Insulet

Omnipod® 5 Competitive Clinical Performance

May, 2026

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For a further list and description of these and other important risks and uncertainties that may affect the Company's future operations, see Part I, Item 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which the Company may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q the Company has filed or will file hereafter. Any forward-looking statement made in this release speaks only as of the date of this release. Insulet does not undertake to update any forward-looking statement, other than as required by law.

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Executive summary

The 2026 American Diabetes Association Standards of Care[1] make it clear: Automated Insulin Delivery (AID) is no longer optional – it is the preferred approach for insulin delivery in both type 1 and type 2 diabetes

- Diabetes is a chronic, progressive disease characterized by either absolute or partial insulin deficiency, leading to various degrees of glycemic variability (hyper and hypoglycemia), impacting overall health and management burden
- Omnipod 5 robust evidence has helped shape ADA guidelines

Context is critical when evaluating AID system performance. Omnipod 5 demonstrates competitive clinical results.

- No head-to-head trials exist
- CGM-measured TIR alone is an incomplete performance metric
- Change in glycemic status (e.g., change in HbA1c/TIR) is the standard for assessing a treatment effect in diabetes. Study population differences in baseline glycemic levels impact results achieved.
- Omnipod 5 is designed for individualized care across the age spectrum and allows for personalized glucose targets. Optimized settings help achieve tighter glucose control.

Across a comprehensive body of evidence, Omnipod 5 demonstrates strong, competitive clinical performance in a broad and representative population

1. American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2026.

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Background

Diabetes is complex. Its management requires stabilizing blood glucose levels, through innovative insulin delivery.

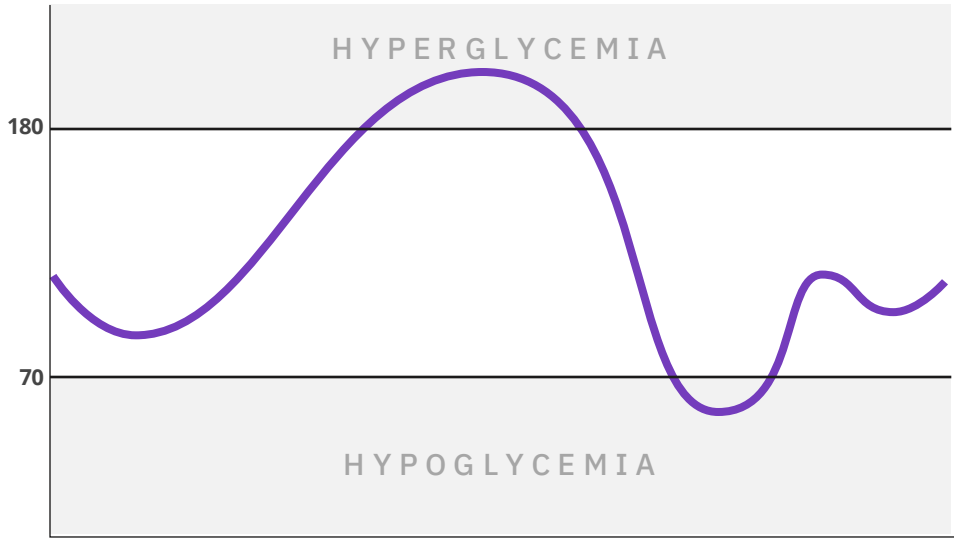
Type 1

The body attacks beta cells resulting in cell death and the need for exogenous insulin, as a form of replacement therapy. Glucose variability (high and low glucose levels) is high.

Type 2

Is characterized by insulin resistance and progressive decline in endogenous insulin production. Residual insulin production attenuates glucose variability (high and low glucose levels). There are multiple treatment options, including insulin treatment.

Illustrative Glucose Profile



Hyperglycemia

Occurs when the body has insufficient insulin, cannot use insulin effectively, or both, leading to glucose building up in the bloodstream instead of being absorbed by cells for energy. Sustained hyperglycemia is linked to complications.

Hypoglycemia

Occurs when the body has insufficient glucose in the blood. Low blood glucose can impair normal bodily and mental functions, quality of life, and in severe cases be life-threatening.

Hypoglycemia in diabetes often results from treatment (sulfonylureas, insulin). Novel approaches to diabetes management, like AID, allow for improved glycemic control without increased hypoglycemia risk, leading to lower glycemic variability

For illustrative purposes

Adapted from Handbook of diabetes, 4th edition. Bilous R, Donnelly R.

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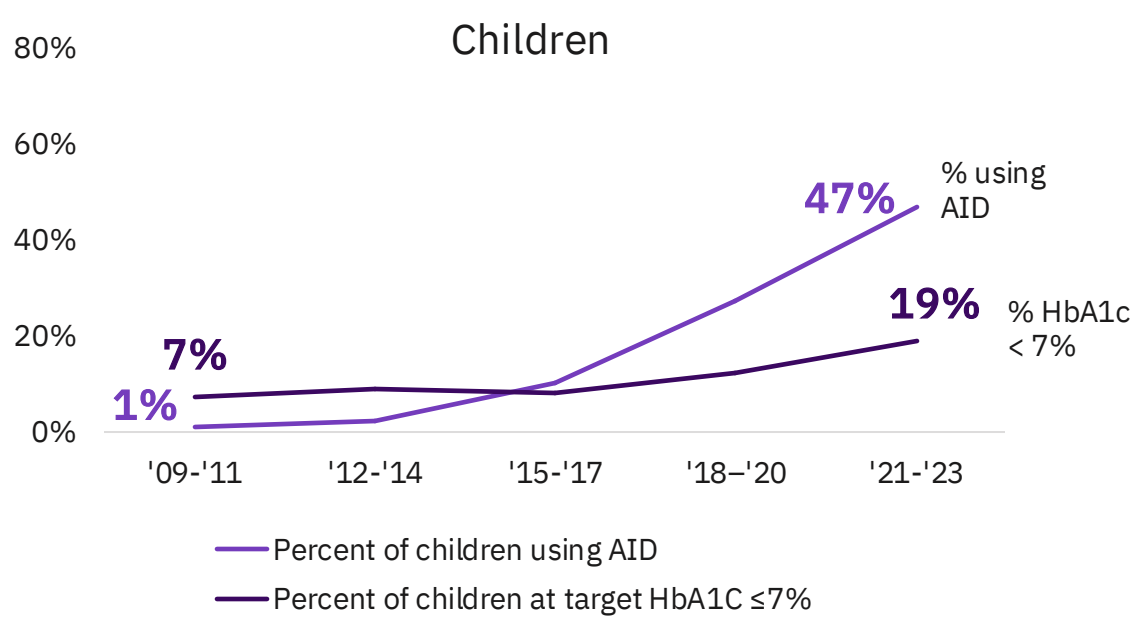
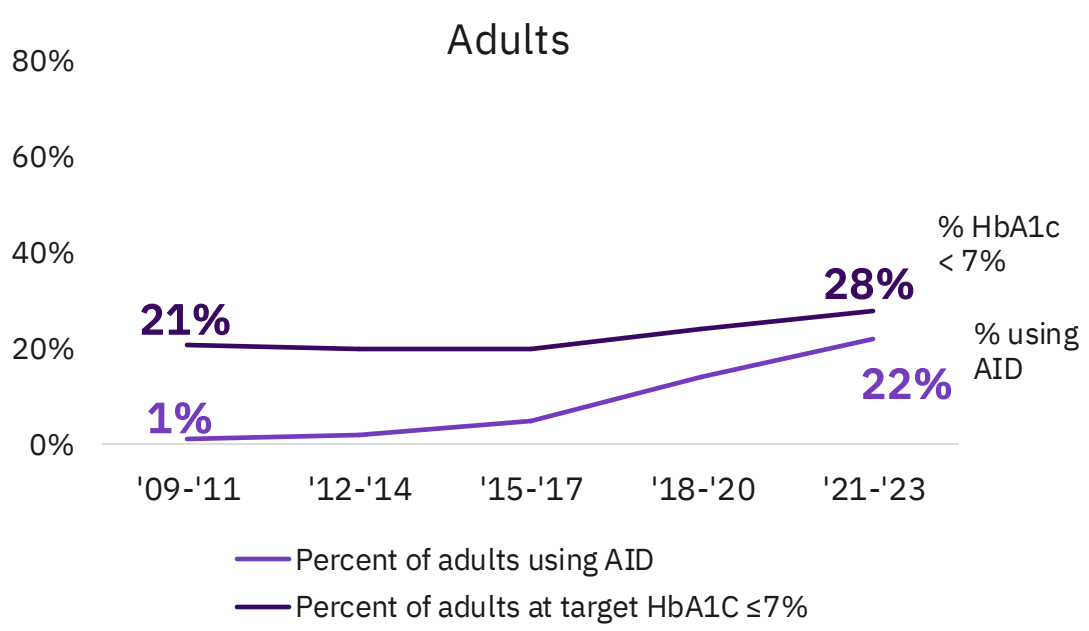
Guidelines recognize AID as standard of care for people with T1 and T2 diabetes, yet AID adoption lags behind

