



## Insulet Issues Medical Device Correction Regarding its Omnipod DASH™ Insulin Management System

February 13, 2020

- [Medical Device Correction Investor FAQs](#)

ACTON, Mass.--(BUSINESS WIRE)--Feb. 13, 2020-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in [tubeless insulin pump](#) technology with its Omnipod® Insulin Management System, today announced a voluntary Medical Device Correction for all Omnipod DASH™ Personal Diabetes Managers (PDMs) distributed globally.

**Consumer safety is Insulet's top priority and this action is taken voluntarily with the knowledge of the FDA.**

As part of our ongoing quality monitoring processes, we have identified that on rare occasions, the Omnipod DASH PDM may suggest an inaccurate bolus amount based on a blood glucose value that is more than 10 minutes old when the user does not exit the bolus calculator as designed or when a system alarm interrupts a bolus calculation. If the user delivers the bolus, this may result in over or under delivery of insulin which may lead to hypoglycemia or hyperglycemia. No injuries have been reported as a result of this potential issue and the Omnipod DASH System is safe for continued use and distribution.

This notice does not affect the Omnipod DASH Pods or the widely distributed Omnipod Insulin Management System. All affected Omnipod DASH users are being notified by email and local mail and replacement devices will be made available starting in March to all Omnipod DASH users. Additional information can be found on our website [www.omnipod.com](http://www.omnipod.com).

For further questions regarding the information provided in this Medical Device Correction, consumers are requested to contact Insulet's 24/7 Customer Care in any of the following markets:

US: 1-800-581-6359

United Kingdom: 0800 011 6132

Netherlands: 0800 0229512

Italy: 800 798 659

**About Insulet Corporation:**

Insulet Corporation (NASDAQ: PODD), headquartered in Massachusetts, is an innovative medical device company dedicated to making the lives of people with diabetes and other conditions easier through the use of 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 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: [www.insulet.com](http://www.insulet.com) and [www.omnipod.com](http://www.omnipod.com).

© 2020 Insulet Corporation. Omnipod and DASH are trademarks or registered trademarks of Insulet Corporation. All rights reserved.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20200213005223/en/>

Source: Insulet Corporation

Deborah R. Gordon  
Vice President, Investor Relations  
(978) 600-7717  
[dgordon@insulet.com](mailto:dgordon@insulet.com)