



omnipod Omnipod 5 Automated Insulin Delivery System User Manual

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Omnipod 5 Automated Insulin Delivery System



INDICATION:

FOR PEOPLE WITH INSULIN REQUIRING TYPE 1 DIABETES AGED 2 YEARS AND OLDER.

Automated Insulin Control

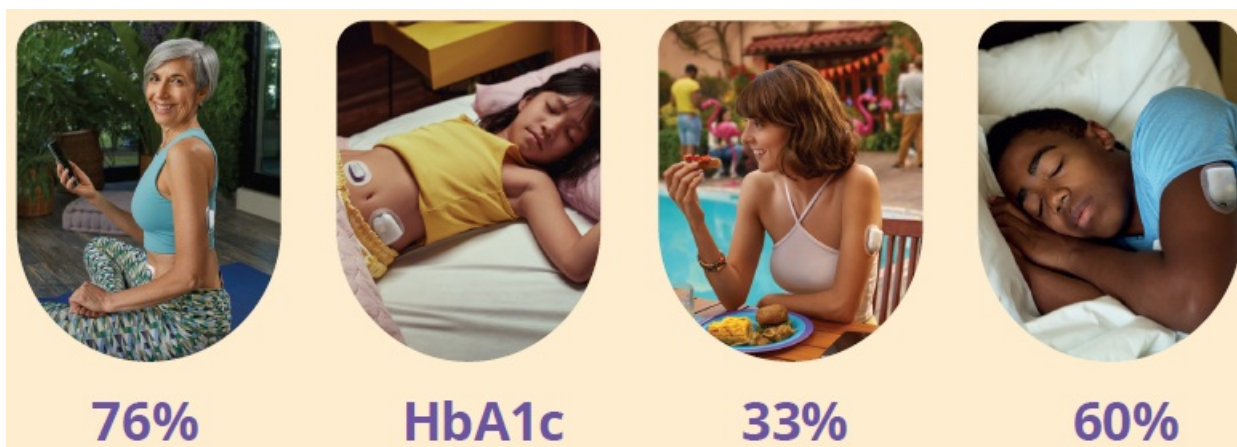
automated insulin control for people with type 1 diabetes¹

Omnipod 5* with SmartAdjust™ technology proactively manages insulin delivery every 5 minutes using a customized glucose target to help minimize the time in hyperglycaemia and hypoglycaemia.^{b,c,d1}

- Choice of glucose targets by the time of day, throughout the day; adjustable from 110–150 mg/dL (6.1–8.3 mmol/L)^e
- The only AID System with SmartBolus calculator, informed with Dexcom G6 CGM value and trend

OMNIPOD 5 IMPROVED GLYCAEMIC CONTROL FOR ADULTS, ADOLESCENTS, AND CHILDREN WITH T1D IN PIVOTAL STUDIES C, D, F1, 2

- 76% time in range at a target of 110mg/dl (6.1mmol/L) in adults and adolescents (14-70 years) and 68% overall TIR in children (2-13.9 years)
- HbA1c was significantly reduced in very young children (2.0-5.9 years), children (6-13.9 years), and adults and adolescents (14-70 years) by 0.5%, 0.7% and 0.4% respectively^{1,2}
- 33% reduced time in hyperglycaemia in children, 24% in adults and adolescents ¹
- 60% reduction in hypoglycaemia overnight and 46% overall in adults and adolescents ¹






Adjustments on the go c,b1

No more multiple daily injections, tubing, or fingersticksh1

- Tubeless, waterproof,i Pod with built-in SmartAdjust™ technology
- Integrated with the accurate Dexcom G6 CGM System j

IN THE OMNIPOD 5 PIVOTAL STUDY

-  Adults reported lower stress when eating compared to prior therapy c,g
-  Parents of children reported better sleep quality compared to prior therapy c,g
-  Adult users and parents of children felt confident in staying safe from the risk of hypoglycaemia compared to prior therapy c,g

Generation AID, CE-marked and coming soon

Omnipod 5*–next generation AID, CE-marked and coming soon

- Improved glycaemic control across all age groups from age 2 in two pivotal studies, while time in hypoglycaemia remained low b,c,d,f 1,2
- No more multiple daily injections, tubing, or fingersticks h1
- Tubeless, waterproof, i Pod with built-in SmartAdjust™ technology

SPEAK REP WITH YOUR

EXPLORE THE BENEFITS OF OMNIPOD 5

Whether better suited to CSII, or in need of a simple tubeless insulin delivery system in the run-up to Omnipod 5... Omnipod DASH® could be a good solution today

Important Safety Information

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. The Omnipod 5 System is intended for single-patient, home use and requires the supervision of the user's healthcare provider. The Omnipod 5 System is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®. Refer to the Omnipod® 5 Automated Insulin Delivery System User Guide and www.omnipod.com/safety for complete safety information including indications, contraindications, warnings, cautions, and instructions.

