For iPhone

OMNIPOD® 5

CAREGIVER GUIDE

FOR iPHONE USERS

omnipod® 5

automated insulin delivery system

Table of contents

This guide will help you feel comfortable taking care of someone with diabetes using the Omnipod® 5 Automated Insulin Delivery System. Let's start with the basics!

What is diabetes?

Diabetes is a chronic disease where the pancreas either does not produce any insulin or does not produce enough insulin for the body. People with diabetes need to replace the insulin their pancreas cannot make, either through injections or an insulin pump (standard or automated).

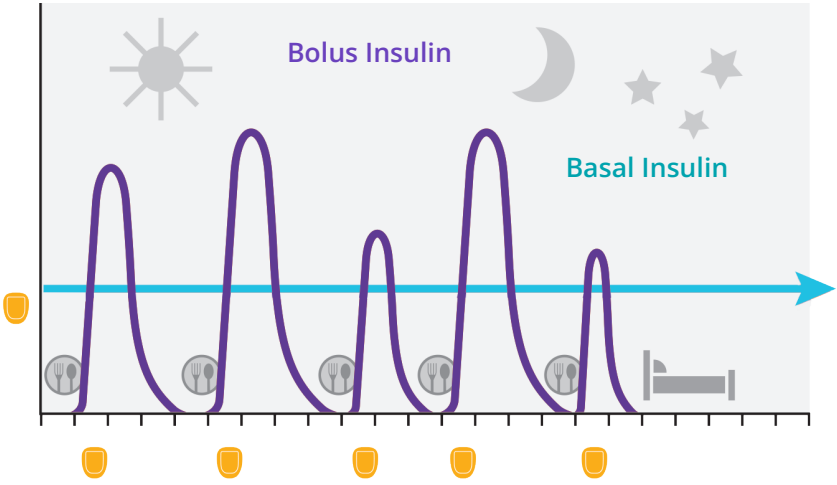
How do insulin pumps work?

Insulin pumps deliver insulin in two different ways, with basal and bolus doses.

Basal insulin covers background insulin needed to keep glucose levels in range between meals and overnight.

Bolus insulin is an additional dose of insulin needed for food (meal bolus) and/or to lower high glucose levels (correction bolus).

Insulin delivery in standard insulin pump therapy

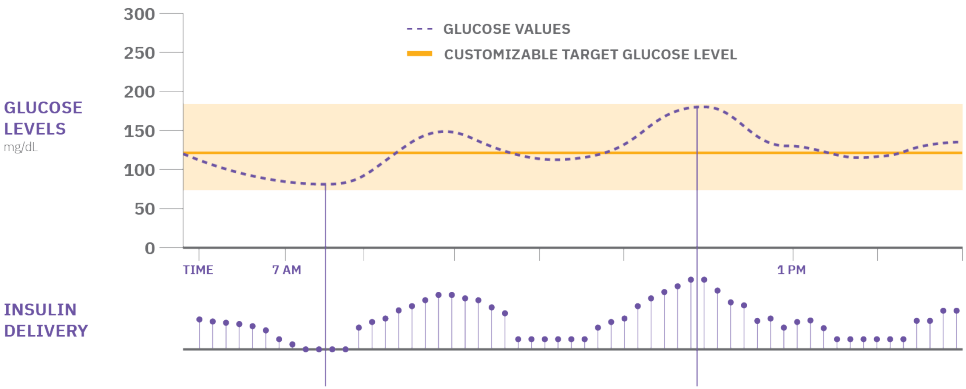


Insulin Delivered From Pod

Insulin delivery in Automated Insulin Delivery (AID) Systems

In AID systems like Omnipod® 5, automated insulin delivery is adjusted automatically based on sensor glucose values. With Omnipod 5, the system automatically increases, decreases or pauses insulin delivery every 5 minutes based on where glucose is predicted to be 60 minutes into the future.

How Omnipod 5 works



HELPS PROTECT AGAINST LOWS[1-3]
When your levels are dropping, SmartAdjust™ technology automatically decreases or pauses insulin delivery.

HELPS PROTECT AGAINST HIGHS[1-3]
When your levels are rising, SmartAdjust™ technology automatically increases insulin delivery.

NOTE!
The Omnipod 5 System will always pause insulin delivery when glucose is below 60 mg/dL.

