

The Omnipod[®] 5 Automated Insulin Delivery System:

A Healthcare Provider's Guide to
Understanding System Behavior
and Optimizing Initiation
and Management





INDICATIONS FOR USE:

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. The Omnipod 5 ACE Pump is intended for single patient, home use and requires a prescription.

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. SmartAdjust technology is intended for the management of type 1 diabetes mellitus in persons 6 years of age and older. SmartAdjust technology is intended for single patient use and requires a prescription.

The Omnipod 5 SmartBolus Calculator is software intended for the management of diabetes in persons aged 6 and older requiring rapid-acting U-100 insulin. The Omnipod 5 SmartBolus Calculator calculates 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. The Omnipod 5 SmartBolus Calculator is intended for single patient, home use and requires a prescription.

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. **Warning:** DO NOT use SmartAdjust technology in pregnant women, critically ill patients, and those on dialysis. The safety of SmartAdjust technology has not been evaluated in these populations. For a full list of warnings and precautions, refer to the Omnipod® 5 Automated Insulin Delivery System User Guide at www.omnipod.com for complete safety information including indications, contraindications, warnings, cautions, and instructions.

CONTRAINDICATIONS:

- 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
 - 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.

COMPATIBLE INSULINS:

- The Omnipod 5 ACE Pump® is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.
- SmartAdjust technology is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.
- The Omnipod 5 SmartBolus Calculator is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.

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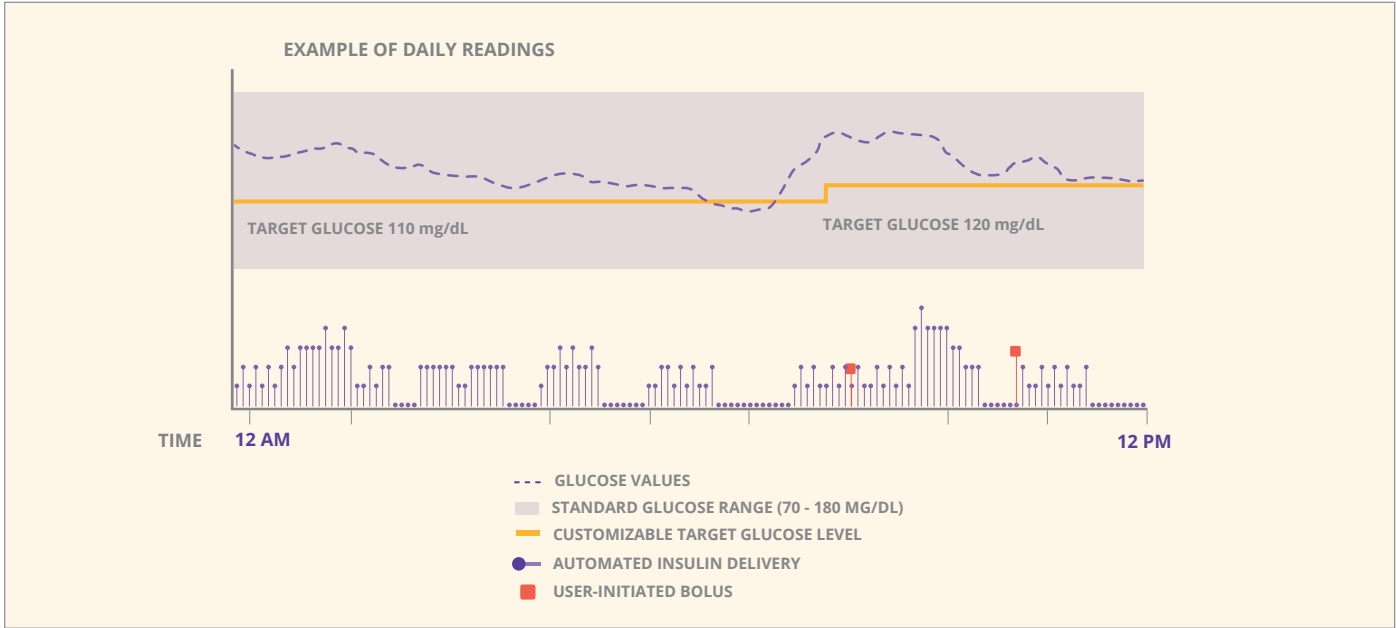
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Omnipod® 5 System Behavior