2026 American Diabetes Association (ADA) guidelines endorse Automated Insulin Delivery systems as the preferred insulin delivery method for T1D and insulin-treated T2D[1]

Only 47% of children and 22% of adults with T1D are using AID. Most people with diabetes are not achieving goals.[2]





1. American Diabetes Association Professional Practice Committee. *Diabetes Care*. 2026. **2.** Adapted from: Fang M, et al. *JAMA Netw Open.* 2025;8(8):e2526353.

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AID Landscape: Omnipod 5 & Other Manufacturers

Evaluating AID performance: The importance of context

No head-to-head trials exist with AIDs

- Reported differences across AID systems are based on indirect comparisons in different populations, not randomized head-to-head (H2H) studies
- In the absence of H2H studies, indirect comparisons can play a role, acknowledging certain limitations

CGM-measured Time in Range (TIR) alone is an incomplete performance metric

- AID performance should be assessed using both HbA1c and TIR
- Differences in CGM accuracy can over- or under-estimate TIR, complicating cross-study comparisons

Study populations differ and baseline glycemic status matters

- Change in glycemic status (e.g., HbA1c reduction) is the standard for assessing treatment effect in diabetes
- End-of-study TIR is strongly driven by baseline glycemic control—populations starting with higher TIR (e.g., 75%) will predictably end with higher TIR (e.g., >80%). TIR alone should not be interpreted in isolation.
- Use of both, **change** in HbA1c (and TIR), and **end-of-study** values, are needed to assess treatment effects

Omnipod 5 is designed for individualized care across the age spectrum and allows for personalized glucose targets

- Preference for higher average glucose levels (with higher glucose targets) can be a choice in individualized care and prioritization of hypoglycemia avoidance
- For tighter glycemic control, selection of optimized settings is associated with a TIR of 80%, with hypoglycemia remaining low

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CGM-measured Time in Range (TIR) alone is an incomplete performance metric. HbA1c is needed to complement the assessment of glycemic control.

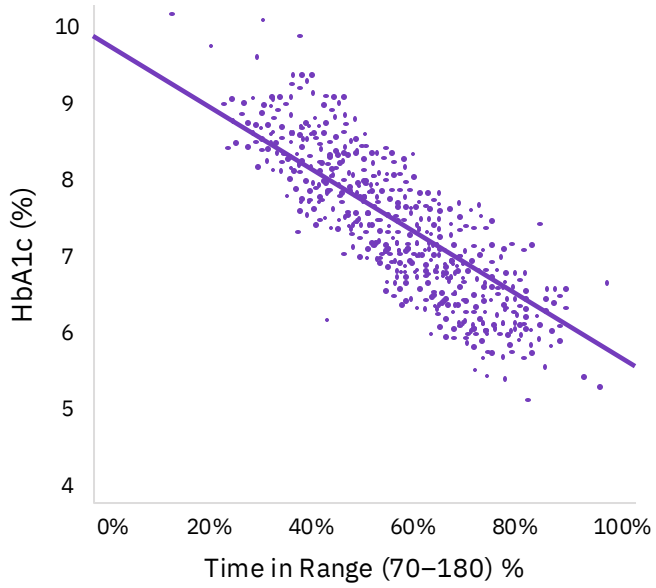
HbA1c

Measures how blood glucose is on average, looking over a 3-month period. It remains the diagnostic standard for assessing population-level health and predicts long-term complication risk.

TIR

Measures how often blood glucose is between 70–180 mg/dL and provides insight into variability. The measurement relies on CGM's sensor accuracy and provides people with diabetes and health care providers with day-to-day management insights.

HbA1c and CGM-measured Time in Range are strongly correlated



There is a high correlation between HbA1C and TIR.

Studies have shown **TIR of 65% to 70% is estimated to be a HbA1c of approximately 7.0%** which is the ADA target for diabetes management.[1-4]

At a population level the metrics are consistent with each other.

Discordant HbA1c and TIR values could signal CGM inaccuracy issues.

1. Beck RW et al. The relationship between time in range, hyperglycemia metrics and HbA1c. *Journal of Diabetes Science and Technology* 2019, Vol. 13(4) 614-626
2. Eliasson B et al. Associations Between HbA1c and Glucose Time in Range Using Continuous Glucose Monitoring in Type 1 Diabetes: Cross-Sectional Population-Based Study. *Diabetes Ther.* 2024, Vol. 15(6) 1301-1312
3. Vigersky RA et al. The Relationship of Hemoglobin A1C to Time-in-Range in Patients with Diabetes. *Diabetes Technol. Ther.* 2019, Vol. 21 (2) 81-85
4. Burckhardt MA et al. What is the Relationship Between Time in Range, Time in Tight Range, and HbA1c in Youth and Young Adults With Type 1 Diabetes? Results From the German/Austrian/Luxembourgian/Swiss Diabetes Prospective Follow-Up Registry. *J Diabetes Sci Technol.* 2024

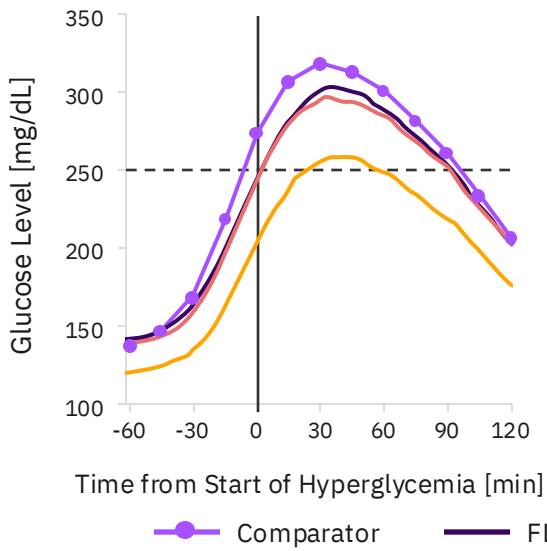
Different CGMs used across AID studies have different accuracy, which limits comparisons across systems

"Simplera showed better glucose control… compared with the other two. This could lead to **misleading** conclusions and potentially **misguided** therapy advice."

