omnipod GO®

User Guide

Omnipod GO™

Contacts and Important Information

Customer Care

1-800-591-3455 — 24 hours/7 days
1-978-600-7850 when calling from outside the United States of America

Customer Care Fax: 877-467-8538

Website: *omnipod.com*

Address: Insulet Corporation
100 Nagog Park, Acton MA 01720

Emergency Services: Dial 911 (USA only; not available in all communities)

Omnipod GO™ Insulin Delivery Device

Start Date _____

Healthcare Provider
Name
Address
Phone
Email

Health Insurance	Pharmacy
Name	Name
Address	Address
Phone	Phone
Policy Number	Email

Patent information at www.insulet.com/patents.

PT-000863-AW REV 010 10/23

Read the entire user guide before operating the Omnipod GO Pod.

Contents

Chapter 1: Introduction

Contents

1.1. Welcome to Your Omnipod GO™ Pod

The Omnipod GO Pod helps manage your diabetes by providing continuous subcutaneous insulin delivery. It may be worn for up to 3 days (72 hours) and can be filled with U-100 rapid-acting insulin. Each Pod is marked with the daily insulin rate it's made to deliver. Additional features include:

- **No Tubing:** There is no tubing with the Omnipod GO Pod. You can swim wearing the Pod. The Pod is waterproof for depths up to 25 feet (7.6 meters) for up to 60 minutes (IP28).
- **Lights and Sounds:** Colored LED lights and beeps help you understand how your Pod is working, and alert you if you need to change your Pod.

1.2. Learning Resources

Start learning to use the Omnipod GO Pod by reading this entire *User Guide*. Also make sure to watch the complete set of step by step instructional videos at

https://www.omnipod.com/go/start

Use the following resources to learn how to use the Omnipod GO Pod.

- This *User Guide*
- *Quick Start Guide*
- Instructional videos at:

https://www.omnipod.com/go/start

If you feel unsure about how to use the Omnipod GO Pod after using these resources, call Customer Care.

1.3. About This User Guide

Note: This *User Guide* is intended for use only with the Omnipod GO Insulin Delivery Device. Each device is marked with Omnipod GO™ and the daily insulin rate. Make sure the marking on your Pod matches your prescribed amount, for example, 20 U/day. If you do not know which Pod you are using, call Customer Care.

This *User Guide* is provided to help you understand the features and functions of the Omnipod GO Pod. It provides step by step instructions on how to properly use the Pod, as well as important warnings and cautions to ensure your safety during use.

Healthcare and treatment are complex subjects requiring the services of qualified healthcare providers. This *User Guide* is informational only and not intended as medical or healthcare advice or recommendations to be used for diagnosis, treatment, or for any other individual needs. This *User Guide* is not a substitute for medical or healthcare advice, recommendations, and/or services from a qualified healthcare provider. This *User Guide* may not be relied upon in any way in connection with your personal healthcare, related decisions, and treatment. All such decisions and treatment should be discussed with a qualified healthcare provider who is familiar with your individual needs.

1.4. Terminology

Term	Description
Blockage (occlusion)	An interruption in insulin delivery. A blockage may result from blocked tubing, Pod malfunction, or from using old or inactive insulin.
Blood glucose	The amount of glucose, or sugar, in the blood.
Blood glucose meter	A device used to check blood glucose.
Cannula	A small, thin tube the Pod inserts under the skin and uses to deliver insulin.
Diabetes, diabetes mellitus	A condition characterized by high blood glucose resulting from the body's inability to use blood glucose for energy. In type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin effectively.
Glucose	A simple sugar used by the body for energy. Without insulin, many cells in the body cannot use glucose for energy.
Hemoglobin A1c (HbA1c)	Blood test used to diagnose diabetes and to gauge how well your diabetes therapy is working for you. A1C reflects your average glucose for the past 2 to 3 months.
Hyperglycemia	High glucose. Higher-than-optimal glucose in the blood; generally above 250 mg/dL.
Hyperosmolar hyperglycemic state (HHS)	A serious condition marked by extremely high blood glucose and severe dehydration. This condition can lead to confusion, seizure, coma, and even death. HHS is generally preceded by an illness or infection and can take days or weeks to develop.
Hypoglycemia	Low glucose. Lower-than-optimal glucose in the blood; generally below 70 mg/dL.
Hypoglycemia unawareness	A condition in which a person does not feel or recognize the symptoms of low glucose in the blood.

Insulin	A hormone that helps the body use glucose for energy. The beta cells of a pancreas make insulin when the pancreas is functioning typically.
Ketoacidosis (Diabetic ketoacidosis, or DKA)	Diabetic ketoacidosis (DKA) is a serious condition in which extremely high blood glucose and a severe lack of insulin cause the body to break down fat for energy. The breakdown of fat releases ketones into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.
Pod site (infusion site)	The place on the body where a Pod's cannula is inserted to deliver insulin.
Syringe (fill syringe)	Small device used to fill the Pod with insulin.
Titration	When your healthcare provider starts your insulin at one infusion rate and periodically raises the dosage until it provides the result you need.
Units (U)	How insulin is measured.
Vial	Small glass bottle.

1.5. Indications for Use

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.

1.6. Compatible Insulins

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

1.7. General Warnings and Safety Information

Warning: Read all the instructions provided in this *User Guide* before using the Omnipod GO Pod. Monitor your glucose with the guidance of your healthcare provider. Undetected high glucose or low glucose can result without proper monitoring.

Warning: DO NOT attempt to use the Omnipod GO Insulin Delivery Device before you have read this *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.

Warning: DO NOT rely upon this *User Guide* in any way in connection with your personal healthcare, related decisions, and treatment. This *User Guide* is informational only and not intended as medical or healthcare advice or recommendations to be used for diagnosis, treatment, or for any other individual needs. This *User Guide* is not a substitute for medical or healthcare advice, recommendations, and/or services from a qualified healthcare provider. All such decisions and treatment should be discussed with a qualified healthcare provider who is familiar with your individual needs.

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

Warning: USE ONLY rapid-acting U-100 NovoLog (insulin aspart), Fiasp (insulin aspart), Humalog (insulin lispro), Admelog (insulin lispro), or Lyumjev (insulin lispro-aabc) in the Omnipod GO Pod as they have been tested and found to be safe for use with the Omnipod GO Pod. If you have questions about using other insulins, contact your healthcare provider.

Warning: AVOID using the Omnipod GO Pod if you do not have adequate hearing and/or vision to let you recognize Pod lights and sounds that signify alerts and alarms. 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.

Warning: AVOID administering insulin, such as by injection or inhalation, while wearing an active Pod as this could result in low glucose. The Omnipod GO Pod cannot recognize insulin administered outside the Pod. Consult your healthcare provider about how long to wait after manually administering insulin before you begin using the Omnipod GO Pod.

Warning: Check your glucose at least once a day, or as advised by your healthcare provider. The Omnipod GO Pod does not check your glucose.

Warning: ALWAYS follow your healthcare provider's guidance on appropriate glucose monitoring to detect high glucose and low glucose.

Warning: Glucose below 70 mg/dL may indicate low glucose. Glucose readings above 250 mg/dL may indicate high glucose. Follow your healthcare provider's suggestions for treatment.

Warning: ALWAYS promptly treat glucose below 70 mg/dL (low glucose) according to your healthcare provider's recommendations. Symptoms of low glucose include weakness, sweating, nervousness, headache, or confusion. If left untreated, low glucose could lead to seizure, loss of consciousness, and death.

Warning: DO NOT wait to treat low glucose or symptoms of low glucose. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe low glucose, which can quickly lead to shock, coma, or death.

Warning: NEVER drive yourself to the emergency room if you need emergency medical care. Ask a friend or family member to take you to the emergency room or call an ambulance.

Warning: DO NOT use the Omnipod GO Pod in oxygen rich environments (greater than 25% oxygen), which include home or surgical areas that use supplementary oxygen and hyperbaric chambers. Hyperbaric, or high pressure, chambers are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to oxygen rich environments could result in combustion of the Pod, which can cause severe burns to the body.

Warning: AVOID using the Omnipod GO Pod at low atmospheric pressure (below 700 hPa). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 10,000 feet (3,000 meters). Change in atmospheric pressure can also occur during take-off with air travel. Unintended insulin delivery can occur if there is expansion of tiny air bubbles that may exist inside the Pod. This can result in low glucose. It is important to check your glucose when flying to avoid prolonged low glucose.

