OMNIPOD® 5
CAREGIVER GUIDE

omnipod

automated insulin
delivery system

5

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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 insulin 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).

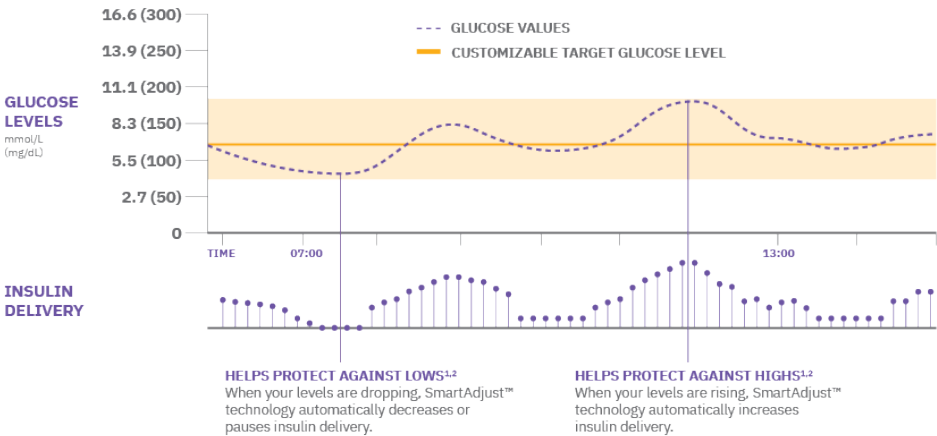### Insulin delivery in standard insulin pump therapy
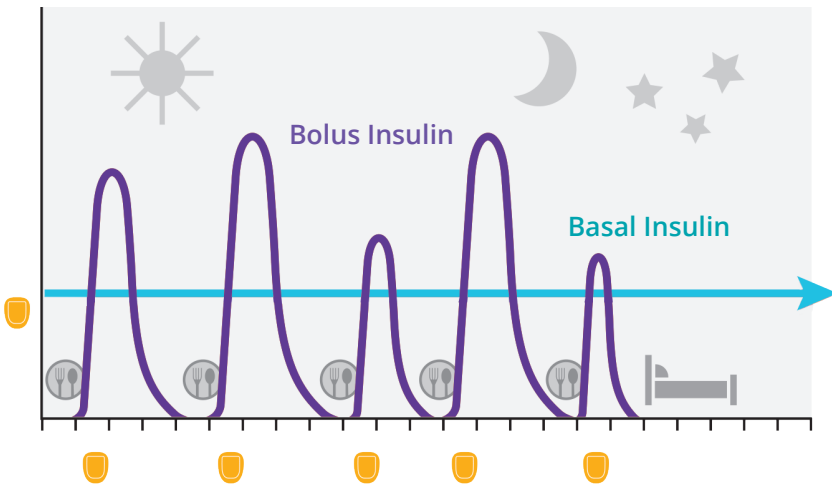
Insulin delivery from an insulin pump, or Pod.

Insulin delivery in Automated Insulin Delivery (AID) Systems

In AID systems like Omnipod 5, 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 now, and where it is predicted to be in 60 minutes[*].

How Omnipod 5 works

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.

For illustrative purposes only.

NOTE!

The Omnipod 5 System will always pause insulin delivery when glucose is below 3.3 mmol/L (60 mg/dL).

[*] Bolusing for meals and corrections is still needed

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 sensor glucose value and trend.

