



Omnipod GO Insulin Delivery Device User Guide

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Omnipod GO Insulin Delivery Device

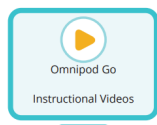


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Before First Use

Warning: DO NOT use the Omnipod GO™ Insulin Delivery Device if you are unable or unwilling to use it as instructed by the User Guide and prescribed by your healthcare provider. Failure to use this insulin delivery device as intended could result in over-delivery or under-delivery of insulin which can lead to low glucose or high glucose.



Find step by step instructional videos here: <https://www.omnipod.com/go/start> or scan this QR Code.



If you have any additional questions or concerns after reviewing the instructional materials, please call 1-800-591-3455.

Warning: DO NOT attempt to use the Omnipod GO Insulin Delivery Device before you have read the User Guide and watched the complete set of instructional videos. Inadequate understanding of how to use the Omnipod GO Pod can lead to high glucose or low glucose.

Indications

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Indications for use

The Omnipod GO Insulin Delivery Device is intended for the subcutaneous infusion of insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with type 2 diabetes.



Contraindications

Insulin pump therapy 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 GO Pod according to instructions.
- do NOT have adequate hearing and/or vision to allow recognition of Pod lights and sounds that signify alerts and alarms.

The Pod must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, and diathermy treatment. Exposure to MRI, CT, or diathermy treatment can damage the Pod.

Compatible Insulins

The Omnipod GO Pod is compatible with the following U-100 insulins: Novolog®, Fiasp®, Humalog®, Admelog®, and Lyumjev®.

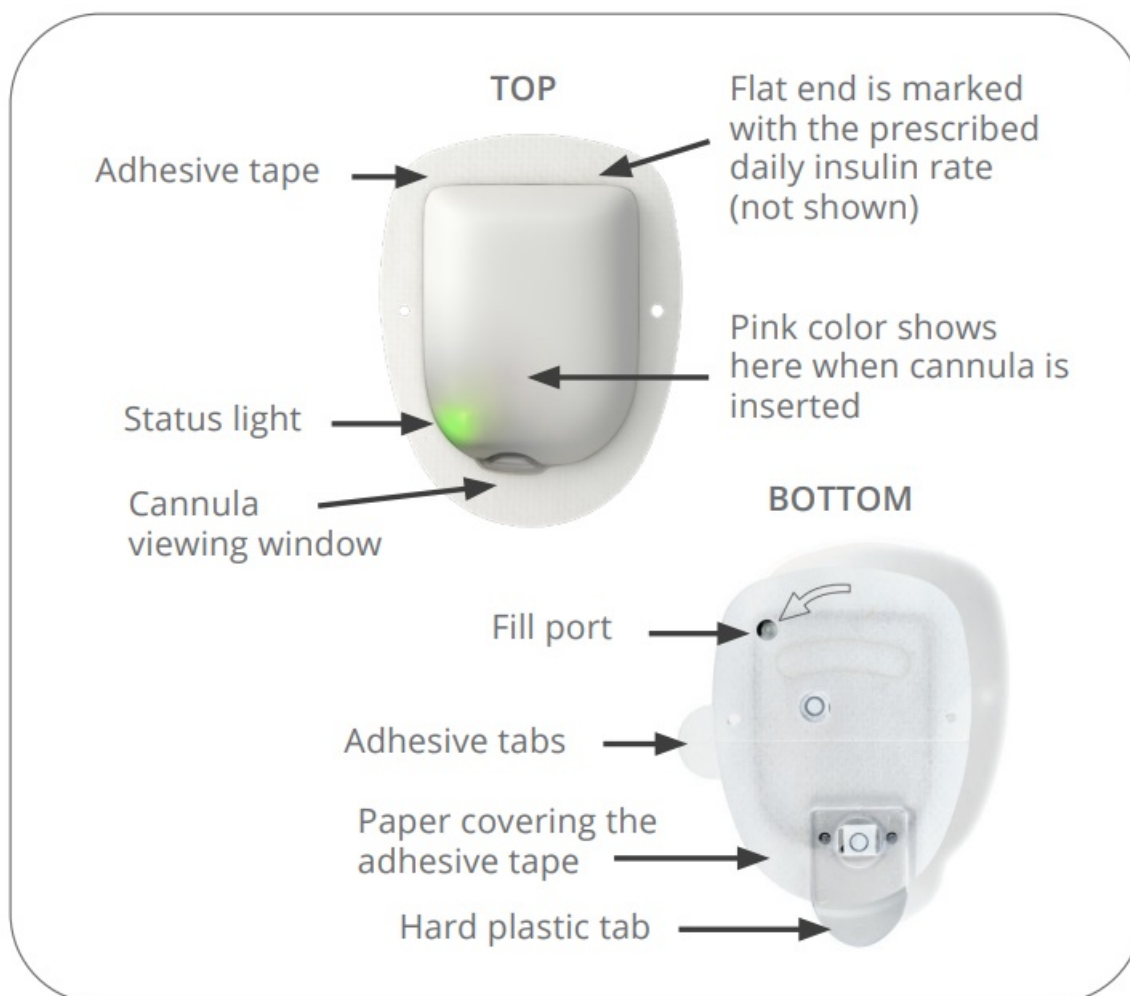
Refer to the Omnipod GO™ Insulin Delivery Device User Guide at www.omnipod.com/guides for complete safety information and full instructions for use.