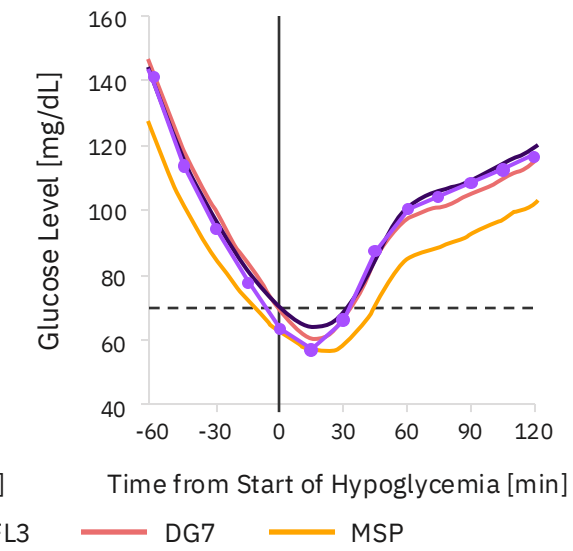
– Dr. Guido Freckmann

Simplera consistently under-read during hyperglycemia

CGM Profile During Hyperglycemia Episode

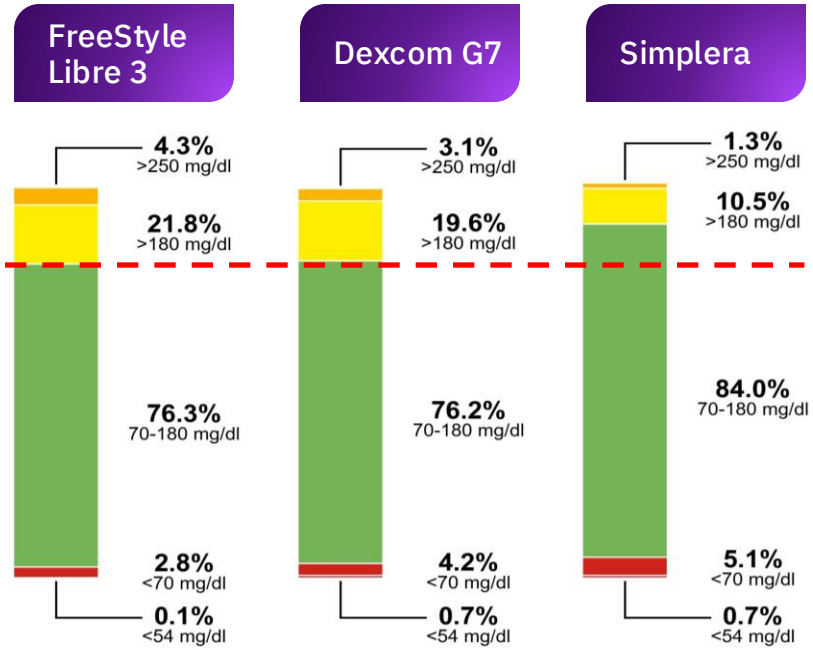


CGM Profile During Hypoglycemia Episode



Comparator FL3 DG7 MSP

Simplera overestimated TIR by 8% compared to FSL3 and G7 when all 3 CGMs worn by SAME patient

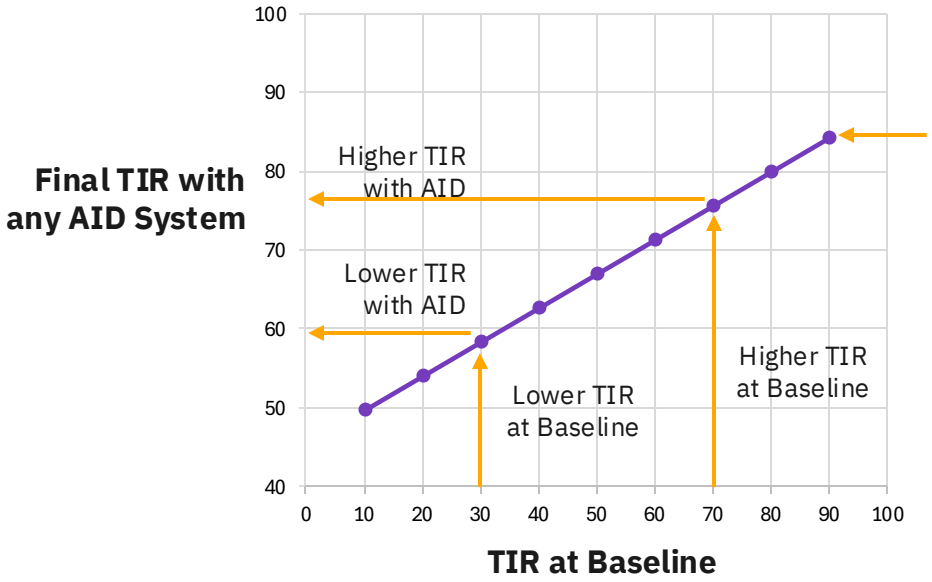


Freckmann G et al. *Diabetes Care*. 2025;48(00):1–5. Twenty-three adults with T1D wore all three sensors in parallel for 15 days.

Baseline glycemic status matters: end of study TIR in AID studies directly correlate with TIR at baseline

Baseline imbalance can distort headline comparisons across studies

- Populations with better glycemic control at baseline (lower HbA1c, or higher TIR, e.g., 75%), will predictably report higher absolute results (e.g., TIR 80% at end of study), even with similar or smaller treatment effects (change from baseline)



Strong relationship between baseline TIR and final TIR for all AID systems[1,2,3]

Omnipod 5:
"The clearest predictor of improved TIR (and HbA1c) was prior low TIR (high HbA1c) and this is in line with prior AID studies focused on individuals with high baseline HbA1c."
– Stimson, et al.[3]

Control-IQ:
"Higher baseline TIR is the strongest predictor of TIR on CLC in children with T1D."
– Schoelwer, et al.[1]

Minimed 780G:
"There was a strong correlation between baseline TIR and TIR post-AHCL indicating that those with higher TIR at baseline tended to have higher TIR post-AHCL."
– Castañeda, et al.[2]

1. Schoelwer et al. Predictors of Time-in-Range (70-180 mg/dL) Achieved Using a Closed-Loop Control System. *DTT*. 2021;23(7):475–81. **2.** Castañeda et al. Predictors of time in target glucose range in real-world users of the MiniMed 780G system. *Diabetes Obes Metab*. 2022;24(11):2212–21. **3.** Stimson, et al. Impact of Omnipod 5 automated insulin delivery on continuous glucose monitoring metrics and predictors of improvement in time in range. *Diabet Med*. 2025;42:e70137.

Independent T1D real-world studies demonstrated strong Omnipod 5 performance within the same clinic population

Omnipod 5 achieved same HbA1c as other AIDs and similar TIR vs. Control-IQ. There is discrepant TIR & HbA1c results between 780G and other AIDs.

It is lower HbA1c that has been proven to reduce risk of long-term complications[1] and thus what is ultimately most important to compare.

