Introducing Omnipod® 5

The first and only tubeless automated insulin delivery system

Automated Glucose Control Simplified

omnipod® 5
automated insulin delivery system

Simplified glucose management

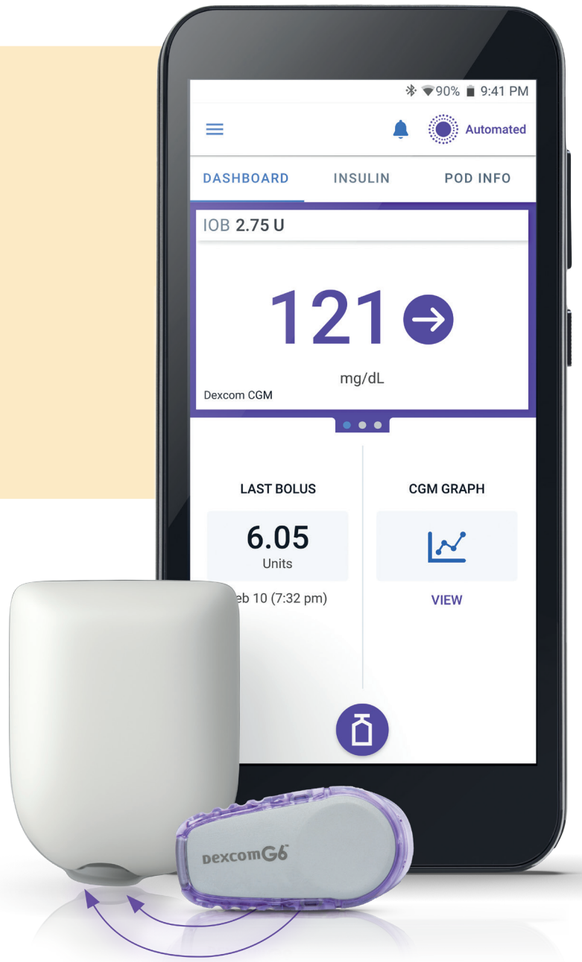
On-body Automated Insulin Delivery System*

Tubeless, waterproof,† wearable Pod
with built-in SmartAdjust™ Technology

Integrated with the Dexcom G6 Continuous Glucose Monitoring System‡
Accurate real-time glucose data[1]

Compatible Smartphone Control§

Your patients can manage diabetes with fewer devices and less hassle



Pod and Dexcom G6 sensor shown without the necessary adhesive. Products shown to scale.

*The Omnipod® 5 Pod is tubeless and waterproof, designed to hold up to 200 units of insulin and replaces an average of 14 injections delivering insulin for up to 72 hours.

†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.

‡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. Dexcom compatible smart devices sold separately: dexcom.com/compatibility.

§For a list of compatible smartphone devices visit omnipod.com/compatibility

References:

1. Shah VN, et al. *Diabetes Technol and Ther.* 2018;20(6)

2. 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 phase. Mean time 70-180mg/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 (12AM-6AM) in adults/adolescents and children, ST vs. 3-mo Omnipod 4: 2.07% vs 0.82%, $P<0.0001$ (comparison is a relative change); 0.78% vs. 0.78%, $P=0.0456$. Results measured by CGM. Mean time >180 mg/dL 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. 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.

3. ADA consensus guidelines: American Diabetes Association. *Diabetes Care.* 2020;43(Suppl. 1):S66–S76.

Meets improved clinical results

omnipod 5 automated insulin delivery system

Adjustable to each patient using SmartAdjust™ Technology

Effective

+ Demonstrated 74% time in range (TIR) in adults and adolescents, and 68% TIR in children.[2]
+ Reduced hypoglycemia overnight by 60% in adults and adolescents, while time in hypoglycemia overnight remained low in children.[2]
+ 53% of children and 66% of adults/adolescents achieved the ADA recommended HbA1c goal (<7%).[2,3]

Customizable

+ Choice of glucose targets by time of day, throughout the day; adjustable from 110-150 mg/dL in 10 mg/dL increments.
+ SmartAdjust™ Technology proactively manages insulin delivery every 5 minutes using a customized glucose target to help protect against highs and lows.[2]
+ SmartBolus calculator, informed with Dexcom CGM value and trend.