About the Pod

The Omnipod GO Insulin Delivery Device helps you manage type 2 diabetes by delivering a constant set amount

of rapid-acting insulin per hour, as prescribed by your healthcare provider, for 3 days (72 hours). Omnipod GO Insulin Delivery Device replaces injections of long-acting, or basal, insulin that help you manage your glucose levels throughout the day and night.

- Hands-free, one-time automatic cannula insertion
- Status lights and audible alarm signals so you see how it's working
- Waterproof for up to 25 feet for 60 minutes*



* **Waterproof rating of IP28**

How to setup the Pod

Prepare

Gather What You Need

- Wash your hands.
- Gather your supplies:

- Omnipod GO Pod package. Confirm the Pod is labeled Omnipod GO.
- A vial (bottle) of room temperature, rapid-acting U-100 insulin cleared for use in the Omnipod GO Pod.

Note: The Omnipod GO Pod is filled with rapid-acting U-100 insulin only. This insulin delivered by the Pod at a constant set amount replaces daily injections of long acting insulin.

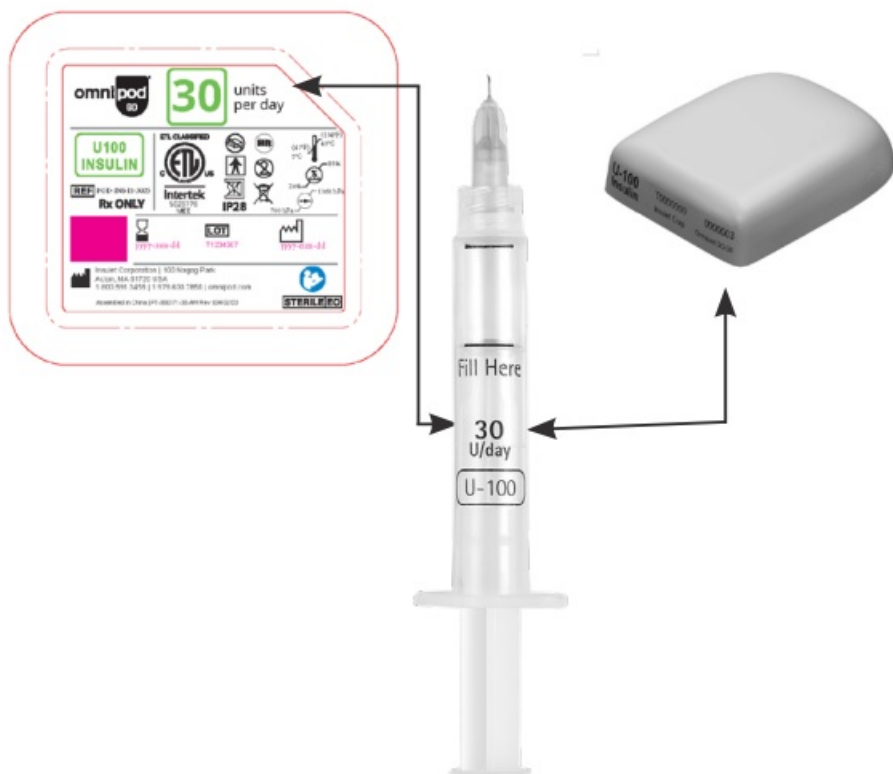
- Alcohol prep swabs.

