



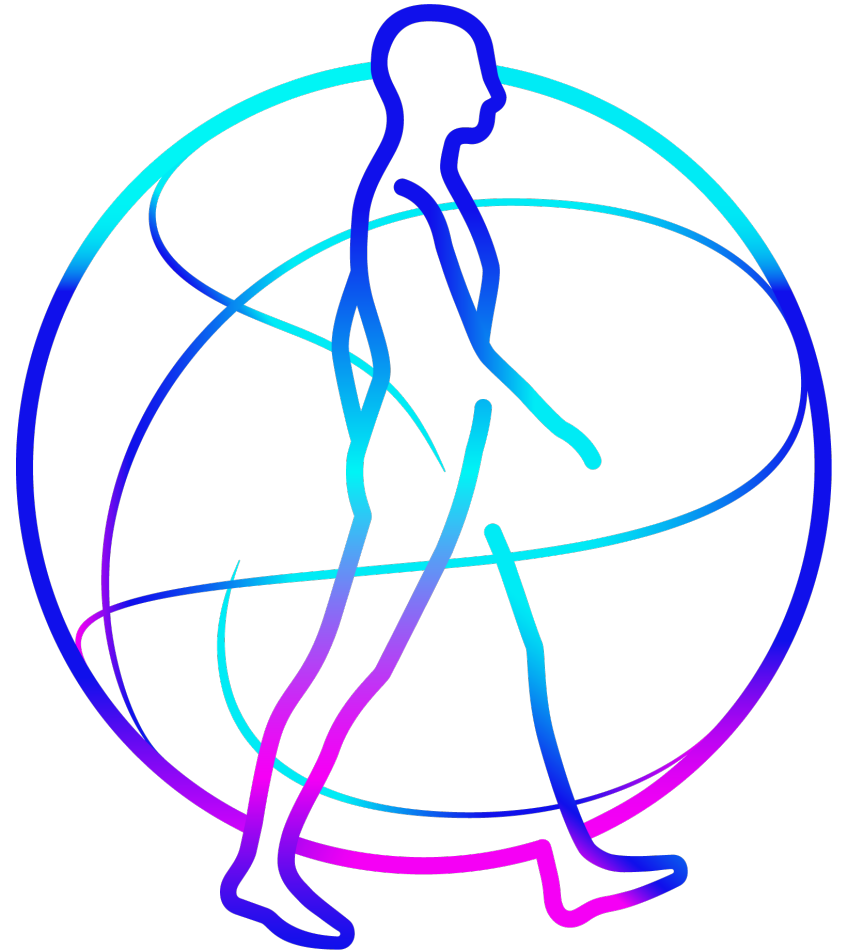
Engineering the extraordinary

Medicare Evidence Development and Coverage Advisory Committee:

Devices for Self-Management of Type 1 and Insulin-Dependent Type 2 Diabetes

May 21, 2024

Robert Vigersky, MD
Chief Medical Officer, Global Medical & Clinical Affairs
Medtronic Diabetes



Disclosures

Robert Vigersky, MD

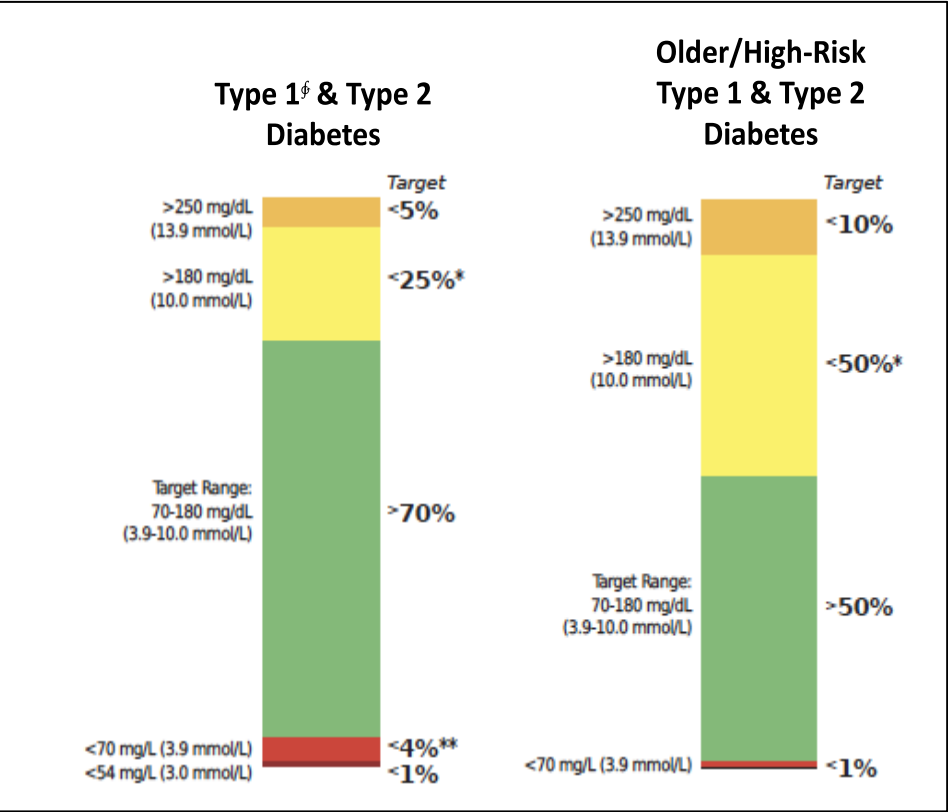
- Employee and shareholder of Medtronic (major)