The Omnipod 5 Automated Insulin Delivery System is the first and only FDA cleared tubeless automated insulin delivery system. The Pod contains SmartAdjust™ technology to automatically increase, decrease, and pause insulin delivery based on current and predicted glucose values. The Omnipod 5 System is intended for the management of type 1 diabetes in persons 6 years of age and older*.

How CGM Trend Affects Automated Insulin Delivery

When CGM values are predicted to be¹:	System Action
Above Target Glucose	Automated insulin delivery generally increases. If CGM values are trending downwards, automated insulin delivery may still decrease or pause even if CGM values are above Target Glucose.
Within Target Glucose	Automated insulin delivery is generally maintained to keep CGM values near Target Glucose.
Below Target Glucose	Automated insulin delivery generally decreases or pauses. If CGM values are trending upwards, automated insulin delivery may still increase even if CGM values are below Target Glucose.
Less than 60 mg/dL	Automated insulin delivery will always pause.



Omnipod® 5 System Communication



Delivery of insulin in Automated Mode or Manual Mode continues as programmed if away from the Controller or smartphone. Users should avoid leaving the Controller or smartphone in a place that would prevent them from hearing alarms or notifications from the Omnipod 5 App.

*The Omnipod 5 System can be used with or without a CGM, but to benefit from automated insulin delivery, it must be paired with the Dexcom G6 CGM. The Omnipod 5 System is cleared for use in ages 6 years+. The Dexcom G6 CGM is sold separately.

*See list of compatible devices at www.omnipod.com/compatibility.
**The Omnipod 5 System must be used with the Dexcom G6 mobile app and is not compatible with the Dexcom receiver.

Omnipod® 5 System Readiness

Expectation Setting

Realistic expectation setting with users before initiating the Omnipod 5 System is essential. Establishing expectations for automated insulin delivery (AID) technology at initiation promotes retention and optimal outcomes².

Over time, the Omnipod 5 System will continue to adapt to the user's needs as it builds history on the user's insulin requirements¹.

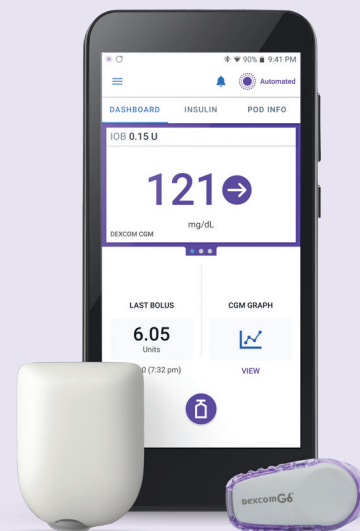
The Omnipod 5 System is also known as a hybrid closed-loop system since user intervention is required.

Prior to initiation, convey necessary user actions:

- Need to deliver bolus for carbohydrate intake at meals and snacks to minimize postprandial hyperglycemia.
- Need to perform Pod & sensor changes.
- Need to respond to alerts & alarms.

Preparing for Initiation

- While AID technology has been shown to improve overall glycemic control³, hypoglycemia and hyperglycemia can still occur. Ensure the user is knowledgeable regarding hypoglycemia prevention and treatment and troubleshooting hyperglycemia.
- Set up realistic goals and a follow-up plan with the user to help ensure success.
- Encourage the user to download the Omnipod 5 Simulator prior to Omnipod 5 System start to experience a system overview and interact with key features and functionality.



Pod shown without the necessary adhesive.