Adaptive

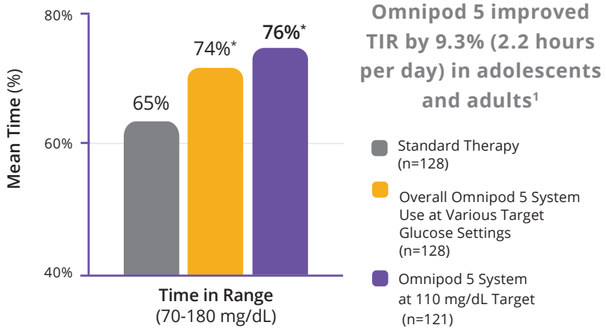
+ Adapts with every Pod change to meet individual insulin needs.
+ Alleviates the burden of adjusting basal insulin programs.
+ Activity feature sets the target glucose to 150 mg/dL and delivers less insulin for up to 24 hours.

In a 3-month clinical study, 3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis (DKA) were reported in children and adults/adolescents during Omnipod 5 System use. These cases were not related to automated insulin delivery malfunction.

Clinical results of SmartAdjust™ Technology in adults & adolescents[1]

More time in range, less time in hypoglycemia and reduction in HbA1c for adults and adolescents[1]:

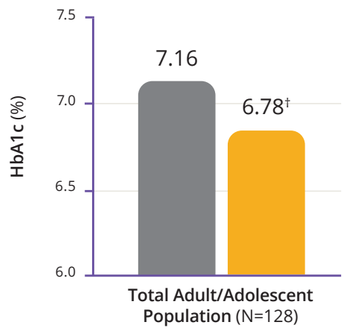
DEMONSTRATED 76% TIME IN RANGE AT A TARGET OF 110 mg/dL[1]



Omnipod 5 improved TIR by 9.3% (2.2 hours per day) in adolescents and adults[1]

- Standard Therapy (n=128)
- Overall Omnipod 5 System Use at Various Target Glucose Settings (n=128)
- Omnipod 5 System at 110 mg/dL Target (n=121)

REDUCED HbA1c BY 0.38%[1]

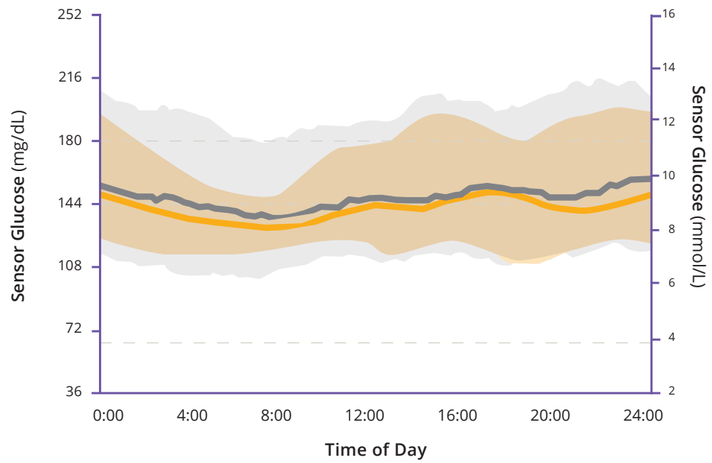


66% achieved ADA-recommended HbA1c goal (<7%)[1,2]

- Standard Therapy
- Omnipod 5 System

DEMONSTRATED 78% TIME IN RANGE OVERNIGHT‡,[1]

SENSOR GLUCOSE PROFILE BY TIME OF DAY



46% reduction of time in hypoglycemia overall[1]

60% reduction of time in hypoglycemia overnight[1]

- Standard Therapy
- Omnipod 5 System

In a 3-month clinical study, 3 cases of severe hypoglycemia and 1 case of diabetic ketoacidosis (DKA) were reported in children and adults/adolescents during Omnipod 5 System use. These cases were not related to automated insulin delivery malfunction.[1]

*AID significant compared to ST with $P<0.05$; Data shown as median (<54, <70) or mean (otherwise).

†$P<0.0001$. Data shown as mean.

‡$P<0.0001$. Data shown as median line and IQR (shaded area) with N=128; overnight period defined as 0:00-6:00. After 3 months of Omnipod 5 System use. The target range (70–180 mg/dL) is indicated by grey dashed lines. Measurements represent a 24-hr period from midnight to midnight.

