

MiniMed™ 780G system

Category:

Best Medical Technology

Company Name:

Medtronic

Product/Solution Name:

MiniMed™ 780G system

Compound/Tech Name:

Meal Detection™ technology

Trade Name:

NYSE: MDT

Corporate Name:

MiniMed™ 780G system

Date of Approval:

2023-04-21

Indications:

Type 1 Diabetes, patients age 7+

Therapeutic Areas:

Automated Insulin Delivery System

General Information File Document upload:

N/A

Background information and need for drug / device:

According to a Stanford publication, 1 people living with diabetes are estimated to make

up to 180 decisions a day to manage their condition, including when and how much insulin to dose. For people living with type 1 diabetes, mealtimes can feel like a constant balancing act where every bite comes with a side of “Did I dose enough insulin?” Addressing one of the biggest mental burdens for people living with type 1 diabetes: mealtimes, the MiniMed™ 780G system is the first and only FDA-approved automated insulin delivery system with Meal Detection™ technology* that adjusts insulin dosing in real-time for snacks and meals. If someone occasionally forgets to dose or miscalculates carbs when they eat, the MiniMed™ 780G system keeps them in target glucose range. Users experience an average of 80% Time in Range**** (the modern approach to measuring the management of diabetes). In a recent survey, 6 MiniMed™ 780G system users said they are enjoying improved quality of life, enjoying higher satisfaction around mealtimes and experiencing better quality sleep.

Background File Document upload:

N/A

History of the development of the solution/product:

The goal of Medtronic Diabetes is to develop technology that “closes the loop” for people living with type 1 diabetes. This means designing a pump that requires minimal to no interaction so that diabetes management is always in the background. The MiniMed™ 780G system is another step closer to this vision with real-time sensing of glucose levels and automated delivery of basal and correction insulin throughout the day to keep those levels in a personalized target range.

The MiniMed™ 780G system was designed to help simplify diabetes management with the following key components:

- Guardian™ 4 sensor: The Medtronic sensor integrated with this system enables no fingersticks with SmartGuard™ technology,** enabling a much more seamless experience.
- Low target rate: With flexible targets as low as 100 mg/dl, users can now choose three different target settings based on a consultation with their healthcare provider for their preferences and needs. This was designed with feedback from users who wanted a target that more closely mimics a healthy pancreas of someone not living with diabetes.
- Longest wearing infusion set: The MiniMed™ 780G system is the only system that offers the Extended™ infusion set that can be worn up to seven days — doubling the wear time of other sets on the market. This means users can now sync their sensor and

infusion set changes on the same day.

Recognized by Fast Company on its 2024 list of World Changing Ideas, the MiniMed™ 780G system has demonstrated positive performance since being approved by the FDA in 2023, such as:

- Real-world results showed patients achieved up to 80% TIR with recommended settings, without increasing lows.^{2,****}
- Multi-continent real-world data demonstrating that use of the MiniMed™ 780G system allows people living with diabetes to meet or exceed internationally recommended targets regardless of region of the world, and successful performance of the AID algorithm under substantial changes to daily routines and lifestyle, including during Ramadan.^{****}
- Results published in The Lancet Diabetes & Endocrinology, from the randomized controlled ADAPT study evaluating the performance of the MiniMed™ 780G system against the standard of care reinforced the significant benefits of automated insulin therapy over standard therapy with a 27.6% increase in Time in Range (TIR) and 1.4% reduction in HbA1C at six months. 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.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

For those living with type 1 diabetes, glucose control is crucial, given the short- and long-term complications that can result from poor control, including impacts on one's eyes, kidneys, heart, and brain.⁵ Control is measured by Time in Range, which is the amount of time blood sugars stay within the ideal target of 70 -180 mg/dL, and an A1C of 7% or below. While A1C measures your average blood sugar levels over the past three months, Time in Range is a more real-time metric. The advent of continuous glucose monitors (CGM) made measuring Time in Range possible as individuals are now able to get a real-time view of where their glucose levels are throughout the day.

CGM tells you where your glucose is, but not how to manage it. A CGM doesn't act. In fact, despite the rapid adoption of CGMs over the past decade, less than 30% of individuals⁴ who use CGM with insulin injections achieve glycemic targets —

highlighting a significant unmet need. CGM alone isn't enough to deliver the outcomes individuals can and should expect to achieve. Every 5-10 points outside of Time in Range has a health impact as a 10% change in Time in Range is equivalent to a 0.8% change in A1C.³

Up to 42 factors may affect blood sugar levels on any given day, including exercise, hormones, sleep, stress, food, and medications. As a result, insulin needs to vary daily, and changes in blood sugars can be unpredictable based on these factors. Adjusting real time matters with diabetes management because a lot can happen within a few minutes. The MiniMed™ 780G system provides a safety net that adjusts for the reality of people's busy lives and provides individuals an automated solution that can take on the real-time insulin adjustments needed. This allows for the possibility of more normalcy in their lives and some relief from the incessant and unrelenting mental burden of managing their condition.

