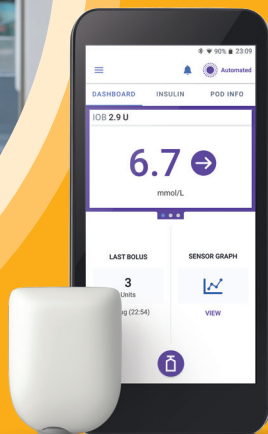


# Omnipod<sup>®</sup> 5

AUTOMATED INSULIN DELIVERY SYSTEM



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

Screen image is an example, for illustrative purposes only. Pod shown without necessary adhesive.

omnipod<sup>®</sup>  
automated insulin  
delivery system  
5

OMNIPOD® 5:

## Automated insulin delivery simplified

Omnipod 5<sup>a</sup> with SmartAdjust™ technology proactively manages insulin delivery every 5 minutes using a customised glucose target to help minimise time in hyperglycaemia and hypoglycaemia.<sup>1,b,c,d</sup>

- Choice of glucose targets by time of day, throughout the day; adjustable from 6.1-8.3 mmol/L in 0.55 mmol/L increments (110mg/dL-150 mg/dL in 10mg/dL increments)<sup>e</sup>
- The only AID System with **SmartBolus Calculator**, informed by sensor value and trend<sup>j</sup>

## Adjustments on the go<sup>1,b,c</sup>

No more multiple daily injections, tubing or finger pricks<sup>1,h</sup>

- Tubeless, waterproof,<sup>i</sup> Pod with built-in SmartAdjust™ technology
- Integrated with the leading sensor brands<sup>j</sup>

## Omnipod 5 pivotal study results<sup>3,4</sup>

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

## Works with these sensors<sup>i</sup>



Dexcom G6



FreeStyle Libre 2 Plus

Sensors shown without necessary adhesive.

## Omnipod 5 improved glycaemic control in adults, adolescents and children with type 1 diabetes (T1D) in pivotal studies<sup>c,d,f,1,2</sup>



**76%**

time in range (TIR) at a target of 6.1 mmol/L in adults and adolescents (14–70 years) and **68%** overall TIR in children (2-13.9 years)<sup>1</sup>



**HbA1c**

was significantly reduced in very young children (2.0–5.9 years), children (6–13.9 years), adults and adolescents (14–70 years) by 0.5%, 0.7% and 0.4% respectively<sup>1</sup>

HbA1c = glycated hemoglobin



**33%**

reduced time in hyperglycaemia in children, and **24%** in adults and adolescents<sup>1</sup>



**60%**

reduction in hypoglycaemia overnight and **46%** overall in adults and adolescents<sup>1</sup>

# Omnipod® 5—simple design, sophisticated technology, improved results

- Improved glucose control across all age groups from age 2 in two pivotal studies, while time in hypoglycaemia remained low<sup>1,2,b,c,d,f</sup>
- No more multiple daily injections (MDI), tubing or finger pricks<sup>1,h</sup>
- Tubeless, waterproof<sup>i</sup> Pod with built-in SmartAdjust™ technology

For more information visit [omnipod.com](https://www.omnipod.com)

**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 supervision of the user's healthcare provider. The Omnipod 5 System is compatible with the following U-100 insulins: NovoLog®/NovoRapid®, Humalog®, Trurapid®/Insulin aspart Sanofi®, Kirsty®, and Admelog®/Insulin lispro Sanofi®. Refer to the Omnipod® 5 Automated Insulin Delivery System User Guide and [www.omnipod.com/safety](https://www.omnipod.com/safety) for complete safety information including indications, contraindications, warnings, cautions, and instructions.

a When used in automated mode with Dexcom G6 or FreeStyle Libre 2 Plus sensor, the Omnipod 5 System adjusts insulin delivery every 5 minutes based on the user's current sensor 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 or FreeStyle Libre 2 Plus sensor. c Prospective pivotal trial in 240 participants with T1D aged 6–70 yrs (128 adolescents/adults aged 14–70 years and 112 children aged 6.0–13.9 years). 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. d Mean time in range (70–180 mg/dL [3.9–10.0 mmol/L]) as measured by sensor 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). Mean time above range (>180 mg/dL [10.0 mmol/L]) as measured by sensor 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 sensor 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]; 12–6AM) as measured by sensor 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. e Glucose targets can be adjusted in up to 8 segments per day. f Prospective trial in 80 participants with T1D aged 2.0–5.9 yrs. Study included a 14-day ST phase followed by a 3-month Omnipod 5 HCL phase. Mean time in range (70–180 mg/dL [3.9–10.0 mmol/L]) in very young children as measured by sensor: 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 sensor: ST vs Omnipod 5 use in very young children (2.2% vs 1.9%, P<0.05). g Prior therapy in adults and children, respectively: 15.6% MDI, 84.4% CSI; 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 6.0–11.9 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 6.0–11.9 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. h If glucose alerts and readings from Dexcom G6 or FreeStyle Libre 2 Plus sensor do not match symptoms or expectations, a blood glucose metre should be used to make diabetes treatment decisions. i The Pod has an IP28 rating for up to 7.6 metres (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. The FreeStyle Libre 2 Plus sensor is water resistant in up to 1 metre (3 feet) of water. Do not immerse longer than 30 minutes. j Compatible with Dexcom G6 and FreeStyle Libre 2 Plus sensor. Dexcom G6 and FreeStyle Libre 2 Plus sensors prescribed separately. The Dexcom G6 sensor must be used with the Dexcom G6 App. The Dexcom G6 receiver is not compatible with Omnipod 5. FreeStyle Libre 2 Plus sensor cannot be used with the LibreLink App, LibreView App and LibreLinkUp App, and it must be started with the Omnipod 5 App only.

AID, automated insulin delivery; CGM/sensor, continuous glucose monitor; CSII, continuous subcutaneous insulin infusion; DKA, diabetic ketoacidosis; HbA1c, glycated hemoglobin; HCL, hybrid closed loop; MDI, multiple daily injection; 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 customisable 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 3. Hood KK, et al. Psychosocial Outcomes with the Omnipod® 5 Automated Insulin Delivery System in Children and Adolescents with Type 1 Diabetes and Their Caregivers *Pediatric Diabetes* 2023 doi: 10.1155/2023/8867625 4. Polonsky WH et al. *Diabetes Res Clin Pract* 2022;190:109998

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