1. Brown S. et al. Diabetes Care (2021). Study in 240 people with T1D aged 6 - 70 years involving 2 weeks standard diabetes therapy followed by 3 months Omnipod 5 use in Automated Mode. Average time with high blood glucose in adults/adolescents and children, standard therapy vs 3-month Omnipod 5: 32.4% vs. 24.7%; 45.3% vs. 30.2%. Average time with low blood glucose in adults/adolescents and children, standard therapy vs 3-month Omnipod 5: 2.9% vs. 1.3%; 2.2% vs. 1.8%. Study funded by Insulet.
2. Sherr JL, et al. Diabetes Care (2022). Study in 80 people with T1D aged 2 - 5.9 yrs involving 2 weeks standard diabetes therapy followed by 3 months Omnipod 5 use in Automated Mode. Average time with high blood glucose in very young children, standard therapy vs 3-month Omnipod 5: 39.4% vs. 29.5%. Average time with low blood glucose in very young children, standard therapy vs 3-month Omnipod 5: 3.43% vs. 2.46%. Study funded by Insulet.
3. Pasquel FJ, et al. JAMA Network Open (2025). Prospective pivotal trial in 305 participants with T2D aged 18-75 yrs. Study included a 14-day standard therapy (ST) phase followed by a 13-week Omnipod 5 hybrid closed-loop phase. Mean time >180 mg/dL as measured by CGM: ST = 54%, 3-mo Omnipod 5 = 34%, P<0.001. Mean time <70 mg/dL as measured by CGM: ST = 0.2%, 3-mo Omnipod 5 = 0.2%.

What is the Omnipod® 5 Automated Insulin Delivery System?

The Omnipod 5 System automatically adjusts insulin delivery every 5 minutes to manage glucose levels. The system will increase, decrease or pause insulin based on the sensor glucose value and trend.

The Omnipod 5 App

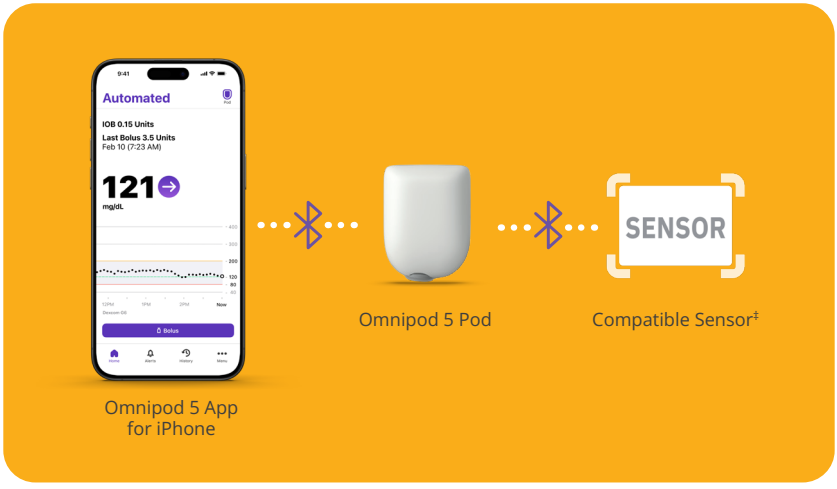
Control the Pod's operations from a compatible smartphone* or the Insulet-provided Controller. Always keep the Omnipod 5 App or Controller close to hear any alerts and alarms.

The Omnipod 5 Pod

Tubeless, wearable and waterproof,† the Pod automatically adjusts and delivers insulin for up to 3 days or 72 hours.