Caution: ALWAYS check that each of the following daily insulin rates matches exactly the rate you were prescribed and expect to take:

- Pod packaging
- flat end of the Pod
- Pod's included fill syringe
- your prescription

If one or more of these daily insulin rates do not match, you could receive more or less insulin than you intended, which can lead to low glucose or high glucose. Applying a Pod under these circumstances could put your health at risk.

For example, if your prescription is marked 30 U/day and your Pod is marked Omnipod GO 30, then your syringe should also be marked 30 U/day.



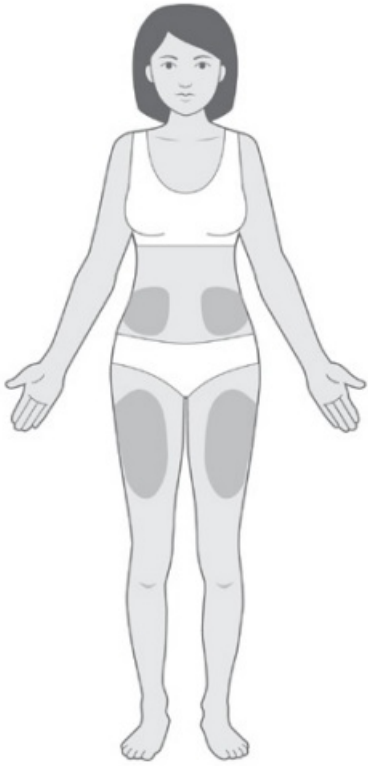
Select Your Site

a. Select location for Pod placement:

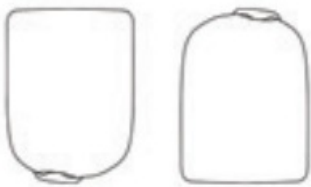
- Abdomen
- Front or side of your thigh
- Upper back of arm
- Lower back or buttocks

b. Choose a location that will allow you to see and hear the Pod alarms.

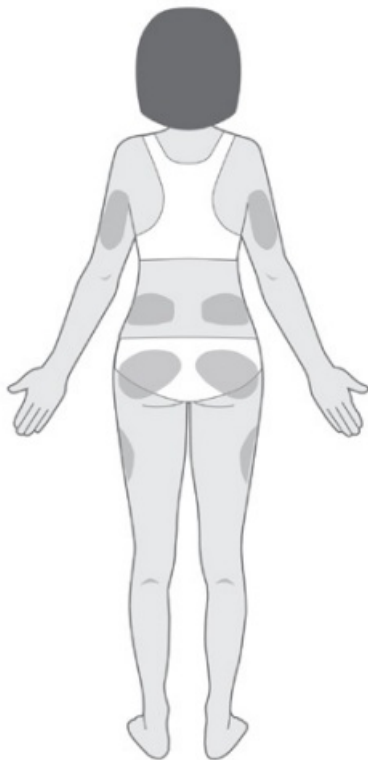
Front



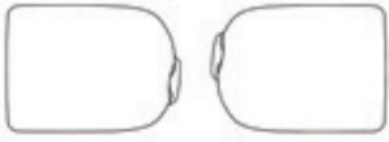
ARM & LEG Position the Pod vertically or at a slight angle.



Back



BACK, ABDOMEN & BUTTOCKS Position the Pod horizontally or at a slight angle.