Devices for Self-Management of Type 1 and Insulin-Dependent Type 2 Diabetes

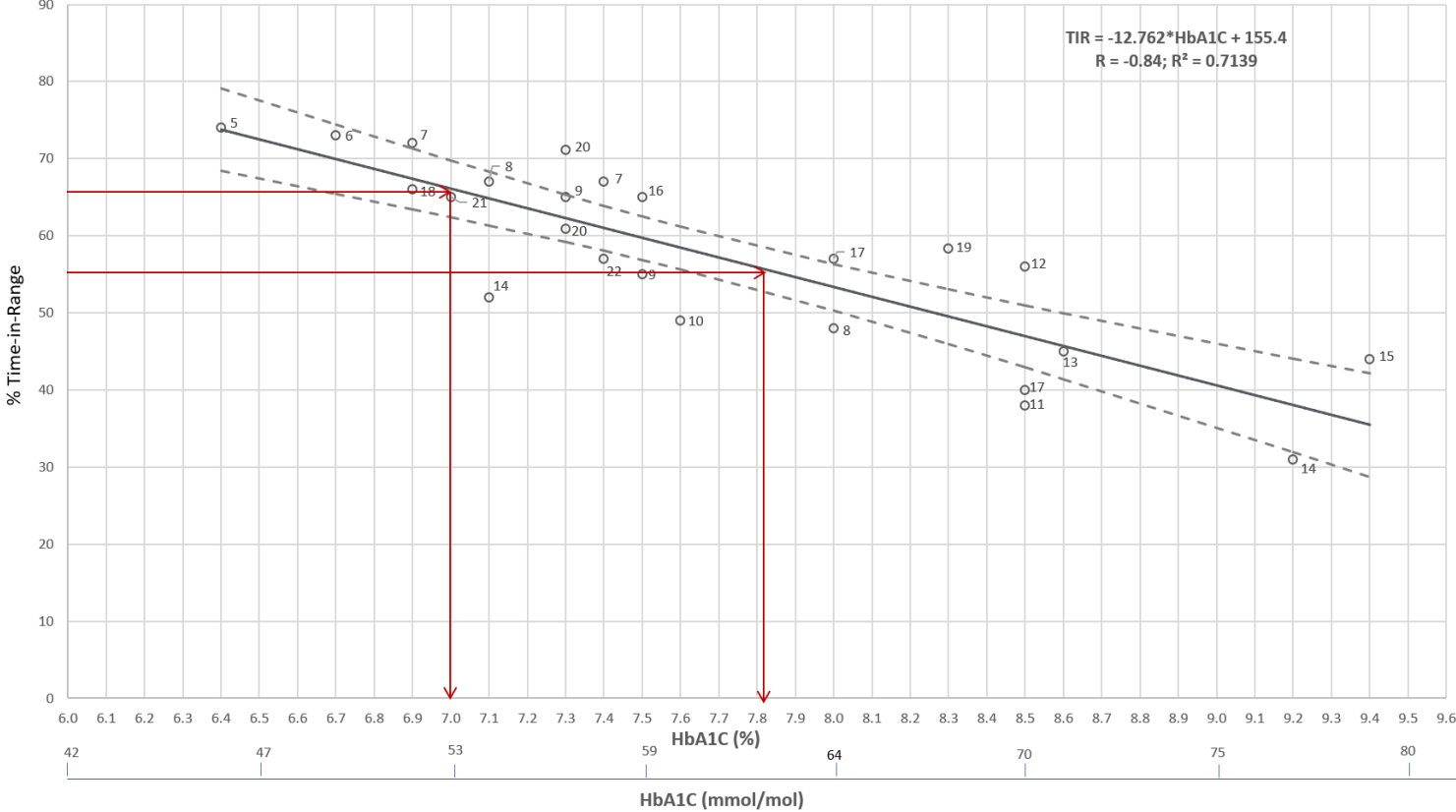
- Strong evidence base (comprised of both clinical and real world data) for these technologies has led to strong support and acceptance among the medical community, as reflected in significant updates to consensus statements and clinical practice guidelines in recent years
- Medtronic recognizes the importance of identifying the most appropriate endpoints for purposes of evaluating coverage specifically for patients with T1D and insulin-dependent T2D in the Medicare population, and supports the categorization and endpoint domains identified in the CER and for this MEDCAC
- The most important, impactful, and measurable endpoints are those categorized in the surrogate marker domain – i.e., HbA1C in addition to CGM-derived endpoints, particularly time in range (TIR)
 - TIR is a measure of the percentage of time a person spends in the internationally accepted consensus and ADA standard target glucose range between 70-180 mg/dL while reducing time spent in hypoglycemia
 - TIR is accurately, readily, and continuously captured by existing digital technology, in contrast to HbA1C, which is lab-derived on an interval-basis
- The effectiveness of device-based therapies is best captured using a composite endpoint comprised of TIR without exceeding the goals for time below range (TBR) as the gold standard surrogate now and into the future, for the following reasons:
 - Validated correlation between TIR and HbA1C
 - TIR is highly correlated with specific diabetes-related complications (e.g., retinopathy, peripheral neuropathy)