Sensor

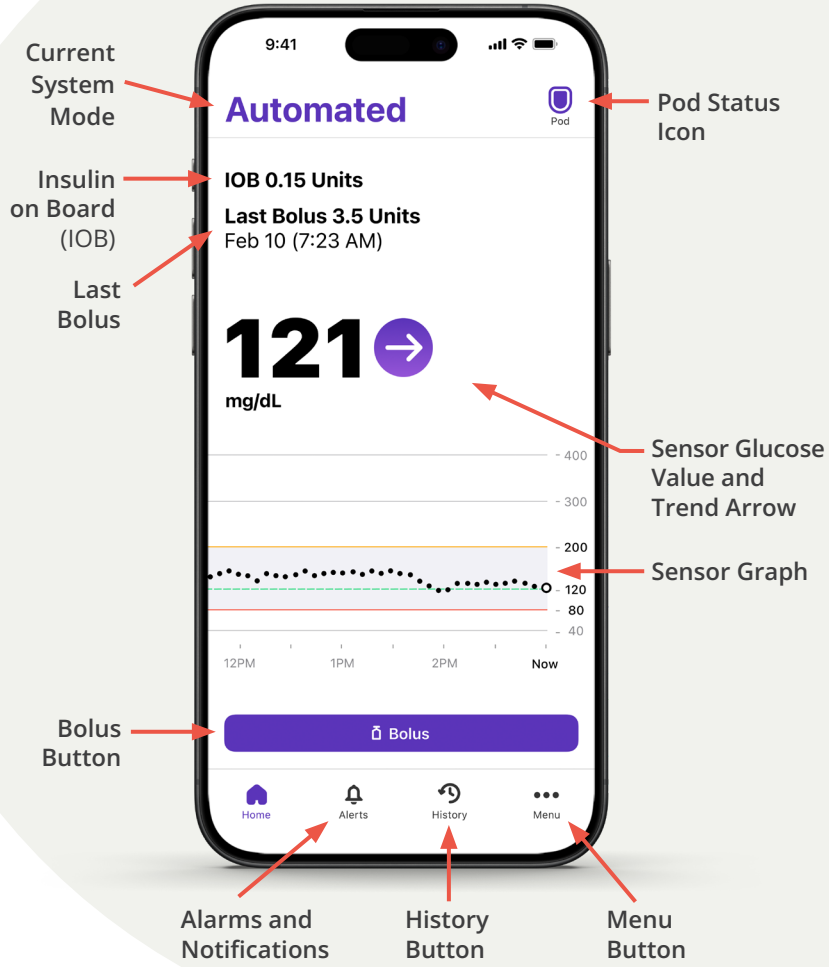
Sends glucose values to the Pod. A separate prescription is required for the Sensor. Refer to the *Instructions for Use* for the compatible Sensor.



Pod shown without the necessary adhesive

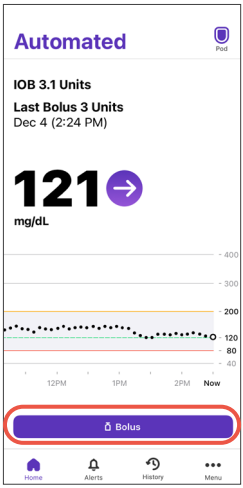
* Go to omnipod.com/compatibility for a list of compatible smartphones.
† The Pod has a waterproof IP28 rating for up to 25 feet for up to 60 minutes. The Omnipod® 5 Controller is not waterproof. Consult Sensor manufacturer Instructions for Use for Sensor waterproof rating.
‡ Compatible Sensors are sold and prescribed seperately.

Omnipod® 5 Home Screen

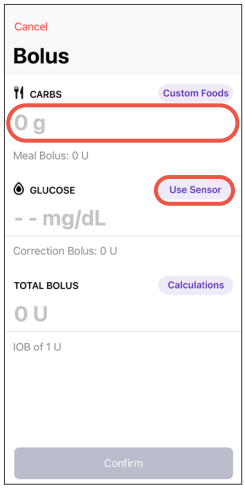


How to deliver a bolus

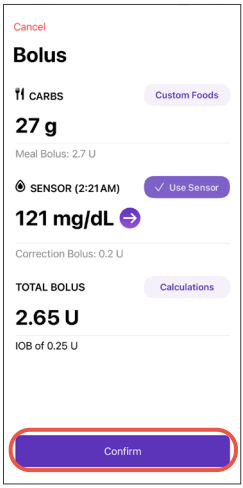
With the Omnipod® 5 System, it is still important and necessary to bolus (deliver an insulin dose) for meals and to bring down high glucose. It is ideal to start a meal bolus at least 15-20 minutes before eating to prevent hyperglycemia.[1]



To start a bolus, tap the Bolus button



Tap on the **CARBS** field to manually enter carbs or tap **Custom Foods** to use previously saved carb counts. Tap **Use Sensor** to use sensor glucose value and trend for a correction bolus*



Tap **Confirm**

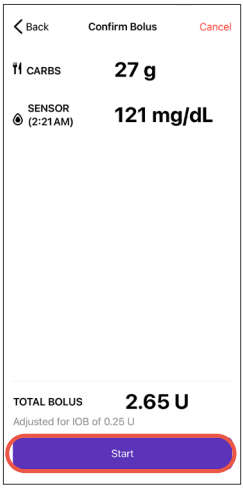
TIP!