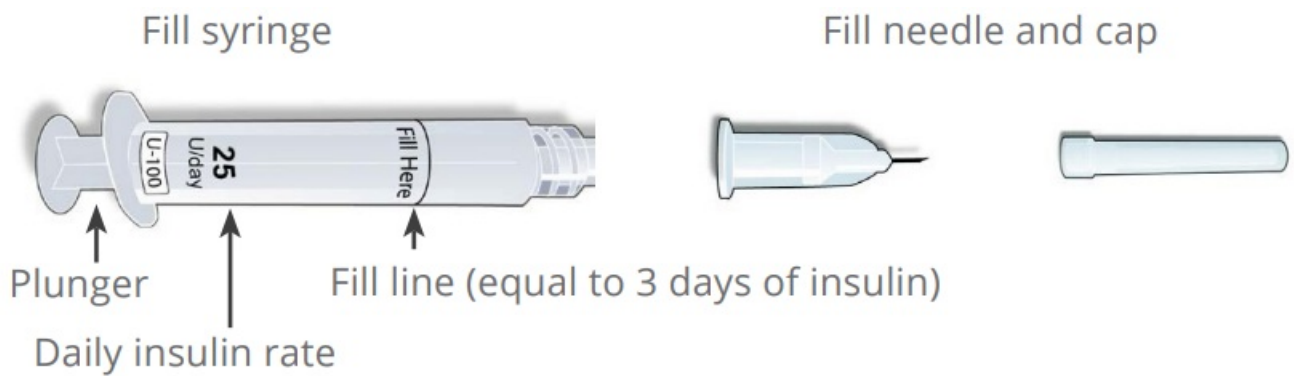


Prepare Your Site

- a. Using an alcohol swab, clean your skin where the Pod will be applied.
- b. Let the area dry.



Fill the Pod



Prepare the Fill Syringe

- a. Remove the 2 pieces of the syringe from the packaging, leaving the Pod in the tray.
- b. Twist the needle onto the syringe for a secure fit.



Uncap the Syringe

- › Remove the protective needle cap by carefully pulling it straight off the needle.



Caution: DO NOT use the fill needle or fill syringe if they appear damaged. Damaged components may not be working properly. Using them may put your health at damaged, stop using the system and call Customer Care for support.

Draw up the Insulin

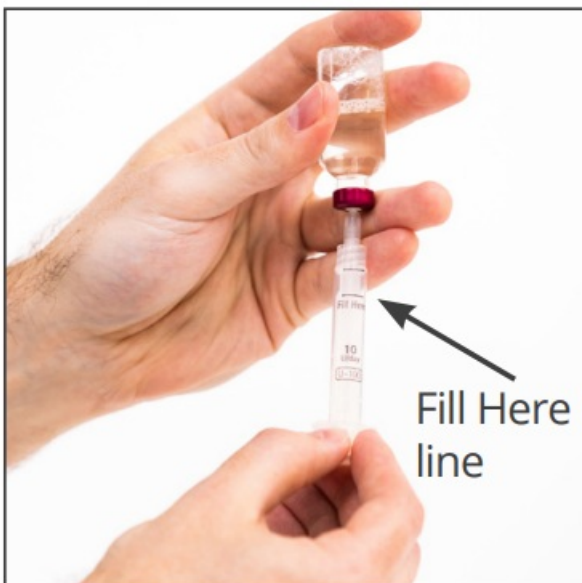
- a. Clean top of insulin bottle with alcohol swab.
- b. You will first inject air into the insulin bottle to make it easier to pull out the insulin. Gently pull back on the plunger to draw air into the fill syringe to the “Fill Here” line shown.



- c. Insert the needle into the center of the insulin bottle and push the plunger in to inject the air.
 d. With the syringe still in the insulin bottle, turn the insulin bottle and syringe upside down.



- e. Pull down on the plunger to slowly withdraw insulin to the fill line shown on the fill syringe. Filling the syringe to the "Fill Here" line equals enough insulin for 3 days.
 f. Tap or flick the syringe to dislodge any air bubbles. Push the plunger up so the air bubbles move into the insulin bottle. Pull down on the plunger again, if needed. Make sure the syringe is still filled to the "Fill Here" line.



Read steps 7–11 a few times **BEFORE** you put on your first Pod. You must apply the Pod within the 3-minute

timeframe before the cannula extends from the Pod. If the cannula is already extended from the Pod it will not insert into your body and it will not deliver insulin as intended.

Fill the Pod

- a. Keeping the Pod in its tray, insert the fill syringe straight down into the fill port. A black arrow on the white paper backing points to the fill port.
 - b. Slowly push down the syringe plunger to completely fill the Pod.
- Listen for 2 beeps to tell you that the Pod knows that you are filling it.



– The Pod light is operating normally if there is no light showing at first.



- c. Remove the syringe from the Pod.
- d. Turn the Pod over in the tray so you can watch for a light.

Caution: NEVER use a Pod if, while you are filling the Pod, you feel significant resistance while slowly pressing the plunger down on the fill syringe. Do not try to force the insulin into the Pod. Significant resistance may indicate that the Pod has a mechanical defect. Using this Pod could result in under-delivery of insulin that can lead to high glucose.

Apply the Pod

The Insertion Timer Starts

- a. Listen for a beep and watch for a blinking amber light to tell you that the cannula insertion countdown has started.



b. Promptly complete steps 9-11. You will have 3 minutes to apply the Pod to your body before the cannula inserts into your skin.