	Henry 2023[2]		Piona 2024[3]		Folk 2025[4]		Gera 2025[5]		Khan 2026[6]			Pavlou 2026[7]	
Study Population	T1D adults & adolescents (N=231)		T1D children/youth (N=613)		T1D adults (N=176)		T1D youth (N=428)		T1D adults (N=213)			T1D adults (N=129)	
Study Arms	**780G** (n=167)	**CIQ** (n=64)	**780G** (n=329)	**CIQ** (n=284)	**OP5** (n=52)	**CIQ** (n=67)	**OP5** (n=214)	**CIQ** (n=214)	**OP5** (n=94)	**CIQ** (n=81)	**780G** (n=38)	**OP5** (n=81)	**780G** (n=48)
Final TIR, %	74†	65	75†	68	68	67	64	62	68	67	73	60	72†
Final HbA1c (change), %	**7.1** (-0.8)	**7.0** (-0.6)	**6.9**	**6.7**	**6.8** (-0.55)	**7.0** (-0.6)	–	–	–	–	–	**7.6** (-0.9)	**7.6** (-0.8)

†TIR inconsistent with HbA1c

1. Diabetes Control and Complications Trial Research Group, et al. N Engl J Med. 1993;329(14):977–86. **2.** Henry Z, et al. *Diabetes Obes Metab*. 2024;26(2):557–66. **3.** Piona C, et al. *Diabetes Obes Metab*. 2024;26(10):4767–71. **4.** Folk S, et al. *J Diabetes Sci Technol*. 2025;19(5):1374–84. **5.** Gera S, et al. *J Clin Endocrinol Metab*. 2025;110(10):e3472–e81. **6.** Khan MS, et al. *Diabet Med*. 2026;43(5):e70251. **7.** Pavlou P, et al. *Diabetes Obes Metab*. 2026;28(4):3424–8.

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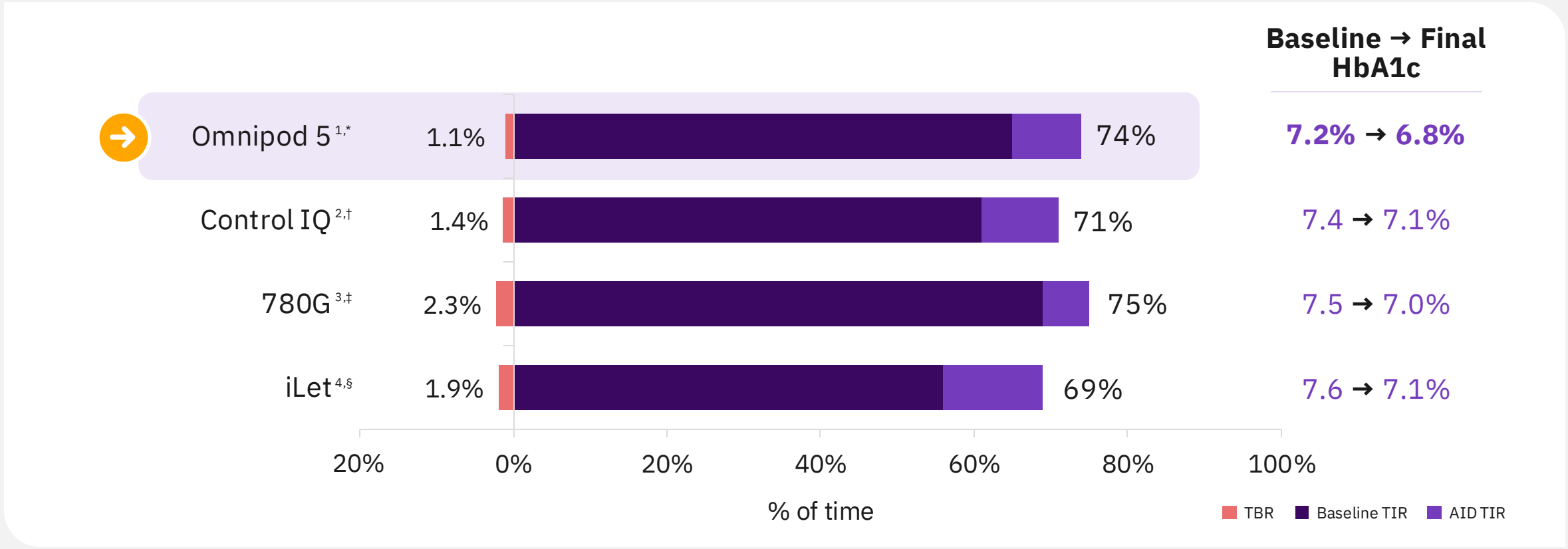
In the absence of head-to-head trials, assessing T1D pivotal studies with similar populations is relevant. Omnipod 5 performs favorably in TIR and HbA1c, with low hypoglycemia.



Results from pivotal trials.
*14-70 years old. †14-71 years old. ‡14-75 years old. §18-79 years old.
Data shown as mean (TIR, A1C) or median (TBR). TBR outcomes with 780G are reported as mean. AID outcomes assessed over 6 months (Control-IQ) or 3 months (all others).
1. Brown SA, et al. *Diabetes Care.* 2021;44(7):1630-1640. **2.** Brown SA, et al. *N Engl J Med.* 2019;381(18):1707-1717. **3.** Carlson AL, et al. *Diabetes Technol Ther.* 2022;24(3):178-189. **4.** Kruger D, et al. *Diabetes Technol Ther.* 2022;24(10):697-711.

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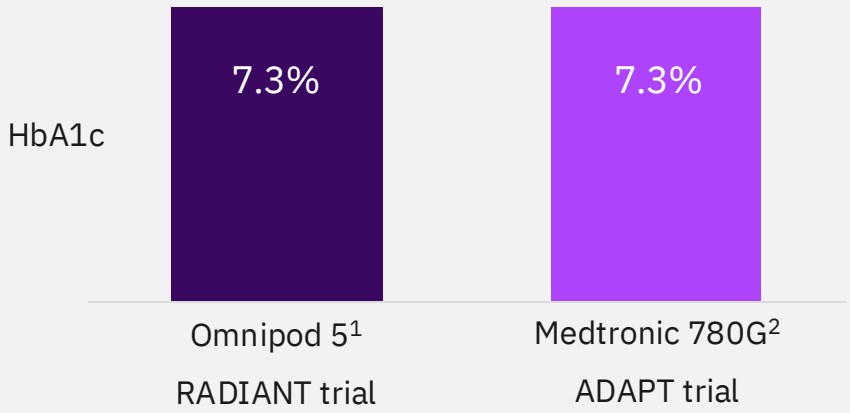
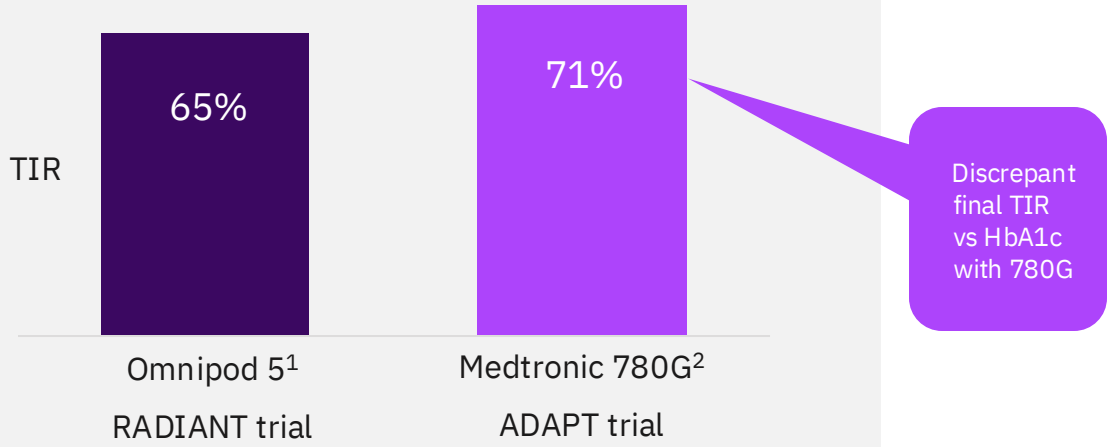
In two randomized controlled trials of AID vs. MDI in T1D, Omnipod 5 and 780G achieved same HbA1c, but TIR is discordant and reported 6% higher with Medtronic sensor