Warning: DO NOT dispose of the Pod as unsorted household waste. ALWAYS dispose of the Pod according to local waste disposal guidelines. The Pod is considered biohazardous after use and can potentially transmit infectious diseases.

1.8. General Precautions

If you observe that your Pod is not working as it should, please contact Customer Care.

Caution: DO NOT use a Pod if you suspect damage after an unexpected event such as dropping or hitting on a hard surface. Using a damaged Pod may put your health at risk as the Pod may not be working properly. If you are unsure if your Pod is damaged, stop using it and call Customer Care for support.

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

Caution: ALWAYS begin using a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to high glucose.

Caution: ALWAYS begin using a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to high glucose.

Caution: Be prepared to check your glucose following amusement park rides and during flying or other situations with sudden changes or extremes of air pressure, altitude, or gravity. Though the Omnipod GO Pod is safe to use at atmospheric pressures typically found in airplane cabins during flight, the atmospheric pressure in an airplane cabin could change during flight, which may affect the Pod's insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight take-off and landing, could affect insulin delivery leading to possible low glucose or injury. If needed, follow your healthcare provider's treatment instructions.

Caution: DO NOT use the Omnipod GO Pod in high atmospheric pressure environments (above 1060 hPa), which can be found in a hyperbaric chamber. Hyperbaric, or high pressure, chambers are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to high atmospheric pressure environments can damage your Pod which could lead to under-delivery of insulin which can lead to high glucose.

Potential Risks

- Wearing a Pod might cause infection. Be aware of signs of infection including: bleeding, pain, and skin irritation including redness. See your healthcare provider if irritation occurs.
- Kinks in the cannula, or dislodging of the cannula can affect insulin delivery. Unexpected high glucose could be a sign of a blockage (occlusion) or other interruption in insulin delivery.
- Air bubbles in the Pod or cannula can affect insulin delivery. If there is a large amount of air in the Pod, it could deliver an inaccurate dose of insulin which can lead to low glucose or high glucose.
- Infusion site complications like scar tissue and infection can make insulin delivery less effective. Unexplained high glucose is a sign of ineffective insulin delivery.
- Hardware defects, software glitches, and Pod failures could cause an interruption in insulin delivery. A Pod failure can lead to high glucose, diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemic state (HHS). Check your Pod light frequently, especially when in loud environments, to ensure you are aware of your Pod's insulin delivery status.

Important User Information

Pay special attention to Warnings and Precautions in this *User Guide*. The words "Warning" and "Caution" are displayed in red, bolded text. A red warning icon is shown before each warning. A yellow caution icon is shown before each caution statement.

You, an adult with diabetes, are the intended user of the Omnipod GO Pod.

It is very important that you review all instructions in this *User Guide* before using the Omnipod GO Pod.

If you still have questions after reading this *User Guide*, contact Customer Care 24 hours a day, 7 days a week.

Emergency Kit

Warning: ALWAYS keep the emergency kit supplies recommended by your healthcare provider on hand to quickly respond to any diabetes emergency or in case your Pod stops working. Always carry supplies to perform a Pod change should you need to replace your Pod at any time.

Warning: NEVER drive yourself to the emergency room if you need emergency medical care. Ask a friend or family member to take you to the emergency room or call an ambulance.

Some items you may need include:

- Glucose tablets or another fast-acting source of carbs
- Blood glucose test strips
- Blood glucose meter
- Lancing device and lancets
- Alcohol prep swabs
- A bottle (vial) of rapid-acting U-100 insulin (see "1.6. Compatible Insulins" on page 6 for insulins cleared for use in the Omnipod GO Pod)
- Several new, sealed Omnipod GO Pods
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod GO Pod
- Phone numbers for your healthcare provider and/or physician in case of an emergency

Tip: Before discontinuing use of the Omnipod GO Pod, ask your healthcare provider what supplies you need to keep on hand.

Tip: Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.

1.9. Healthcare Provider Dosing Considerations

Your healthcare provider determines and prescribes the amount of insulin you need per day based on their experience and based on professional guidelines for insulin therapy.

Depending on your needs, or the actual amount of insulin you have been taking currently, the Pod may be prescribed for any of these options: 10 units per day, 15 units per day, 20 units per day, 25 units per day, 30 units per day, 35 units per day or 40 units per day.

If you're already using insulin, your healthcare provider may consider reducing your prescribed daily insulin rate when you start using the Omnipod GO Pod.

Your healthcare provider may change your prescription to a different option for your Pod as your insulin needs change.

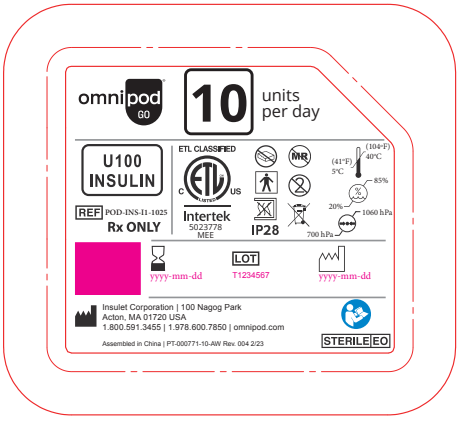
Caution: DO NOT use long-acting insulin in the Pod. If you have used long-acting insulin in the past, note that the Pod is designed to use rapid-acting, a different, faster insulin that requires a separate prescription. Using incorrect insulin could result in high glucose or low glucose.

1.10. Understanding Your Pod's Daily Insulin Rate and Your Syringe's 3-day Fill Line

The following images show the different Pod options and the syringe that comes with each Pod. You'll see that for each prescribed Pod, the syringe that comes with it is marked with a "Fill Here" line and a daily insulin rate, for example, 25 U/day. Use only the syringe that came with your Pod to ensure you get the prescribed daily insulin for 3 days.

Note: The location of the "Fill Here" line marked on the syringe is specific to each daily insulin rate.

Omnipod GO-10



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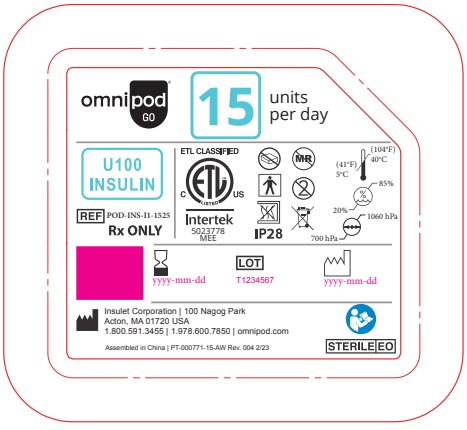

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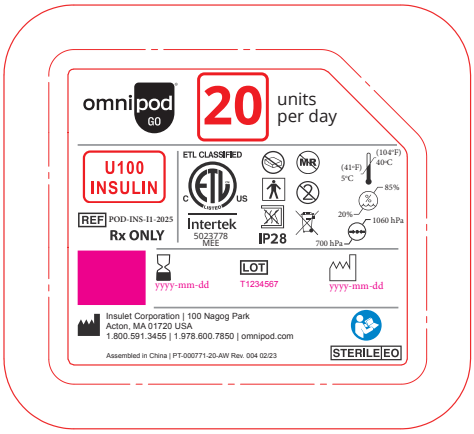

