OMNIPOD® 5

CAREGIVER GUIDE

omnipod
automated insulin
delivery system
5

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 type 1 diabetes?

Type 1 diabetes is a chronic disease where the pancreas produces little to no insulin. People with diabetes need to replace the insulin their pancreas cannot make, either through injections or an insulin pump (standard or automated).
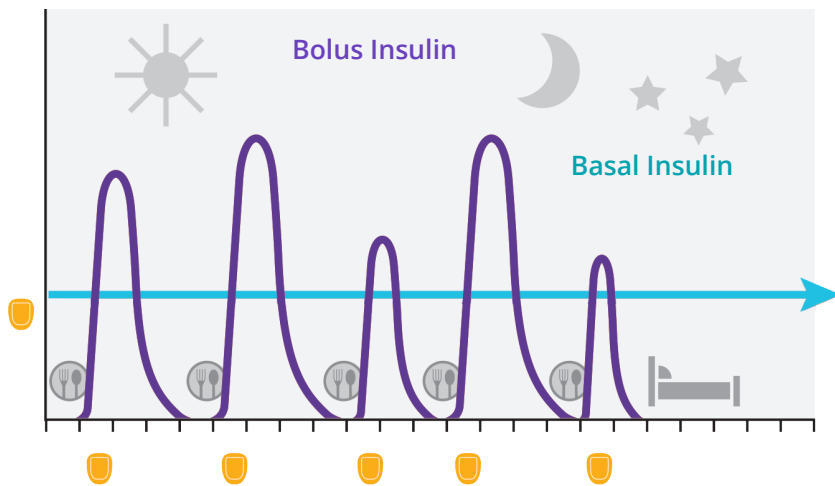
How do insulin pumps work?

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).

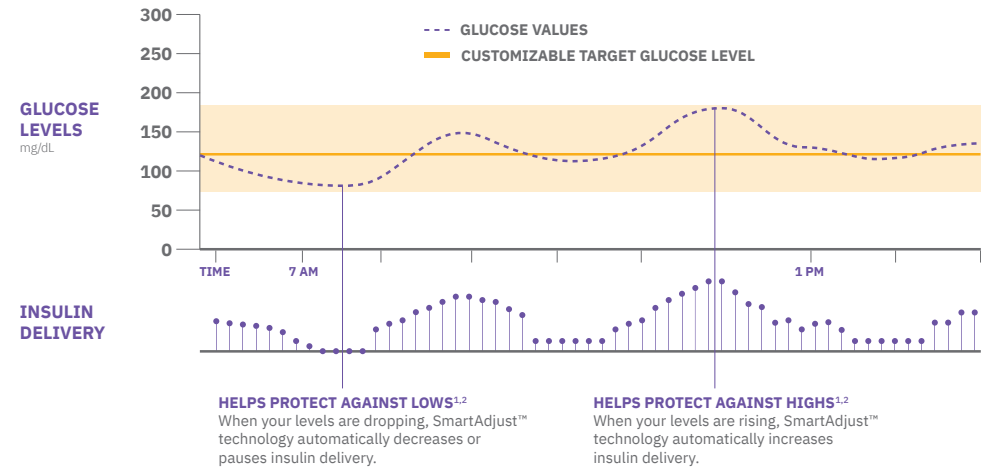## Insulin delivery in standard insulin pump therapy

Bolus Insulin

Basal Insulin

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 CGM/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

GLUCOSE VALUES

CUSTOMIZABLE TARGET GLUCOSE LEVEL

GLUCOSE LEVELS mg/dL

INSULIN DELIVERY

TIME   7 AM   1 PM

HELPS PROTECT AGAINST LOWS[1,2]
When your levels are dropping, SmartAdjust™ technology automatically decreases or pauses insulin delivery.

HELPS PROTECT AGAINST HIGHS[1,2]
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. 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 in Target Glucose range (from CGM) for standard therapy vs Omnipod 5 in adults/adolescents = 64.7% vs. 73.9% and children = 52.5% vs. 68.0%. Brown et al. Diabetes Care (2021).
2. 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 in Target Glucose range (from CGM) for standard therapy vs Omnipod 5 = 57.2% vs. 68.1%. SherrJL, et al. Diabetes Care (2022).