1st and 2nd International Consensus Report on CGM Recommends and ADA Endorses:

Target = 70-180 mg/dL; Time spent between 70-180 mg/dL per day >70% and >50% for Older/High Risk Persons¹



The relationship between Time in Range and A1c²



1. Battelino T, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range Diabetes Care 2019;42(8): 1593-1603.
2. Vigersky R, et al. Diabetes Technol Ther. 2019;21(2):81.85

Case Study

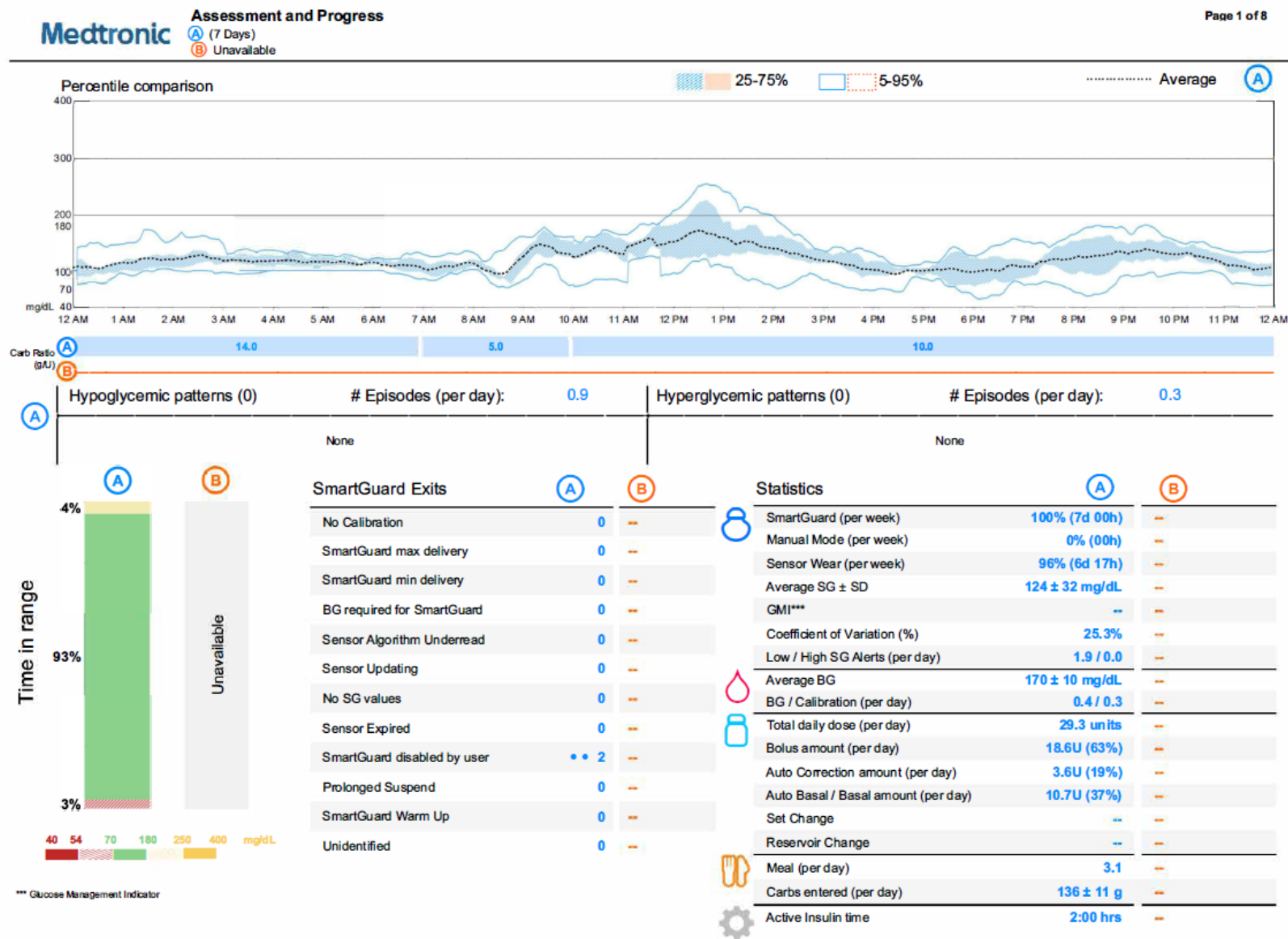
Case Details

Age: 69

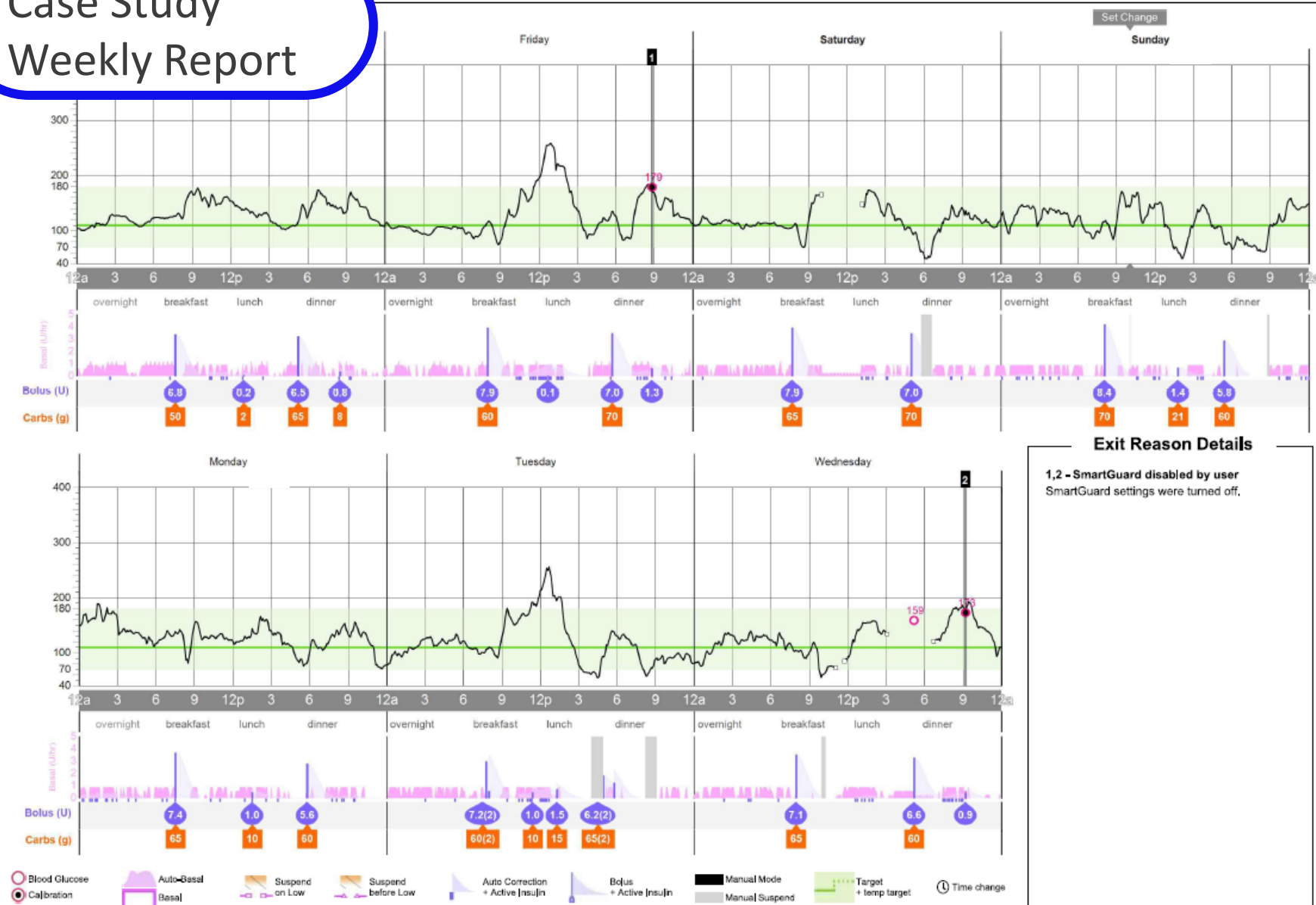
Years with diabetes: 58

A1C: 6.3%

- Averaging 16% TBR on non-automated insulin delivery pump
