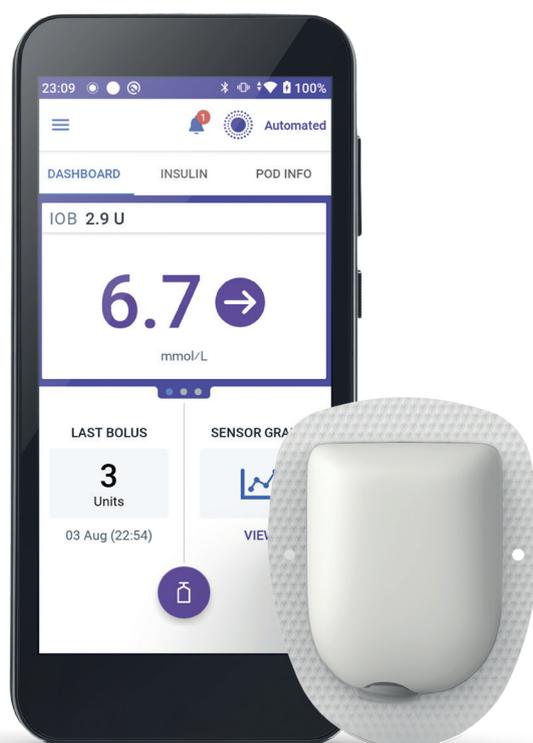


Clinical Implementation of the Omnipod® 5 Automated Insulin Delivery System

Key Considerations for Training and Onboarding

Omnipod 5 System

- ✓ Offers innovations that may help lower barriers to automated insulin delivery (AID) therapy and reduce the burden of diabetes self-management.^{1,2}
- ✓ First fully on-body AID system that integrates with compatible sensors*.
- ✓ Algorithm is embedded within each Pod, and continuous glucose sensor data are directly transmitted to the Pod every 5 minutes to adjust insulin delivery.
- ✓ Once the Pod and glucose sensor are activated, delivery of insulin in Manual or Automated Mode continues as programmed if the Pod is not near the Controller†.
- ✓ Omnipod 5 System uses total daily insulin (TDI) to determine a baseline adaptive basal rate for each user, which the algorithm uses to adapt insulin delivery.
- ✓ During onboarding, the system estimates a TDI based on the user's Basal Program (from manual mode). This allows automated mode to be enabled immediately with the first active Pod, in which automated maximal delivery is more restrained.
- ✓ TDI is updated with each Pod change, permitting the system to adapt to users' insulin needs across time.



In clinical trials, the Omnipod 5 System was found to be safe and effective across a diverse cohort of study participants of all ages, from 2-70 years old.^{1,2}

1. Brown S et al. Multicenter trial of a tubeless, on-body automated insulin delivery system with customisable glycaemic targets in paediatric and adult participants with type 1 diabetes. *Diabetes Care*. 2021;44(7):1630-1640. Study funded by Insulet.

2. Sherr JL et al. Safety and glycaemic 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; 45(8):1907-1910 doi: 10.2337/dc21-2359. Study funded by Insulet.

*Compatible glucose sensors sold separately and require a separate prescription.

† It is recommended to keep the Omnipod 5 controller nearby as it displays important information such as alerts and alarms.

Omnipod 5 System Activity Feature

Michelle



45 years old

Michelle walks for exercise several times each week and takes a strength training class twice a week. **She enables the Activity feature 1–2 hours before each activity** and her glucose is stable after walks, but a pattern of hyperglycaemia is evident after strength training.

Clinician Insight

- **Different forms of exercise affect glucose levels differently.**
- The **Activity feature** reduces insulin delivery to minimize risk of hypoglycaemia during aerobic activity, but may not be needed for anaerobic exercise, during which counter-regulatory hormones may cause hyperglycaemia.
- After discussing her exercise schedules, her clinician advises Michelle to **use the Activity feature for her walks but not during strength training.**

Trusting the Omnipod 5 System Algorithm

Kristi



7 years old

When using sensor-augmented pump therapy, Kristi had a severe nocturnal hypoglycaemic event. She is transitioning to the Omnipod 5 System but her parents still tolerate hyperglycaemia overnight, just in case. If Kristi's glucose is <10 mmol/L at bedtime, she eats a snack without insulin. If her glucose drops to <6.7 mmol/L when asleep, her mum wakes Kristi to take fast-acting carbohydrates.

