you turn off and disconnect the remote controller function from the pump, Medtronic advises you follow these security precautions to minimize the potential cybersecurity risk:

- Turn off the easy bolus when not intending to use the remote bolus option.
- Be attentive to pump alerts, especially when the easy bolus option is turned on.

Get medical help right away if you:

- Have symptoms of severe hypoglycemia (such as excessive sweating, feeling very tired, dizzy and weak, being pale, and a sudden feeling of hunger).
- Have symptoms of diabetic ketoacidosis (such as excessive thirst, frequent urination, nausea and vomiting, feeling very tired and weak, shortness of breath).
- Think your insulin pump settings or insulin delivery changed unexpectedly.

Be aware, that in August 2018, Medtronic initiated this recall (https://wayback.archive-it.org/7993/20201222123754/https:/www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-remote-controllers-minimed-insulin-pumps-potential-cybersecurity-risks) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and provided instructions on how to disable the remote bolus feature, when not in use, to protect the security of your insulin pump when using an optional remote controller. At that time, only device users whose pumps were under warranty received the recall notification. On October 5, 2021, Medtronic expanded the recall to include notification to anyone who Medtronic believes may still be using the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps and have purchased a remote controller.

Patients and health care providers should also be aware of the FDA Safety Communication (https://wayback.archive-it.org/7993/20201222123754/https:/www.fda.gov/medical-devices/safety-communications/certain-medtronic-minimed-insulin-pumps-have-potential-cybersecurity-risks-fda-safety-communication) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) from June 27, 2019, related to specified Medtronic MiniMed Insulin Pumps.

Contact Information

If you have questions or need additional information about this recall, call Medtronic's 24-Hour Technical Support line at 1-800-378-2292.

Additional Resources

- Medical Device Recall Database Entry Model MMT500 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=170857)
- Medical Device Recall Database Entry Model MMT503 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=170858)
- Medtronic Patient Letter (https://www.medtronicdiabetes.com/customer-support/product-and-service-updates/notice16-letter) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- Medtronic Security Bulletin (https://global.medtronic.com/xg-en/product-security/security-bulletins/minimed.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Department of Homeland Security Cybersecurity Infrastructure Security Advisory (https://us-cert.cisa.gov/ics/advisories/ICSMA-18-219-02)
- Medtronic Recalls Remote Controllers for MiniMed Insulin Pumps for Potential Cybersecurity Risks (2019) (https://wayback.archive-it.org/7993/20201222123754/https:/www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-remote-controllers-minimed-insulin-pumps-potential-cybersecurity-risks) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- FDA Safety Communication: Certain Medtronic MiniMed Insulin Pumps Have Potential Cybersecurity Risks (2019) (https://wayback.archive-it.org/7993/20201222123754/https:/www.fda.gov/medical-devices/safety-communications/certain-medtronic-minimed-insulin-pumps-have-potential-cybersecurity-risks-fda-safety-communication) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- FDA News Release (2019) (https://wayback.archive-it.org/7993/20201222123754/https:/www.fda.gov/news-events/press-announcements/fda-warns-patients-and-health-care-providers-about-potential-cybersecurity-concerns-certain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- FDA Medical Device Cybersecurity (/medical-devices/digital-health-center-excellence/cybersecurity)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.