Adults with type 1 diabetes

omnipod 5 automated insulin delivery system

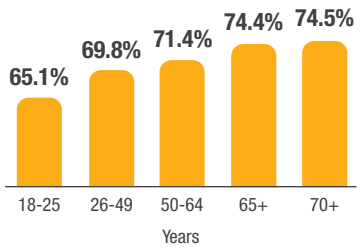
Proven real-world glycemic results with Omnipod® 5[1]

The largest published U.S. dataset across the current AID landscape[1-4]

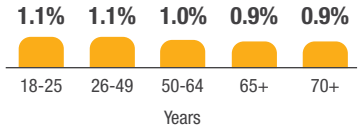
47,740 users ages 18+ with type 1 diabetes

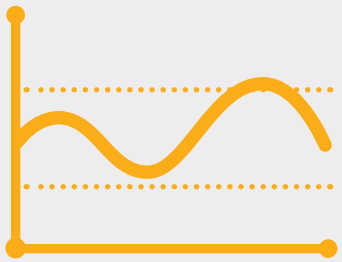
Adults achieved **~70% time in range** with **1.03% time below range** at an average target of 110 mg/dL[5]

Time in range
(70-180 mg/dL)



Time in hypoglycemia
(<70 mg/dL)





Users transitioning from MDI succeed with Omnipod 5

71.3% time in range with 0.90% time spent below range[6]

Automatic upload of data minimizes selection bias

Pivotal trial TIR and TBR under real-world conditions with Omnipod 5[7]

94.1% time in Automated Mode at an average target of 110 mg/dL[8]

To access the full clinical article, simply scan the code.

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Due to the study design of this real-world evidence, there was no collection of adverse events such as Severe Hypoglycemia and Diabetic Ketoacidosis. This data highlights the glycemic results at the 110 mg/dL Target Glucose and does not represent the real-world use of the Omnipod 5 System at a Target Glucose of 120, 130, 140, or 150 mg/dL.

References: 1. Forlenza G, et al. Real-world evidence of Omnipod 5 Automated Insulin Delivery System use in 69,902 people with type 1 diabetes. *Diabetes Technol Ther.* 2024. doi: 10.1089/dia.2023.0578 **2.** Messer LH, Breton MD. Therapy settings associated with optimal outcomes for t:slim X2 with Control-IQ technology in real-world clinical care. *Diabetes Technol Ther.* 2023;25(12):877-882. doi: 10.1089/dia.2023.0308 **3.** Castañeda J, Arrieta A, van den Heuvel T, Battelino T, Cohen O. Time in tight glucose range in type 1 diabetes: predictive factors and achievable targets in real-world users of the MiniMed 780G system. *Diabetes Care.* Published online December 19, 2023. doi:10.2337/dc23-1581 **4.** Arunachalum S, Velado K, Vigersky RA, Cordero TL. Glycemic outcomes during real-world hybrid closed-loop system use by individuals with type 1 diabetes in the United States. *J Diabetes Sci Technol.* 2023;17(4):951-958. doi:10.1177/19322968221088608. **5.** Forlenza G, et al. *Diabetes Technol Ther.* Real-world data from 28,612 adults with type 1 diabetes using Omnipod 5 at the Target Glucose of 110 mg/dL had a median TIR (70-180 mg/dL) of 69.9% and TBR (<70 mg/dL) of 1.03%. Omnipod 5 results based on users with ≥90 days CGM data, ≥75% of days with ≥220 readings available. 2024. **6.** Forlenza G, et al. *Diabetes Technol Ther.* 5,091 adults with type 1 diabetes who utilized MDI prior to Omnipod 5 had a median TIR (70-180 mg/dL) of 71.3% and median TBR (<70 mg/dL) of 0.90% while using Omnipod 5 at the 110 mg/dL glucose target. Omnipod 5 results based on users with ≥90 days CGM data, ≥75% of days with ≥220 readings available. 2024. **7.** Forlenza G, et al. *Diabetes Technol Ther.* 69,902 people with type 1 diabetes using the Omnipod 5 System at the 110 mg/dL glucose target had a TIR (70 mg/dL-180 mg/dL) of 67.8% and TBR (<70 mg/dL) of 1.62%. Omnipod 5 results based on users with ≥90 days CGM data, ≥75% of days with ≥220 readings available. Sherr JL, et al. Prospective trial in 80 participants with T1D aged 2-5.9 yrs. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop (HCL) phase. Mean time in range (70-180 mg/dL) in very young children (2-5.9 yrs) as measured by CGM: ST=57.2%, 3-mo Omnipod 5=68.1%, *P*<0.05. Median time in hypoglycemic range (<70 mg/dL) as measured by CGM: ST vs. Omnipod 5 use in very young children (2-5.9 yrs) (3.43% vs. 2.46%, *P*=0.0204). Brown S, et al. *Diabetes Care.* Prospective pivotal trial in 240 participants with T1D aged 6-70 yrs [adults/adolescents (n=128; aged 14-70 yrs) children (n=112; aged 6-13.9 yrs)]. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop phase. Mean time 70-180 mg/dL as measured by CGM in adults/adolescents and children, ST vs. 3-mo Omnipod 5: 64.7% vs. 73.9%; 52.5% vs. 68.0%, *P*<0.0001, respectively. Median time <70 mg/dL in adults/adolescents and children, ST vs. 3-mo Omnipod 5: 2.0% vs. 1.1%, *P*<0.0001; 1.4% vs. 1.5%, *P*=0.8153, respectively. Results measured by CGM. 2021;44:1630-1640. **8.** Forlenza G, et al. *Diabetes Technol Ther.* 28,612 adult Omnipod 5 users with type 1 diabetes utilizing the 110 mg/dL glucose target spent a median of 94.1 time in automated mode. Omnipod 5 results based on users with ≥90 days CGM data, ≥75% of days with ≥220 readings available. 2024.

Safety and intended use information: The Omnipod 5 System is indicated for use by individuals with type 1 diabetes mellitus in persons 2 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®, 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, 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 omnipod.com/safety for additional important safety information.

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