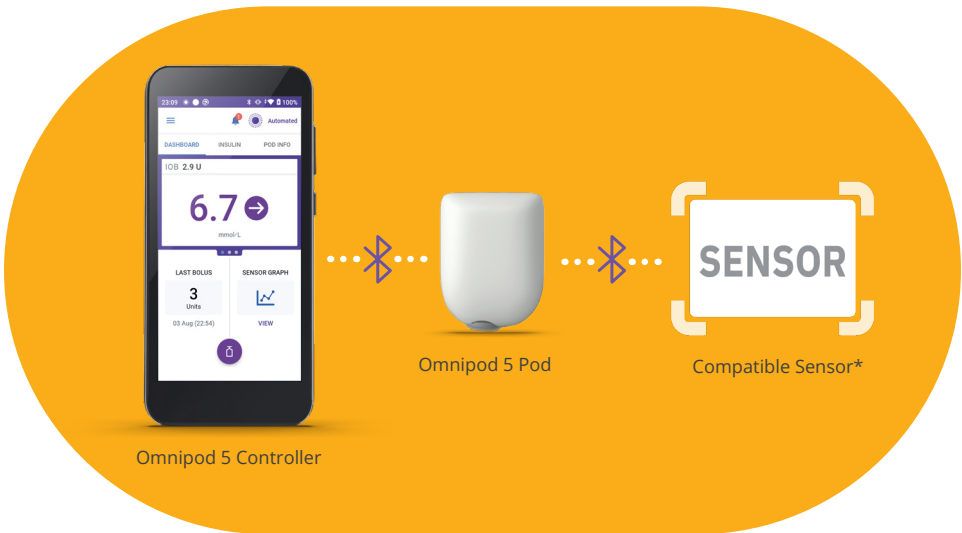### The Omnipod 5 Controller

Control the Pod's operations from the Insulet-provided Controller. Always keep the 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.

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.
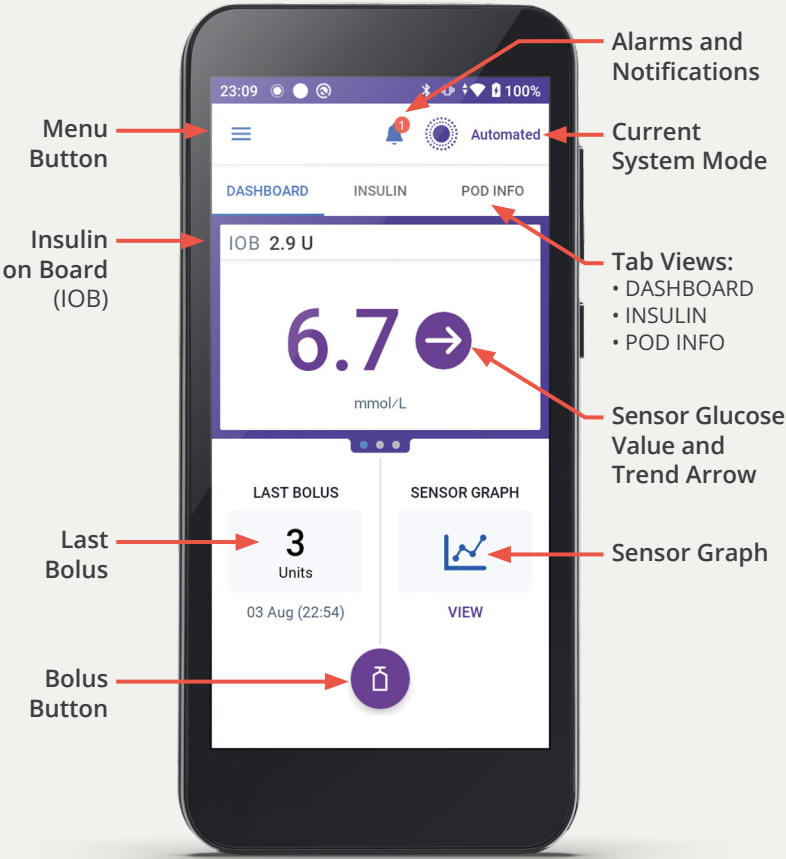
Omnipod 5 Pod

Compatible Sensor*

Omnipod 5 Controller

Pod shown without the necessary adhesive

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

* Sensor availability varies by market. Compatible Sensors are sold and prescribed seperately.