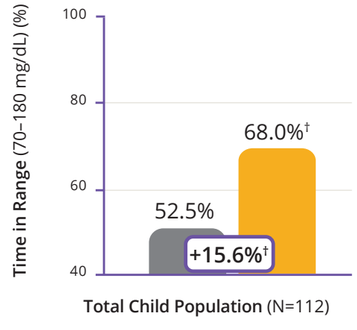
§$P<0.0001$. Data shown as median line and IQR (shaded area) with n=112; overnight period defined as 0:00–6:00. After 3 months of Omnipod 5 System use.

Clinical results of SmartAdjust™ Technology in children[1]

omnipod 5 automated insulin delivery system

Improved HbA1c and time in range across age groups, while time in hypoglycemia remained low[1]:

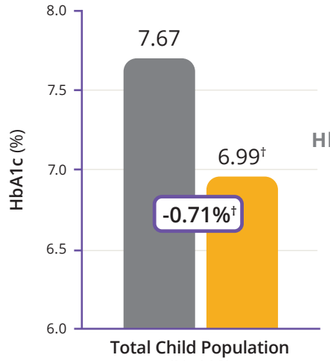
DEMONSTRATED 68% TIME IN RANGE[1]



Improved TIR by 15.6% (3.7 hours per day)[1]

- Standard Therapy
- Omnipod 5 System

REDUCED HbA1c BY 0.71%[1]

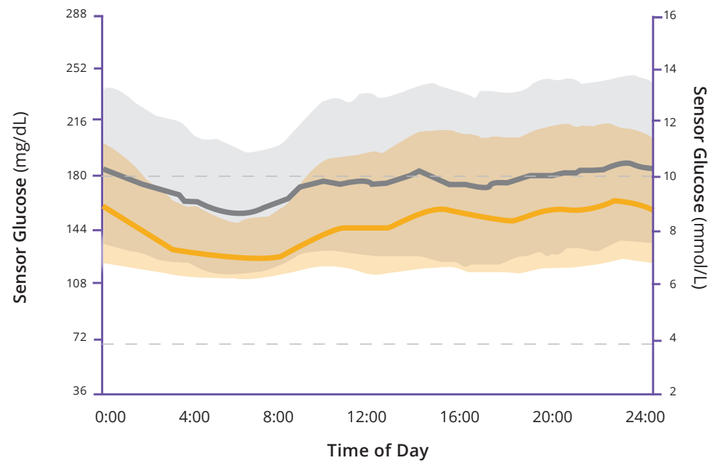


53% of children achieved ADA HbA1c goal of <7%[1,2]

- Standard Therapy
- Omnipod 5 System

DEMONSTRATED 78% TIME IN RANGE OVERNIGHT§,[1]

SENSOR GLUCOSE PROFILE BY TIME OF DAY



Time in hypoglycemia overnight remained low[1]

- Standard Therapy
- Omnipod 5 System

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. Mean time 70-180mg/dL, as measured by CGM, during 110mg/dL Target BG in adults/adolescents (n=121)=75.6%. Mean time 70-180mg/dL as measured by CGM in adults/adolescents: ST=64.7%, 3-mo Omnipod 5=73.9%, $P<0.0001$. Mean HbA1c in adults/adolescents and children, ST vs 3-mo Omnipod 5: 7.16% vs 6.78%, $P<0.0001$; 7.67% vs 6.99%, $P<0.0001$, respectively. Mean time 70-180mg/dL in adults and adolescents (12AM-6AM) as measured by CGM: ST =64.3 %, 3-mo Omnipod 5=78.1%, P<0.0001. Median time <70 mg/dL in adults and adolescents as measured by CGM: ST=2.00%, 3-mo Omnipod 5=1.09%, P<0.0001. Comparison is a relative change. Median time <70 mg/dL in adults/adolescents (12AM - 6AM) as measured by CGM: ST=2.07%, 3-mo Omnipod 5=0.82%, P<0.0001. Comparison is a relative change. Results measured by CGM. Median time <70 mg/dL in children (12AM - 6AM) as measured by CGM: ST=0.78%, 3-mo, Omnipod 5=0.78%, $P=0.0456$. Mean time 70-180mg/dL in children (12AM-6AM) as measured by CGM: ST=55.3%, 3-mo Omnipod 5=78.1%, $P<0.0001$.