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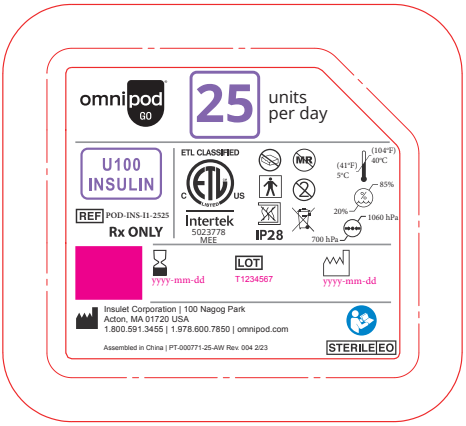
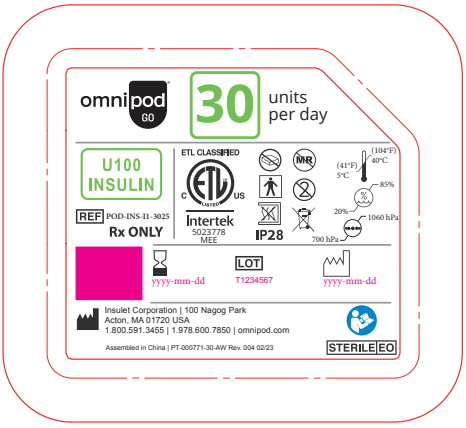
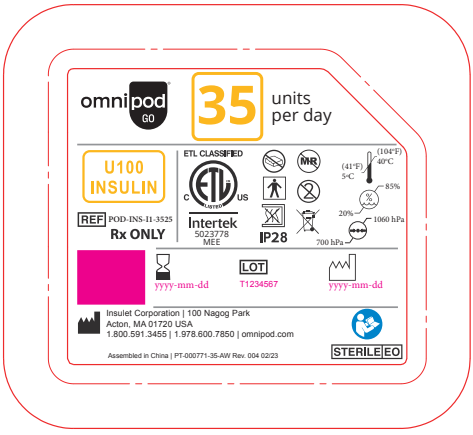


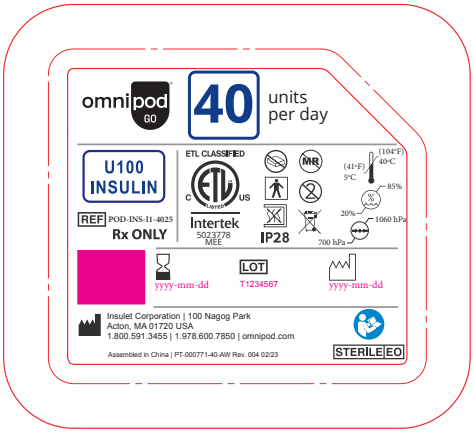
Omnipod GO-30



Omnipod GO-35



Omnipod GO-40



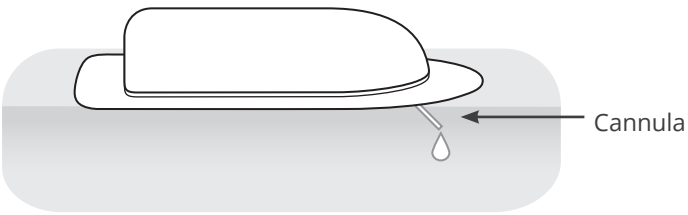
Chapter 2: Applying or Removing a Pod

Contents

2.1. About the Pod

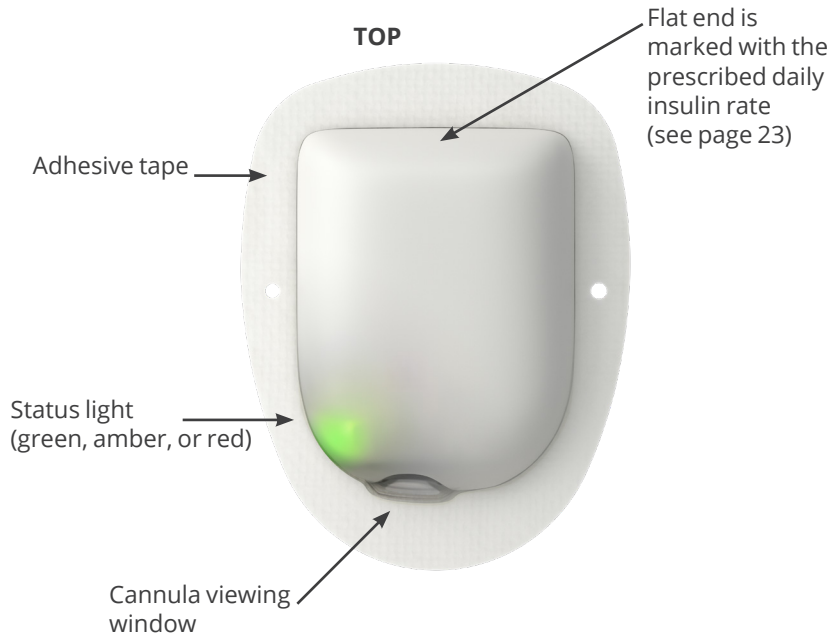
The Pod is a lightweight device that you fill with insulin and wear directly on your body. The Pod delivers insulin into your body through a small, flexible tube called a cannula. You apply the Pod to your skin with an adhesive tape, similar to an adhesive bandage.

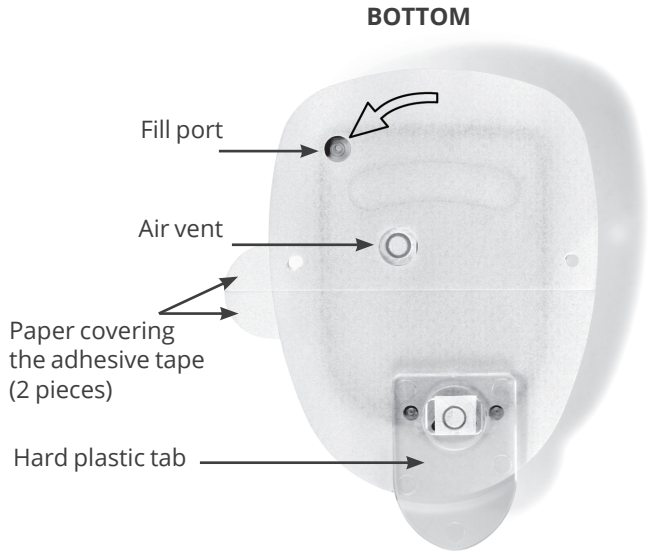
You won't manually turn the Pod ON or OFF. After you fill the Pod with insulin, the Pod will immediately prepare to insert the cannula 3 minutes after you see the amber light, so you'll need to have the Pod properly applied to your skin before the 3 minutes are up. If it takes you longer, the Pod will be unable to deliver insulin to you and you'll need to start over with a new Pod.



The Pod automatically delivers the amount of insulin that it was prescribed to deliver. You should change yo ur Pod at least once every 3 days. Consult with your healthcare provider if you feel your insulin needs to be adjusted.

Tip: Read this entire chapter and use the Learning Resources listed on page 2 before using the Omnipod GO Pod for the first time and any time you need a refresher about the process.


TOP
Flat end is marked with the prescribed daily insulin rate (see page 23)
Adhesive tape
Status light (green, amber, or red)
Cannula viewing window


BOTTOM
Fill port
Air vent
Paper covering the adhesive tape (2 pieces)
Hard plastic tab

Warning: DO NOT allow small children or pets access to small parts, such as the Pod and its accessories, including the hard plastic tab. Small parts could be swallowed and pose a choking hazard. If ingested or swallowed, these small parts could cause internal injury or infection.

Warning: DO NOT wear a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin. Applying a Pod under these circumstances could put your health at risk.

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.

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

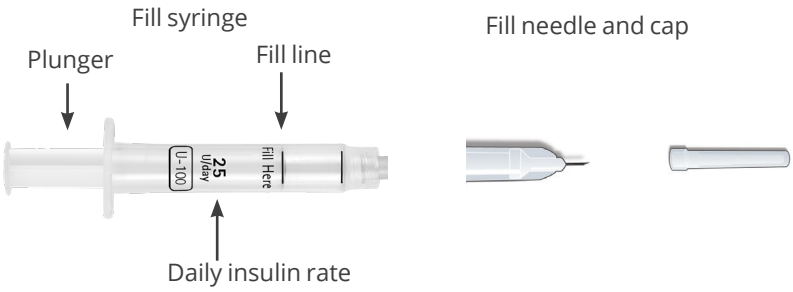
- The sterile package is damaged or is found open.
- The Pod or its fill needle was dropped after being removed from the package.
- The expiration (Exp. Date) on the package and the Pod has passed.

Caution: ALWAYS follow these steps in preparing your Pod site. If your site is not cleaned properly or if your hands are dirty, you increase your risk of infection.

- Wash your hands.
- Clean the top of the insulin bottle with an alcohol prep swab.
- Clean your Pod site with soap and water or an alcohol prep swab, and let it dry completely.
- Keep sterile materials away from any possible contamination.

2.2. About the Fill Syringe and Fill Needle

When you open your Pod package, in addition to the Pod, you will find accessories, including a fill syringe and a fill needle with a needle cap covering it. You will use these to draw insulin from the insulin bottle and then to fill your Pod with insulin.