If snacking or having a second helping, do not re-enter the glucose value. Enter only the carbohydrates to keep from adding too much insulin at once. If glucose is still high a few hours after the snack or second helping, you can give a correction bolus then.

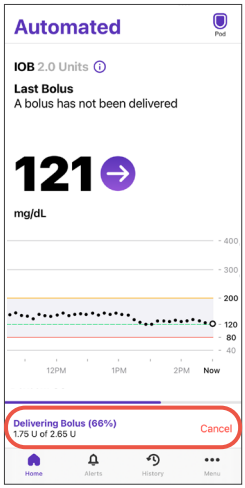
* Tap Glucose field to manually enter your BG

1. Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

Omnipod 5 App screens are for educational purposes and may vary depending on operating system.
Consult your healthcare professional before using these features and for personalized recommendations.



Review the entries to ensure they are correct, then tap **Start**



Confirm the screen says Delivering Bolus and shows a progress bar before moving away from the Omnipod 5 App

TIP!

The SmartBolus Calculator suggests insulin amounts based on glucose value, trend and active insulin. Tap Calculations to see additional information.

Omnipod 5 App screens are for educational purposes and may vary depending on operating system.
Consult your healthcare professional before using these features and for personalized recommendations.

Managing glucose levels

Low glucose (hypoglycemia)

Low glucose is when the amount of glucose drops below 70 mg/dL. If the person with diabetes has any of the symptoms below, check glucose to confirm. If symptoms do not match sensor readings, test glucose with BG meter. Always follow the treatment plan provided by the primary caregiver and/or healthcare provider.

Symptoms of hypoglycemia include:

1. Check glucose if you think (or they feel) that they are low
2. Treat the low glucose with 5-15 grams of fast-acting carbohydrates[1]
3. Check again in 15 minutes to make sure the glucose is going up
4. If still under 80 mg/dL, treat again

SOURCES OF **15 GRAMS** OF **CARBS**

- 3-4 glucose tabs
- 1 tablespoon of sugar
- ½ cup (4oz) juice or regular soda (not diet)

Potential causes of low glucose:

Food
- Did they eat as many carbohydrates as planned?
- Did they wait to eat after taking their insulin?

Activity
- Were they more active than usual?

Medication
- Did they take more insulin or medication than usual?

TIP!

These are the most common symptoms to look for:

Low:_____ High: _____

_____ _____

1. Boughton CK, Hartnell S, Allen JM, Fuchs J, Hovorka R. Training and Support for Hybrid Closed-Loop Therapy. J Diabetes Sci Technol. 2022 Jan;16(1):218-223.

High glucose (hyperglycemia)

High glucose is when there is too much glucose in their blood, usually over 250 mg/dL. If you notice any of the symptoms below or they feel them, check glucose to confirm. Always follow the treatment plan provided by the primary caregiver and/or healthcare provider.

Symptoms of hyperglycemia include:


Frequent Urination


Feeling Tired


Blurry Vision


Weight Loss


Thirsty

1. Check glucose. If BG is >250 mg/dL, check for ketones
2. If there are ketones present, follow the healthcare provider's guidance to give a bolus and perform a Pod change. Recheck BG in 2 hours. If it is still high, contact healthcare provider
3. If ketones are not present, give correction bolus from Pod and check BG again in 2 hours. If BG is the same or higher, follow step number 2, even if there are no ketones
4. Continue to monitor glucose as it lowers

Warning: If the person with diabetes is experiencing persistent nausea and/or vomiting, or has diarrhea over two hours, contact their healthcare provider immediately. In an emergency, another person should take them to the emergency room or call an ambulance; they should NOT drive themselves.

Potential causes of high glucose:

Food
- Did they increase their portion size of carbohydrates without accounting for it?
- Did they correctly calculate how much insulin to take?

Activity
- Were they less active than usual?

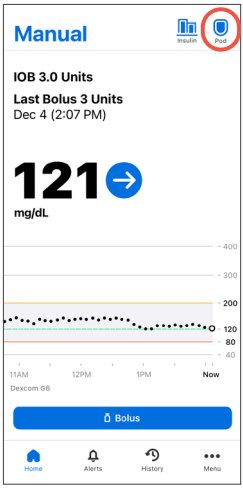
Wellness
- Are they feeling stressed or scared?
- Do they have a cold, flu or other illness?
- Are they taking any new medications?
- Have they run out of insulin in their Pod?
- Has their insulin expired?