- Transitioned to the MiniMed™ 780G system
- Excellent TIR of 93% on 780G but TBR of 3% may still be too high for age
- Weekly and daily reports provide information for recommendations on settings and behavior changes



Case Study Weekly Report



Exit Reason Details

1,2 - SmartGuard disabled by user
SmartGuard settings were turned off.

Observations

- TIR is good but there are too many lows
- User is disabling SmartGuard™ to deliver boluses
- May be entering “fake carbs”

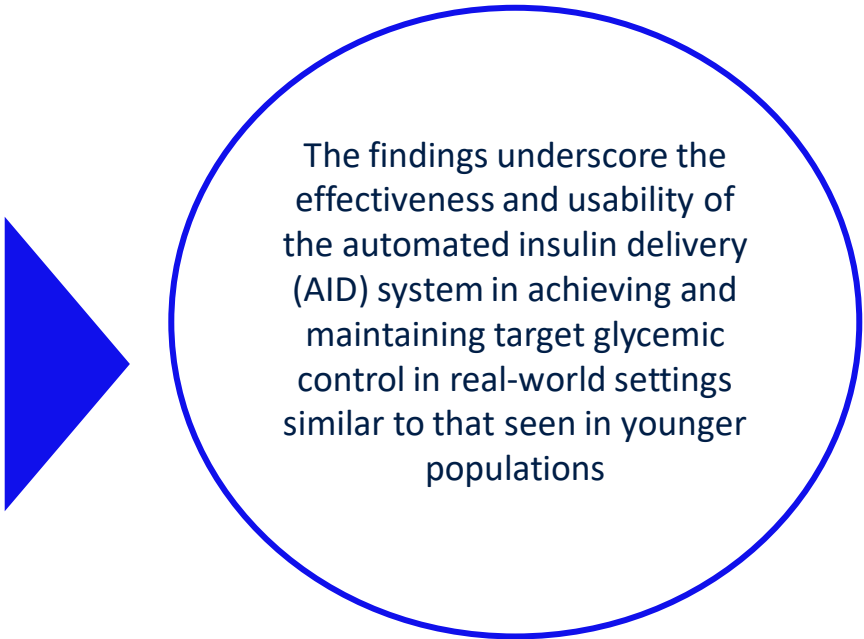
Real-World Data on MiniMed™ 780G System and Glycemic Outcomes for Age 65+ Users with CGM-Derived Targets

N=5,394

A significant proportion of older individuals met international targets:

- 84.1% had a TIR >70%
- 95.8% maintained a TBR70 <4%
- 97.1% kept TBR54 <1%
- 74.0% had a TAR180 <25%
- 79.3% had a TAR250 <5%

Category	Real-world data from US ²
	MiniMed™ 780G System (Age 65 Years and Older)
Number of subjects	5,394
Average TIR (70–180 mg/dL) ¹	79.6%
TIR (70–180 mg/dL) >70% ¹	84.1%
TBR70 (<70 mg/dL) <4% ¹	95.8%
TBR54 (<54 mg/dL) <1% ¹	97.1%
TAR180 (>180 mg/dL) <25% ¹	74.0%
TAR250 (>250 mg/dL) <5% ¹	79.3%



1. Battelino T, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range Diabetes Care 2019; 42(8): 1593-1603.
2. Medtronic data on file; June 2023-November 2023.