Review the daily insulin rate marked on your syringe to confirm that you have the correct fill syringe for your Pod.

For example, if your prescription is marked 25 U/day and your Pod is marked Omnipod GO-25, then your syringe should also be marked 25 U/day.

Caution: NEVER use insulin that is expired or cloudy in the Pod as it may be damaged. Using damaged or expired insulin could cause high glucose and put your health at risk.

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 risk. If you are unsure if any of your components are damaged, stop using the Pod and call Customer Care for support.

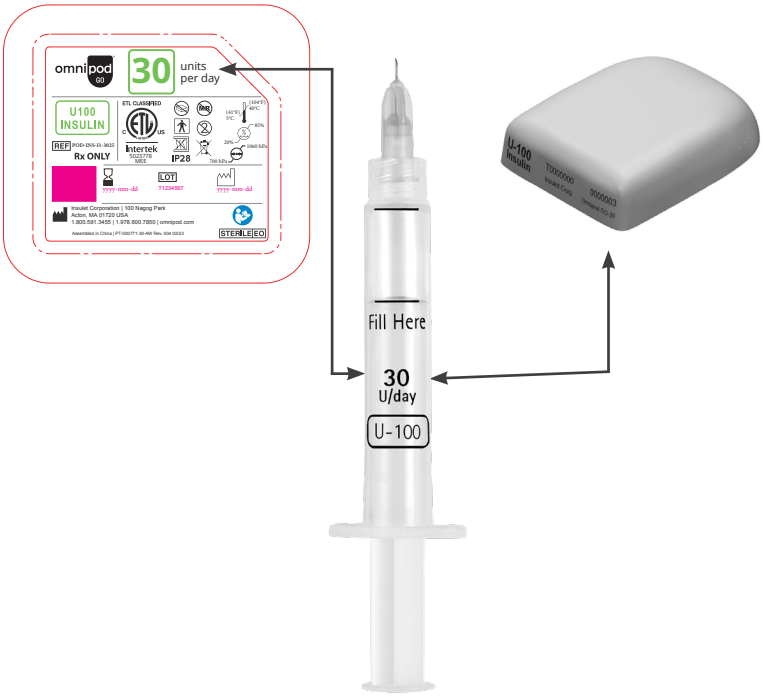
2.3. Before You Fill and Apply Your Pod

1. Gather the necessary supplies:
   - A bottle of rapid-acting U-100 insulin cleared for use in the Omnipod GO Pod. See "1.6. Compatible Insulins" on page 6 for a list of the insulin types that can be used with the Omnipod GO Pod.
   - An unopened Omnipod GO Pod prescribed to you
   - Alcohol prep swabs
2. Wash your hands before starting . Keep them clean throughout the Pod change process.
3. Check the insulin for signs of deterioration according to the manufacturer's instructions for use.
4. Check the Pod's packaging for damage. If undamaged, open it and inspect the Pod for signs of damage.
5. If the insulin or Pod is below 50°F (10°C), allow it to warm up to room temperature before proceeding.
6. Confirm that you are using the correct Omnipod GO Pod prescribed to you. Look for the prescribed daily insulin rate on the package.
7. Select your Pod site, the spot where you plan to apply this Pod on your body.

2.4. Using the Right Pod and Fill Syringe

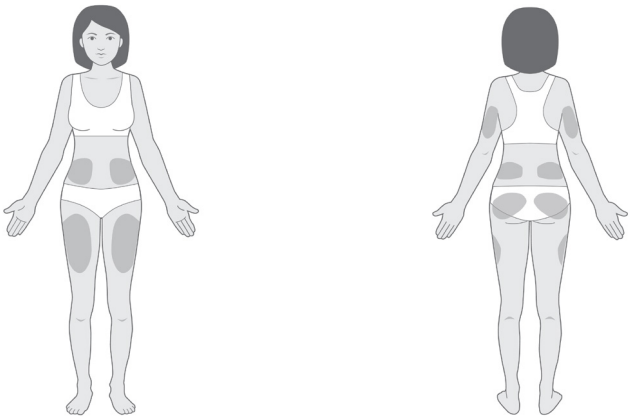
Before you use a Pod, verify the amount of insulin your Pod will deliver daily by checking the marking on the following:

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



2.5. Select the Pod Site (Infusion Site)

Caution: ALWAYS rotate (change) Pod sites to help prevent Pod site complications like scar tissue and infection. Rotating Pod sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption.



Select the site for your Pod as described below and shown in the diagram.

Guidelines for Pod site selection

Select a smooth site with a layer of fatty tissue and easy access and viewing, especially for checking the Pod status light. If you select a lean site instead of a fatty one, see page 35 for details about squeezing your skin after applying the Pod.

Tip: Make sure you can easily see the Pod status light in the lower left corner of the Pod either directly or indirectly (using a mirror).

The site should be the correct distance away from these:

- At least 1 inch (2.5 cm) away from the previous site to avoid skin irritation.
- At least 2 inches (5 cm) away from your navel.

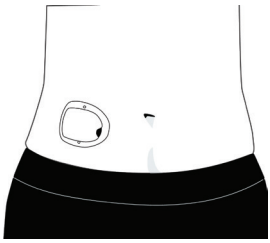
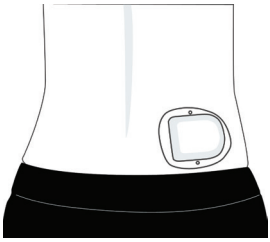
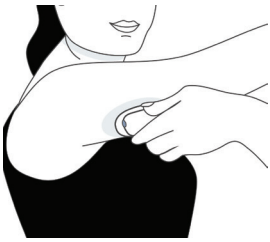
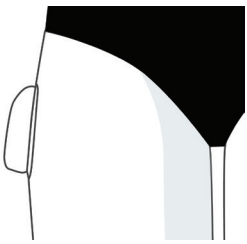
Site should NOT be near these:

- Avoid where belts, waistbands, or tight clothing may rub against or dislodge the Pod.
- Avoid where the Pod will be affected by folds of skin or a lot of hair.
- Avoid placing the Pod over a mole, tattoo, or scar, where insulin absorption may be reduced.
- Avoid areas of the skin with an infection.

2.6. Understand Pod Positioning

Depending on which Pod site you select, there are different ways to position the Pod. Select a Pod site and check the following table to see how to position the Pod.

Note: Use only 1 Pod on your body at a time.

Pod Site	How to Position the Pod
Abdomen 	Horizontal or diagonal 
Lower back, Hip, Buttocks 	Horizontal or diagonal 
Upper arm (back side only) 	Up and down or at a slight angle 
Thigh 	Up and down or at a slight angle 

2.7. Prepare the Pod Site

To reduce the risk of infection at the Pod site:

1. Wash your hands with soap and water.
2. Wash your selected Pod site with soap and water.

> **Note:** Antibacterial soap may irritate skin, especially at the Pod site. Ask your healthcare provider how to treat any skin irritation.

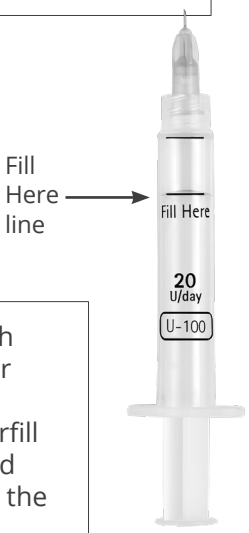
3. Dry the Pod site with a clean towel.
4. Use an alcohol prep swab to disinfect the Pod site. Start at the center of the site and gently rub outward in a circular motion.
5. Let the Pod site air-dry thoroughly. Do not blow on the site to dry it.

2.8. Fill the Syringe to the "Fill Here" Line

Follow every step to fill the syringe that came with the Pod with insulin:

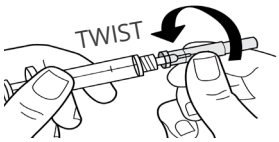
> **Caution:** Handle the fill needle with care to avoid accidental injury.

> **Caution:** ALWAYS fill the fill syringe to the marked "Fill Here" line. Using less insulin could cause the Pod to run out of insulin before the 3-day expected delivery time. Using more insulin will result in wasting the excess insulin.