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

23:09

Automated

DASHBOARD   INSULIN   POD INFO

IOB 2.9 U

6.7

mmol/L
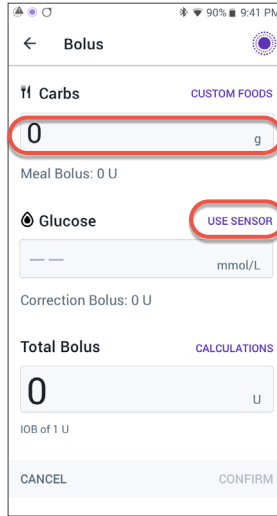
LAST BOLUS

3
Units

03 Aug (22:54)

SENSOR GRAPH

VIEW

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 hyperglycaemia.[1]
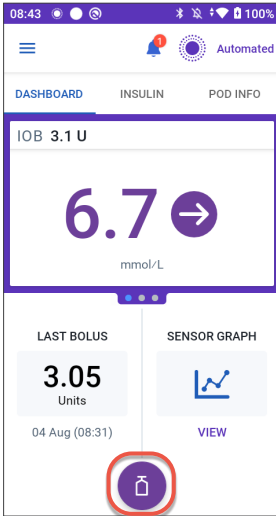
To start a bolus, tap the Bolus button

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*
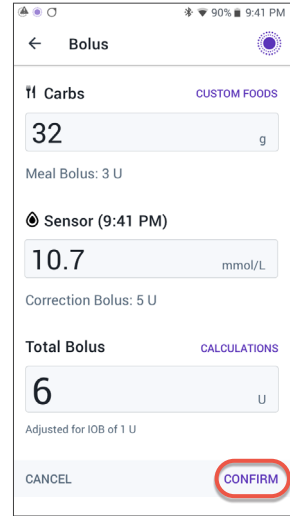
Tap **CONFIRM**

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.

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* Tap Glucose field to manually enter blood glucose level

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.
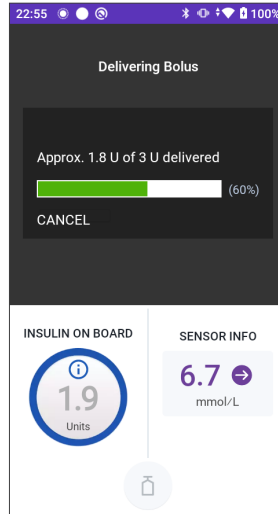
Omnipod 5 screens are for educational purposes only.

Consult your healthcare professional before using these features and for personalised recommendations.
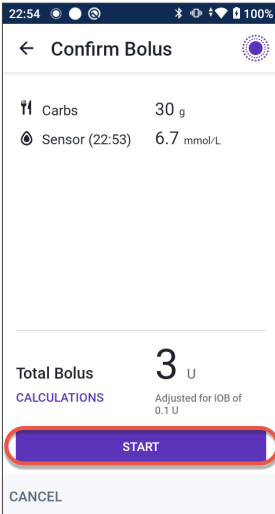
Review the entries to ensure they are correct, then tap START

Confirm the screen says Delivering Bolus and shows a green progress bar before leaving the Omnipod 5 Controller

TIP!

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

Omnipod 5 screens are for educational purposes only.
Consult their healthcare professional before using these features and for personalised recommendations.

Managing glucose

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

Low glucose (hypoglycaemia)

Low glucose is when the amount of glucose drops below 3.9 mmol/L (70 mg/dL). If symptoms indicate a low glucose, check sensor glucose to confirm. If symptoms do not match Sensor, check blood glucose levels with blood glucose meter (BG meter).

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 4 mmol/L (70 mg/dL), treat again.[4]

Symptoms of hypoglycaemia include:

Irritable Hungry Weak

Confused Sweaty

Potential causes of low glucose:

Food
- Did they eat as many carbohydrates as planned?
- Did they delay eating after taking their insulin?

Activity
- Were they more active than usual?