Pod
- Is the Pod inserted properly? The small tube under the skin can dislodge or bend.
- **When in doubt, change the Pod**

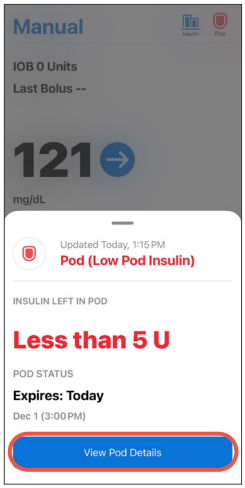
Note: The Omnipod 5 System cannot track insulin that is administered outside of the System. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.

How to change a Pod

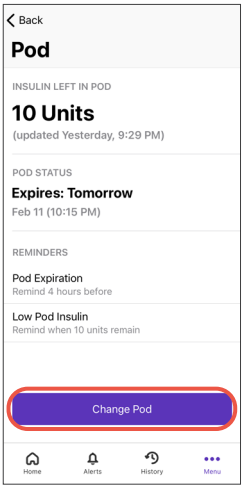
The Pod should be changed every 72 hours or when it has run out of insulin. There also may be rare instances when a Pod change is necessary for the system to keep working.



To deactivate and change Pod, tap the **Pod Status icon**



Tap **View Pod Details**



Tap **Change Pod**, and then tap **Deactivate Pod**. If the Pod has already been deactivated, tap **Set Up New Pod** after tapping the Pod Status Icon

Removing old Pod

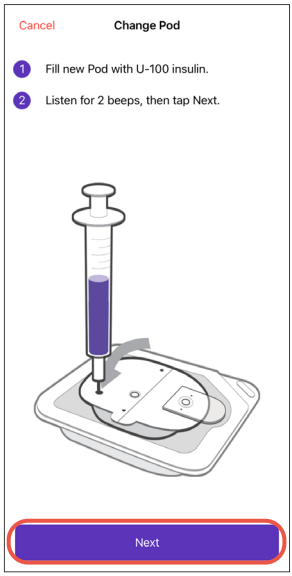
1. Gently lift the edges of the adhesive tape from the user's skin and remove the entire Pod. Remove the Pod slowly to help avoid possible skin irritation
2. Use soap and water to remove any adhesive that remains on the skin, or, if necessary, use an adhesive remover
3. Check the infusion site for signs of infection
4. Dispose of the used Pod according to local waste disposal regulations

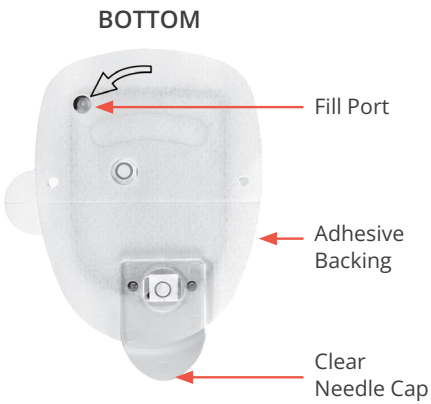
Caution: Do not apply a new Pod until you have deactivated and removed the old Pod. A Pod that has not been deactivated properly can continue to deliver insulin as programmed, putting the user at risk of over infusion and possible hypoglycemia.

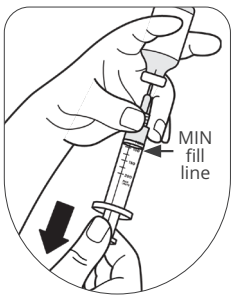
Filling a new Pod

1. Take the fill needle and twist clockwise onto syringe. Remove protective cap on needle
2. Pull back on plunger to draw air into syringe equal to the amount of insulin
3. Empty air into vial of insulin
4. Turn vial and syringe upside down and withdraw insulin
5. Tap or flick syringe to remove any bubbles

Leaving the Pod in its tray, insert the syringe straight down into the fill port and empty out all of the insulin. Be sure the Pod beeps twice. Put the Controller/App right next to the Pod and press **Next.**





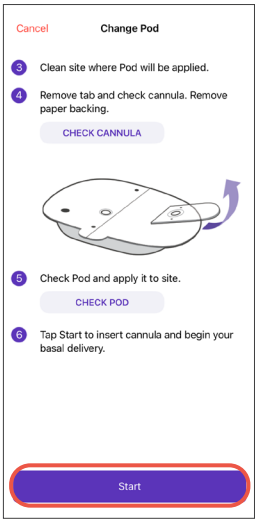


TIP!