2. ADA consensus guidelines: American Diabetes Association. *Diabetes Care.* 2020;43(Suppl. 1):S66–S76.

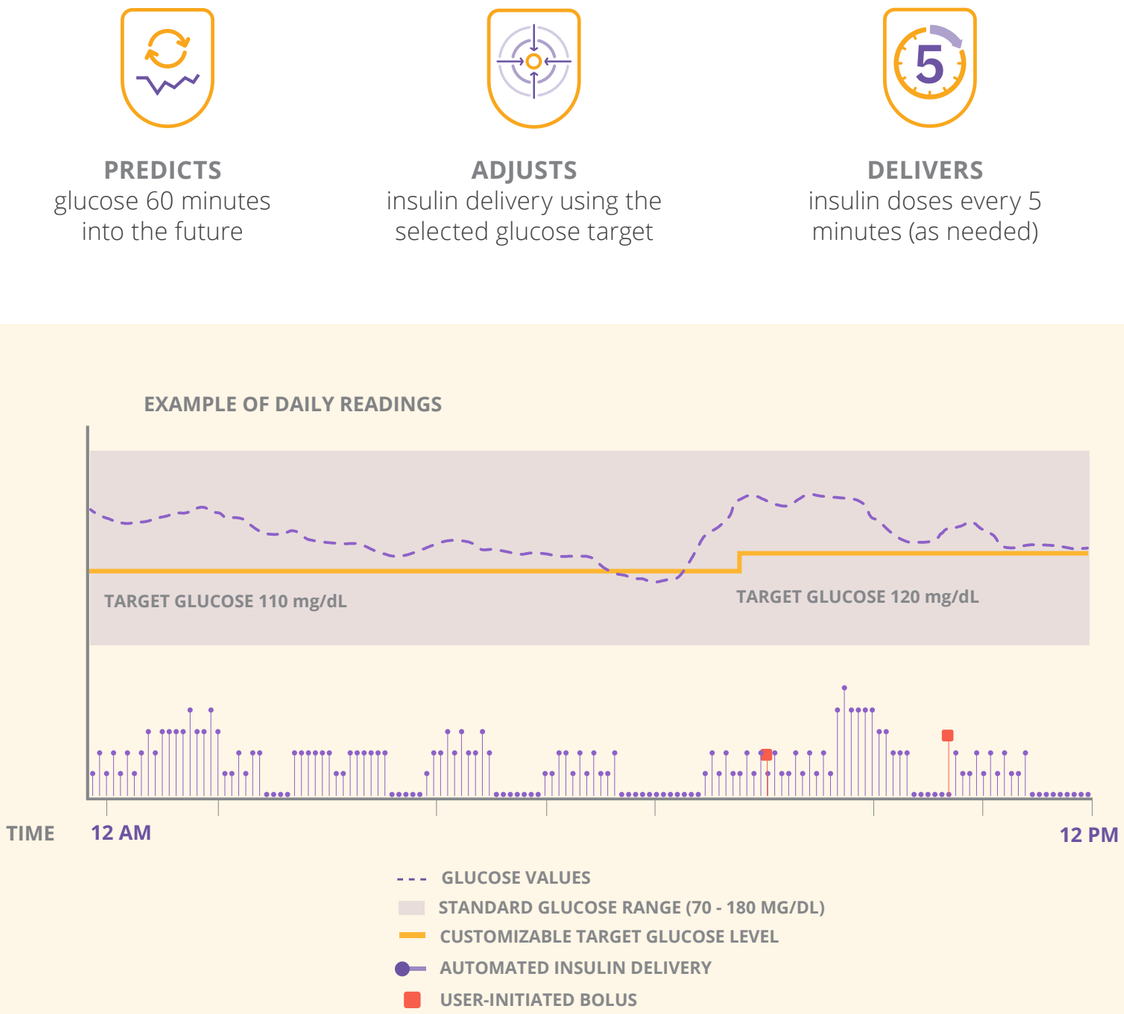
Customizable treatment

How SmartAdjust™ Technology works

PREDICTS
glucose 60 minutes into the future

ADJUSTS
insulin delivery using the selected glucose target

DELIVERS
insulin doses every 5 minutes (as needed)