Omnipod® 5 System Start

First Time Setup

The Omnipod 5 App can be downloaded to a compatible* smartphone and is also integrated into the Omnipod 5 Controller. If using the Omnipod 5 App on a compatible smartphone, users will need to sign into the Insulet-provided Controller first.

Setting up the system for the first time will include signing in with an Omnipod ID and entering initial insulin settings. To create an Omnipod ID, users will visit [Omnipod.com/setup](https://omnipod.com/setup) to create their account,

link data management accounts, and learn about training options.

After Omnipod 5 App setup is complete, the user will then activate a Pod and connect their CGM to the Omnipod 5 System.

The Pod should be changed at least once every 3 days or after delivering 200 units of insulin, whichever comes first.

*See list of compatible devices at www.omnipod.com/compatibility.

Pod Placement

Careful Pod and CGM placement are important to optimize connectivity. Place the Pod so it is:

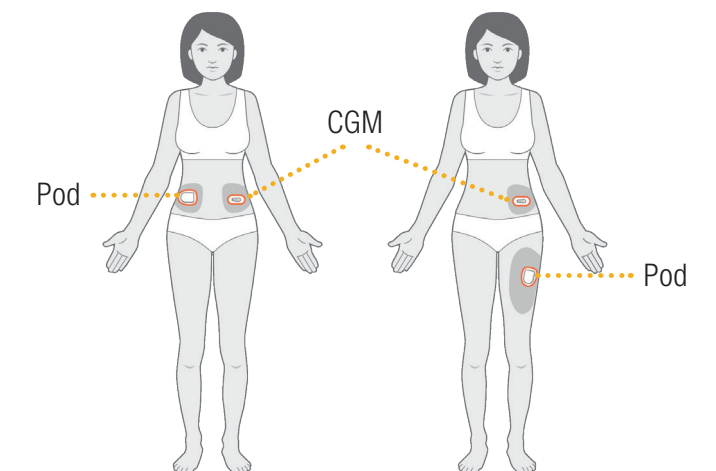
- In direct line of sight of the CGM
- At least three inches from the CGM sensor site
- Horizontal or diagonal on the abdomen, hip, lower back, or buttocks
- Vertical or at a slight angle on the upper arm or thigh
- Avoiding sites where belts, waistbands, or tight clothing may rub against or dislodge the Pod or CGM
- Avoid placing the Pod over a mole, tattoo, or scar, where insulin absorption could be reduced

Connecting the CGM is done by entering the Dexcom transmitter serial number into the Omnipod 5 App. The connection process can take up to 20 minutes.

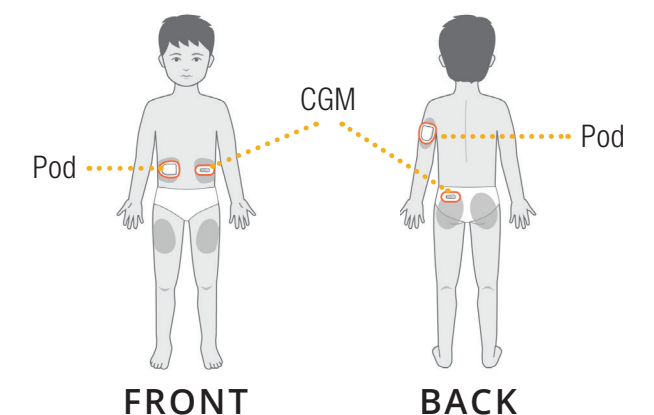
Note: The Dexcom G6 receiver cannot be used with the Omnipod 5 System because the Omnipod 5 System is compatible only with the G6 app on a smartphone. All sensor and transmitter-specific actions are controlled through the Dexcom G6 app.**

**Dexcom CGM sold separately. The Omnipod 5 System must be used with the Dexcom G6 mobile app and is not compatible with the Dexcom receiver. All Dexcom G6 alerts are configured and driven by the Dexcom G6 app.

