Medtronic News

Studies show promising results for individuals with type 2 diabetes and young children with type 1 diabetes on MiniMed™ 780G system

Data supports the potential of future indication expansion for the MiniMed™ 780G system. LENNY trial results published in Lancet Diabetes & Endocrinology.

GALWAY, Ireland and CHICAGO, June 20, 2025 /PRNewswire/ -- Medtronic, a global leader in healthcare technology, will present data at the American Diabetes Association (ADA) 85th Scientific Sessions in Chicago, highlighting improved glycemic outcomes for individuals with insulin-intensive type 2 diabetes on the MiniMed™ 780G* system under investigational use. Participants in a clinical trial achieved an average 8.6% increase in Time in Range (TIR), reaching 84.9%, well above the ADA goal of 70%, and a HbA1C reduction from 7.7% to 6.9%, meeting ADA targets for diabetes management.

Separately, results from the Medtronic LENNY trial werepublished[i] in ***The Lancet Diabetes & Endocrinology***. This multi-center, randomized controlled, crossover trial evaluated the MiniMed™ 780G system in young children (ages 2-6 years) with type 1 diabetes in a home setting. Results showed those using the MiniMed™ 780G system with SmartGuard™ achieved a 0.6% lower HbA1C and 9.9% higher Time in Range when compared to a baseline therapy of manual mode or hybrid closed loop without autocorrections. Parents and caregivers also reported improved sleep quality and lower fear of hypoglycemia when the system was used in auto mode (with SmartGuard™) compared to manual mode.

Benefits of automated insulin delivery (AID) systems for type 2 diabetes

While the standard of care for type 2 diabetes often includes lifestyle modifications and oral medications, many individuals require intensive insulin therapy to achieve optimal glucose management.

The ADA's 2025 Standards of Care[ii] now endorse the use of AID systems for adults with insulin-intensive type 2 diabetes, recognizing their potential to significantly improve clinical outcomes — an important validation of the growing role of diabetes technology in transforming chronic disease management.

A 31-site single arm trial evaluated the MiniMed™ 780G system paired with the Simplera Sync™ sensor in a cohort of 236 individuals with type 2 diabetes. Results were promising across all clinical outcome metrics including Time in Range (TIR), Time in Tight Range (TITR), Time Above Range (TAR) compared to the run-in period where hybrid closed loop (auto basal only) or open-loop delivery was used. Time below range (TBR) remained stable.

"As the industry moves toward broader indications of automated insulin delivery systems, we see tremendous potential to improve outcomes and quality of life for millions of people managing type 2 diabetes with insulin," said Dr. Robert Vigersky, Chief Medical Officer, Medtronic Diabetes. "Our teams are committed to advancing smart, connected technologies that reduce the daily burden of care and bring precision to insulin therapy like never before."

	Baseline[a]	**Study[b]**	**Change (Study - Baseline)**	***P***
Participants, N	236	232	--	--
Time in AHCL, %	--	92.4 ± 15.7	--	--
A1C, %	7.7 ± 0.9	6.9 ± 0.7[c]	-0.8 ± 0.9[c]	<0.0001
Mean SG, mg/dL	152.9 ± 21.2	140.7 ± 13.3	-12.3 ± 19.5	<0.0001