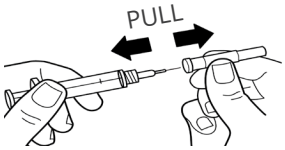


> **Caution:** USE ONLY a fill syringe that came with the Omnipod GO Pod prescribed for you. Never use a different syringe to fill the Pod. Using the wrong syringe to fill the Pod could result in overfill or underfill of the Pod, which can lead to wasted insulin or the Pod running out of insulin before the 3-day expected delivery time.

Clean the insulin bottle and assemble the fill syringe



1. Use an alcohol prep swab to clean the top of the insulin bottle.
2. Leaving the Pod in its tray, remove the 2 pieces of the fill syringe from the packaging.
3. Twist the fill needle onto the fill syringe for a secure fit.
4. Carefully pull outward to remove the protective cap from the fill needle. Discard cap.

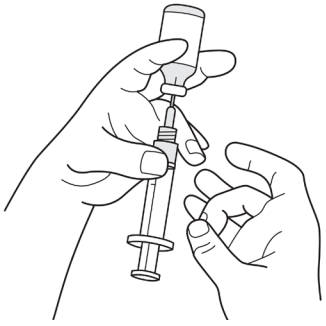


Inject air into the insulin bottle

1. Locate the "Fill Here" line on the syringe.
2. Draw air into the fill syringe up to the "Fill Here" line.
3. Insert the fill needle straight down into the center of the insulin bottle and inject the air. Injecting air makes it easier to withdraw insulin from the bottle.

> **Warning:** NEVER inject large bubbles or pockets of air from the fill syringe when filling a Pod with insulin. Air in the Pod takes up space where the insulin should be and can affect insulin delivery. Injecting air into a Pod could cause over-delivery or under-delivery of insulin, which can lead to low glucose or high glucose.

Turn the insulin bottle upside down and fill the syringe



1. While holding the plunger down, turn the insulin bottle and the fill syringe upside down.
2. Pull down on the plunger to fill the syringe to the "Fill Here" line.

Flick the syringe, push out air bubbles, and fill to the "Fill Here" line

If there are air bubbles in the syringe, do the following steps. Repeat as needed.

1. With the fill syringe still in the bottle, flick the side of the fill syringe with your fingertip to dislodge any air bubbles so they collect at the top of the syringe.

2. Push the plunger up to expel any air bubbles out of the fill syringe and into the insulin bottle.
3. Pull down on the plunger again, if necessary, to continue to fill the syringe to the "Fill Here" line. Once filled, remove the syringe from the bottle.

2.9. Fill the Pod

Be sure you've followed all instructions earlier in this chapter before you proceed to fill the Pod.

Caution: ALWAYS insert the fill syringe into the fill port and not into any other location on the Pod. Do not insert the fill syringe more than once into the fill port. Use only the fill syringe and needle that came with your Pod. The fill syringe is intended for single use only and should be used only with the Omnipod GO Pod it is packaged with. Failure to follow these instructions may result in damage to your Pod.

Caution: DO NOT insert the fill syringe at an angle into the insulin fill port. Insert the fill syringe only *straight down* into the insulin fill port. Inserting the syringe at an angle may damage the syringe or the Pod.

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.

Tip: Read sections 2.9 through 2.14 a few times before you put on your first Pod. This way you are comfortable not only with the steps to first fill the Pod, you also understand the steps to apply the Pod before the 3 minutes have passed after seeing the amber light.

To Fill the Pod with Insulin

After you fill the Pod with insulin, the Pod will immediately prepare to insert the cannula 3 minutes after you see the Pod's amber light.

After filling, do not delay in completing the steps needed to apply the Pod to your skin. Always handle the Pod with care, because if you drop it, you need to start over with a new Pod.

1. Find the arrow on the underside of the Pod. The arrow points to the insulin fill port. Only the insulin fill port has an arrow pointing to it.

Tip: Hold the Pod steady in its tray to make filling easier.

2. Insert the fill syringe straight down—not at an angle—into the insulin fill port.
3. Slowly push down the syringe plunger to completely fill the Pod.

   Listen for two beeps to tell you that the Pod knows you are filling it.
4. Make sure to completely empty the fill syringe into the Pod, even after hearing the 2 beeps.

   After filling the Pod, ALWAYS continue to the next step immediately. The Pod light is operating normally if there is no light showing on the Pod at first. Soon after filling, you will see the amber light which tells you to follow the instructions to apply the Pod to your body. If 3 minutes pass after you see the amber light and before applying the filled Pod, the Pod becomes unusable.

Note: If you filled the Pod and still do not hear the two beeps, please call Customer Care.

5. Remove the fill syringe from the insulin fill port. The port is self-sealing; insulin will not leak after the fill syringe is removed.
6. Discard the fill syringe in a sharps container.

Caution: ALWAYS dispose of a used Pod or fill syringe according to local disposal guidelines.

➢ Proceed immediately to the section starting on the following page.

2.10. Take Actions to Apply the Pod Properly While the Amber Light is Flashing

After the Pod is filled with insulin, wait to confirm the cannula insertion timer lights and sounds are working. When you hear the Pod beep and see the Pod's blinking amber light, you have confirmed they work. Then, don't delay. Continue with the next steps.

➢ Complete all the steps in section 2.11 on page 31 through section 2.14 ending at the top of page 37. Do this within 3 minutes of seeing the amber light.

Caution: DO NOT apply a Pod if you see the cannula is extended beyond the adhesive backing after the tab on the Pod is removed. This cannula cannot be inserted, resulting in under-delivery of insulin which can lead to high glucose.

Caution: DO NOT apply a filled Pod if the Pod light is already blinking green. Once the Pod light is blinking green, the Pod has already deployed its cannula and can no longer insert the cannula in your skin to deliver insulin.

Caution: DO NOT use a Pod if it does not show the normal lights and sounds for setup and insulin delivery described in this *User Guide*. Using an improperly functioning Pod could result in under-delivery of insulin which can lead to high glucose. Discard a non-functioning Pod and apply a new Pod.

2.11. Remove (Snap Off) the Pod's Hard Plastic Tab

Hold the Pod securely as you snap off the Pod's hard plastic tab.

Before You Remove the Hard Plastic Tab

Before you remove the hard plastic tab, hold the Pod properly and securely:

1. Turn the Pod so the hard plastic tab is up and facing you.
2. Hold the hard plastic tab between your thumb (on the flat side) and your index finger (underneath).
3. Hold the Pod steady with your other hand.

Snap Off the Hard Plastic Tab

1. Pry or snap off the hard plastic tab by lifting it with your index finger like when opening a beverage can. You'll feel resistance, but keep lifting the tab until it snaps off.
2. Throw the hard plastic tab away.

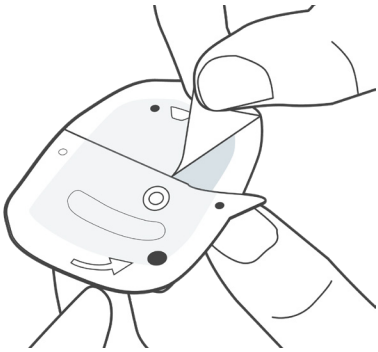
   When you snap off a hard plastic tab, it is normal to see a drop of insulin.
3. If the Pod is dropped, wet, dirty, damaged, or its cannula extends beyond the adhesive backing, dispose of the Pod and begin again with a new Pod.

Note: Do not use the Pod if you have dropped it, as it could result in infection.

2.12. Remove (Peel Off) the Paper from the Adhesive Tape

The adhesive tape on the bottom of the Pod is covered by 2 small pieces of paper (the paper backing), each with a paper pull tab.

Remove the paper backing as follows:



1. Grasp the Pod on the sides with only your fingertips.
2. Gently pull the paper tab away from the middle of the Pod, pulling the adhesive's paper backing slowly toward the end of the Pod and off. Be careful not to remove the adhesive tape itself. Do not allow the adhesive tape to fold back on itself.
3. In the same way, carefully remove the other half of the paper backing.

2.13. Inspect the Pod

Inspect the Pod so that you can confirm you should still use it:

➢ Examine the Pod. Dispose of the Pod if it has been dropped, or if the adhesive tape is folded, torn, or damaged, and begin again with a new Pod.