Clinician Insight

- On initiating the Omnipod 5 System, **setting Kristi's overnight target (9:00 p.m. to 7:00 a.m.) to 8.3 mmol/L may be helpful.** As her parents learn to trust the algorithm, Kristi's overnight target can be gradually lowered to 6.1 mmol/L.
- **To prevent hypoglycaemia overnight, the Omnipod 5 System will reduce/pause insulin if Kristi's glucose falls.** Only if her glucose is <3.9 mmol/L would her family wake Kristi to take fast-acting carbohydrate. In automated mode, the system will always pause insulin when the last sensor glucose value recorded was <3.3 mmol/L. **This way, Kristi's clinician can balance both her risk and her parents' fear of hypoglycaemia.**

The Omnipod 5 System at Mealtimes

James



37 years old

After using the Omnipod 5 System for one month, James' glucose levels are at target before meals, but he is experiencing hyperglycaemia after meals that persists for 2–3 hours, despite him giving meal boluses 15–20 minutes before eating.

Clinician Insight

- The Omnipod 5 System reduces and/or pauses insulin delivery if glucose is trending down or below target, resulting in little insulin on board (IOB) before mealtimes.
- Due to the lower IOB before meals compared to his prior therapy, **James may need a stronger insulin-to-carb ratio (ICR)** when starting AID therapy.
- **James' clinician recommends strengthening his ICR by 10–20% (e.g., from 20 to 18)** to improve post-meal glycaemia and also **recommends turning off James' reverse correction** setting. This will enable the bolus calculator to deliver a full meal bolus, even if the glucose level is below the target.

The Omnipod 5 System and Mealtime Bolusing

Teresa



16 years old

Independent in her self-care but Teresa struggles to hit her glycaemic targets. Although her Time in Range (TIR) has improved since switching to Omnipod 5 System from sensor-augmented pump therapy, it is still only 50% and needs to increase. Teresa experiences persistent hyperglycaemia after meals, and her pump report indicates that she is delivering only 1.5 meal boluses each day on average.

Clinician Insight

- Although the AID algorithm will automatically increase insulin delivery as glucose rises, this is not sufficient to fully counter postprandial excursions.
- **Teresa still needs to bolus before every meal to reduce hyperglycaemia and increase her TIR.**
- Her clinician advises more parental involvement and **emphasises the importance of bolusing at all mealtimes** to Teresa and her parents. Together they agree **to identify strategies to increase bolus consistency** that involve shared responsibility.

Before onboarding people with diabetes to the Omnipod 5 System

Understand the SmartBolus Calculator

- Uses the user-programmed **Insulin to Carb Ratio, Correction Factor, and Duration of Insulin Action** for meal and manual correction boluses.
- **Uses glucose-sensor trend information** to adjust bolus doses, depending on whether the user's glucose trend is rising or falling.
- **Correct Above Value** - SmartBolus Calculator will only suggest a correction if current glucose is above the Correct Above value.
- **Reverse Correction** – reduces suggested bolus when the current glucose is below the Target Glucose value. **Users can turn reverse correction off** if their glucose is often below target at mealtimes and they experience post-meal hyperglycaemia. With reverse correction off, users will receive their full bolus dose for mealtime carbs.



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This summary has been provided as part of the Omnipod Academy, an educational service provided for Healthcare Professionals by Insulet International.

Setting Realistic Expectations is Important

- **Omnipod 5 System** cannot take over the entire insulin regimen for a user – they cannot 'set-it-and-forget-it'.
- **Provide guidance on system limitations** and issues such as infusion-site failure, pump malfunction and skin irritation.
- Users should expect to **wear both a Pod and glucose sensor 24/7** to maximise time in automated mode and to bolus for meals.
- Users must be prepared to **respond to glucose-sensor alarms** and manage situations such as a lost sensor signal.
- **Omnipod 5 system can help improve diabetes management** and reduce self-care burden, but self care is still necessary.
- **Trusting the AID system is important**
Reassure users that the system has been tested to safely deliver insulin based on current sensor glucose values and trends.

Adapted from; Berget C, et al. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People With Diabetes. *Clin Diabetes* 2022; 40:168-184

Always read the label and follow the directions for use.

Omnipod® 5 is indicated for people with type 1 diabetes in persons aged 2 and older requiring insulin. Warning: SmartAdjust technology should not be used by anyone under the age of 2 years old or by people who require less than 5 units of insulin per day. Please see [Omnipod.com/safety](https://www.omnipod.com/safety) for important safety information.

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