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

SOURCES OF
15 GRAMS OF
CARBS

- 3-4 glucose tabs
- 15mL of sugar
- 125mL of juice or regular soda (not diet)

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.
4. NHS. Low Blood Sugar (hypoglycaemia). NHS. Published August 3, 2023. https://www.nhs.uk/conditions/low-blood-sugar-hypoglycaemia/

High glucose (hyperglycaemia)

High glucose is when there is too much glucose in the blood, usually over 13.9 mmol/L (250 mg/dL). It is important to check glucose before treating for hyperglycaemia.

Symptoms of hyperglycaemia include:

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

1. Check glucose. If BG is >13.9 mmol/L (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 there are no ketones, 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 BG 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 ran 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.**

TIP!

These are the most common symptoms to look for:

Low:_____
_____

High: _____
_____

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.
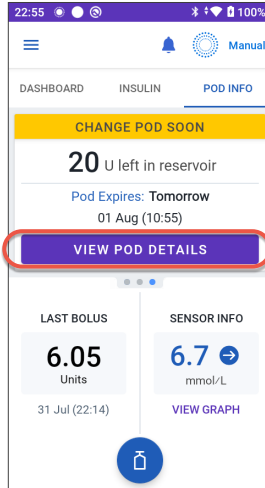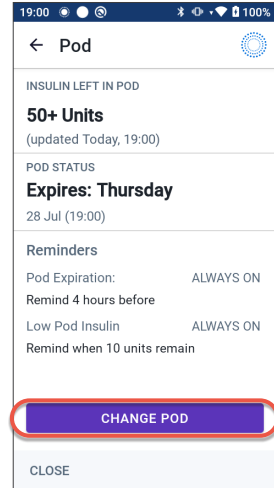
How to change a Pod

The Pod should be changed every 72 hours or when it has run out of insulin. There may also be instances when a Pod change is necessary for the System to keep working.
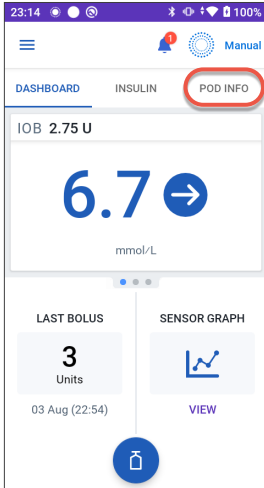
To deactivate and change Pod, tap **POD INFO**

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 an 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-delivery of insulin and possible hypoglycaemia.

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.
6. Leaving the Pod in its tray, insert the syringe straight down into the fill port and empty out all of the insulin. Make sure the Pod beeps twice. Put the Controller right next to the Pod and press NEXT.
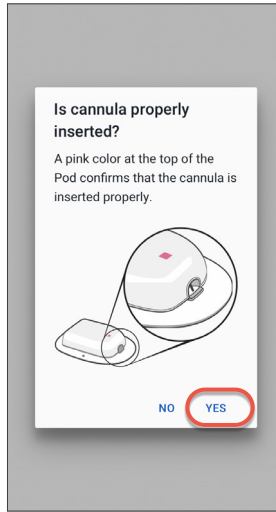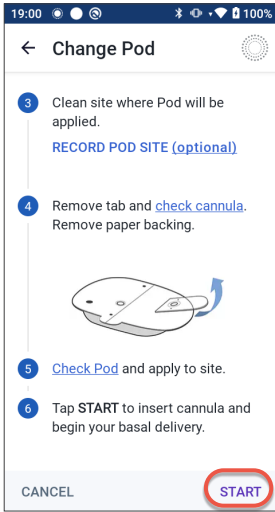
BOTTOM