CV of SG, %	25.1 ± 4.8	25.6 ± 4.8	0.4 ± 3.3	0.073[h]
TBR <54 mg/dL, %	0.0 ± 0.1	0.0 ± 0.1	-0.0 ± 0.1	0.277
TBR <70 mg/dL, %	0.3 ± 0.5	0.3 ± 0.4	0.0 ± 0.5	0.056
TITR 70-140 mg/dL, %	45.3 ± 19.7	58.1 ± 13.6	13.0 ± 18.8	<0.0001[h]
TIR 70-180 mg/dL, %	76.4 ± 15.9	84.9 ± 9.7	8.6 ± 14.4	<0.0001
TAR >180 mg/dL, %	23.4 ± 15.9	14.8 ± 9.7	-8.6 ± 14.5	<0.0001
TAR >250 mg/dL, %	3.5 ± 5.2	1.7 ± 2.5	-1.8 ± 4.6	<0.0001
TDD, U	61.0 ± 36.1	76.1 ± 44.1	14.5 ± 25.1	<0.0001
Basal and bolus insulin				
Total basal, U	34.6 ± 21.3	39.8 ± 23.9	4.9 ± 16.8	<0.0001
Total bolus, U	26.5 ± 20.7	36.3 ± 23.8	9.6 ± 15.1	<0.0001
Auto bolus, U	--	13.7 ± 11.1	--	--
Auto bolus, %TDD	--	17.2 ± 8.5	--	--
Auto bolus, %Total bolus	--	39.3 ± 21.8[d]	--	--
System-initiated insulin				
Automated insulin, U	0.5 ± 3.4	51.2 ± 33.4	50.7 ± 33.7	<0.0001
Automated insulin, %TDD	0.9 ± 5.8	65.9 ± 17.3	65.0 ± 17.8	<0.0001
Daily carbohydrate, g	119.1± 87.4	127.7 ± 88.9	7.7 ± 84.6	0.571
ICR	7.6 ± 4.0[d]	6.9 ± 3.8[e]	-0.6 ± 1.5[f]	<0.0001
Weight, kg	98.0 ± 22.8[g]	98.4 ± 23.0[c]	0.7 ± 4.7[c]	0.006
BMI, kg/m^2	34.0 ± 7.3[g]	34.2 ± 7.4[c]	0.2 ± 1.7[c]	0.006

Table 1. Glycemic outcomes, insulin delivery and weight during MiniMed™ 780G system use with the Simplera Sync™ sensor in adults with type 2 diabetes

Data are shown as mean±SD.

[a]Open loop (with or without predictive low glucose management) or HCL. AHCL was inadvertently (temporarily) enabled on 13 systems.

[b]Data represent the last 6 weeks of the study period with glucose target set at the investigator's discretion.

[c]N=229, [d]N=231, [e]N=228. [f]N=224.[g]N=235.

[h]Paired two-sided *t*-test; otherwise, Wilcoxon signed-rank test.

BMI, Body mass index; CV, Coefficient of variation; ICR, Insulin-to-carb ratio; SG, Sensor glucose; TAR, Time above range; TBR, Time below range; TIR, Time in range; TITR, Time in tight range; TDD, Total daily dose; U, Units.

The MiniMed™ 780G system has not been approved for use in type 2 diabetes by U.S. FDA or other regulatory bodies.

Impact on families of young children with diabetes

Managing type 1 diabetes in young children and toddlers can be challenging for families. Data from the Lenny trial, published in *The Lancet Diabetes & Endocrinology,* highlighted how young children aged 2-6 years old achieved improved glycemic outcomes using the MiniMed™ 780G system.

"To preserve brain development and minimize long-term diabetes complications, it is essential that blood glucose

concentrations are maintained close to healthy ranges from disease onset in early life," said Prof. Tadej Battelino, MD, Head of Department of Pediatric and Adolescent Endocrinology, UMC Ljubljana, Slovenia. "We are hopeful that if the data continues to be strong, the MiniMed™ 780G system can help make this possible."

After a run-in phase, subjects using the MiniMed™ 780G system with the Guardian™ 4 sensor were randomized into two sequences, consisting of a 12-week auto mode period (advanced hybrid closed loop), a 2-week wash-out phase and 12-week manual mode period (with suspend before low feature activated), or vice-versa. In total, there were 98 subjects across 12 centers in 4 countries. Results showed significantly** better glycemic management in auto mode, as shown in Figure 1 and Table 2 below. With no severe hypoglycemic events, the study showed an acceptable safety profile. Participants in auto mode spent on average 145 minutes per day more in range than those in manual mode. This improvement was primarily driven by a reduction in hyperglycemia, which is a major contributor to long-term complications.

