

SmartAdjust™ Technology

automatically increases, decreases, or pauses insulin delivery, every five minutes, to your personal needs which may help to protect against highs and lows.¹

omnipod[®]
5
automated insulin
delivery system



Treats using a personalised target, not a set range.

HOW IT WORKS



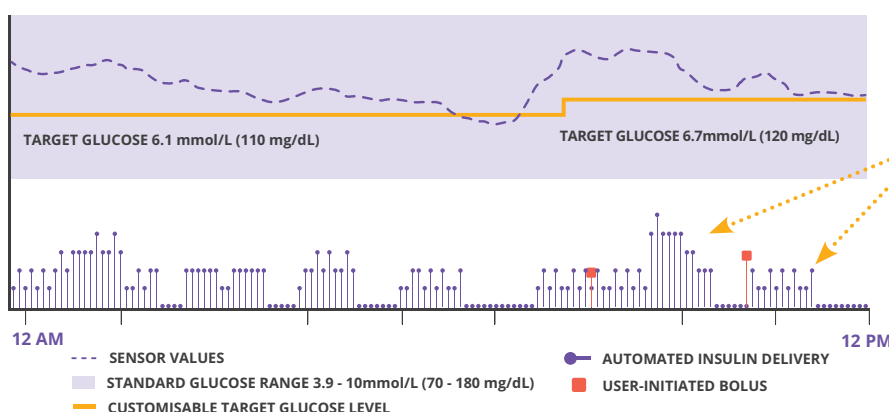
Predicts glucose
60 minutes
into the future



Adjusts
insulin delivery
using the selected
Target Glucose



Delivers
insulin doses
every 5 minutes
(as needed)



Responds to current & predicted glucose values with microbolus doses of insulin. If prediction is above the Target Glucose, it will deliver larger microboluses.

Graph for illustrative purposes only

+ Adaptive

- SmartAdjust™ technology, embedded within the Pod, determines an adaptive basal rate based on the user's total daily insulin (TDI)
- The adaptive basal rate serves as a baseline and updates with each pod change based upon user's TDI from previous Pods
- The insulin dose is determined using the current and predicted glucose value, insulin history, and chosen target glucose

+ Customisable

- Target Glucose setting directly impacts automated insulin delivery
- Choose between five targets: 6.1, 6.7, 7.2, 7.8, 8.3 mmol/L (110, 120, 130, 140, 150 mg/dL)
- Set up to eight segments in a 24-hour period

+ Proactive

- Uses the sensor value and trend to predict glucose values 60 minutes into the future
- Based on this prediction, SmartAdjust™ technology will increase, decrease, or pause insulin every 5 minutes using the Target Glucose value

1. Brown S. et al. Diabetes Care. 2021;44:1630-1640. 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 (HCL) phase, then the option to continue onto a 12-month extension phase. Mean time in range (70-180mg/dL)(3.9 - 10mmol/L) during 110mg/dL (6.1mmol/L) Target BG in adults/adolescents (n=121) = 75.6%. Mean time in range (70-180mg/dL)(3.9 - 10mmol/L); 12AM to <6AM) in adults/adolescents and children during ST vs 3-mo Omnipod 5: 64.3% vs 78.1%, 55.3% vs 78.1%, P<0.0001, respectively. Mean HbA1c: ST vs Omnipod 5 use in adults/adolescents (14-70 yrs) and children (6-13.9 yrs), respectively (7.16% vs 6.78%, P<0.0001; 7.67% vs 6.99%, P<0.0001). Median time in range in adults/adolescents (<70 mg/dL)(3.9mmol/L); 12AM-6AM) ST = 2.07%, 3-mo Omnipod 5 = 0.82%, P<0.0001. Comparison is a relative change. Mean time 70-180mg/dL(3.9 - 10mmol/L) ST vs Omnipod 5 in adults/adolescents and children: 64.7% vs 73.9%, P<0.0001; 52.5% vs 68.0%, P<0.0001, respectively. Median time <70 mg/dL(3.9mmol/L) ST vs Omnipod 5 in adults/adolescents and children: 2.0% vs 1.1%, P<0.0001; 1.4% vs 1.5%, P=0.8153, respectively. Mean time >180 mg/dL(10mmol/L) in adults/adolescents and children, ST vs 3-mo Omnipod 5: 32.4% vs 24.7%; 45.3% vs 30.2%, P<0.0001, respectively. Timed-related results measured by CGM.

What to expect from this technology



First Pod

- Automated Mode can be activated immediately
- Estimates TDI based on the programmed basal rate. As a safety measure, maximum automated insulin delivery is restrained
- After 48 hours of wear and a subsequent Pod change, SmartAdjust™ technology uses insulin delivery history to set the adaptive basal rate and initial safety restraints are removed



Ongoing Wear

- SmartAdjust™ technology continues to adapt based on insulin delivery history. Given the adaptive nature, glycaemia should improve across time from a few days to a few weeks
- Encourage bolusing for meals and corrections as needed so TDI reflects actual insulin needs
- The more precise the inputs are to the algorithm during this time, the faster it can adapt. Inputs include basal/bolus ratio, target glucose, insulin to carb ratio and duration of insulin action.

Optimisation

- Adjust Target Glucose setting as needed
- Adjust SmartBolus Calculator settings as you would traditional pump therapy, including insulin to carbohydrate ratio, correction factor, and duration of insulin action



ACTIVITY FEATURE TIPS

- Sets the Target Glucose to 8.3mmol/L (150 mg/dL) AND reduces automated insulin delivery
- Enable 1-2 hrs before any activity where reduced insulin is needed
- Set for 1 hour up to 24 hours (in 1 hr increments) and full automated insulin delivery resumes upon completion or cancellation

THE ABCs OF BEST PRACTICES²

(A)SSESS:

- Insulin delivery history and bolusing habits so that starting settings are reflective of physiological needs and safe and effective in **Manual Mode**
- Programmed basal rate to account for **40-50% of (TDI)** to optimise initiation

(B)OLUS:

- Bolus for carbs and corrections as needed to inform system of TDI needs
- Bolus **15-20 minutes before eating**
- Avoid overriding suggested boluses as **hypoglycaemia can occur** due to IOB (Insulin on Board) from automated insulin delivery

(C)ONSIDER:

- Strengthening IC ratios as a **key lever** to adjust bolus insulin
- Treating hypoglycaemia **with fewer carbs** as SmartAdjust™ technology may have already reduced/suspended insulin delivery
- Using the **Activity feature** for times of reduced insulin needs

2. 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

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 a prescription and/or ongoing supervision of a qualified healthcare provider. The Omnipod 5 System is compatible with the following U-100 insulins: NovoLog®/NovoRapid®, Humalog®/Liplog®, Trurapi®/Insulin aspart Sanofi®, Kirsty®, and Admelog®/Insulin lispro Sanofi®. The Omnipod 5 Insulin 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 Pod 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 (iCGMs) and The Omnipod 5 Pod 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 finger pricks), 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 hypoglycaemia, 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 component.

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.

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 hypoglycaemia or hyperglycaemia.

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