ADULT PLACEMENT EXAMPLES



PEDIATRIC PLACEMENT EXAMPLES



Beginning Automated Mode

An active Pod and CGM transmitter serial number are required to switch to Automated Mode. Users can switch to Automated Mode immediately with the first Pod.

- With the first Pod wear, since no recent insulin delivery history is available, SmartAdjust™ technology uses the user-entered Basal Program as a baseline to initiate automated insulin delivery. As a safety measure, automated insulin delivery will be more restrained for the first Pod.
- With subsequent Pod changes, SmartAdjust™ technology uses the “adaptive basal rate” as a baseline for automated insulin delivery.
 - The adaptive basal rate is based on insulin delivery history.
 - Adaptivity adjusts with each Pod change to meet individual insulin needs.



Omnipod® 5 System Management and Optimization

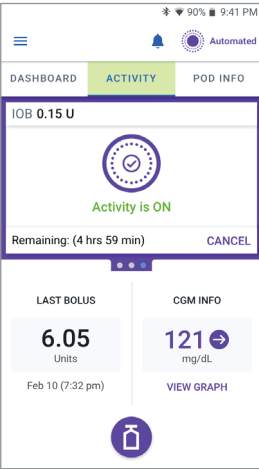
Adjustable Settings

Automated Insulin Delivery	
Target Glucose is the only adjustable setting that directly impacts automated insulin delivery. <ul style="list-style-type: none">Customizable to user needs110, 120, 130, 140, 150 mg/dLUp to 8 time segments Target Glucose is used for both the target for automated insulin delivery in Automated Mode as well as the target for correction bolus dosing in Automated and Manual Modes.	
Manual Basal Delivery	SmartBolus Calculator
Adjusting Basal Program segments only impacts Manual Mode basal insulin delivery. <ul style="list-style-type: none">Basal Program (Manual Mode)	SmartBolus Calculator settings impact suggested bolus doses in Automated and Manual Modes and include: <ul style="list-style-type: none">Target Glucose and Correct Above ValuesInsulin to Carb RatioCorrection FactorDuration of Insulin ActionReverse CorrectionMinimum Glucose for Calculations

The Activity Feature

The Activity feature is an optional feature in Automated Mode. When enabled, the Activity feature reduces automated insulin delivery and temporarily sets the Target Glucose to 150 mg/dL. The Activity feature is ideal during times of anticipated decreases in insulin needs such as aerobic exercise, or other periods of caution towards hypoglycemia.

Activity can be set for 1-24 hours in one-hour increments. Upon cancellation or expiration of the defined time period, full automated insulin delivery starts on its own and SmartAdjust™ technology returns to using the Target Glucose defined in settings.



Screen images shown in this guide are examples only and are not suggestions for user settings.

SmartBolus Calculator

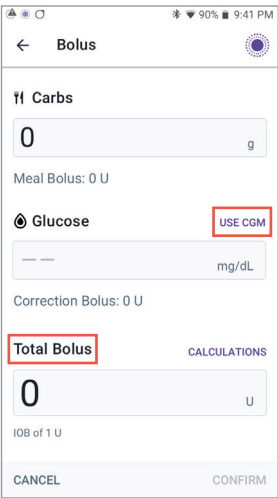
Omnipod 5 is the only system to incorporate CGM value *and* trend into the Bolus Calculator.

CGM-Informed

- Automatically increases or decreases suggested bolus based on CGM value and trend.
- Available in both Automated and Manual Modes.

Insulin on Board (IOB)

- May reduce the suggested bolus based on existing IOB.
- IOB may come from previous meal boluses, previous correction boluses, or automated insulin deliveries.



Troubleshooting System Communication

Pod & CGM

At times, the Pod and CGM may lose connection while in Automated Mode. Common reasons for loss of communication may include:

- Pod and CGM not being within line of sight on the body.
- Temporary loss of communication due to environmental interference.
- Sensor warm-up or required calibration.