When used in automatic mode with Dexcom G6 CGM, the Omnipod 5 System makes adjustments to insulin delivery every 5 minutes based on the user's current CGM value, glucose values predicted 60 minutes in the future, glucose trend, and past insulin delivery to bring glucose to a user-defined target. b Requires a Dexcom G6 CGM. c Prospective pivotal trial in 240 participants with T1D aged 6–70 yrs (128 adolescents/adults aged 14–70 years and 112 children aged 6–13.9 years). The study included a 14-day ST phase followed by a 3-month Omnipod 5 HCL phase. The incidence rates of severe hypoglycemia and diabetic ketoacidosis during the AID phase were 4.8 and 1.2 events per 100 person-years, respectively.1 d Meantime in range (70–180 mg/dL [3.9–10.0 mmol/L]) as measured by CGM in adults/adolescents and children ST vs 3-month Omnipod 5: 64.7% vs 73.9%, $P<0.0001$; 52.5% vs 68.0%, $P<0.0001$, respectively. Mean HbA1c: baseline vs Omnipod 5 use in adults/adolescents and children, respectively (7.16% vs 6.78%, $P<0.0001$; 7.67% vs 6.99%, $P<0.0001$).

Meantime above range (>180 mg/dL [10.0 mmol/L]) as measured by CGM in adults/adolescents and children ST vs 3-month Omnipod 5: 32.4% vs 24.7%; 45.3% vs. 30.2%, $P<0.0001$, respectively. Median time below range (<70 mg/dL [3.9 mmol/L]) as measured by CGM in adults/adolescents and children ST vs 3-month Omnipod 5: 2.0% vs 1.1%, $P<0.0001$; 1.4% vs 1.5%, $P=0.8153$, respectively. Median time below range (<70 mg/dL [3.9 mmol/L]; 12 AM – <6 AM) as measured by CGM in adults/adolescents and children ST vs 3-month Omnipod 5: 2.07% vs 0.82%, $p<0.0001$; 0.78% vs 0.78%, $P=0.0456$, respectively. Comparisons are relative changes.1 e Glucose targets can be adjusted in up to 8 segments per day. f Prospective trial in 80 participants with T1D aged 2–5.9 yrs. The study included a 14-day ST phase followed by a 3-month Omnipod 5 HCL phase.

Meantime in range (70–180 mg/dL [3.9–10.0 mmol/L]) in very young children as measured by CGM: ST = 57.2%, 3-month Omnipod 5 = 68.1%, $P<0.05$. Mean HbA1c: ST vs Omnipod 5 use in very young children 7.4% vs 6.9%, $P<0.05$. Median time below range (<70 mg/dL [3.9 mmol/L]) as measured by CGM: ST vs Omnipod 5 use in very young children (2.2% vs 1.9%, $P<0.05$).2 g Prior therapy in adults and children, respectively: 15.6% MDI, 84.4% CSII; 9.6%MDI, 90.4% CSII. During the Omnipod 5 pivotal trial, adults aged 18–70 years (N=111) experienced an improvement in eating distress survey score after 3 months of Omnipod 5 use compared to ST: mean T1-DDS Eating Distress Subscale: 1.74 vs. 1.97, respectively.

Parents of children aged 6–11.9 years (N=82) and adults aged 18–70 years (N=111) experienced an improvement in hypoglycaemia confidence survey score after 3 months of Omnipod 5 use compared to ST: mean HCS score = 3.59 vs 3.34; and 3.65 vs 3.52, respectively. Parents of children 6–11.9 years (N=82) experienced an improvement in sleep quality survey score after 3 months of Omnipod 5 use compared to ST: mean PSQI Overall Sleep Quality Subscore = 0.70 vs 1.13, respectively.1 h If glucose alerts and readings from Dexcom G6 do not match symptoms or expectations, a blood glucose meter should be used to make diabetes treatment decisions. i The Pod has an IP28 rating for up to 25 feet for 60 minutes. The controller is not waterproof. The Dexcom G6 sensor and transmitter are water-resistant and may be submerged under eight feet of water for up to 24 hours without failure when properly installed. j Dexcom G6 CGM System sold separately. The Omnipod 5 System must be used with the Dexcom G6 app and is not compatible with the Dexcom G6 receiver.

AID, automated insulin delivery; CGM, continuous glucose monitor; CSII, continuous subcutaneous insulin infusion; DKA, diabetic ketoacidosis; HbA1c, glycated hemoglobin; HCL, hybrid closed loop; MDI, multiple daily injections, ST, standard therapy; T1D, type 1 diabetes.


References

1. Brown S et al. Multicenter trial of a tubeless, on-body automated insulin delivery system with customizable glycemic targets in pediatric and adult participants with type 1 diabetes. *Diabetes Care*. 2021;44(7):1630-1640.
2. Sherr JL et al. Safety and glycemic outcomes with a tubeless automated insulin delivery system in very young

children with type 1 diabetes: a single-arm, multicenter clinical trial. Diabetes Care. 2022; doi: 10.2337/dc21-2359 [Online ahead of print].

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Documents / Resources

	<p>omnipod Omnipod 5 Automated Insulin Delivery System [pdf] User Manual Omnipod 5 Automated Insulin Delivery System, Omnipod 5, Automated Insulin Delivery System , Insulin Delivery System, Delivery System</p>
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References

- [Important Safety Information | Insulin Pump Therapy | Omnipod](#)