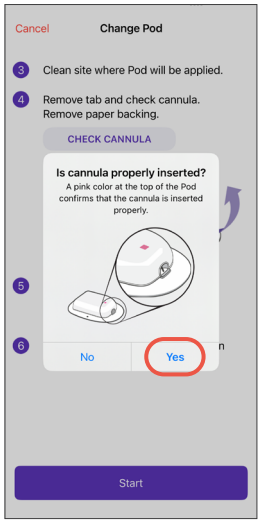
You must fill the Pod with at least 85 units of insulin, but no more than 200 units.

Fill the Pod with ____ units

Pod placement



Carefully follow the on-screen instructions. See below for proper Pod locations



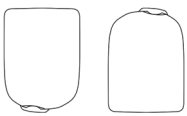
Check the Pod after insertion to ensure that the cannula was properly inserted by looking to see if the pink window is visible

TIP!

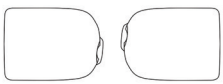
For optimal connectivity, the Pod should be placed in direct line of sight of the Sensor. Always put the Pod in a new location.

Pod positioning

Arm & Leg:
Position the Pod **vertically** or at a slight angle.



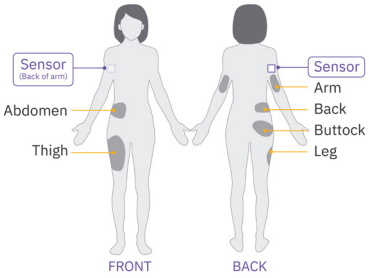
Back, Abdomen & Buttocks:
Position the Pod **horizontally** or at a slight angle.

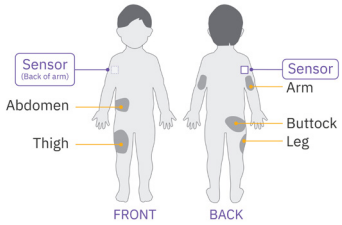


Pod shown without the necessary adhesive.

Pod & Sensor placement examples

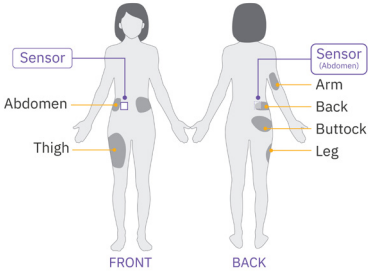
The Pod should be placed within the line of sight of the Sensor, meaning they are worn on the same side of the body such that the two devices can "see" one other without your body blocking their communication.

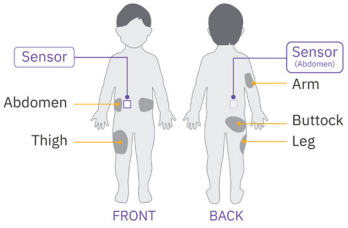




For Sensors indicated for the back of the upper arm*, consider these Pod placements that work best:

- On the same arm as Sensor
- Same side, abdomen
- Same side, lower back (adult only)
- Same side, thigh
- Same side, upper buttocks
- Opposite side, back of the arm





For Sensors indicated for the abdomen*, consider these Pod placements that work best:

- Same side, abdomen
- Opposite side, abdomen
- Same side, thigh
- Same side, lower back (adult only)
- Same side, upper buttocks
- Same side, back of the upper arm

For Sensors indicated for the buttock*, consider these Pod placements that work best:

- Same side, buttock
- Opposite side, buttock
- Same side, abdomen
- Same side, thigh
- On the back of either arm

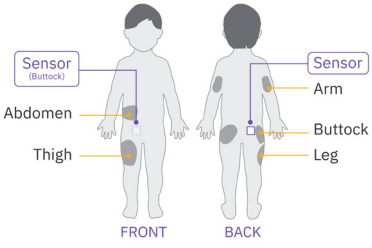
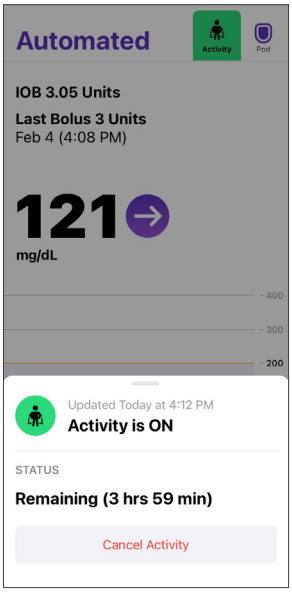


*Illustration for example only. Please refer to the Instructions for Use for your compatible Sensor for approved Sensor placement and separation distances.