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 CGM/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.
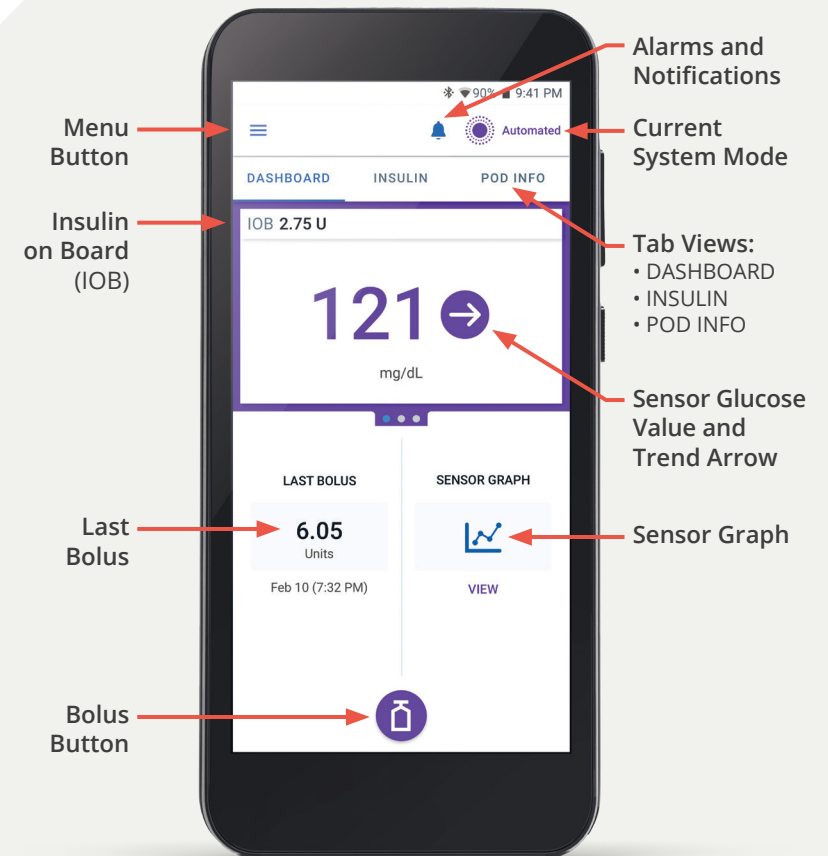
The Omnipod 5 Pod

Tubeless, wearable and waterproof,[†] the Pod with SmartAdjust™ technology, automatically adjusts and delivers insulin for up to 3 days or 72 hours.

Compatible continuous glucose monitor (CGM)/sensor

Continuously sends glucose values to the Pod so that SmartAdjust™ technology can automatically adjust insulin delivery.

Omnipod® 5 Home Screen

Menu Button

Insulin on Board (IOB)

Last Bolus

Bolus Button

Alarms and Notifications

Current System Mode

Tab Views:
• DASHBOARD
• INSULIN
• POD INFO

Sensor Glucose Value and Trend Arrow

Sensor Graph

Phone screen labels:
Automated
DASHBOARD   INSULIN   POD INFO
IOB 2.75 U
121
mg/dL
LAST BOLUS   SENSOR GRAPH
6.05 Units
Feb 10 (7:32 PM)
VIEW

* Please go to omnipod.com/compatibility for a list of compatible smartphones.
[†] The Pod has an IP28 rating for up to 25 feet for 60 minutes. The Omnipod 5 Controller is not waterproof.
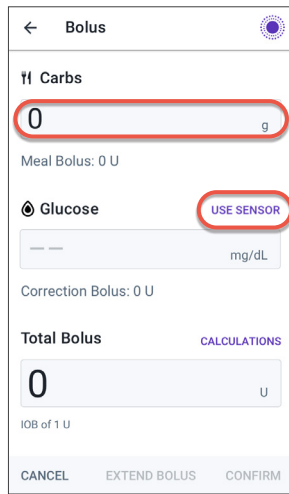
Omnipod 5 App screens are for educational purposes and may vary depending on operating system. Consult your healthcare professional before using these features and for personalized recommendations.
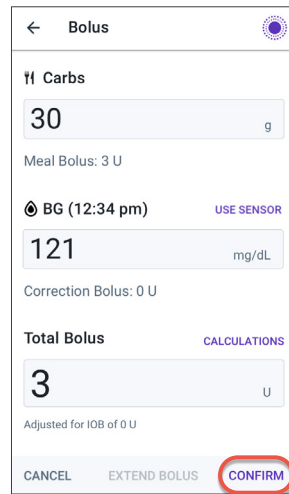
How to deliver a bolus

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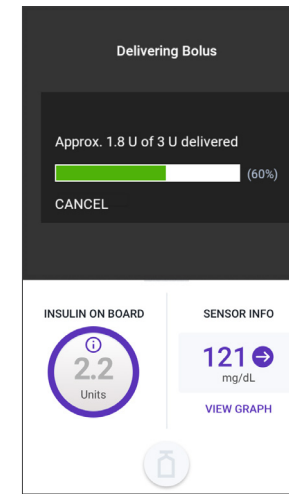
To start a bolus, tap the Bolus button

Tap on the **Carbs** field to enter the amount of carbohydrates to be eaten
Tap **USE SENSOR** to use CGM/sensor glucose value and trend for a correction bolus*

Tap **CONFIRM**

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

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

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.