Both studies were in populations with high baseline HbA1c

Final HbA1c achieved by adults with T1D is identical in both studies



Final TIR of 780G is inconsistent with HbA1c



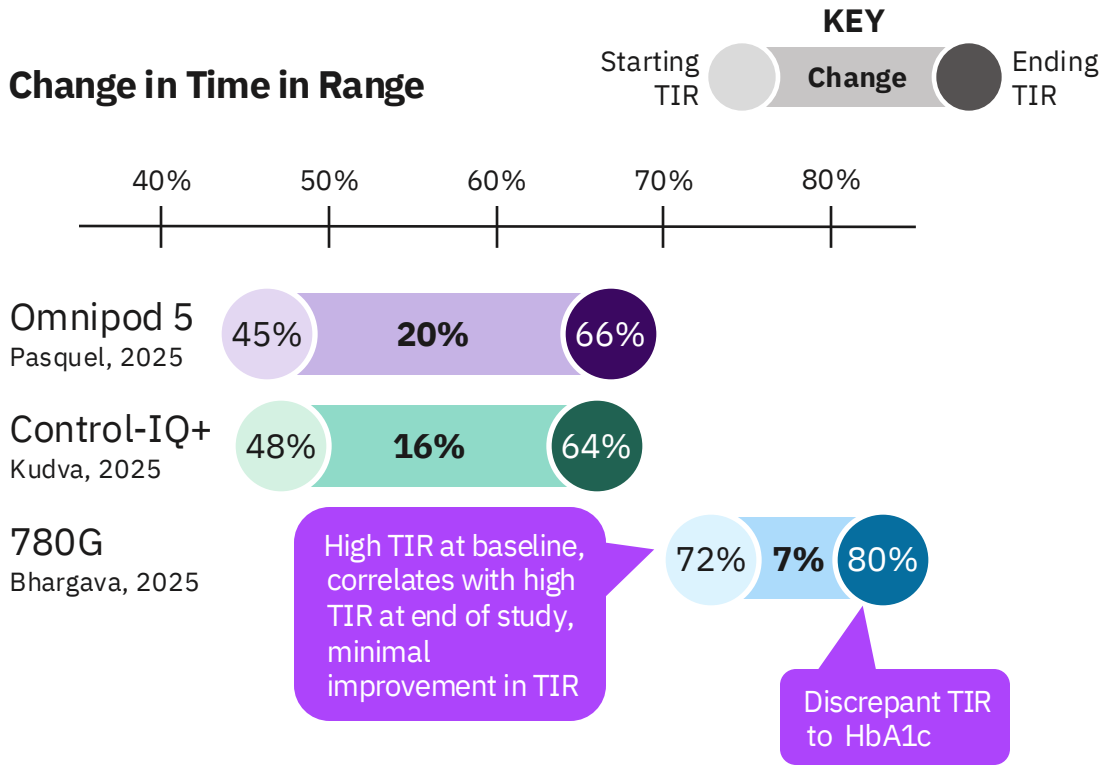
1. Wilmot E, et al. *Lancet D&E*. 2026;14(4):305–16. **2.** Choudhary P, et al. *Lancet Diabetes Endocrinology*. 2022; 10: 720–31.

Omnipod 5 shows competitive results in glycemic improvement alongside a larger reduction in insulin in a representative population

Insulet's trial enrolled a more racially diverse cohort, reflective of the T2D population, and delivered the largest TIR improvement—a differentiation validated by a recent type 2 diabetes meta-analysis[4]

	Omnipod 5[1]	Medtronic 780G[2]	Control-IQ+[3]
	Adults (18 yr+)		
HbA1c	**-0.8%** 8.2% / 7.4%	**-0.7%** 7.9% / 7.2%	**-0.9%** 8.2% / 7.3%
TIR	**+20%** 45% / 66%	**+7%** 72% / 80%	**+16%** 48% / 64%
TDI change in units	**-23 U** 80 / 57	**+14 U** 77 / 92	**-8 U** 95 / 87
Weight change, kg	**+0.8** 99.7 / 100.4	**+1.0** 105.8 / 107.3	**+2.6** 100.5 / 103.1
Minority Race	**~50%**	**~20%**	**~40%**

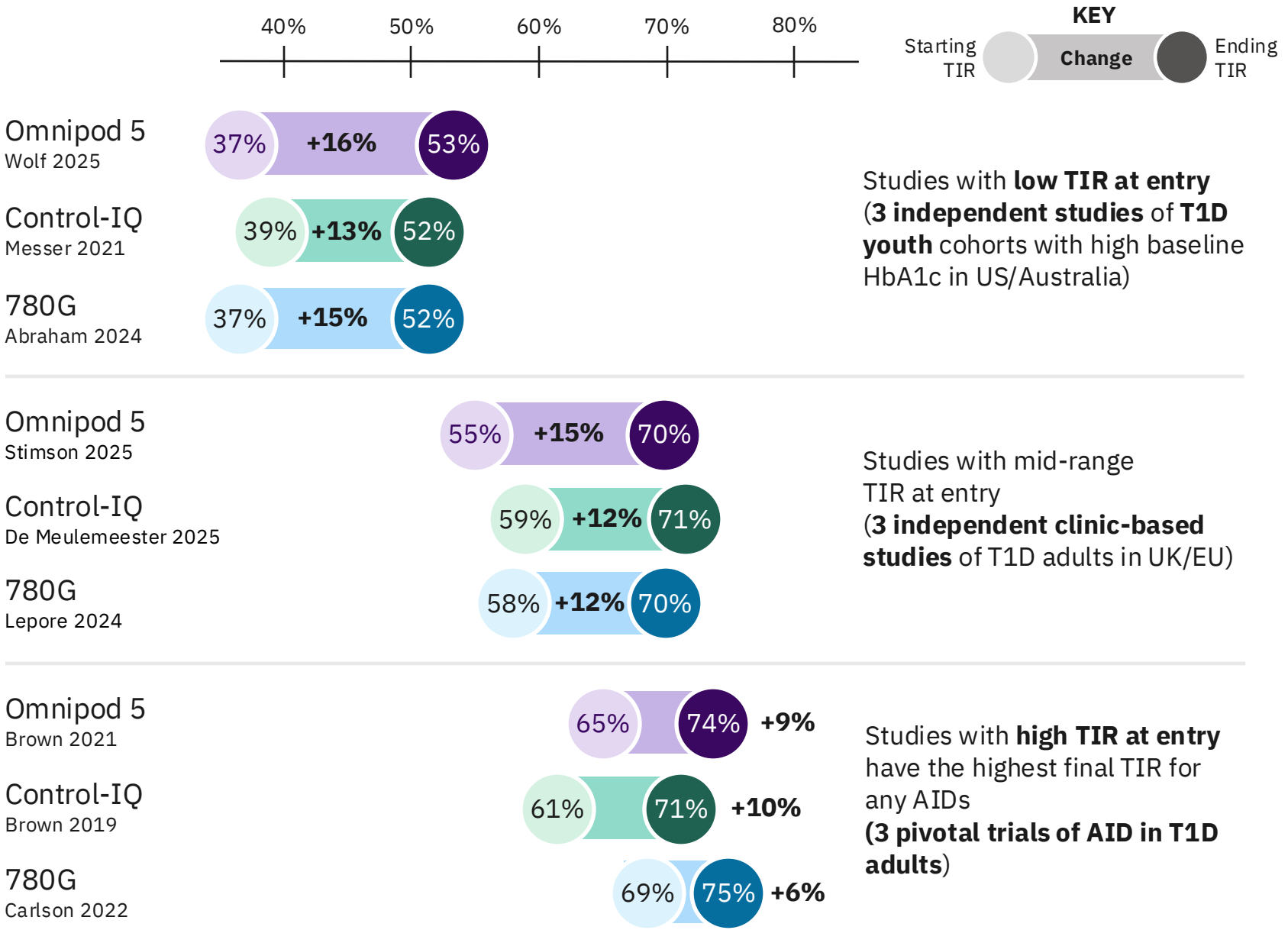
Except for race, data are change, followed by baseline / end of study values with the HCL study arm. All results are mean. Discrepancies in change are due to rounding.