Managing activity and exercise

What is the Activity feature?

While in Automated Mode, there may be times when you would like less insulin automatically delivered. When the Activity feature is started, the Omnipod 5 algorithm reduces insulin delivery and automatically sets the Target Glucose to 150 mg/dL for the time you choose.



When can the Activity feature be used?

During activities like sports, swimming, yard work, a walk in the park, or any other time when the glucose level tends to go low.

How do I start the Activity feature?

1. Tap the menu button
2. Tap **Activity**
3. Enter the desired duration, then tap **Confirm**
4. Tap **Start**

TIP!

It is recommended to start the Activity feature 60-120 minutes before activity[1]. This is when we like to use the Activity feature:

_____

_____

_____

_____

1. Berget C, Sherr JL, DeSalvo DJ, Kingman R, Stone S, Brown SA, Nguyen A, Barrett L, Ly T, Forlenza GP. Clinical Implementation of the Omnipod 5 Automated Insulin Delivery System: Key Considerations for Training and Onboarding People with Diabetes. Clin Diabetes. 2022;40(2):168-184.

The Pod has a waterproof IP28 rating for up to 25 feet (7.6 meters) for up to 60 minutes. The Omnipod® 5 Controller is not waterproof. Consult Sensor manufacturer Instructions for Use for Sensor waterproof rating.

Notifications, alerts and alarms

Follow the instructions on the screens to acknowledge the alarms and take action.

Hazard alarms

High priority alarms that indicate a serious problem has occurred and a Pod change may be needed

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WARNING:

Respond to Hazard Alarms as soon as possible. Hazard Alarms indicate that insulin delivery has stopped. Failure to respond to a Hazard Alarm can result in under-delivery of insulin, which can lead to hyperglycemia.

Advisory alarms

Lower priority alarms that indicate a situation exists that needs attention

Notifications

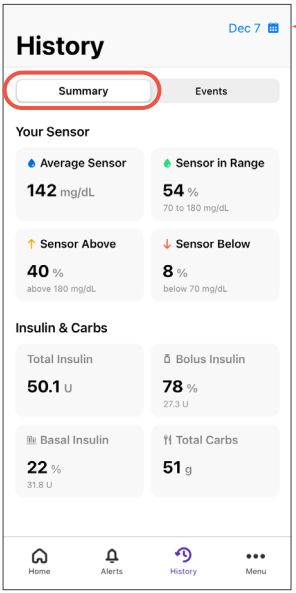
Reminder of an action that should be performed

Viewing history

To view the history summary and detail information, tap the History button on the toolbar of the Home screen.

Summary section

- The Summary section is broken up into Your Sensor, which highlights daily glucose history, and Insulin & Carbs, which shows insulin use and entered carbs

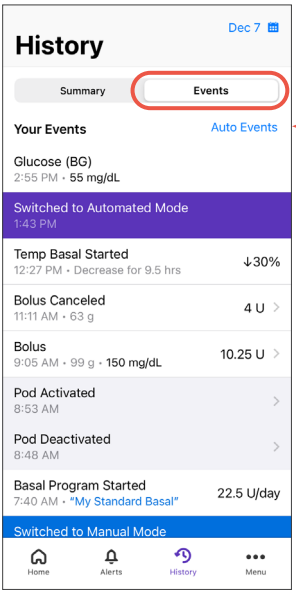


Date

- You can select a different date to view the summary and events from that day

Events section

- You can see record of previous activity from the Pod, including bolus history, switches between modes, and activation of different features, such as the Activity feature
- Tap any row to see more details about that event



Auto Events tab shows microbolus deliveries from Automated Mode

System states

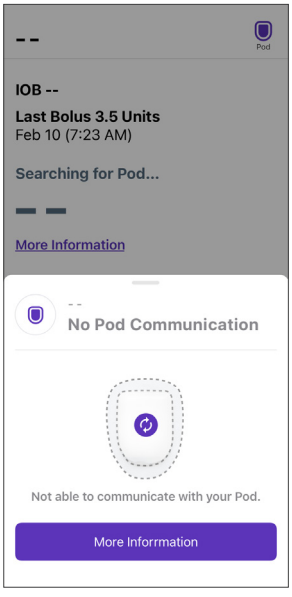
There are times when the Pod, Sensor, and/or Omnipod 5 App have issues communicating, but there are simple steps that can fix these issues.