If the Pod is not applied to your skin in time, you will see the cannula extended from the Pod. If the cannula is already extended from the Pod, it will not insert into your body and will not deliver insulin as intended. You must discard the Pod and start the setup process again with a new Pod.

Remove the Hard Plastic Tab

- a.** Holding the Pod securely, snap off the hard plastic tab.
 - It is normal to need to apply a little pressure to remove the tab.
- b.** Look at the Pod to confirm the cannula is not extending from the Pod.



Remove the Paper from the Adhesive

- a. Grasp the Pod on the sides with only your fingertips.
- b. Using the 2 small tabs on the side of the adhesive paper backing gently pull each tab away from the middle of the Pod, pulling the adhesive paper backing slowly towards the end of the Pod.
- c. Make sure the adhesive tape is clean and intact.



Do NOT touch the sticky side of the adhesive.



Do NOT pull off the adhesive pad or fold it.



Caution: DO NOT use a Pod and its fill needle under the following conditions, as this could increase your risk of infection.

- The sterile package is damaged or is found open.
- The Pod or its fill needle was dropped after being removed from the package.
- The expiration (Exp. Date) on the package and the Pod has passed.

Apply the Pod to the Site

- a. Continue to grasp the Pod on the sides with only your fingertips, keeping your fingers off the adhesive tape.
- b. CONFIRM the Pod's cannula is not extended from the Pod before you apply the Pod.

You MUST apply the Pod while the amber light is blinking. If the Pod is not applied to your skin in time, you will see the cannula extended from the Pod.

If the cannula is already extended from the Pod, it will not insert into your body and will not deliver insulin as intended. You must discard the Pod and start the setup process again with a new Pod.

- c. Apply the Pod to the site you cleaned, at the recommended angle for the site you chose.



Do NOT apply the Pod within two inches of your navel or over a mole, scar, tattoo or where it will be affected by folds of skin.



- d.** Run your finger around the adhesive edge to secure it.
- e.** If the Pod was applied to a lean area, gently pinch the skin around the Pod while you wait for the cannula to insert. Make sure to not pull the Pod off your body.
- f.** Listen for a series of beeps letting you know that you have 10 more seconds until the cannula will be inserted into your skin.



Check the Pod

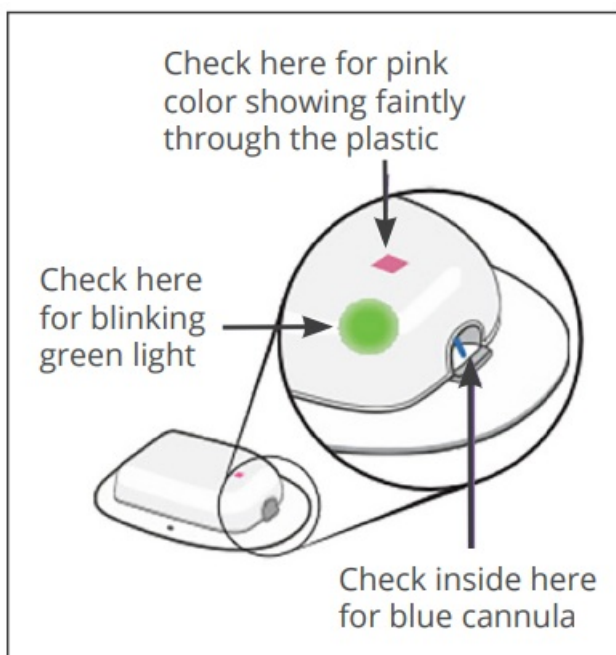
a. After you apply the Pod you will hear a click sound and may feel the cannula insert into your skin. Once that happens, confirm that the status light is blinking green.

- If you had gently pinched the skin, you can release the skin once the cannula has inserted.



b. Check that the cannula was inserted by:

- Looking through the cannula viewing window to verify that the blue cannula is inserted in the skin. Regularly check the Pod site after insertion.
- Looking at the top of the Pod for a pink color under the plastic.
- Checking that the Pod shows a blinking green light.



ALWAYS check your Pod and Pod light more frequently when in loud environments for prolonged periods of time. Failure to respond to the alerts and alarms from your Omnipod GO Pod could result in under-delivery of insulin, which can lead to high glucose.