Median time spent in automated mode was 97% for adults and adolescents and 96% for children[1]

Unique to Omnipod® 5

The only automated insulin delivery system with:

+ **No more multiple daily injections, tubing, or fingersticks***
  Fully integrated with the Dexcom G6 CGM for accurate, real-time glucose data[2]

+ **SmartBolus calculator**
  Informed with Dexcom CGM value and trend for bolus recommendations

+ **Accessibility through the pharmacy channel**
  Electronically prescribe; no c-peptide required

95% of clinical study participants elected to continue using Omnipod 5 into the extension phase[1]

*If your glucose alerts and readings from Dexcom G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.

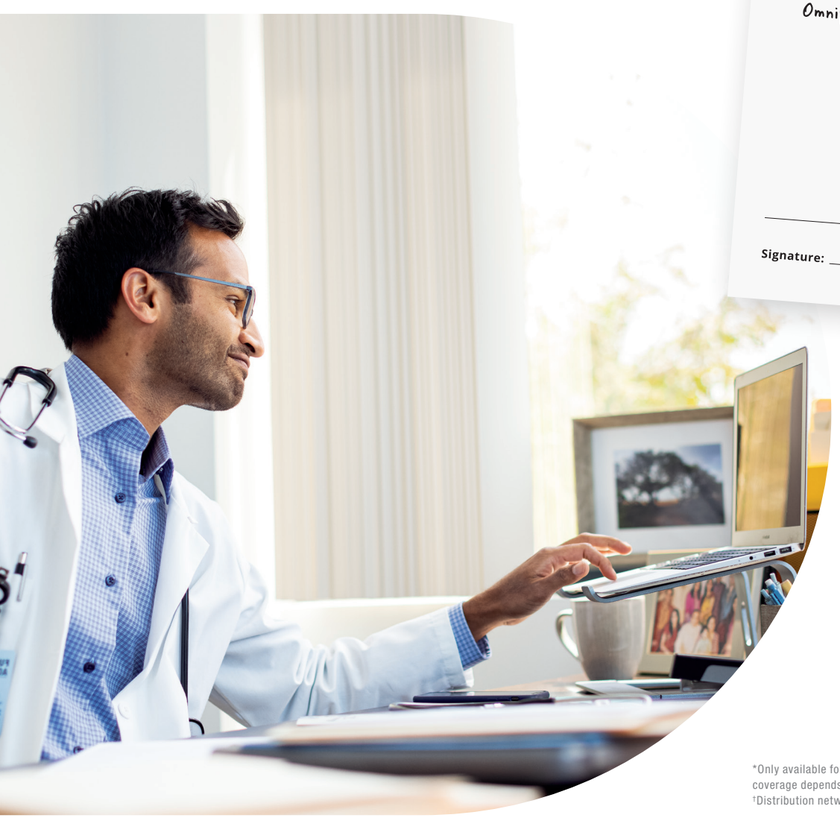
1. Brown S. et al. *Diabetes Care.* 2021;44:1630-1640. Prospective pivotal trial in 240 participants with T1D aged 6-70 yrs. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop phase, then the option to continue onto a 12-month extension phase.
2. Shah VN, et al. *Diabetes Technol and Ther.* 2018;20(6)

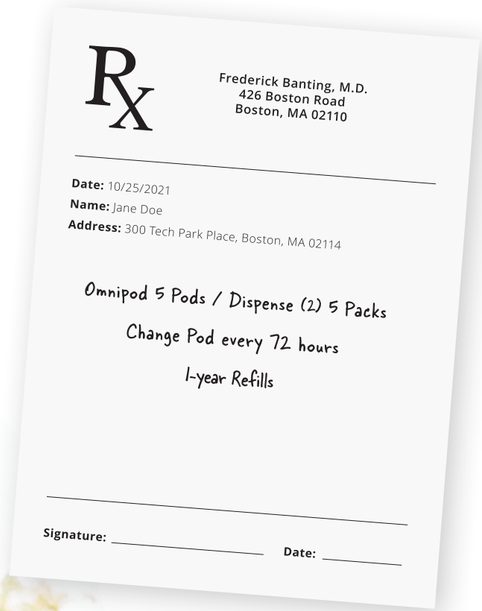
No DME contract commitments and fewer restrictions

Prescribe Omnipod® 5 today for your patients, even if they're already on an insulin pump or locked into a DME contract*

+ Your MDI patients can try the benefits of AID without worrying about a long-term (4-year) contract commitment
+ No c-peptide test or Medicare MDI step-through requirements

Simply eRx directly to the patient's pharmacy when available and covered.