1. Pasquel. *JAMA Network Open*. 2025; 8(2):e2459348. Omnipod 5 pivotal ages 18-75 yrs. **2.** Bhargava. *Diab Tech & Ther*. 2025;27(5):366–75. 780G Pivotal trial ages 18-80 yrs. **3.** Kudva. *N Engl J Med*. 2025 May 8;392(18):1801-1812. Control-IQ pivotal trial ages ≥ 18 yrs. 4. Hespanhol LC, et al. Diabetes Care. 2026. Online ahead of print.

AID system performance is consistent

Starting point TIR shapes final results



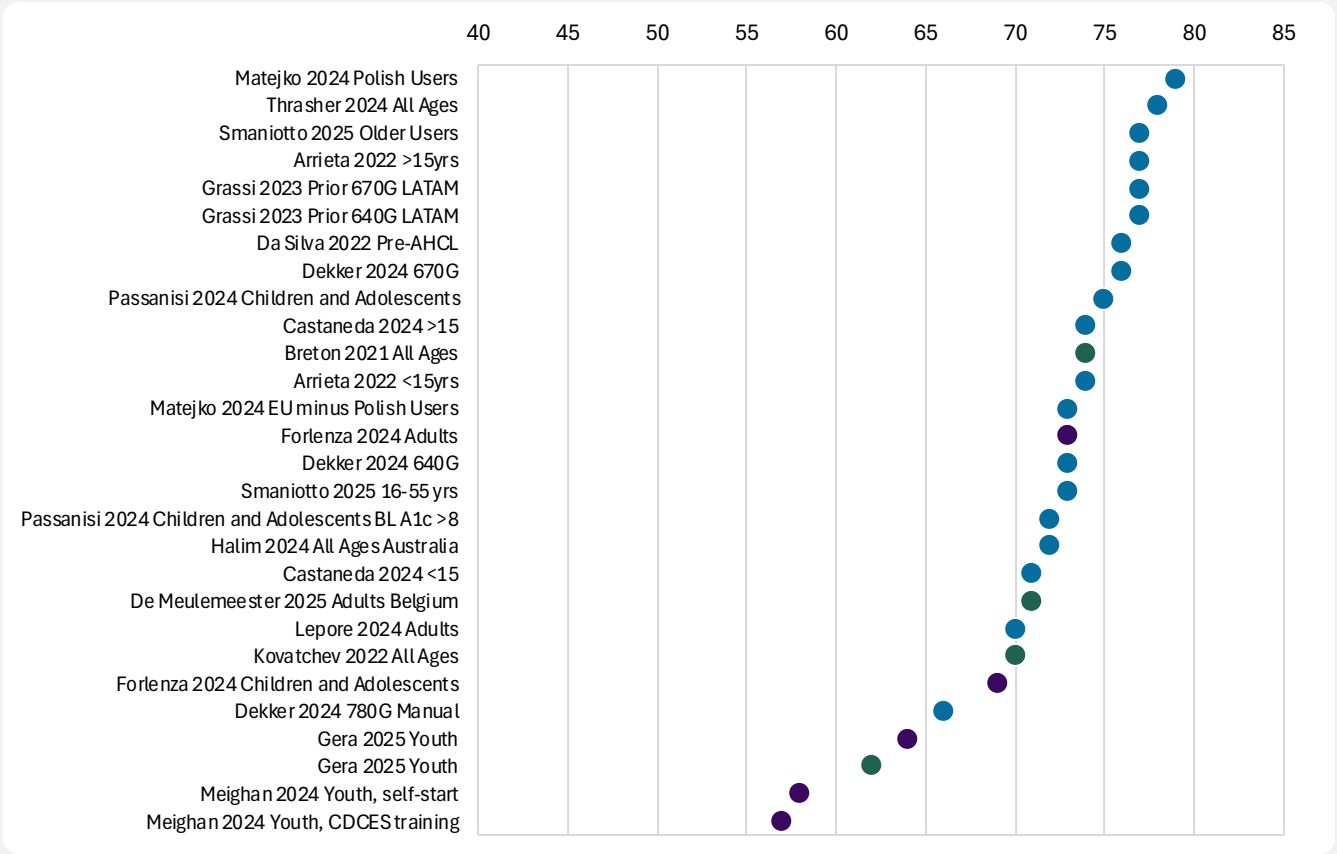
Wolf RM, et al. *DTT*. 2025;27(6):469–78.
Messer LH, et al. *DTT*. 2021;23(12):837–43.
Abraham MB, et al. *Diabetes Care*. 2025;48(1):67–75.
Stimson RH, et al. *Diabet Med*. 2025;42(3):e15465.
De Meulemeester J, et al. *Diabetologia*. 2025;68(5):948–60.
Lepore G, et al. *DTT*. 2024;26(1):49–58.
Brown SA, et al. *N Engl J Med*. 2019;381(18):1707–17.
Brown SA, et al. *Diabetes Care*. 2021;44(7):1630–40.
Carlson AL, et al. *DTT*. 2022;24(3):178–89.

A recent meta-analysis highlights the importance of evaluating change in TIR when assessing therapy benefit. A single TIR value alone can be misleading, due to population differences.