The MiniMed™ 780G system is the only system with Meal Detection™ technology algorithm that automatically adjusts and corrects† glucose levels every 5 minutes,§ delivering up to 288 adjustments a day – which is nearly impossible to match with manual injections. The MiniMed™ 780G system helps cover undercounted carbs and an occasionally missed meal dose. Combined with the new Guardian™ 4 sensor with SmartGuard™ technology, fingersticks (which have often been an ongoing, multiple-times-a-day burden of living with diabetes) are no longer required.** The MiniMed™ 780G system takes on more of the diabetes management so people can do less manual and mental work to keep their glucose in range. Instead of making 180 daily decisions, the system handles much of the constant background calculations so people can finally live life not chained to disease management.

*Taking a bolus 15 – 20 min before a meal helps to keep blood sugar levels under control after eating.

† Refers to auto correct, which provides bolus assistance. Can deliver all correction doses automatically without user interaction, feature can be turned on and off.

§ Refers to SmartGuard™ feature. Individual results may vary

** 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.

****Due to inherent real-world study limitations, caution is advised when attempting to extrapolate these results to new patients. There could be significant differences.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

References/citations superscripted above:

<https://scopeblog.stanford.edu/2014/05/08/new-research-keeps-diabetics-safer-during-sleep/>

Choudhary P. et al, Lancet Diabetes Endocrinol. 2022; [https://doi.org/10.1016/S2213-8587\(22\)00245-5](https://doi.org/10.1016/S2213-8587(22)00245-5)

Gabbay, M.A.L., Rodacki, M., Calliari, L.E. et al. Time in range: a new parameter to evaluate blood glucose control in patients with diabetes. Diabetol Metab Syndr 12, 22 (2020). <https://doi.org/10.1186/s13098-020-00529-z>

Foster NC, Beck RW, Miller KM, Clements MA, RickelsMR, DiMeglio LA, MaahsDM, TamborlaneWV, Bergenstal R, Smith E, Olson BA, Garg SK. State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016-2018. Diabetes Technol Ther. 2019 Feb;21(2):66-72. Doi: 10.1089/dia.2018.0384. Epub2019 Jan 18. Erratum in: Diabetes Technol Ther. 2019 Apr;21(4):230. PMID: 30657336; PMCID: PMC7061293.

https://www.who.int/health-topics/diabetes#tab=tab_1

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<https://www.linkedin.com/pulse/next-frontier-diabetes-que-thanh-dallara-wkire/?trackingId=fIT64ihHTK6ZNJ60dJUzVQ%3D%3D>

Other references:

Medtronic MiniMed™ 780G system website:

https://www.medtronicdiabetes.com/products/minimed-780g-insulin-pump-system?utm_source=google&utm_campaign=Pumps+-+BRAND+-+Core+-+Exact_fy24_pumps_asbly&utm_medium=cpc&gclid=CjwKCAjw69moBhBgEiwAUFCx2PkHtyf8FsgL5tEORVFCL48FWdrr_sNmD91oDYyF_HnSVZFA3EHlThoC37AQAvD_BwE&gclidsrc=aw.ds

Real World Performance:

<https://www.medtronic.com/content/dam/medtronic-com/us-en/hcp/therapies-conditions/diabetes/documents/mm780g-rwe.pdf>

ADAPT Study:

<https://news.medtronic.com/2022-09-01-Medtronic-ADAPT-study-results-published-in-The-Lancet-Diabetes-Endocrinology-show-improved-glycemic-control-and-treatment-satisfaction-among-those-using-MiniMed-TM-780G-system--compared-to-insulin-injections#:~:text=Additionally%2C%20the%20sensor%20was%20being,in%20fear%20of%20hypoglycemia3>.

Clinical Summaries:

<https://www.medtronic.com/content/dam/medtronic-com/us-en/hcp/therapies-conditions/diabetes/documents/mm780g-adapt-6m.pdf>

Initiating Pediatric Patients Directly from MDI:

<https://www.medtronic.com/content/dam/medtronic-com/us-en/hcp/therapies-conditions/diabetes/documents/mm780g-children-initiation-protocol.pdf>

References File Document upload:

N/A