Fill Port

Adhesive Backing

Clear Needle Tab

MIN fill line
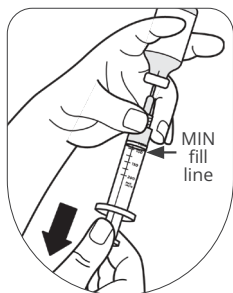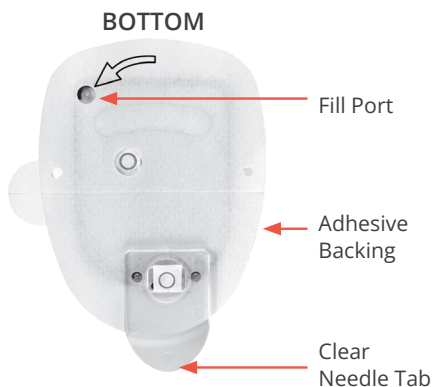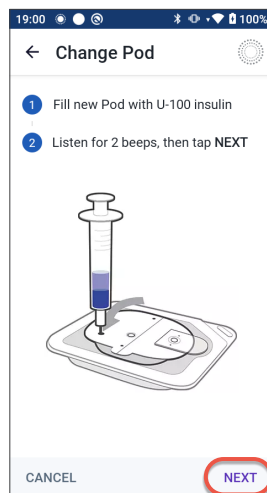
TIP!

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

Fill the Pod with _____ units

13

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
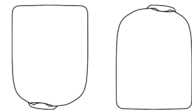
TIP!

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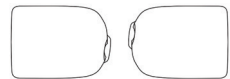
Pod positioning

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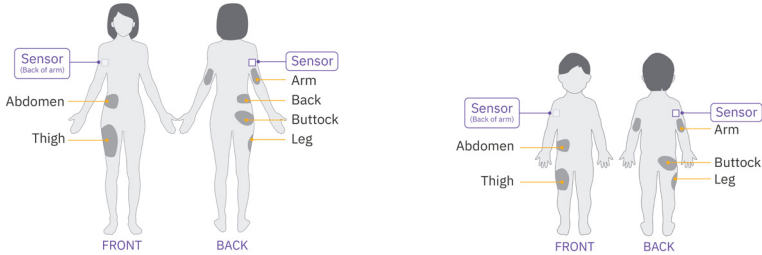

Back, Abdomen & Buttocks:
Position the Pod **horizontally** or at a slight angle.

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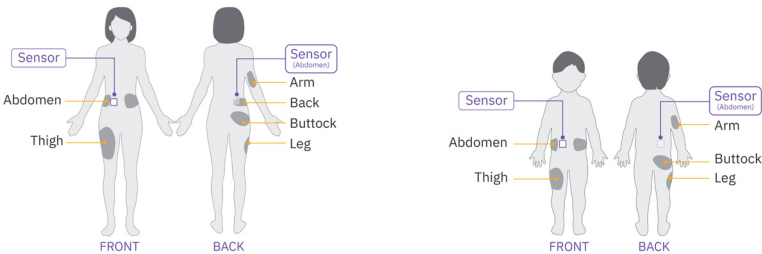
For Sensors indicated for the abdomen*, consider these Pod placements that work best:

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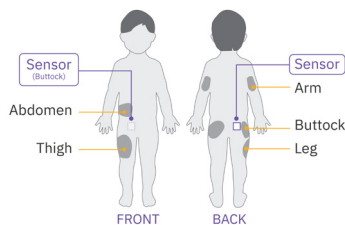
*Illustration for example only. Please refer to the Instructions for Use for your compatible Sensor for approved Sensor placement and separation distances

Managing activity and exercise
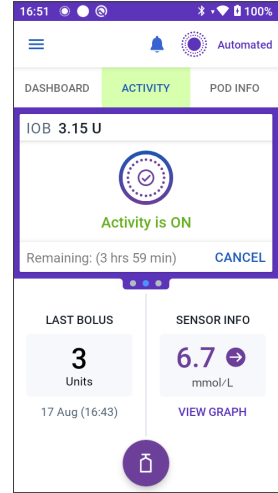
What is the Activity feature?

While in Automated Mode, there may be times when you would like less insulin automatically delivered. When you start the Activity feature, the SmartAdjust™ technology reduces insulin delivery and automatically sets the Target Glucose to 8.3 mmol/L (150 mg/dL) for an amount of 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 glucose tends to decrease.

