

FDA Drug Recall

Insulet Recalls Omnipod DASH Insulin Management System's Personal Diabetes Manager (PDM) for Risk of Battery Swelling, Leakage, or Extreme Overheating

11/16/2022

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

- Product Name: Insulet Omnipod DASH Insulin Management System Personal Diabetes Manager (PDM)
- Product Models:
 - 18239 ASM Omnipod DASH PDM
 - PT-000010: Assembly, DASH Final PDM U100, mg/dL
 - PT-000011: Assembly, DASH Final PDM U100, mmol/L
- Serial Numbers: All serial numbers
- Distribution Dates: July 27, 2018 to August 31, 2022
- Devices Recalled in the U.S.: 248,288
- Date Initiated by Firm: October 17, 2022

Device Use

The Omnipod DASH Insulin Management System is used to deliver insulin at set and variable rates to manage diabetes in people who need insulin. It includes two main parts: The wearable and tubeless pump which delivers the insulin, called the Pod, and a remote controller called the Personal Diabetes Manager (PDM). The PDM is a small, reusable handheld rechargeable battery-powered locked-down Android mobile device with features similar to a smartphone. The Pod is controlled exclusively using the PDM and the two parts interact wirelessly using secure Bluetooth.

Reason for Recall

Insulet is recalling the Omnipod DASH Insulin Management System's Personal Diabetes Manager (PDM) after receiving reports of PDM battery issues, including:

- Battery swelling
- Fluid leakage from the battery
- Extreme overheating that may pose a fire hazard

Users could be exposed to battery fluid and extreme heat, including the potential for an explosion and/or fire, which could lead to serious injury or death.

Insulet reports 455 complaints involving these battery issues, including three fires. There have been no reports of injuries or deaths.

Who May be Affected

- People who manage insulin levels using the Omnipod DASH Insulin Management System PDM.
- Health care providers with patients who manage their insulin levels using the Omnipod DASH Insulin Management System PDM.

What to Do

On October 17, 2022, Insulet sent users an Urgent Medical Device Correction email and letter. The letter recommended the following actions for the Omnipod DASH Insulin Management System PDM:

- Monitor the DASH Insulin Management System PDM for any of the following issues:
 - **Back cover bulging or cannot close. Do not apply pressure to the back cover if it is deformed in any way.** The PDM's gel skin will need to be removed to observe these issues, but do not remove the back cover.
 - **Extreme overheating (that may pose a fire hazard) or an odor while charging, during use, or in storage.**
 - **Device turns off immediately after being removed from the charger or fails to turn on** within 45 minutes of being connected to the charger.
 - **Battery loses charge very quickly** (faster than usual) or takes more than 1.5 hours to reach 80% charge.
- If the above issues occur:
 - **Stop using the system and do not charge the Omnipod DASH Insulin Management System PDM.**
 - **Switch to a backup insulin plan as soon as possible.**
 - **Contact the Customer Care team promptly at 1-800-641-2049** to request a temporary replacement device.
- If the above issues do NOT occur:
 - Continue to use the Omnipod DASH Insulin Management System PDM, but always inspect the PDM to make sure there are no signs of battery issues before charging.
 - **Do not remove the battery for any reason**, even if recommended by the User Guide. Instead, call the Customer Care team at 1-800-641-2019 for instructions.
 - **Do not continue to charge the DASH PDM beyond 85%** of charge. Remove from charging once the device reaches 85%.
 - **Do not charge the PDM:**
 - **Overnight**
 - **In environments with temperatures of 87°F (31°C) or higher**
 - **In direct sunlight**
 - **Do not use or charge the PDM if it feels unusually warm to the touch.**
 - **Do not use the PDM while charging.**

The company notes that users do not need to call Customer Care to receive an updated Omnipod DASH Insulin Management System PDM—these devices will be shipped to all current customers in the coming months when available. This includes users who received temporary PDMs.

Contact Information

Users with questions can visit the Insulet website at www.omnipod.com/insulet-alerts[External Link](#) [Disclaimer](#) or call 1-800-641-2049 to speak with the Insulet Customer Care team 24 hours a day, 7 days a week.

Additional Resources:

- [Medical Device Recall Database Entry](#)
- [Company Press Release: Insulet Issued Voluntary Medical Device Correction for Omnipod DASH® Personal Diabetes Manager on October 17, 2022](#)[External Link Disclaimer](#)

How do I report a problem?

Health care professionals and consumers [may report adverse reactions or quality problems](#) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.

Source: <https://www.fda.gov/medical-devices/medical-device-recalls/insulet-recalls-omnipod-dash-insulin-management-systems-personal-diabetes-manager-pdm-risk-battery>