Caution: DO NOT apply a Pod if you see the cannula is extended beyond the adhesive backing after the tab on the Pod is removed. This cannula cannot be inserted, resulting in under-delivery of insulin which can lead to high glucose.

Caution: If you plan to dispose of a filled Pod without using it, DO NOT hold or carry the Pod until the Pod light is blinking green. Holding the Pod in your hand for an extended period of time when the cannula is about to deploy could result in injury.

Note: If you are disposing of a damaged Pod, see page 48 to stop it from sounding alarms.

2.14. Apply the Pod

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.

Caution: ALWAYS apply the Pod before the blinking amber light turns green. Applying the Pod after the light turns green means that the cannula deployed before you could apply the Pod.

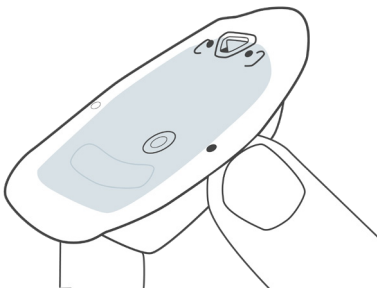
Caution: After filling the Pod, ALWAYS continue to the next step immediately. If the cannula is already deployed, the Pod becomes unusable.

Caution: DO NOT use sprays, strong detergents, or solvents on or near your Pod. The use of spray sunscreen, DEET-containing bug spray, personal care sprays, and other aerosols, detergents, and strong chemicals on the Pod can irritate the infusion site or damage the Pod, increasing the risk that the Pod housing will crack. Pod damage may result in the ingress of external fluids which can impact the ability of the Pod to function properly. This may result in the over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

1. After you have inspected the Pod, be ready to position it as described below for your chosen site.

Pod Site	How to Position the Pod
Abdomen	Horizontal or diagonal
Hip	Horizontal or diagonal
Lower back	Horizontal or diagonal
Buttocks	Horizontal or diagonal
Upper arm	Up and down or at a slight angle
Thigh	Up and down or at a slight angle

2. If the Pod's status light is Red or Green before you apply it, dispose of the Pod and start over with filling a new Pod.
3. If the Pod's status light is amber, grasp the Pod on the sides with only your fingertips, keeping your fingers off the adhesive tape.
4. Apply the Pod to the site you cleaned, at the recommended angle for the site you chose.
5. Run your finger around the adhesive tape to secure it. Confirm the Pod is securely attached.



Note: The adhesive tape is designed for one-time use. After a Pod is placed on your body, do not attempt to move that Pod to another site.

Note: The Pod's adhesive tape keeps it securely in place for up to 3 days. If necessary, several products are available to help with peeling adhesive tape. Ask your healthcare provider about these products. Avoid getting any lotion, creams, sprays, or oils near the Pod site as these products may loosen the adhesive tape.

Tip: ALWAYS apply the Pod as directed. If you are applying a Pod in a place that does not have a lot of fatty tissue, squeeze the skin around the Pod until after the Pod has inserted the cannula. Blockages (occlusions) may result if you do not use this technique for lean areas.

6. If you applied the Pod to a lean area, gently pinch the skin around the Pod while you wait for the cannula to insert. Make sure not to pull the Pod off your body.
7. Confirm your Pod is working properly by listening to the Pod and observing the Pod, looking for the signs described next.

Confirm the Automatic Cannula Insertion

Once the time is up, the cannula will automatically insert.

1. After you apply the Pod, listen for a click sound and for the Pod to beep once. Watch for the Pod status light to turn to a blinking green.

   This means the cannula has been deployed and your Pod is working.

Note: As soon as the soft cannula is inserted, the needle retracts back into the Pod so only the soft cannula remains for insulin delivery. The needle does not remain in your skin.

2. Confirm that the Pod is securely attached to your body.
3. If you had gently pinched your skin, you can release the skin once the cannula is inserted. The cannula can be inserted only once with each Pod.

4. Check the Pod site. Verify that there is no wetness or scent of insulin.

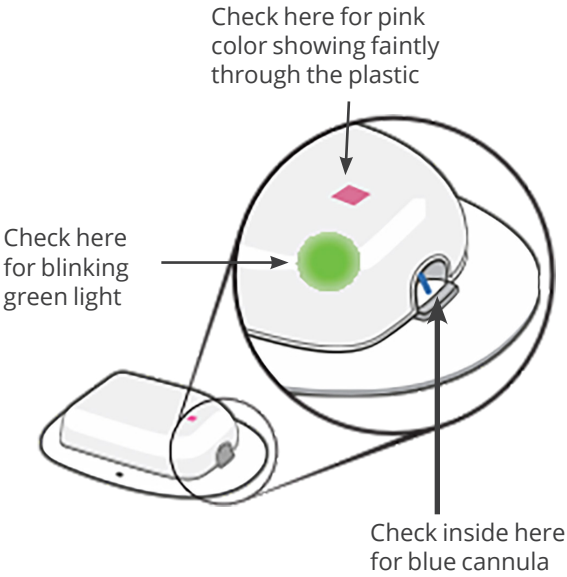
   The presence of either may indicate that the cannula has not been properly inserted or has dislodged.

5. Check the Pod light.

   When the Pod's light has started blinking green, that means that the cannula has been deployed and your Pod is working.

6. Check the Pod by verifying the cannula's insertion. The reason you check this is that your Pod can only deliver insulin as intended if its cannula is properly inserted.

   - Look through the viewing window on the end of the Pod to verify that the blue cannula is inserted into the skin.
   - Look at the top of the Pod for a pink color showing faintly under the plastic.



Tip: Consider adding Pod site and Pod light checks to some of your daily routines, such as when you wake up, before each meal, before going to bed, or before brushing your teeth.

Caution: ALWAYS check the Pod site after insertion to ensure that the cannula was properly inserted. An improperly inserted cannula could result in under-delivery of insulin which can lead to high glucose.

Caution: ALWAYS check often to make sure insulin is not leaking from your Pod site. If you touch the area around the Pod and notice wetness or notice the scent of insulin on your fingers afterwards, this could mean that insulin is not being absorbed. ALWAYS check often in this way to ensure the Pod is securely attached and the soft cannula is not dislodged. A loose or dislodged cannula could interrupt insulin delivery, which can lead to high glucose.

Warning: NEVER inject insulin (or anything else) into the fill port while the Pod is on your body. Attempting to do so could result in over-delivery or under-delivery of insulin, which can lead to low glucose or high glucose.

2.15. Remove a Pod

After 3 days of normal use, your Pod will automatically stop delivering insulin. Before you remove a Pod, confirm with Pod lights and beeps that it is time to replace the Pod.

If your Pod light is solid red or blinking red, you need to remove your Pod because it is not delivering insulin. If you want to continue to receive insulin, replace the Pod with a new Pod.

For more details about the meaning of Pod lights and sounds, see page 41.

Warning: DO NOT apply a new Pod until you have removed the old Pod. Use only 1 Pod on your body at a time. If your old Pod has not expired, it could continue to deliver insulin while you wear it. This could result in the over-delivery of insulin, which can lead to low glucose.

Caution: NEVER reuse the Pod or fill syringe or try to use a fill syringe that did not come with your Pod. Always dispose of the used Pod and fill syringe according to local disposal guidelines. Only use a new Pod with the included fill syringe with each Pod change. Always carry supplies to perform a Pod change should you need to replace your Pod at any time.

Remove the Pod from your body:

1. Gently lift the edges of the adhesive tape from your skin and remove the entire Pod.

> **Tip:** 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.
   a. Check the Pod site for signs of infection (see "Avoid Pod Site Infections" in the next section).
   b. Dispose of the used Pod according to local waste disposal regulations.

> **Caution:** Once you have removed and discarded the Pod, promptly begin using a new Pod. Going too long without insulin can lead to high glucose.

2.16. More Information about Pod Use

Avoid Pod Site Infections

Check the Pod site at least 3 times a day, or as advised by your healthcare provider. Be aware of signs of infection, including pain, swelling, redness, discharge, or heat at the Pod site. If you suspect an infection, immediately remove the Pod and apply a new Pod in a different location. Then contact your healthcare provider.

> **Caution:** ALWAYS rotate (change) Pod sites to help prevent Pod site complications like scar tissue and infection. Rotating Pod sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption.

Caution: ALWAYS follow these steps in preparing your Pod site. If your site is not cleaned properly or if your hands are dirty, you increase your risk of infection.