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 prior to 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 7.6 metres (25 feet) 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

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 hyperglycaemia.

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

- Scroll 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
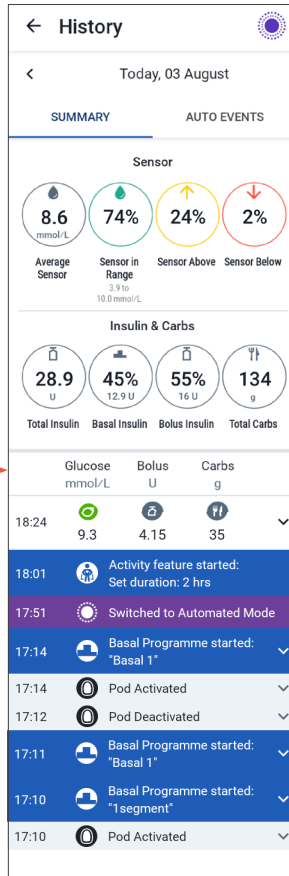
Date

- Tap AUTO EVENTS to see automated details
- Tap SUMMARY to view the average Sensor glucose value and Sensor in Range

System states

There are times when the Pod, Sensor, and/or Omnipod 5 Controller 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 Controller 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 and active Pod closer – within 1.5 meters (5 feet) of each other to try to restore communication.

• If the issue remains, the Omnipod 5 Controller 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.
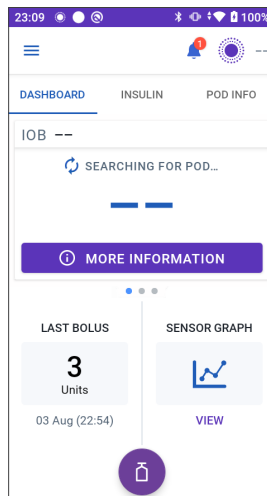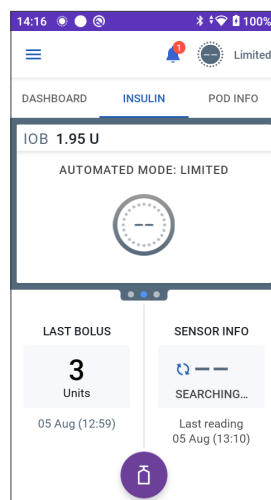
Automated Mode: Limited

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, SmartAdjust technology 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: Limited. The Omnipod 5 App will display 'Limited' on the Home Screen. The System will remain in Automated: 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, SmartAdjust technology never gives more than the Basal Programme 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 event that the 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: **0800 011 6132***

Important User Information

The Omnipod 5 Automated Insulin Delivery System is a single hormone insulin delivery system intended to deliver U-100 insulin subcutaneously for the management of type 1 diabetes in persons aged 2 and older requiring insulin.

The Omnipod 5 System is intended to operate as an automated insulin delivery system when used with compatible Continuous Glucose Monitors (CGM). When in automated mode, the Omnipod 5 system is designed to assist people with type 1 diabetes in achieving glycaemic targets set by their healthcare providers. It is intended to modulate (increase, decrease or pause) insulin delivery to operate within predefined threshold values using current and predicted sensor glucose values to maintain blood glucose at variable Target Glucose levels, thereby reducing glucose variability. This reduction in variability is intended to lead to a reduction in the frequency, severity, and duration of both hyperglycaemia and hypoglycaemia.

The Omnipod 5 System can also operate in a Manual mode that delivers insulin at set or manually adjusted rates.

The Omnipod 5 System is intended for single patient use. The Omnipod 5 System is indicated for use with rapid acting U-100 insulin.

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 and using a Dexcom Sensor as it could lead to falsely elevated sensor 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, 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 hypoglycaemia or hyperglycaemia.

omnipod®

Customer Care: **0800 011 6132***

Insulet International One King Street, Hammersmith, London W6 9HR

omnipod.com