*Only available for users with valid prescription and coverage through their pharmacy benefit. Exact coverage depends on patient's insurance plan. Upgrades subject to user's insurance coverage.
†Distribution network may be limited at initial launch.

Discover the pharmacy advantage

+ Available nationwide through the pharmacy and mail order, including major retailers CVS and Walgreens†
+ Patients can pick up Pods at the same place as their insulin†
+ Easy upgrade to future technology once available and **covered by insurance***

Prescribing Omnipod 5 is simple and convenient with the Omnipod 5 Intro Kit

+ Send a prescription for the kit to the patient's desired pharmacy Omnipod 5 G6 Intro Kit (Gen 5) (NDC 08508-3000-01)
+ Omnipod 5 G6 Pods (Gen 5): Refill 5-pack (NDC 08508-3000-21)

Omnipod 5 Intro Kit

An Omnipod® Product Specialist is available to help you and your office staff with PAs or appeals. Contact a specialist at 844-810-5217, Monday-Friday, 8am to 8pm.

Easy access to patient data

Completely wireless and eliminates in-clinic cable upload

+ **Uses Wi-Fi or cellular** connection for automatic data upload

Timely and convenient data

+ **Automatic upload** of insulin delivery and CGM data at your fingertips*

Clear insights for enhanced treatment decisions

+ Combined insulin and CGM **data summary reports**

*Must be connected to WiFi or cellular data, and Omnipod 5 users must have WiFi or cellular data access to receive updates in Glooko.

Streamline in-person and remote patient visits

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automated insulin delivery system

Automated Glucose Control Simplified

Improved Clinical Results

+ Demonstrated improved HbA1c and time in range across age groups, while time in hypoglycemia remained low[1]
+ Predictive, adaptive SmartAdjust™ Technology automatically adjusts insulin delivery every 5 minutes to help protect against highs and lows[1]

Simplified Glucose Management

+ On-body automated insulin delivery; fewer devices and less hassle*
+ Customizable glucose targets throughout the day; adjustable from 110-150 mg/dL†
+ The only AID System with SmartBolus calculator; incorporates CGM value and trend

E-prescribe through the pharmacy. Insurance coverage available through the pharmacy benefit‡

For more information about Dexcom G6, visit **www.provider.dexcom.com**

Dexcom G6

To learn more about Omnipod 5, scan here to join our OmnipodConnect HCP community.

***Safety and Intended Use Information:** The Omnipod 5 System is indicated for use by individuals with Type 1 diabetes mellitus in persons 6 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 6 years old. SmartAdjust technology should also NOT be used in people who require less than 6 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 www.omnipod.com/safety for additional important safety information.

*The Omnipod 5 Pod is tubeless and waterproof, designed to hold up to 200 units of insulin and replaces an average of 14 injections delivering insulin for up to 72 hours.

†Glucose targets can be adjusted in 10 mg/dL increments.

‡Only available for users with valid prescription and coverage through their pharmacy benefit. Exact coverage depends on patient's insurance plan. Upgrades subject to user's insurance coverage.

References:

1. Brown S. et al. *Diabetes Care.* 2021;44:1630-1640. Prospective pivotal trial in 240 participants with T1D aged 6-70 yrs. Study included a 14-day standard therapy (ST) phase followed by a 3-month Omnipod 5 hybrid closed-loop phase, then the option to continue onto a 12-month extension phase. 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 <70 mg/dL, 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 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. Mean time 70-180mg/dL in adults/adolescents and children, ST vs. 3-mo. Omnipod 5: 64.7% vs. 73.9%, P<0.0001; 52.5% vs. 68.0%, P<0.0001, respectively. Timed-related results measured by CGM.

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