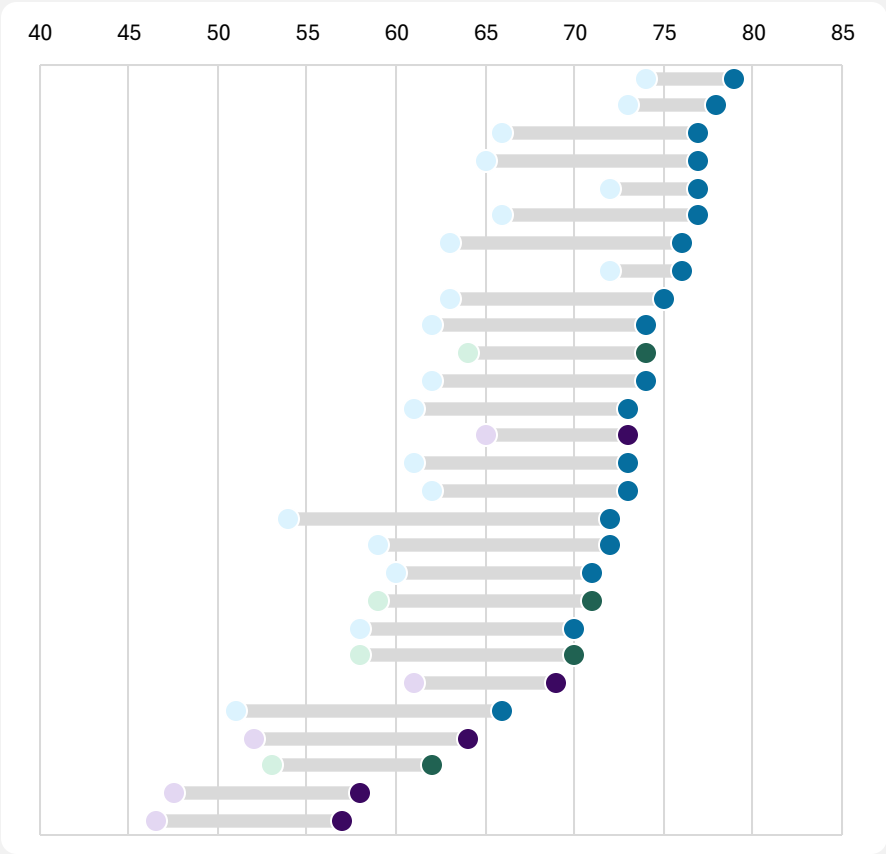
OP5 CIQ 780G

KEY Starting TIR — Change — Ending TIR

A recent meta-analysis focused on end of study TIR, across a select group of studies, implying a higher TIR for 780G



When you assess TIR change from baseline in those same studies, a comparable effect is observed across systems

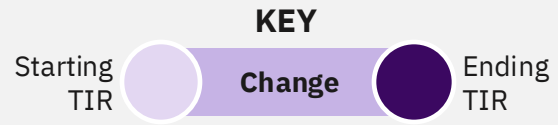


Pöhlmann J, DOM. 2026 Jan;28 Suppl 1(Suppl 1):13-34. Arrieta A, et al. DOM. 2022;24(7):1370–9. Breton MD, et al. DTT. 2021;23(9):601–8. Castaneda J, et al. Diabetes Care. 2024;47(5):790–7. Da Silva J, et al. DTT. 2022;24(2):113–9. De Meulemeester J, et al. Diabetologia. 2025;68(5):948–60. Dekker P, et al. JDST. 2024:19322968241290259. Forlenza GP, et al. DTT. 2024;26(8):514–25. Gera S, et al. JCEM. 2025;110(10):e3472–e81. Grassi B, et al. DOM. 2023;25(6):1688–97. Halim B, et al. DTT. 2024;26(3):190–7. Kovatchev BP, et al. Diabetes Care. 2022;45(11):2636–43. Lepore G, et al. DTT. 2024;26(1):49–58. Matejko B, et al. DRCP. 2024;216:111832. Meighan S, et al. DTT. 2024;26(10):773–9. Passanisi S, et al. Diabetes Care. 2024;47(6):1084–91. Smaniotto V, et al. DOM. 2025;27(4):2242–50. Thrasher JR, et al. DTT. 2024;26(S3):24–31.

Wealth of independent studies of Omnipod 5 demonstrate strong and reproducible glycemic improvement, across the spectrum of diabetes control, representative of real-life

Change in % Time in Range across 19 Omnipod studies





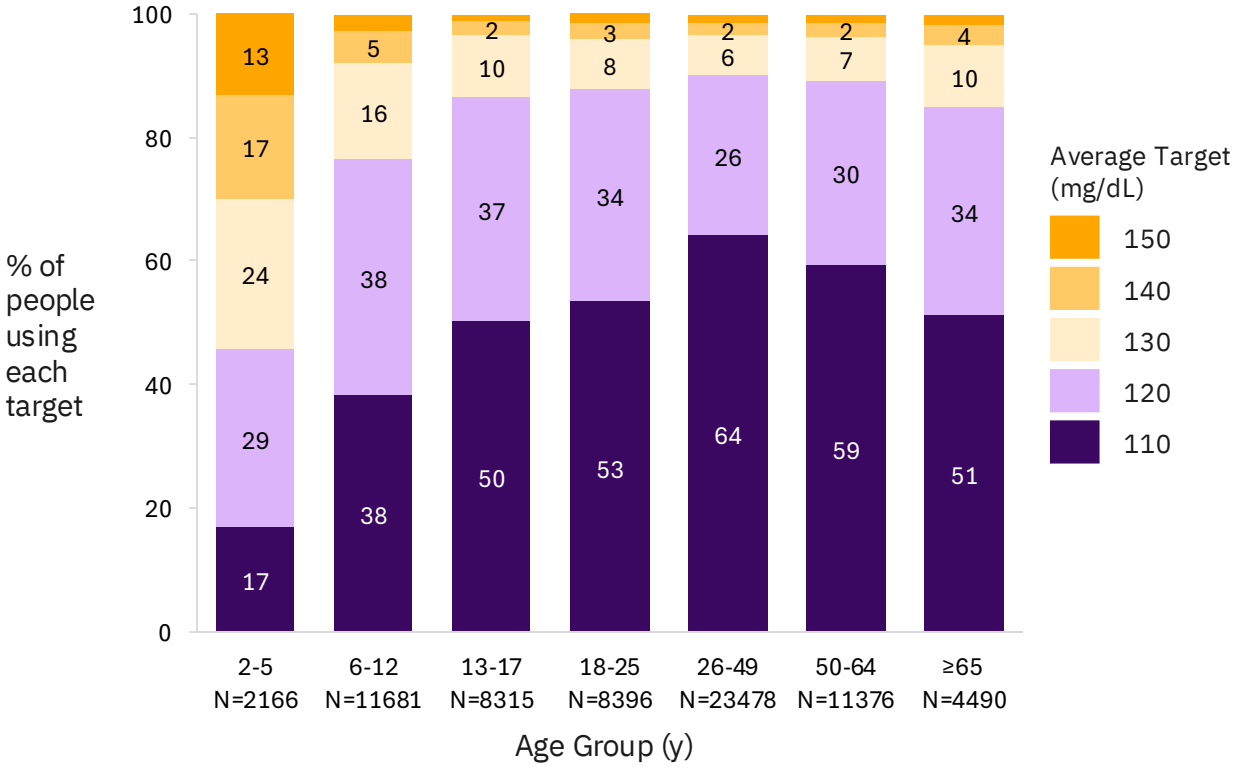
Average **13% TIR improvement** in independent clinic studies with Omnipod 5 in US, UK, and Italy

Omnipod 5 delivered **clinically meaningful** TIR improvement in **all patients**, especially those with poor baseline control who are often **overlooked as candidates for AID**

Angelino S, et al. Front Endocrinol. 2025;16:1717249. Aslam A, et al. DOM. 2024;26(8):3462–5. Berget C, et al. DOM. 2025;27(9):4942–9. Busi PS, et al. DTT. 2026;28(3_suppl):174S. Carletti L, et al. DTT. 2026;28(3_suppl):337S. Chapman A, et al. Diabet Med. 2025;42(4):e70000. Folk S, et al. JDST. 2025;19(5):1374–84. Granados A, et al. JPEM. 2025;38(4):340–4. Kaan D, et al. DTT. 2026;28(3_suppl):164–5S. Khan MS, et al. Diabet Med. 2026;43(5):e70251. Li M, et al. Diabetes Spectr. 2025;38(4):423–30. Marks BE, et al. DTT. 2023;25(11):782–9. Ng SM, et al. DTT. 2025;27(7):562–6. Pavlou P, et al. DOM. 2026;28(4):3424–8. Stimson RH, et al. Diabet Med. 2025;42(3):e15465. Stimson RH, et al. Diabet Med. 2024;41(12):e15453. Stimson RH, et al. Diabet Med. 2025;42(11):e70137. Tinti D, et al. DOM. 2025;27(8):4567–70. Wolf RM, et al. DTT. 2025;27(6):469–78.