When this occurs, SmartAdjust™ technology can no longer fully adjust automated insulin delivery and Automated Mode becomes “Limited”.

In Automated Mode: Limited, the Omnipod 5 System will deliver basal insulin based on a calculation of user-entered settings and past insulin delivery history. When the System enters Limited state, SmartAdjust technology never gives more than the Basal Program that would be active during Manual Mode.

Check the Dexcom G6 app to see if there are any necessary CGM actions required to re-establish communication. Full Automated Mode will automatically resume once CGM values become available.

Pod & Omnipod 5 App

At times, the Omnipod 5 App may lose communication with the active Pod. If this occurs, the POD INFO tab on the Omnipod 5 App will display “No Pod Communication” and the user will have the option to tap MORE INFORMATION for details.

When there is no Pod communication, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode.

Bring the Controller or smartphone within 5 feet of the Pod to restore communication.

Automated Mode Exits

A user will be prompted to switch to Manual Mode to complete certain actions. These actions include:

- Manually pausing and starting insulin delivery.
- Editing a Basal Program.
- Changing the time or time zones.

In rare instances, a user will be required to switch to Manual Mode if they receive an Automated Delivery Restriction. This advisory alarm occurs in Automated Mode when insulin was either paused or at maximum delivery for too long. The user will be instructed to use a meter to check their blood glucose (BG) and determine next steps. The user will need to switch to Manual Mode for at least five minutes and should not return to Automated Mode until confirming CGM accuracy.

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Viewing History:

The Omnipod 5 App includes a CGM Graph to display CGM readings and historical insulin delivery.

The History summary, including CGM time in range details and insulin delivery, and a list of automated events can also be accessed from the History Detail screen.

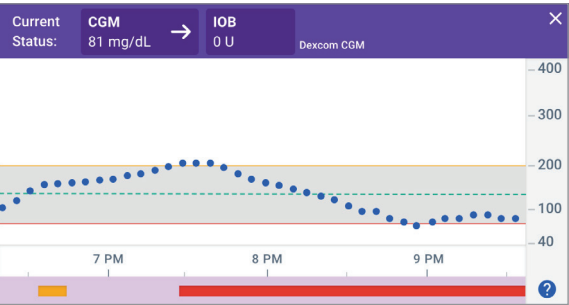
Cloud-Based Management:

The Omnipod 5 App will provide automatic flow of data to the cloud-based data management system on an hourly basis. This allows healthcare providers to review insulin delivery and sensor glucose patterns without manual uploads.

Connectivity to cellular data or Wi-Fi is important when using the Omnipod 5 System. Staying connected to cellular data or Wi-Fi will allow notification of important over-the-air updates as well as seamless auto-uploading of data to Insulet’s secure cloud. The Omnipod 5 Controller is equipped with a SIM card that allows connection to cellular data at no cost.



History		
Today, November 28		
SUMMARY		AUTO EVENTS
	CGM mg/dL	Insulin Amount U
11:35 am		Switched to Manual Mode
11:33 am	124	0.15
11:28 am	127	0.05
11:23 am	138	0.05
11:18 am	--	0
11:13 am	139	0
11:08 am	151	0
11:03 am	169	0.1





References

1. Forlenza G et al. First Outpatient Evaluation of a Tubeless Automated Insulin Delivery System with Customizable Glucose Targets in Children and Adults with Type 1 Diabetes. *Diabetes Technology & Therapeutics*. 2021;23(6). 2. Boughton CK, Hartnell S, Allen JM, Fuchs J, Hovorka R. Training and Support for Hybrid Closed-Loop Therapy. *Journal of Diabetes Science and Technology*. September 2020. doi:10.1177/1932296820955168 3. American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes - 2021. *Diabetes Care* 2021; 44(Suppl.1); S85-S99.

Medical Disclaimer: This handout is for information only and is not a substitute for medical advice and/or services from a healthcare provider. This handout may not be relied upon in any way in connection with personal healthcare related decisions and treatment.

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