Medtronic News

Children achieve Time in Range mirroring well-controlled adults for the first time in real-world study of the MiniMed™ 780G system

Harder to manage pediatric and adolescent patients achieve 74% Time in Range, and 82% overnight Time in Range, well surpassing clinical consensus guidelines for glycemic control

DUBLIN, Oct. 19, 2021 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a leading global healthcare technology company, recently announced one-year, real-world clinical data on 3,211 pediatric and adolescent patients with type 1 diabetes 15 years old and below using the MiniMed™ 780G system[1] with the Guardian™ Sensor 3. Data on this subset of patients on the system in Europe showed an average Time in Range of 74% — surpassing Clinical Consensus Guidelines and closely mirroring Time in Range for adults at 77%. Overnight Time in Range of 82% also mirrored that of adults (82%) demonstrating that the Advanced Hybrid Closed Loop (AHCL) algorithm offers even stronger glycemic control and protection against lows while children are sleeping. The MiniMed 780G system delivers near real-time basal insulin and auto correction boluses (every 5 minutes) to address underestimated carb counts and occasional missed meal doses to deliver more Time in Range.

"These results are extremely encouraging. Glycemic control has been much harder to achieve in children due to unpredictable factors common in this age group, including physical growth and development, hormonal changes and active lifestyles. In fact, young adults around the age of 15 have the highest reported A1C in the T1D Exchange Registry, which includes data on over 31,000 individuals with type 1 diabetes and demonstrates the unique challenges in younger populations. Because the algorithm in the MiniMed 780G system adjusts basal and correction insulin doses in near real-time every 5 minutes thereby providing near real-time course correction, it helps make up for underestimated carbohydrate counting and occasional late or missed meal doses," said Robert Vigersky, M.D., chief medical officer of the Diabetes business at Medtronic. "The Medtronic AHCL algorithm offers advanced protection and permits unprecedented personalization in insulin delivery by offering a wide range of Active Insulin Time settings and three different glucose targets. These improvements reinforce that the MiniMed 780G system is a better alternative than previous therapy these patients were on, even for those who were relatively well-controlled."

From an experience perspective, younger users remained in Advanced Hybrid Closed Loop (AHCL) mode, also referred to as the SmartGuard™ algorithm, for an average of 93% of the time, similar to the 92% observed in users over 15 years old. When the pediatric group set a blood glucose target of 110mg/dL (6.1 mmol/L) and an Active Insulin Time (AIT) of two hours, they achieved an average Time in Range of 77% and a Glucose Management Indicator (GMI) of 6.7%. With these settings, they only spent 2.7% of their time <70 mg/dL (5.9 mmol/L).

The real-world performance analysis aggregates information from children 15 years old and below whose caregivers agreed to allow Medtronic to use anonymized data that was automatically uploaded their data to CareLink™ Personal from August 27, 2020 to July 22, 2021. A large majority of pediatric users included in the analysis are achieving glycemic goals recommended by major diabetes professional organizations, including:

- 75.3% of pediatric users had a Glucose Management Indicator (GMI) less than 7%, which mirrors the average A1C level that would be expected based on mean glucose.
- 69.6% of pediatric users had a Time in Range above 70%.
- 67.5% of pediatric users achieved both, a GMI less than 7% and a Time in Range above 70%.

A sub-analysis of patients 15 years old and younger with at least 10 days of CGM data both pre- and post-AHCL initiation (n=661) showed substantial improvements across both Time in Range and GMI – even among those who were relatively well controlled at baseline. This group saw a 12% increase in Time in Range, to 74% on average — equivalent to an additional 2.8 hours/day in the target range. From a user experience perspective, results also showed patients were able to stay in AHCL

mode 93% of the time once it was initiated.

	Pre-AHCL Initiation	Post-AHCL Initiation	Change
Number of users, *n*	661	661	
Total Daily Dose (of insulin), *units*	30.5	34.6	**+ 4.1***
Time in AHCL, *%*	-	92.8	
Mean SG, *mg/dL*	163	146	**- 17***
GMI, %	7.2	6.8	**- 0.4***
Overall Time in Range, %	62.1	73.8	**+11.7***
Users with GMI <7%, *%*	37.8	72.5	**+ 34.7***
Users with TIR >70%, *%*	31.3	67.6	**+ 36.3***

The MiniMed 780G system's SmartGuard algorithm (also referred to as the AHCL algorithm) automates the delivery of insulin every five minutes — personalizing these doses to auto-correct highs and lows 24 hours a day based on CGM readings.[2,3] Autocorrection dosing is designed to correct highs that may result from forgetting to bolus insulin prior to eating a meal, missing it altogether or underestimating the carbohydrate content in the meal resulting in an inaccurate dose of insulin. This feature offers an additional layer of protection and provides extra coverage to help reduce the burden associated with diabetes management and improve outcomes by bringing users closer to the target range throughout the day and night.

"We know that adolescents in particular lead very active lives and often eat on the go — running from one activity to the next. This system was designed to help individuals living with diabetes have some extra coverage and protection when life gets in the way and they're not able to manage their diabetes in the way they'd like to," said Julie Foster, vice president of Customer Experience for the Diabetes business at Medtronic. "We're confident we've designed a system that keeps lifestyle and experience front and center as we work to help make life easier for people living with diabetes."

The MiniMed 780G system is the most advanced insulin pump system from Medtronic, currently approved for the treatment of type 1 diabetes in people age 7 to 80 years. The system enables the personalization of glucose goals with an adjustable target setting as low as 100 mg/dL (5.5 mmol/L). The MiniMed 780G system is now available in 38 countries across Europe, the Middle East and Africa, and is currently being reviewed by the Food and Drug Administration (FDA) for approval in the U.S.

Time in Range

Clinical consensus regarding Time in Range means that a person living with diabetes should be in the recommended range of 70-180 mg/dL (3.9 – 10 mmol/L) for at least 70% of time to be well-controlled. This may increase the likelihood that short and long-term complications of this chronic disease can be avoided.

About the Diabetes Business at Medtronic (www.medtronicdiabetes.com)

Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, 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 90,000+ passionate people across 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 all. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE: MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and 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.

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[1] Not approved by FDA and not for sale in the U.S.

[2] Carlson, A.L. et al. Safety and glycemic outcomes during the MiniMed™ Advanced Hybrid Closed-Loop system pivotal trial in adolescents and adults with type 1 diabetes. Diab Tech Ther 2021; in press.

[3] Collyns.O. et al Improved Glycemic Outcomes With Medtronic MiniMed Advanced Hybrid Closed-Loop Delivery: Results From a Randomized Crossover Trial Comparing Automated Insulin Delivery With Predictive Low Glucose Suspend in People With Type 1 Diabetes. Diab Care 2021, 44: 969-975

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