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

* 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.

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

Managing and responding to glucose levels can be challenging. The Omnipod 5 System automates insulin delivery, helping to protect against highs and lows.[1,2] Sometimes though, you may still need to respond to highs and lows. Always follow the treatment plan provided by the primary caregiver and/or healthcare provider.

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 CGM/sensor readings, test glucose levels with BG meter.

Irritable   **Hungry**   **Weak**   **Confused**   **Sweaty**

1. Check glucose level if you think or they feel that they have a low glucose level.
2. Treat the low glucose level with 5-15 grams of fast-acting carbohydrates.[3]
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 a low glucose:

Food
• Did they eat as many carbohydrates as planned?
• Did they delay eating after taking their insulin or medication?
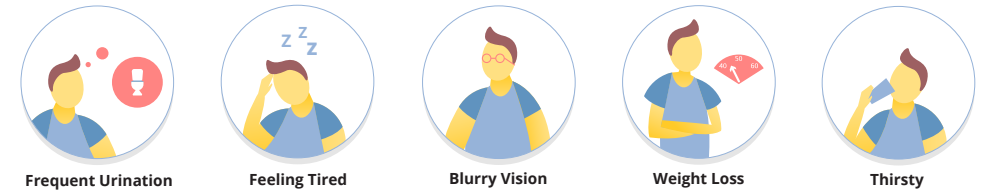
Activity
• Were they more active than usual?

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

1. 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 in Target Glucose range (from CGM) for standard therapy vs Omnipod 5 in adults/adolescents = 64.7% vs. 73.9% and children = 52.5% vs. 68.0%. Brown et al. Diabetes Care (2021).
2. 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 in Target Glucose range (from CGM) for standard therapy vs Omnipod 5 = 57.2% vs. 68.1%. SherrJL, et al. Diabetes Care (2022).
3. 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.

Frequent Urination   **Feeling Tired**   **Blurry Vision**   **Weight Loss**   **Thirsty**

1. Check glucose.
2. If glucose is higher than 250mg/dL follow their healthcare provider's instructions for checking for ketones.
3. If ketones are not present, take a correction bolus from Pod as prescribed.
4. Continue to monitor glucose and treat as instructed by their healthcare provider.

Potential causes of a 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?

Pod
• Is the Pod inserted properly? The small tube under the skin can dislodge or bend
  – When in doubt change the Pod

TIP!
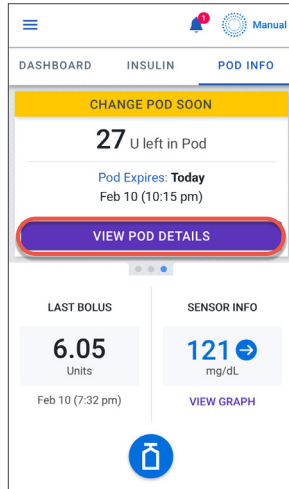These are the most common symptoms to look for:

