

New MiniMed™ 780G system data demonstrates ability to address persistent blood sugar challenges for people with type 1 diabetes

With its advanced algorithm that provides autocorrections every 5 minutes, the latest data demonstrated that the MiniMed™ 780G system decreased rates of early morning hyperglycemia, known as dawn phenomenon, and improved overnight sleep

DUBLIN and ORLANDO, Fla., June 21, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, is presenting a comprehensive body of new data at the American Diabetes Association's (ADA) 84th Scientific Sessions that showcases the benefits of the MiniMed™ 780G system. New data shows how the system addresses hyperglycemia and nighttime burden, adding to the established body of evidence that demonstrates the system's ability to tackle unique and burdensome challenges of diabetes, such as managing highs and meal-time management or carb counting, while also mirroring outcomes across a wide-ranging patient population.

Tackling hyperglycemia to improve long-term health with type 1 diabetes

Among the burdens of living with diabetes, hyperglycemia can often be overshadowed by hypoglycemia. Yet, in the U.S., only 26% of people living with diabetes achieve HbA1c levels of <7.0%.¹ Reducing the time spent with high blood sugars continues to be a significant unmet need as it can lead to serious health problems impacting multiple organs.² For children, prolonged highs can have adverse effects on memory, IQ, executive functioning, and learning.³

One cause of high blood sugars is the dawn phenomenon, an increase in glucose levels in the early morning.⁴ This can be a common occurrence for those living with diabetes and may add to feelings of frustration with diabetes. An encouraging new retrospective analysis of real-world data (n= 6026) showed that this morning peak was nearly eliminated for users who upgraded from the MiniMed™ 770G system to the MiniMed™ 780G system. The data assessed the elevation of sensor glucose levels >20 mg/dL from 3 - 6 a.m. compared to 12 – 3 a.m. at least 30% of the nights. The transition from the MiniMed™ 770G system to the MiniMed™ 780G system decreased dawn phenomenon rates from 12.2% to 4.5%. Time in Range also increased from 87.7% to 91.4% from 12 – 6 a.m., which is consistent with dawn phenomenon trends.

Early and consistent management of hyperglycemia is critical as it has protective effects on the body that can last for decades.⁵ "For those living with type 1 diabetes, dawn phenomenon can be a stressful occurrence that feels out of one's control," explained Robert Vigersky, MD, Chief Medical Officer, Medtronic Diabetes. "The introduction of the MiniMed™ 780G system has made it easier to maintain target glucose range with less effort to protect against hyperglycemia.^{6,7} It's been an absolute gift for my patients who have struggled with stubborn highs throughout their diabetes journey."

Reducing nighttime burden

For individuals living with type 1 diabetes, CGM-generated alerts and the need to deliver manual boluses disrupt sleeping through the night adding to the burden of diabetes. The MiniMed™ 780G system is designed to reduce the burden of diabetes throughout the day and night. Additional real-world data from a retrospective analysis presented at ADA (n=8019; <7 y/o, previously on the MiniMed™ 770G system who had greater than 14 nights on both systems) demonstrated that users had fewer overnight sleep interruptions and Time in Range improvements as a result of the automatic adjustments in insulin and correction[†] of glucose levels every 5 minutes, including during sleep.[§] With the MiniMed™ 780G system, nighttime alerts decreased 45% for all users and 55% for those who used recommended optimal settings. Additionally, uninterrupted sleep, a greatly desired outcome for those living with diabetes, increased by 30 and 36 minutes per night, respectively. These results add to the diabetes burden reduction that MiniMed™ 780G system users experience with an advanced algorithm with frequent,

every 5-minute autocorrections.

The continued evolution of the MiniMed™ 780G system to reduce burden

Along with evidence on the currently available MiniMed™ 780G system, additional data will be presented on the next iteration of the system,* which aims to further reduce diabetes management burden through its design. The system is intended to be paired with the Simpler Sync™ sensor, a disposable, all-in-one continuous glucose monitor (CGM) designed to require no overtape.

A 24-site, single arm study evaluated the use of the next iteration of the MiniMed™ 780G system algorithm paired with the Simpler Sync™ sensor. Results were promising across all clinical outcomes metrics including Time in Range (TIR), Time in Tight Range (TITR) and Time Above Range (TAR), compared to the run-in group where hybrid closed loop (auto basal only) or open-loop delivery was used. The study included the use of recommended optimal settings (ROS) (100 mg/dL set target with an active insulin time of 2 hours) related to TIR, TITR, and TAR.

"The MiniMed™ 780G system has firmly established itself as a proven automated insulin delivery system," said study investigator Gregory Forlenza, MD, professor and pediatric endocrinologist at the Barbara Davis Center. "With the next iteration of the system and this next-generation Simpler Sync™ sensor, the overall experience for people living with type 1 diabetes could be enhanced and may prove to be a compelling option for diabetes management — particularly when leveraged in combination with recommended optimal settings."