- Wash your hands.
- Clean the top of the insulin bottle with an alcohol prep swab.
- Clean your Pod site with soap and water or an alcohol prep swab, and let it dry completely.
- Keep sterile materials away from any possible contamination.

Caution: ALWAYS check for signs of infection often. If a Pod site shows signs of infection:

- Immediately remove the Pod and apply a new one at a different site.
- Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

If you see blood in your cannula, check your glucose to ensure insulin delivery has not been affected. If you experience unexpected high glucose, change your Pod.

Check That Your Pod is Working Properly

- Check your glucose at least daily, or as recommended by your healthcare provider, to make sure your Pod is working properly.
- Check your Pod status light at least 3 times a day, or as recommended by your healthcare provider, to make sure your Pod is working properly. Check more frequently when in loud environments for prolonged periods of time when you may not be able to hear a Pod alarm.

If you observe any problems with the Pod, remove the old Pod, then apply a new one.

Caution: ALWAYS check often to make sure insulin is not leaking from your Pod site. If you touch the area around the Pod and notice wetness or notice the scent of insulin on your fingers afterwards, this could mean that insulin is not being absorbed. ALWAYS check often in this way to ensure the Pod is securely attached and the soft cannula is not dislodged. A loose or dislodged cannula could interrupt insulin delivery, which can lead to high glucose.

Warning: AVOID using the Omnipod GO Pod if you do not have adequate hearing and/or vision to let you recognize Pod lights and sounds that signify alerts and alarms. 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.

Develop Good Habits for Pod Use

- Develop a routine so you can change your Pod at a convenient time. If you know of an upcoming event that could interfere with changing your Pod, you can change your Pod early to avoid a disruption in insulin delivery.
- If your next planned Pod site has a lot of hair, clip or shave it 24 hours before applying the Pod. Clipping or shaving ahead of time helps avoid skin irritation. Applying the Pod to the smooth skin helps the Pod stay in place.
- Always wear the Pod in a location where you can see the light and hear the beeps. If necessary, use a mirror to see the light.
- Confirm that the daily insulin rate marked on your Pod and syringe matches your prescription and the rate marked on the Pod packaging.
- Check the Pod light more frequently when in loud environments for prolonged periods of time when you may not be able to hear a Pod alarm.

For additional information on using your Pods as effectively as possible, see the following sections:

- For care of your Pod, see "Chapter 4: Taking Care of Your Pod and Your Diabetes" on page 49.
- To learn about the Pod alarms, see page 46.
- To understand the Pod's lights and beeps, see "Chapter 3: Understanding Pod Lights and Sounds and Alarms" on page 41.

Chapter 3: Understanding Pod Lights and Sounds and Alarms

Contents

3.1. Introduction to How the Pod Communicates

The Omnipod GO Pod communicates through its lights and sounds. Hazard alarms are high priority alarms that indicate a problem has occurred. When a Hazard alarm occurs (solid red light) or when your Pod expires normally (blinking red light), you must remove your Pod and apply a new one.

Caution: ALWAYS respond to a red or blinking red Pod light as soon as possible. A red or blinking red Pod light indicates that insulin delivery has stopped and you need to change your Pod to continue receiving insulin. Failure to respond to a red or blinking red Pod light could result in the under-delivery of insulin which can lead to high glucose.

Warning: AVOID using the Omnipod GO Pod if you do not have adequate hearing and/or vision to let you recognize Pod lights and sounds that signify alerts and alarms. 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.

The following sections describe what to do about lights and sounds while using the Pod.

What do the Red, Amber or Green Pod Light Colors Mean?

The Pod light colors mean the following:

- Red: Change your Pod. It is not delivering insulin.
- Amber (Yellow): During Pod setup, apply the Pod to your body according to instructions within 3 minutes.
- Green: Normal insulin delivery.
- No light: Change your Pod. It is not delivering insulin.

What do the Pod's Sounds Mean?

The meaning of the Pod's sounds depends on these situations:

- While filling and applying the Pod

  You are filling your Pod with insulin and applying it. Hearing 2 beeps means your Pod knows you are filling it. Continue filling. Next, 1 beep means you have 3 minutes or less to apply your Pod.

  Nearly 3 minutes have passed. A pattern of beeps that repeats 3 times means the Pod will insert the cannula in 30 seconds or less. Your Pod should be on your body already. If your Pod site is lean, squeeze the skin around it. Wait up to 15 seconds without a Pod light for 1 more beep to show that your Pod is beginning to deliver insulin.

- Any time while setting up a Pod or using it

  If your Pod beeps in a pattern that repeats 5 times, this means the Pod has stopped delivering insulin. Change your Pod. If the Pod sounds a continuous tone, the Pod has stopped working due to a rare problem. Change your Pod.

Note: After your insulin delivery starts, the Pod will not beep again unless it has a problem or it is time to change your Pod.

If you have removed a Pod and it continues to sound an alarm, you can silence it as described on page 48.

Caution: DO NOT use a Pod if it does not show the normal lights and sounds for setup and insulin delivery described in this *User Guide*. Using an improperly functioning Pod could result in under-delivery of insulin which can lead to high glucose. Discard a non-functioning Pod and apply a new Pod.

3.2. During Pod Setup

To inform you about how setup activities are coming along, and to let you know when it's time to apply the Pod to your body:

- The Pod light will blink amber (yellow)
- You will hear the Pod beep, even when the light is not on

During Pod Setup			
Pod Light	**Pod Sound**	**What it means**	**What to do**
No light	2 beeps	You have successfully filled the Pod with the minimum amount it needs to operate. Keep filling until the syringe is empty so that your Pod will give you 3 days worth of insulin.	Continue with the Pod setup process. If you have filled the Pod with the correct amount, but did NOT hear the 2 beeps, do not continue. Contact Customer Care.

Note: The blinking amber light described next starts within a minute after the 2 beeps.

During Pod Setup (continued)			
Pod Light	**Pod Sound**	**What it means**	**What to do**
Color: Amber blinking Time: 3 minutes 	1 beep	The 3 minute countdown starts. After it finishes, the Pod will automatically insert the cannula. Do not delay in the Pod setup process.	Apply the new Pod to your body as instructed, within 3 minutes of seeing the amber light and before the light turns green.
Color: Amber blinking Time: 10 seconds 	A beep pattern of 6 beeps that sounds 3 times in a row	The Pod will insert the cannula in 30 seconds or less.	If your Pod site is a lean area (see page 35), you should gently squeeze the skin around the Pod at this time so the cannula can be properly inserted.
No light for 20 seconds or less	1 beep (you may have to wait up to 20 seconds for it)	The Pod is preparing to start insulin delivery. The beep means the Pod has inserted the cannula and insulin delivery has started.	Wait and listen for 1 beep. It may take 20 seconds. If you have waited longer than 20 seconds and there is still no green light, contact Customer Care.

3.3. During Pod Use

A Pod delivers insulin for 3 days (72 hours). The Pod will blink green when you start using it and during the delivery time. Your Pod won't beep while it is delivering insulin.

During Pod Use		
Pod Light	**What it means**	**What to do**
Color: Green blinking Time: 72 hours 	Your Pod is working correctly and delivering insulin.	Check your Pod site and Pod light 3 times a day or as instructed by your healthcare provider. Check your glucose once a day or as instructed by your healthcare provider.

3.4. When the Pod has Stopped: Alarms

A Red solid or Red blinking Pod light means that your Pod is not delivering insulin and you'll need to remove it. No light at all for 2 or more minutes after filling the Pod or no light during use means that your Pod is not working properly and you'll need to remove it. To continue receiving insulin, replace it with a new Pod.

Warning: DO NOT apply a new Pod until you have removed the old Pod. If your old Pod has not expired, it could continue to deliver insulin while you wear it. This could result in the over-delivery of insulin, which can lead to low glucose.

Caution: ALWAYS begin using a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to high glucose.