Low: _____
_____

High: _____
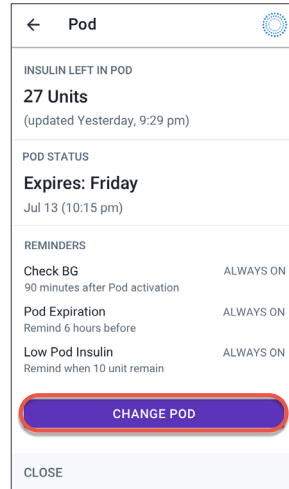_____

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 **POD INFO**

Tap **VIEW POD DETAILS**

Tap **CHANGE POD**, and then tap **DEACTIVATE POD**. If the Pod has already been deactivated, tap **SET UP NEW POD** on the home screen
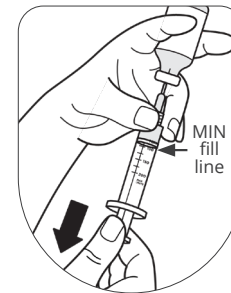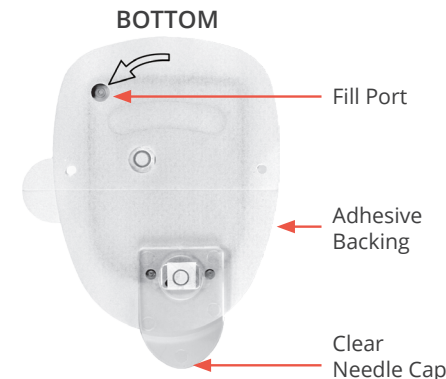
Removing old Pod

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.
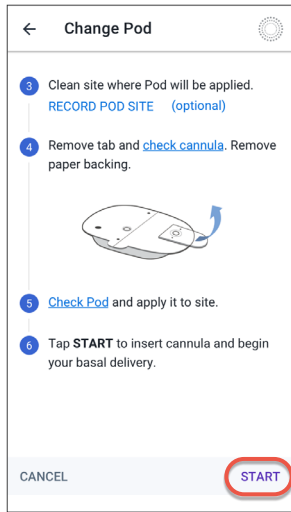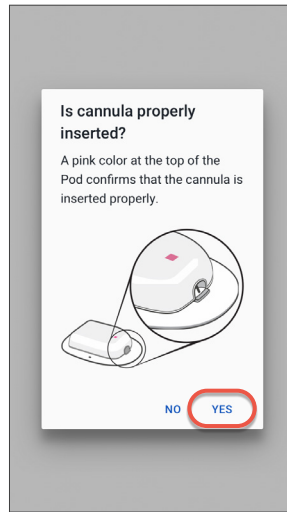

BOTTOM

Fill Port

Adhesive Backing

Clear Needle Cap

MIN fill line

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 right 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
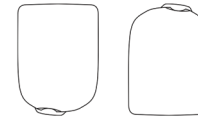
TIP!
For optimal connectivity, the Pod should be placed in direct line of sight of the CGM/sensor. Always put the Pod in a new location.

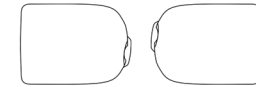## Pod positioning

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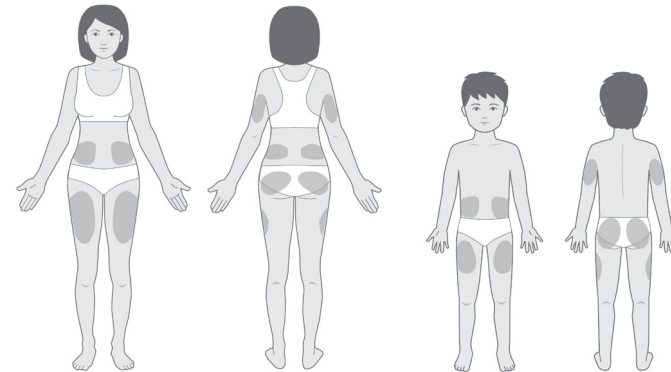Position the Pod **vertically** or at a slight angle.

Pod shown without the necessary adhesive.

Back, abdomen & buttocks:
Position the Pod **horizontally** or at a slight angle.
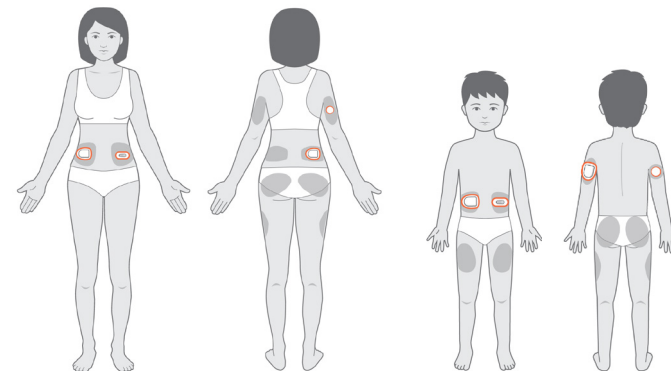

Pod placement

CGM/sensor placement
The Pod and CGM/sensor should be worn in line of sight, which means worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.