The MiniMed™ 780G system** is currently available for ages 7 and above in over 100 countries globally and will be launching with the Simpler Sync™ sensor in parts of Europe in late July. Currently, Simpler Sync™ is investigational and not approved for commercial use in the U.S.*

Safety and Glycemic Outcomes Using the MiniMed™ 780G system with an All-in-One Disposable Sensor with Transmitter						
3-month study period (n=109, ages 7-17; n=107, ages 18-80)						
	Youths (ages 7-17)			Adults (ages 18-80)		
	Run-in (N=112)	Study (N=109)	ROS (N=41)	Run-in (N=110)	Study (N=107)	ROS (N=44)
Time in Smart Guard, %	14.5±31.3	93.5±11.3	96.9±3.1	33.2±40.3	96.6±6.6	97.5±3.7
Mean SG, mg/dL	180.4±27.1	154.4±17.6	149.0±15.3	161.0±18.7	142.2±12.8	136.5±12.0
Percentage of time spent at glucose ranges						
<70 mg/dL (% TBR)	1.6±1.7	1.9±1.4	1.9±1.2	1.7±1.9	1.5±1.4	1.7±1.4
70-140 mg/dL (% TITR)	32.1±14.1	49.2±9.7	52.7±9.2	39.2±13.0	56.1±10.5	61.6±9.9
70-180 mg/dL (% TIR)	54.4±15.7	71.4±9.9	74.7±9.3	66.5±12.6	80.2±8.1	83.8±7.4
>180 mg/dL (% TAR)	44.0±16.1	26.7±10.1	23.3±9.4	31.8±13.1	18.2±8.4	14.5±7.7

Caption: Glycemic metrics and insulin delivered during youth and adult MiniMed™ 780G system investigational use with the disposable all-in-one Simplerla Sync™ sensor

To view this data at the 84th American Diabetes Association (ADA) Scientific Sessions in Orlando, Florida, view the company's previous announcement [here](#) for presentation times.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on [LinkedIn](#).

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.

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.

*Investigational. Not approved by the FDA for any use and not commercially available in the US.

**MiniMed™ 780G system is for type 1 ages 7 and over. Prescription required. WARNING: Do not use SmartGuard™ feature for people who require less than 8 units or more than 250 units of insulin/day. For details, see <https://bit.ly/780gRisks>

† 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.

1. Ebekozen O, Mungmode A, Sanchez J, Rompicherla S, Demeterco-Berggren C, Weinstock RS, Jacobsen LM, Davis G, McKee A, Akturk HK, Maahs DM, Kamboj MK. Longitudinal Trends in Glycemic Outcomes and Technology Use for Over 48,000 People with Type 1 Diabetes (2016-2022) from the T1D Exchange Quality Improvement Collaborative. Diabetes Technol Ther. 2023 Nov;25(11):765-773. doi: 10.1089/dia.2023.0320. Epub 2023 Oct 16. PMID: 37768677.
2. The Diabetes Control and Complications Trial Research Group. The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus. N Engl J Med 1993; 329:977-986
3. Mauras N, Buckingham B, White NH, Tsalikian E, Weinzimer SA, Jo B, Cato A, Fox LA, Aye T, Arbelaez AM, Hershey T, Tansey M, Tamborlane W, Foland-Ross LC, Shen H, Englert K, Mazaika P, Marzelli M, Reiss AL; Diabetes Research in Children Network (DirecNet). Impact of Type 1 Diabetes in the Developing Brain in Children: A Longitudinal Study. Diabetes Care. 2021 Apr;44(4):983-992.

4. O'Neal, Teri B. "Dawn Phenomenon." U.S. National Library of Medicine, 16 May 2023, www.ncbi.nlm.nih.gov/books/NBK430893/.
5. Lachin JM, Bebu I, Nathan DM; DCCT/EDIC Research Group. The Beneficial Effects of Earlier Versus Later Implementation of Intensive Therapy in Type 1 Diabetes. *Diabetes Care*. 2021 Aug 11;44(10):2225–30.
6. Arrieta A, Battelino T, Scaramuzza AE, Da Silva J, Castañeda J, Cordero TL, Shin J, Cohen O. Comparison of MiniMed™ 780G system performance in users aged younger and older than 15 years: Evidence from 12 870 real-world users. *Diabetes Obes Metab*. 2022 Jul;24(7):1370-1379.
7. Beck RW, Bergenstal RM, Riddlesworth TD, Kollman C, Li Z, Brown AS, Close KL. Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. *Diabetes Care*. 2019 Mar;42(3):400-405. doi: 10.2337/dc18-1444. Epub 2018 Oct 23. PMID: 30352896; PMCID: PMC6905478.

Contacts:

Ashley Patterson	Ryan Weispfenning
Public Relations	Investor Relations
+1 (818) 576-3025	+1 (763) 505-4626

SOURCE Medtronic plc

<https://news.medtronic.com/2024-06-21-New-MiniMed-TM-780G-system-data-demonstrates-ability-to-address-persistent-blood-sugar-challenges-for-people-with-type-1-diabetes>