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Medtronic launches first Smart MDI system in Europe for people who manage their diabetes with multiple insulin injections

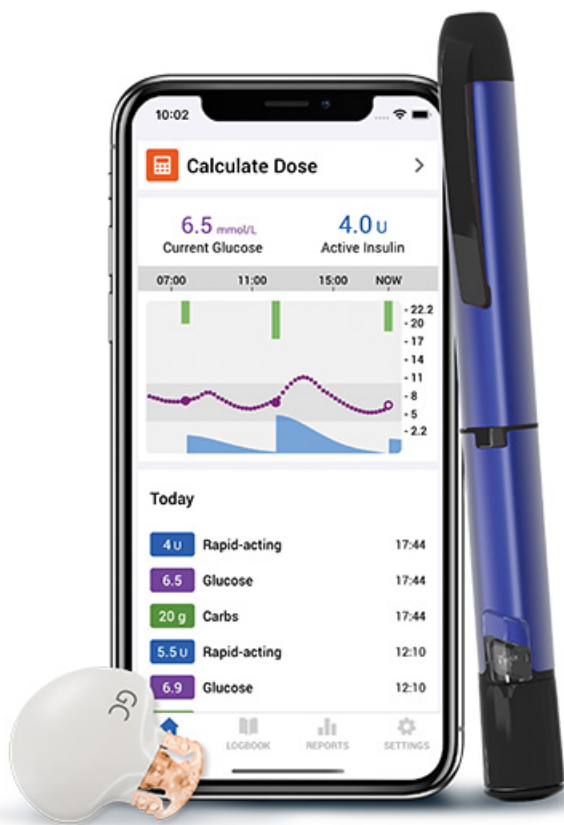
Combination of InPen™ smart insulin pen system integrated with Guardian™ 4 CGM helps people with diabetes on multiple daily injections (MDI) stay ahead of their glucose levels^{i,ii}

Today Medtronic announced the European launch of its Smart MDI system, which combines personalized insulin dosing information from the InPen™ smart insulin pen with the power of predictive glucose alerts from the Guardian™ 4 smart continuous glucose monitoring (CGM) system. This newest CGM system from Medtronic combines the power of real-time CGM with the convenience of no fingersticks^{iii,iv} for calibration or diabetes treatment decisions. The InPen™ system is the first smart insulin pen approved in Europe that's integrated with real-time^v CGM via one convenient smartphone app.

The Smart MDI system automatically^{vi} records real-time glucose values and trends, insulin doses, tracks active insulin, and recommends mealtime and correction doses based on an auto-populated bolus calculator, giving people on MDI everything they need to manage their diabetes in one place. Rather than switching between apps, users can see all their information in real-time, in one view – making it easier to make smarter dosing decisions to manage their glucose levels. Combined insulin dose and glucose reports can be easily shared with care partners and healthcare professionals as well.

“For most people who inject insulin multiple times a day to manage their diabetes, the burden of constant mental decisions impacts their health and lifestyle”, says Dr. Ohad Cohen, Sr. Medical Affairs Director for Medtronic Diabetes in Europe and Professor of Medicine at Sheba Medical Center, Israel. “And we know that not all patients are ready to use an automated insulin delivery system. I am confident this system will lead to more informed dosing decisions and reduce the burden of diabetes management for many people looking to improve their glycemic control while not compromising on their lifestyle.”

In June 2021, Medtronic presented real-world clinical results that compared glycemic outcomes for 1,736 individuals before and after using the InPen smart insulin pen for 90 days with a glucose monitor (CGM). Data showed an increase in Time in Range of 2.3% for people whose glucose management indicator (GMI) was >8% and an increase of 5% Time in Range for people whose Glucose Management Indicator (GMI) was >9.5%. In both



groups, people did not experience any increase in Time Below Range (TBR)^{vii} (hypoglycemia) during the study period.

Definitions

Smart MDI - For people who manage their diabetes with multiple insulin injections, Smart MDI (multiple daily injections) therapy is intended to relieve the physical and mental effort required to manage diabetes, by using an ecosystem of smart-enabled technology to increase patient compliance and adherence. Medtronic Diabetes Smart MDI system is a combination of smart-enabled diabetes management tools that seamlessly work together to provide real-time insights and cumulative reports. The combination is made up of the following devices:

- Smart CGM (Guardian™ 4 system)
- Smart insulin pen (InPen™ system)

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^{viii}. This may increase the likelihood that short and long-term complications of this chronic disease can be avoided^{ix}.

Glucose Management Indicator (GMI) - GMI mirrors the A1C level expected based on average glucose measured using continuous glucose monitoring (CGM) values.

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.

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ⁱ Abraham SB, et al. Improved Real-World Glycemic Control with Continuous Glucose Monitoring System Predictive Alerts. Journal of Diabetes Science and Technology 2021; 15(1):91-97

ⁱⁱ Smith M, et al, E5, SIPs Improve Time Below Range in MDI Therapy, AMCP Congress 2020

ⁱⁱⁱ If CGM readings do not match SG or expectations, use a blood glucose meter to make diabetes treatment decisions. Refer to System User Guide.

^{iv} The Smart MDI system uses the Guardian™ 4 CGM in Europe; this product and its labeling is currently under review in the U.S. with investigational use only status.

^v Data may not appear or be delayed in certain instances, including when there is no internet connection. Use a blood glucose meter to make diabetes treatment decisions.

^{vi} Some User interactions are needed.

^{vii} Time Below Range is the percent of time spent below 70 mg/dl.

^{viii} Battelino T, et al. Diabetes Care 2019; 42(8): 1593-1603.

^{ix} Bellido V, et al. Diabetes Res Clin Pract 2021; Jul 177:108917.

<https://news.medtronic.com/Medtronic-launches-first-Smart-MDI-system-in-Europe-for-people-who-manage-their-diabetes-with-multiple-insulin-injections>