Managing activity and exercise
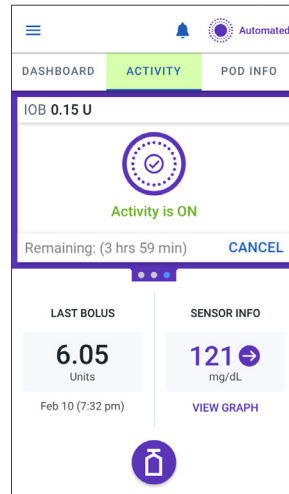
What is the Activity feature?

While in Automated Mode, there may be times when you would like less insulin automatically delivered. When the Activity feature is started, the SmartAdjust™ technology 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**

≡	🔔 ◉ Automated
DASHBOARD	**ACTIVITY** POD INFO

IOB **0.15 U**

◉

Activity is ON

Remaining: (3 hrs 59 min)　　**CANCEL**

LAST BOLUS	SENSOR INFO
6.05 Units	**121** → mg/dL
Feb 10 (7:32 pm)	**VIEW GRAPH**

TIP!

This is when we like to use the Activity feature:

_____

_____

_____

_____

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.

The Pod has an IP28 rating for up to 25 feet for 60 minutes. The Controller is not waterproof.

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

WARNING:

Respond to Hazard Alarms as soon as possible. Pod Hazard Alarms indicate that insulin delivery has stopped. Failure to respond to a Hazard Alarm can result in hyperglycemia.

Advisory alarms

Lower priority alarms that indicate a situation exists that needs attention
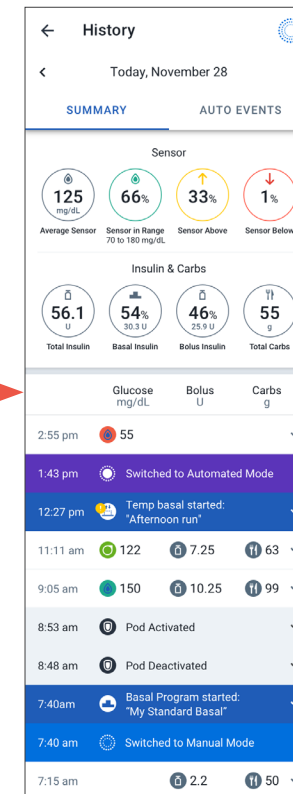
Notifications

Reminder of an action that should be performed

Viewing history

To view the history summary and detail information go to the History Detail screen by tapping the Menu button (≡) and then tapping History Detail.

Details section
• Swipe to see expanded details
• 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

Date
• Tap AUTO EVENTS to see automated details
• Tap SUMMARY to view the average CGM/sensor glucose value and Sensor in Range
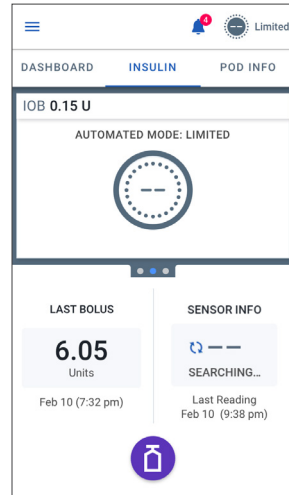
System states

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

Automated Mode: Limited

Automated Mode: Limited occurs when the Pod and CGM/sensor lose connection while in Automated Mode. When this occurs, the system can no longer fully adjust automated insulin delivery but will continue to deliver a steady basal insulin until CGM/sensor glucose values return.

What should you do?

- First make sure the Pod and sensor are in a direct line of sight and are "able to see each other"
- Check to see if there are any sensor actions that you need to take to re-establish communication between the Pod and sensor
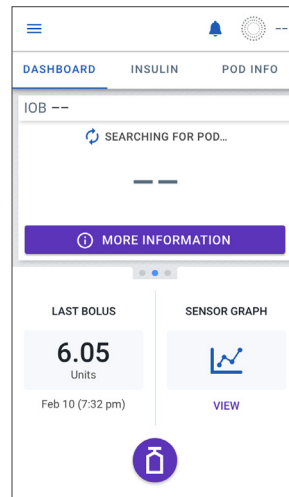
No Pod communication

There may be times when the Pod and Omnipod 5 Controller/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 Omnipod 5 Controller/App and active Pod closer – within 5 feet of each other to try to restore communication
- If the communication 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

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
☐ CGM/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 CGM/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. 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)/sensor 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 is intended to calculate a suggested bolus dose based on user-entered carbohydrates, most recent CGM/sensor glucose value (or blood glucose reading if using fingerstick), rate of change of the CGM/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/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, CGM/sensor 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.

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.

omnipod®

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

Insulet Corporation, 100 Nagog Park, Acton, MA 01720

omnipod.com