



## Insulet's Omnipod® DASH™ Insulin Management System Receives FDA 510(k) Clearance

June 4, 2018

*DASH System Features Sleek, Color Touch-Screen Handheld Personal Diabetes Manager, Bluetooth-Enabled, Waterproof<sup>1</sup>, Tubeless Pump and Suite of User-Friendly Mobile Applications*

*No-Cost Personal Diabetes Manager with Purchase of Pods*

BILLERICA, Mass.--(BUSINESS WIRE)--Jun. 4, 2018-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the leader in [tubeless insulin pump](#) technology with its Omnipod® Insulin Management System (Omnipod System), today announced FDA 510(k) clearance of the Omnipod DASH™ Insulin Management System (Omnipod DASH). This clearance lays the foundation for a steady cadence of innovation that furthers Insulet's mission to empower users to enjoy simplicity, freedom, and healthier lives with their differentiated technology.

"Omnipod DASH was inspired by Padders and embodies what users on multiple daily injections have been asking for in a diabetes management system," said Patrick Sullivan, Chairman and Chief Executive Officer. "Our number one priority is to continue to minimize the daily strain on those impacted by diabetes and we are confident this system, and eliminating the system's upfront cost, do just that."

Omnipod DASH was built to be simple, discreet and easy-to-use. The system features Bluetooth wireless technology for connectivity between the color touch-screen Personal Diabetes Manager (PDM), tubeless waterproof pump (Pod), and is optimized for use with the CONTOUR® NEXT ONE Blood Glucose (BG) Meter for the seamless transfer of blood glucose readings to the PDM's bolus calculator. Bluetooth functionality also provides connectivity to the Omnipod DISPLAY™ and Omnipod VIEW™ apps. The DASH PDM will be offered at no cost with the purchase of Pods.

The Omnipod DISPLAY and Omnipod VIEW apps will provide users and their caregivers quick and easy access to their insulin therapy information on their smartphones. Omnipod DISPLAY allows users to discreetly monitor their PDM data on their smartphones along with other Podder-inspired features including "Find my PDM". Omnipod VIEW allows parents and caregivers to monitor their loved ones' diabetes more easily and with greater peace of mind. The iOS Today View widget allows users and their care teams to see their or their loved ones' PDM and continuous glucose monitor (CGM) data on one smartphone screen with one swipe.

"I'm thrilled with the new Omnipod DASH System," said Tessa Mellinger, a college student with Type 1 diabetes who was part of the DASH user testing and development. "The PDM display is easy to read, the steps to managing basal rates are user friendly, and the food library is really helpful. The fact that it looks like a smartphone makes it cool to carry and may help eliminate those awkward questions from strangers."

Insulet would like to thank the Centers for Devices and Radiological Health (CDRH) branch of the FDA for its collaborative efforts, timely review and ultimate clearance of the Omnipod DASH Insulin Management System submission. Insulet looks forward to working with Captain Alan Stevens and his team as the Company continues to work on its robust innovation pipeline.

Submission for FDA 510(k) clearance of the Omnipod DASH was announced in January, and while today's clearance allows Insulet to commercialize this product in the United States, the Company is taking a measured approach through a limited market launch to ensure an ideal user experience at full market release. Full market release is estimated to begin in early 2019 in the United States.

For more information on product details, availability and a comprehensive list of FAQs, please visit the [Omnipod website](#).

<sup>1</sup> The Pod has a waterproof IPX8 rating for up to 25 feet for 60 minutes. The PDM is not waterproof.

### **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 multiple therapeutic areas. Founded in 2000, more than 140,000 users across the globe rely on Insulet's Omnipod Insulin Management System to bring simplicity and freedom to their lives. For more information, please visit: [www.insulet.com](http://www.insulet.com), [www.myomnipod.com](http://www.myomnipod.com) and [www.omnipodeurope.com](http://www.omnipodeurope.com).\*

\*Starting July 1, 2018, Insulet will assume direct distribution of its Omnipod Insulin Management System in Europe, including sales, marketing, training and customer support activities. This will allow Insulet to be closer to the diabetes community and identify opportunities to support European customer needs over the long-term, as it already does in the United States and Canada.

### **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 22, 2018 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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