Medtronic News

FDA Approves Medtronic MiniMed™ 780G System - World's First Insulin Pump with Meal Detection Technology* Featuring 5-Minute Auto Corrections†§

Available in Europe since 2020, this new system delivers the strongest clinical outcomes and best user experience to-date within the Medtronic family of pumps

DUBLIN, April 21, 2023 /PRNewswire/ -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced U.S. Food and Drug Administration (FDA) approval of its MiniMed™ 780G system with the Guardian™ 4 sensor requiring no fingersticks while in SmartGuard™ technology‡. This milestone marks the approval of the only system with meal detection technology* that provides automatic adjustments and corrections† to sugar levels every 5 minutes§. The system provides insulin to help account for when users occasionally forget to bolus or underestimates the number of carbs in their meal.

"Mealtimes prove to be one of the biggest challenges for people living with type 1 diabetes and now for the first time, the MiniMed 780G system addresses this unmet need with automatic, real-time insulin corrections," said Que Dallara, EVP and President of Medtronic Diabetes. "A lot can happen to blood sugars in the span of an hour or even just a few minutes, so we've designed our system for real life – the algorithm adapts to the user and helps compensate for everyday challenges that are quite common around mealtimes. We built in features informed by extensive customer feedback and we're excited to deliver a system with ease of use at the forefront."

Key System Features

The MiniMed 780G system features the lowest glucose target setting (as low as 100 mg/dL) in any automated insulin pump on the market[1] and one that more closely mirrors the average glucose of someone not living with diabetes. With this setting, the pump will "treat to target" and will automatically deliver basal insulin adjustments and autocorrections to a set target. It's also the only pump with an infusion set that can be worn for up to 7 days, doubling wear time** with advanced materials that help reduce insulin preservative loss, maintain insulin flow and stability, resulting in a reduced risk of infusion set occlusion.[2] Combined with the new Guardian™ 4 sensor requiring no fingersticks with SmartGuard™ technology‡, the MiniMed 780G system delivers a user-friendly design with 94% of users saying they're satisfied with the impact the system has on their quality of life[3]. Importantly, users also reported remaining in SmartGuard™ technology 95% of the time[4].

"My last two years on the MiniMed 780G system as part of the clinical trial have been incredible for me," said Terry Weland, a Medtronic customer for 25 years. "The system is so easy to use. I don't know anyone who's perfect at carb counting and there are times when you're not as on top of things as you'd like to be. I don't stress over my diabetes like I used to because I know the system has my back. I love that I can sync my sensor and infusion set changes to every 7 days, which streamlines my routine."

Clinical Study

In the U.S. pivotal trial of the MiniMed 780G system, users experienced 75% Time in Range (blood sugar between 70-180 mg/dL), with overall Time Below Range of 1.8%[5]. The system provided even greater protection at night with an overnight Time in Range of 82%, and overnight Time Below Range of 1.5%. With use of the

lower target of 100 mg/dL and active insulin time (AIT) set to two hours, Time in Range reached 78.8% without increasing hypoglycemia. These results are mirrored by the real-world evidence across Europe where the MiniMed 780G system has been approved since 2020 and is now available in 105 countries.

Results from the randomized controlled ADAPT study evaluating the performance of the MiniMed 780G system[1] against multiple daily injections (MDI) used in conjunction with an intermittently scanned CGM (isCGM) reinforced the significant benefits of automated insulin therapy over standard therapy. Initial 6-month results, published in *The Lancet Diabetes & Endocrinology*, showed AHCL system users experienced a 27.6% increase in Time in Range (TIR) and 1.4% reduction in HbA1C compared to those on MDI + isCGM without increased time in hypoglycemia. This improvement was even greater overnight with a TIR increase of 30.2%. At the close of the 6-month study period, all participants on MDI + isCGM crossed over to the MiniMed 780G system. At one year, these significant improvements were reproduced in this cross-over group and sustained in those that started on AHCL therapy at the start of the trial.

The system is approved for users seven years old and above with type 1 diabetes. Medtronic will begin taking pre-orders on May 15, 2023, with first shipments planned for later this summer. Customers on the company's MiniMed™ 770G system today will be eligible to upgrade their device to the MiniMed 780G through a no-cost, remote software upgrade. Visit www.medtronicdiabetes.com for the latest launch updates.

About Medtronic Diabetes (www.medtronicdiabetes.com)
Medtronic Diabetes is on a mission to alleviate the burden of diabetes by empowering individuals to live life on their terms, with the most advanced diabetes technology and always-on support when and how they need it. We've pioneered first-of-its-kind innovations for over 40 years and are committed to designing the future of diabetes management through next-generation sensors (CGM), intelligent dosing systems, and the power of data science and AI while always putting the customer experience at the forefront.

About Medtronic
Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals, and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

*Taking a bolus 15 – 20 minutes before a meal helps to keep blood sugar levels under control after eating.
† Refers to auto correct, which provides bolus assistance. Can deliver all auto correction doses automatically without user interaction, feature can be turned on and off.
§ Refers to SmartGuard™ feature. Individual results may vary.
**The extended wear infusion set can be worn for up to 7 days. Current infusion sets are recommended for up to 3 days of wear.
‡ Fingersticks required in manual mode & to enter SmartGuard™. If symptoms don't match alerts & readings, use a fingerstick. Refer to user guide. Pivotal trial participants spend avg of > 93% in SmartGuard™.

1. Arrieta A, et al. Diabetes Obes Metab. 2022;10.1111/dom.14714
2. Zhang G, et al. Development of the Extended Infusion Set and Its Mechanism of Action. J Diabetes Sci Technol. 2022 Jul 25:19322968221112120. doi: 10.1177/19322968221112120. Epub ahead of print. PMID: 35876264.
3. Medtronic data on file: MiniMed™780G users survey conducted in April – May 202in UK, Sweden, Italy,

Netherlands and Belgium. N 789
4. Carlson, A.L. et al. Safety and glycemic outcomes of the MiniMed™ AHCL system in subjects with T1D. Diab Tech Ther. ahead of print http://doi.org/10.1089/dia.2021.0319
5. Data on file from CIP 321: Pivotal Trial (Age 14- 75). N=152. 2020; 16 US sites.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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