No Pod Communication

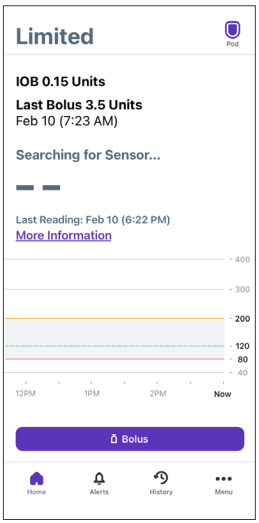
There may be times when the Pod and Omnipod 5 App are unable to communicate. If you see a “No Pod Communication” message, don’t worry. The Pod is still delivering insulin according to its last instructions and will update the Pod status when communication is restored.

What should you do?

- First bring the smartphone with the Omnipod 5 App and active Pod closer – within 5 feet of each other to try to restore communication.
- If the issue remains, the Omnipod 5 App will offer you options to resolve the communication issue. Leave any options to discard or deactivate Pod as last choice after trying the other options.



Automated Mode: Limited



At times, the Pod and Sensor may lose communication while in Automated Mode. There are several reasons this could happen, including:

- The Pod and Sensor not being within line of sight on the body
- Temporary loss of communication due to environmental interference
- Sensor warm-up
- If the Sensor is paired with another device

When this happens, the Omnipod 5 algorithm can no longer adjust automated insulin delivery based on glucose because the Pod is not receiving updated glucose information from the Sensor.

After 20 minutes of the Pod not receiving sensor glucose values, you move into a state of Automated Mode called Automated Mode: Limited. The Omnipod 5 App will display 'Limited' on the Home Screen. The System will remain in Automated Mode: Limited until Sensor communication is restored or the Sensor warm-up period ends.

After 60 minutes, if communication has not been restored, the Pod and Controller will alarm.

What should you do?

- Make sure the Pod and Sensor are in direct line of sight. If they are not, at the next device change, position the new one so that they are now in line of sight.

Is it still delivering insulin?

Yes, it is still delivering insulin. The System looks at the basal rate in Manual Mode at the current time of day and the Automated Mode Adaptive Basal Rate for this Pod and chooses the lower of the two values every 5 minutes. In this way, the algorithm never gives more than the Basal Program that would be active during Manual Mode.

Without sensor glucose information, the rate delivered in Automated: Limited will not adjust up or down for current or predicted glucose.

Supplies to have on hand:

Always keep an emergency kit with you to quickly respond to any diabetes emergency or in the case that your Omnipod® 5 System stops working. Always carry supplies to perform a Pod change should you need to replace your Pod at any time.

- ☐ Several new Pods
- ☐ A vial of insulin and syringes
- ☐ Glucose tabs or other fast-acting carbohydrates
- ☐ Sensor supplies
- ☐ Blood glucose meter and strips
- ☐ Ketone meter and strips or ketone urine strips
- ☐ Lancets
- ☐ Alcohol swabs
- ☐ Glucagon kit
- ☐ Omnipod 5 Caregiver Guide

Notes:

Add additional information here, such as daily schedule, or how to change a Sensor.

Contact Information

Primary Caregiver: _____

Customer Care: **1-800-591-3455**

Important User 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 and type 2 diabetes mellitus in persons 18 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. The Omnipod 5 algorithm 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 **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.

WARNING: The Omnipod 5 System should NOT be used by anyone under the age of 2 years old. The Omnipod 5 System 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 sensor 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, Sensor, and Transmitter 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.

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 hypoglycemia or hyperglycemia.

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Customer Care: **1-800-591-3455**
Insulet Corporation, 100 Nagog Park, Acton, MA 01720
omnipod.com

For more information on indications, warnings and complete instructions on how to use the Omnipod® 5 System, please consult the Omnipod 5 User Guide.