



## Insulet Issued Voluntary Medical Device Correction for Omnipod DASH® Personal Diabetes Manager on October 17, 2022

November 4, 2022

ACTON, Mass.--(BUSINESS WIRE)--Nov. 4, 2022-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), announced on October 17, 2022, a [Medical Device Correction for all Omnipod DASH® Personal Diabetes Managers](#) (PDMs) distributed globally. This action was taken voluntarily with the knowledge of the FDA and other regulatory agencies.

Insulet received reports from Omnipod DASH users regarding PDM battery issues, including battery swelling and leakage, and in rare cases, extreme overheating, which has resulted in reports of fire. The Company's investigation determined that the Omnipod DASH PDM is at increased risk of malfunction if overcharged beyond the maximum battery voltage, which could potentially lead to serious injury or death.

There have been 50 complaints about this issue. No serious injuries or deaths have been reported as a result of this potential issue.

As previously communicated to Omnipod DASH users, Insulet has identified an update to the Omnipod DASH PDM that will resolve this issue. The Company expects to begin shipping updated Omnipod DASH PDMs to all current Omnipod DASH customers in the coming months.

"Safety is our top priority, and we have been urgently addressing this issue," said Michael Spears Senior Vice President, Regulatory Affairs & Compliance. "We are committed to helping our customers navigate the replacement process and address any concerns they have. We are confident that a software update will resolve this issue."

All affected Omnipod DASH consumers are being notified by email and local mail. Insulet has been providing customers with instructions to help reduce the risk of PDM battery issues. Users who experience any issues with their battery should contact Insulet's dedicated Customer Care team at 1-800-641-2049, which is available in the U.S. 24 hours a day, 7 days a week. Country-specific Customer Care phone numbers are available on [www.omnipod.com](http://www.omnipod.com).

This Medical Device Correction does not affect Omnipod DASH Pods, the Omnipod® Insulin Management System, or the Omnipod® 5 Automated Insulin Delivery System. Additional information, including instructions to customers to mitigate risk, can be found on the Company's website at [www.omnipod.com/insulet-alerts](http://www.omnipod.com/insulet-alerts).

### **About Insulet Corporation:**

Insulet Corporation (NASDAQ: PODD), headquartered in Massachusetts, is an innovative medical device company dedicated to simplifying life for people with diabetes and other conditions through its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet's latest innovation, the Omnipod® 5 Automated Insulin Delivery System, is a tubeless automated insulin delivery system, integrated with a continuous glucose monitor to manage blood sugar with no multiple daily injections, zero fingersticks, and is fully controlled by a compatible personal smartphone. Insulet also leverages the unique design of its Pod by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across other therapeutic areas. For more information, please visit: [insulet.com](http://insulet.com) and [omnipod.com](http://omnipod.com).

### **Forward-Looking Statement:**

This press release may contain forward-looking statements concerning Insulet's expectations, anticipations, intentions, beliefs, or strategies regarding the future. These forward-looking statements are based on its current expectations and beliefs concerning future developments and their potential effects on Insulet. There can be no assurance that future developments affecting Insulet will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, and other risks and uncertainties described in its Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 24, 2022 in the section entitled "Risk Factors," and in its other filings from time to time with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

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