In real-life, HCPs and users are leveraging the full spectrum of target glucose settings with Omnipod 5, highlighting its differentiation in delivering individualized care

In real-world use, Omnipod 5 users are selecting different glycemic targets according to individual goals (e.g., 2–5 years of age population benefits from more conservative targets)



- Omnipod 5 was designed to allow for users to **customize their therapy to their goals**.
  - 57-82% of pediatric users have multiple targets
  - 38-45% of adult users have multiple targets
- Omnipod 5 has the broadest range of target glucose options to enable user choice
- **Preference for higher average glucose levels** (with higher glucose targets) can be a choice in individualized care and **prioritization of hypoglycemia avoidance**
- It is important to remember the target glucose settings in interpreting clinical results
- With use of **Optimized Settings,** Omnipod 5 Users **achieve 80% TIR**

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Omnipod 5 target use data from Forlenza GP, et al. Diabetes Technol Ther. 2024;26(8):514–25.

Optimized settings of 110 mg/dL Target Glucose, ISF x TDI ≤ 1500, I:C Ratio x TDI ≤ 350

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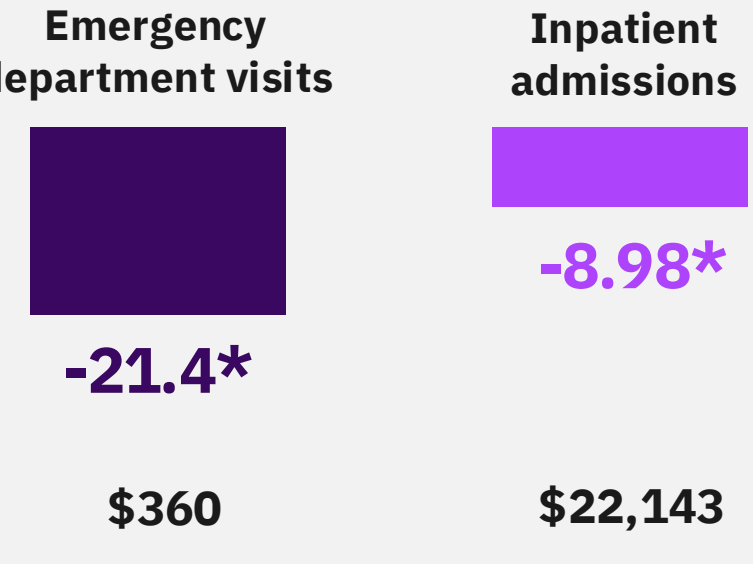
Omnipod 5 use in T2D is associated with fewer diabetes-related events compared with tubed systems, translating into potential medical cost savings

Absolute difference in predicted diabetes-related event rates per 1,000 T2D user years with **Omnipod 5 vs tubed systems**



$207K

Estimated payer diabetes-related medical cost savings per 1,000 T2D user years of Omnipod 5 vs. tubed systems

US claims data: 110,061 Omnipod 5; 113,454 tubed systems

*$p<0.05$.

Komodo (US) claims data analysis. weighted estimates based on individuals aged ≥2 years initiating Omnipod 5 or another tubed system from 1 August 2022 - 31 May 2024 with ≥180 days pre-initiation observation, followed until (1) health insurance enrolment ends, (2) filled a prescription for a different pump type, or (3) reached end of study period: 31 May 2025. All analyses adjusted for demographic and clinical covariates and used stabilized inverse probability weighting based on propensity scores, with models incorporating conservative heteroskedastic-robust standard errors. For T1D, age was modelled categorically with groups. For T2D, age was modelled as continuous. Average cost per event are based on insurer paid amount among commercial claims. Data on File. RF-042026-00021

Omnipod 5 demonstrates strong, competitive clinical performance across a broad and representative population

- **Headline claims oversimplify a complex evidence landscape**
- **Comparative assessment requires context, population characteristics, and proper interpretation**

When evaluating AID systems, it is important to consider:

- No RCT head-to-head trials exists
- CGM measured Time in Range (TIR) alone is an incomplete performance metric
- Change from baseline is the standard for assessing diabetes efficacy
- Population characteristics can influence outcomes
- AID settings allow for individualized care and significantly impact results

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Appendix

Glossary of abbreviations

640G	Medtronic 640G	**HCP**	Health care provider
670G	Medtronic 670G	**I:C**	Insulin-to-carbohydrate ratio
780G	Medtronic 780G	**ISF**	Insulin sensitivity factor
ADA	American Diabetes Association	**LATAM**	Latin America
AHCL	Advanced hybrid closed-loop system	**MDI**	Multiple daily injections
AID	Automated insulin device	**MSP**	Medtronic Simplera
ATTD	Advanced Technologies & Treatments for Diabetes	**OP5**	Omnipod 5
BL	Baseline	**RCT**	Randomized controlled trial
CDCES	Certified Diabetes Care and Education Specialist	**RWE**	Real-world evidence
CGM	Continuous glucose monitor	**T1 or T1D**	Type 1 diabetes
CIQ	Control-IQ	**T2 or T2D**	Type 2 diabetes
CLC	Closed-loop control system	**TBR**	Percentage of time below range < 70 mg/dL
EU	European Union	**TDI**	Total daily insulin
FSL3 or FL3	Abbott FreeStyle Libre 3 Sensor	**TIR**	Percentage of time in target range 70-180 mg/dL
G7	Dexcom G7	**UK**	United Kingdom
H2H	Head-to-head	**US**	United States
HbA1c or A1c	Hemoglobin A1c		

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The Omnipod 5 Automated Insulin Delivery System is indicated for use by individuals with type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older. The Omnipod® 5 System is intended for single patient, home use and requires a prescription. The Omnipod® 5 System is compatible with the following U-100 insulins: NovoLog®, Humalog®, Kirsty®, and Admelog®.

The Omnipod® 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod® 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values.

The Omnipod® 5 SmartBolus Calculator is intended to calculate a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value.

Warning: SmartAdjust™ technology should NOT be used by anyone under the age of 2 years old. SmartAdjust™ technology should also NOT be used in people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.

The Omnipod® 5 System is NOT recommended for people who are unable to monitor glucose as recommended by their healthcare provider, are unable to maintain contact with their healthcare provider, are unable to use the Omnipod® 5 System according to instructions, are taking hydroxyurea and using a Dexcom Sensor as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia, and do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod® 5 System, including alerts, alarms, and reminders. Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components. Visit www.omnipod.com/safety for additional important safety information.

Warning: DO NOT start to use the Omnipod® 5 System or change settings without adequate training and guidance from a healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia.

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