NEWS RELEASE

Insulet Announces FDA 510(k) Clearance of Omnipod® 5 Algorithm Enhancements that Redefine Insulin Delivery and Simplify the Pod Experience

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- New 100 mg/dL Target Glucose setting offers more customization and tighter glucose management.
- Enhanced algorithm helps users remain in Automated Mode to improve the user experience.
- Most requested new features enable healthcare providers to more effectively modify diabetes therapy to meet needs of people with diabetes.

ACTON, Mass.--(BUSINESS WIRE)-- Insulet Corporation (NASDAQ: PODD) (Insulet or the Company), the global leader in **tubeless insulin pump** technology with its Omnipod® brand of products, today announced it has received FDA 510(k) clearance for significant enhancements to the Omnipod 5 Automated Insulin Delivery System. These updates to the Omnipod 5 algorithm set a new benchmark in tubeless diabetes technology by offering a lower 100 mg/dL Target Glucose option and a more seamless automated experience.

“This is the most significant algorithm advancement to our Omnipod 5 System since its launch in 2022,” said Eric Benjamin, Insulet Executive Vice President and Chief Operating Officer. “These new features address the two most requested enhancements and reflect our relentless commitment to delivering meaningful innovation for those living with diabetes and the healthcare providers who support them. Every improvement we make is designed to strengthen clinical outcomes while making the Pod experience simpler, more personalized, and so seamless it disappears into everyday life.”

More Flexibility with a Lower Target Glucose Setting

The new 100 mg/dL Target Glucose expands Omnipod 5’s customization range to six settings between 100-150

mg/dL in 10 mg/dL increments. This flexibility allows healthcare providers to tailor insulin delivery more precisely, supporting individuals seeking tighter glucose management or those striving to meet specific glucose goals. It also directly impacts automated insulin delivery and improves the algorithm's responsiveness. Real world evidence has shown that lowering the glucose target is associated with increased time in range, with no clinically meaningful change in Time Below Range[1] (TBR).

Designed with Patients and HCPs in Mind

In addition, the upgraded Omnipod 5 algorithm helps users stay in Automated Mode with fewer interruptions, even during prolonged high glucose events. These advancements are designed to deliver strong clinical results with increased flexibility and greater ease of use, with fewer interruptions to daily life.

"These enhancements to the Omnipod 5 algorithm are a meaningful step forward. As a clinician, it's exciting to offer patients a system that not only supports strong clinical outcomes but also builds their confidence in managing diabetes daily. More target glucose options and fewer interruptions mean a better experience for people with diabetes and their families," said Dr. Anita Swamy, MD, Pediatric Endocrinologist and Medical Director of the Chicago Children's Diabetes Center.

The updates to the Omnipod 5 algorithm are anticipated to launch in the United States in the first half of 2026, where Omnipod 5 is cleared for people aged 2 and older with type 1 and aged 18 and older with type 2 diabetes.

[1] Forlenza G, et al. Presented at: ATTD; March 19-22, 2025; Amsterdam, NL. Real-world data from 403 people with type 1 diabetes aged 2+ using the Omnipod 5 System who transitioned from the (150 mg/dL or 8.3 mmol/L) to (110 mg/dL or 6.1 mmol/L) Target Glucose. Each Target Glucose was used for a consecutive period of 14-90 days. Median time in Range (70-180 mg/dL) (3.8-10 mmol/l) improved 11.8% ($p<0.05$). Median time (<70 mg/dL or <3.8 mmol/l) +0.23% ($p<0.05$). Real-world data from 58 people with type 2 diabetes (T2D) aged 18+ using the Omnipod 5 System who transitioned from 150 mg/dL to 110 mg/dL Target Glucose. Each Target Glucose was used for a consecutive period of 14-90 days. Median time in Range (70-180 mg/dL) improved 10.4% ($p<0.05$). Median time < 70 mg/dL +0.04% (non-significant). Omnipod 5 results based on users with ≥75% of days with ≥220 readings available. Data on File. RF-042025-00013

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 tubeless disposable Pod provides up to three days of non-stop insulin delivery,

without the need to see or handle a needle. Insulet's flagship innovation, the Omnipod 5 Automated Insulin Delivery System, integrates with a continuous glucose monitor to manage blood sugar with no multiple daily injections, zero fingersticks, and can be controlled by a compatible personal smartphone in the U.S. or by the Omnipod 5 Controller. 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, visit Insulet.com or omnipod.com.

Investor Relations:

Clare Trachtman
Vice President, Investor Relations
(978) 218-0889
ctrachtman@insulet.com

Media:

Angela Geryak Wiczek
Senior Director, Corporate Communications
(978) 932-0611
awiczek@insulet.com

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