

Insulet – Recall of Omnipod DASH Insulin Management System

- On November 16, 2022, the [FDA announced](#) a consumer level, class I recall of the [Omnipod DASH Insulin Management System](#) after receiving reports of battery issues. The battery of the Personal Diabetes Manager (PDM) may swell, leak battery fluid, or overheat.
- The recalled insulin management systems were distributed between July 2018 to August 2022.

Product Description	Product Models	Serial Numbers
Insulet Omnipod DASH Insulin Management System Personal Diabetes Manager (PDM)	<ul style="list-style-type: none"> 18239 ASM Omnipod DASH PDM PT-000010: Assembly, DASH Final PDM U100, mg/dL PT-000011: Assembly, DASH Final PDM U100, mmol/L 	All serial numbers

- 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.
- To date, Insulet reports 455 complaints involving these battery issues, including three fires. There have been no reports of injuries or deaths.
- The Omnipod DASH Insulin Management System is an insulin pump and includes a wearable, tubeless insulin Pod that is controlled by a smartphone-like PDM.
- On October 17, 2022, [Insulet sent](#) users an Urgent Medical Device Correction email and letter. The letter recommended specific actions for the Omnipod DASH Insulin Management System PDM. Refer to the [press release](#) for details.
- Insulet is currently shipping replacement Omnipod DASH Insulin Management Systems to all current users.
- Contact the Insulet Customer Care Team at **1-800-641-2049** for more information.



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