Understanding Pod Lights and Sounds

What the Pod lights mean



For more information see Chapter 3 “Understanding Pod Lights and Sounds and Alarms” in your Omnipod GO Insulin Delivery Device User Guide.

Remove Pod

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



Tips

Tips to be safe and successful

- ✓ Confirm that the amount of insulin you are using matches your prescribed amount and the amount on the Pod packaging.
- ✓ Always wear your Pod in a location where you can see the lights and hear the beeps. Respond to alerts/alarms.
- ✓ Regularly check your Pod site. Check often to make sure the Pod and cannula are securely attached and in place.
- ✓ Check your glucose levels and the status light on the Pod at least a few times each day to make sure your Pod is working properly.
- ✓ Discuss your glucose levels with your healthcare provider. Your healthcare provider may change the prescribed amount until you find the right dose for you.
- ✓ Do not change the prescribed amount without discussing it with your healthcare provider.
- ✓ Mark when your Pod is due to be changed on the calendar so it's easy to remember.



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Low Glucose

Low glucose is when the amount of sugar in the bloodstream drops to 70 mg/dL or lower. Some signs that you are

having a low glucose include:



Irritable



Hungry



Weak



Confused



Sweaty

If you have any of these symptoms, check your glucose levels to confirm. If you are low, then follow the 15-15 Rule.

The 15-15 Rule

Eat or drink something that is equal to 15 grams of carbohydrate (carbs). Wait 15 minutes and recheck your glucose. If your glucose is still low, repeat again.



Sources of 15 grams of carbs

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

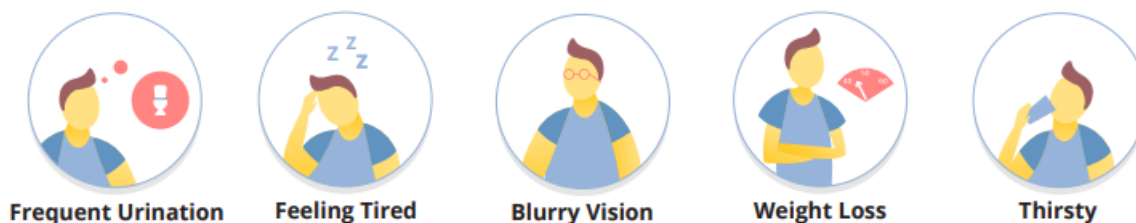
Think about why you had a low glucose

- Pod Prescribed amount
 - Did you use a Pod with an amount higher than what your healthcare provider prescribed?
- Activity
 - Were you more active than usual?
- Medication
 - Did you take any new medications or more medication than usual?



High Glucose

Generally, high glucose is when there is too much sugar in your blood. Signs or symptoms that you have a high glucose include:



If you have any of these symptoms, check your glucose levels to confirm. Discuss your symptoms and glucose levels with your healthcare provider.

Tip: If you are in doubt, it is always better to change your Pod.

Note: Ignoring status lights and beeps or wearing a Pod that is not delivering insulin may result in high glucose.

Think about why you had a high glucose

- Pod Prescribed amount
 - Did you use a Pod with an amount lower than what your healthcare provider prescribed?
- Activity
 - Were you less active than usual?
- Wellness
 - Are you feeling stressed or scared?
 - Do you have a cold, flu or other illness?
 - Are you taking any new medications?



Note: Pods only use rapid-acting insulin so you have no long acting insulin working in your body. With any interruption in insulin delivery your glucose can rise quickly, so it is important to always check your glucose when you think it is high.

Customer Support

For more information on indications, warnings and complete instructions on how to use Omnipod GO Insulin Delivery Device, please consult your Omnipod GO User Guide.

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Patent information at www.insulet.com/patents.

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Documents / Resources

The cover of the "Omnipod GO Insulin Delivery Device Quick Start Guide". It features a photograph of a smiling woman wearing a hat and a patterned shirt. The Omnipod logo is in the top right corner, and the title "Quick Start Guide" is at the bottom.	<p>Omnipod GO Insulin Delivery Device [pdf] User Guide</p> <p>GO Insulin Delivery Device, GO, Insulin Delivery Device, Delivery Device, Device</p>
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References

-  [Omnipod | Insulin Pump Therapy, Simplified](#)
-  [Patents | Insulet](#)
-  [Product Guides | Omnipod](#)
-  [Omnipod GO™ Training Videos | Omnipod](#)