"We're hopeful that if the data continues to be strong, we will receive future indication expansion so the most vulnerable group, small children under 7 years, and their families can also benefit from this technology ", said Prof. Ohad Cohen, M.D., senior global medical affairs director, Medtronic Diabetes.

Table 2: Glycemic metrics during the run-in phase, the manual mode period, and the auto mode period.

	Run-in	Manual Mode	Auto Mode
HbA1c, %	7.53 ± 0.96	7.61 ± 0.91	7.00 ± 0.53
HbA1c, mmol/mol	58.8 ± 10.5	59.7 ± 9.9	53.0 ± 5.8
Mean glucose, *mg/dl*	169.6 ± 25.7	169.1 ± 23.1	150.2 ± 10.7
SD of SG, mg/dl	65.0 ± 14.7	65.4 ± 13.2	61.8 ±10.9
GMI, %	7.4 ± 0.6	7.4 ± 0.5	6.9 ± 0.3

Table 2: Glycemic metrics during the run-in phase, the manual mode period, and the auto mode period. During manual mode, the suspend before low (SBL) feature was activated. During run-in, the system was also used in manual mode with SBL activated. Data are shown as mean ± SD.

The emotional toll of diabetes for parents and caregivers

Managing type 1 diabetes in toddlers and young children can be emotionally stressful for parents and caregivers due to the need for constant blood sugar monitoring, dietary management, insulin administration and disrupted routines and sleep. A survey of caregivers in the LENNY trial indicated that when their child used auto mode, they experienced relatively low fear of hypoglycemia and high sleep quality.

	Run-in	Manual Mode	Auto Mode
Parent hypoglycemia fear survey (HFS-P)	44.75 ± 14.9	42.9 ± 13.3	40.9 ± 13.2
Pittsburgh Sleep Quality Index (PSQI)	7.1 ± 3.8	7.1 ± 4.0	5.9 ± 3.2

Table 3: Parent hypoglycemia fear survey and Pittsburgh Sleep Quality Index during the run-in phase, the manual mode period and the auto mode period. During manual mode, the suspend before low (SBL) feature was activated. During run-in, the system was also used in manual mode with SBL activated.

Medtronic will seek future expansion of indications for a broader population

The MiniMed™ 780G system currently is not indicated for use in in type 2 diabetes or young children under 7 years old by the

U.S. Food and Drug Administration (FDA) or other regulatory bodies. Medtronic intends to work with global regulators towards expanding access to its diabetes technology for insulin-intensive type 2 diabetes, as well as a lower age indication for those with type 1 diabetes.

About the Diabetes Business at Medtronic

Medtronic Diabetes is on a mission to make diabetes more predictable, so everyone can embrace life to the fullest 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

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway,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.

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.

*MiniMed™ 780G system is for type 1 ages 7 years 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. See the User Guide for a detailed list of information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For details, see https://bit.ly/780gRisks

** Significance was shown via confidence intervals

§ Refers to SmartGuard™ feature. Individual results may vary.

† 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.

[i] Battelino et al. Efficacy and safety of automated insulin delivery in children aged 2–6 years (LENNY): an open-label, multicentre, randomised, crossover trial; Lancet Diabetes Endocrinol 2025

[ii] American Diabetes Association Professional Practice Committee: Diabetes Care 2025;48(Supplement_1):S146–S166 https://doi.org/10.2337/dc25-S007

Contacts:

Ashley Patterson	Ryan Weispfenning
Global Communications	Investor Relations
+1-818-576-3025	+1-763-505-4626

SOURCE Medtronic plc

Additional assets available online: Photos (1)

https://news.medtronic.com/2025-06-20-Studies-show-promising-results-for-individuals-with-type-2-diabetes-and-young-children-with-type-1-diabetes-on-MiniMed-TM-780G-system