When the Pod Has Stopped			
Pod Light	**Pod Sound**	**What it means**	**What to do**
Color: Red blinking Time: about 12 hours  This Pod's blinking will continue for about 12 hours, even if you have removed this Pod.	A set of 3 beeps followed by a set of 2 beeps. This pattern will sound 5 times with a 1 second break.	Red light means to change your Pod. The Pod has stopped delivering insulin because it has expired.	1. Remove your Pod. 2. Apply a new Pod to continue to receive insulin.
Color: Solid Red Time: Varies 	Alarm sound pattern: A set of 3 beeps followed by a set of 2 beeps. This pattern will sound 5 times with a 1 second break. This will happen again 15 minutes later.	Red light means to change your Pod. The Pod has stopped delivering insulin due to an alarm.	Remove your Pod. Follow the instructions on page 48 to silence the alarm, if needed. Apply a new Pod to continue to receive insulin.
	Alternate alarm sound pattern for only a rare problem with the Pod: You will hear a continuous tone which lasts until the Pod battery runs out.		

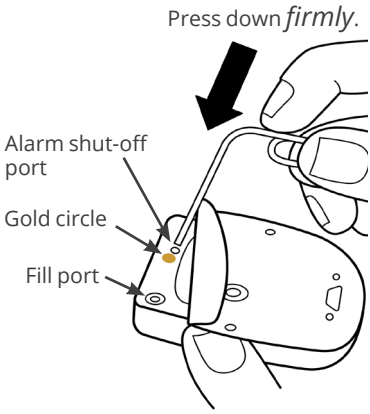
When the Pod Has Stopped (continued)			
Pod Light	**Pod Sound**	**What it means**	**What to do**
No light	No sound.	The Pod you have been wearing has not been delivering insulin for an extended period of time. 4 hours passed since the Pod experienced a Hazard alarm, or 12 hours passed since the Pod expired.	1. Remove your Pod. 2. Apply a new Pod to continue to receive insulin.

3.5. Silencing Alarms

If a Pod alarm continues unexpectedly, follow the directions in this section.

To permanently silence a Pod's alarm:

1. If the Pod is on your body, remove it.
2. Peel back a little bit of the adhesive tape from the bottom of the Pod at the square end (see figure).
3. Locate the alarm shut-off port to the right of the gold circle. The alarm shut-off port can be felt with a fingernail or paper clip as a soft plastic.



4. Firmly press a paper clip or similar item straight down into the alarm shut-off port. You need to apply enough force to break a thin layer of plastic. If an alarm is sounding, the alarm will stop.

Chapter 4: Taking Care of Your Pod and Your Diabetes

Contents

4.1. Pod and Insulin Storage

The Omnipod GO Insulin Delivery Device has no user-serviceable parts. If you need assistance operating or maintaining the Omnipod GO Pod, call Customer Care. Always store your Pods in a safe place to ensure others cannot use them.

Caution: DO NOT expose Pods or to extreme temperatures that are outside the temperature ranges shown on page 65. They won't work properly after that exposure. Store all Pods and supplies, including unopened Pods, in a cool, dry place.

Extreme heat or cold can damage Pods and cause them to malfunction.

It is especially important to store your insulin in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discolored. Insulin that is cloudy or discolored may be old, contaminated, or inactive. Check the insulin manufacturer's instructions for use and the insulin's expiration date.

4.2. Pods and the Environment

Avoid Extreme Temperatures

Warning: DO NOT expose a Pod to direct sunlight for long periods of time. Remove your Pod prior to using hot tubs, whirlpools, or saunas. These conditions could expose the Pod and the insulin inside it to extreme temperatures which could lead to high glucose.

The Pod's operating temperature has been tested and found to operate safely between 41°F and 104°F (between 5°C and 40°C). Under normal circumstances, your body temperature keeps the Pod within a range of 73°F and 100°F (between 23°C and 38°C).

Caution: NEVER use a blow dryer or hot air to dry the Pod. Extreme heat can damage the electronics.

If you remove your Pod to avoid exposing it to extreme temperatures, remember to apply a new Pod as soon as you can.

Note: Check with your healthcare provider for guidelines if you will not use a Pod for extended periods.

Note: Ask your pharmacist if you have questions about your rapid-acting insulin's maximum exposure temperature.

Water and Your Pod

Warning: DO NOT expose your Pod to water at depths greater than 25 feet (7.6 meters) or for longer than 60 minutes. That exposure can damage the Pod, which could result in the over-delivery or under-delivery of insulin, which can lead to low glucose or high glucose.

The Pod is waterproof for depths up to 25 feet (7.6 meters) for up to 60 minutes (IP28). After swimming or similar exposure to water, rinse off the Pod with clean water and gently dry it with a towel.

4.3. Cleaning Your Pod

Pods are waterproof. If you need to clean a Pod, gently wash it with a clean, damp cloth, or you can use mild soap and water. However, do not use strong detergents or solvents, as they can damage the Pod's casing or irritate the Pod site.

Caution: DO NOT use sprays, strong detergents, or solvents on or near your Pod. The use of spray sunscreen, DEET-containing bug spray, personal care sprays, and other aerosols, detergents, and strong chemicals on the Pod can irritate the infusion site or damage the Pod, increasing the risk that the Pod housing will crack. Pod damage may result in the ingress of external fluids which can impact the ability of the Pod to function properly. This may result in the over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

Caution: USE CAUTION while cleaning the Pod on your body. Hold the Pod securely so the cannula does not kink and the Pod does not loosen or fall off.

4.4. Pod Site Checks

At least 3 times a day, or as advised by your healthcare provider, use the Pod's viewing window to inspect the Pod site. If it helps you, use a mirror to get a better view. Check the site for:

- Leakage or scent of insulin, which may indicate the cannula has dislodged
- Signs of infection, such as pain, swelling, redness, discharge, or heat

Caution: ALWAYS check for signs of infection often. If a Pod site shows signs of infection:

- Immediately remove the Pod and apply a new one at a different Pod site.
- Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

If you see blood in your cannula, check your glucose to ensure insulin delivery has not been affected. If you experience unexpected high glucose, change your Pod.

Tip: Consider adding Pod site checks to some of your daily routines, such as when you wake up, before each meal, before going to bed, or before brushing your teeth.

4.5. Being Aware of Your Glucose

Being aware of your glucose helps you manage your diabetes. Check your glucose once a day, or as advised by your healthcare provider.

You may need to check your glucose:

- Whenever you feel nauseated or sick
- Whenever your glucose has been running unusually high or low, or if you suspect that your glucose is high or low
- As directed by your healthcare provider

If your glucose values are too low, treat immediately according to your healthcare provider's instructions. Contact your healthcare provider as needed for guidance.

If your glucose values are too high, or if you are having symptoms that are not consistent with your blood glucose and you have followed all instructions described in this User Guide, contact your healthcare provider as needed for guidance.

4.6. Traveling and Vacations

It is important that you check your glucose while you are traveling. Changes in time zones, activity levels, and meal times can all affect your glucose.

Proper preparation is important when traveling. The following sections will help you prepare for your travels.

Keep Supplies Accessible

On airplanes, trains, and buses, keep these items with you, rather than checking them:

- Extra Pods
- Snacks and low glucose treatment, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- Bottles (vials) of insulin (cargo area temperatures may affect insulin)
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod GO Pod
- Prescriptions for all medications

- Medications and supplies with their original prescription label
- The name and phone number of your physician and of a physician at your final destination

Note: Medications may have different brand names outside your country. Ask the pharmacist for help.

Note: Keep your emergency kit with you during trips or vacations (see "Emergency Kit" on page 11). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

Tip: When you travel outside the country or for long periods of time, be sure to take extra Pod supplies. Prior to departure, contact your healthcare provider to inquire about additional Omnipod GO Pods for your trip.

Airports and Flying

Before traveling by plane, familiarize yourself with the airport's security procedures and prepare your diabetes supplies for the security process and flight.

Airport security

Prepare for your travel:

- Airport security checks and screening procedures may change, so review the airport website and the TSA website for travel updates before your trip.
- Arrive at the airport 2-3 hours before your flight.
- Have your insulin management supplies easily accessible to ensure that airport security checks run smoothly.

Airport security offers the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. You must request this before the screening process begins. Your medical supplies should be in a separate bag when you approach the security officer.

To prevent contamination or damage to your supplies, you should be asked at the security checkpoint to display, handle, and

repack your own supplies during the visual inspection process. Any medication and/or associated supplies that cannot be cleared visually must be submitted for X-ray screening.

If you are concerned about going through the walk-through metal detector, notify the security officer that you're wearing an insulin pump. You should advise the security officer that the insulin pump cannot be removed because it is inserted with a cannula (tubing) under the skin.

Visit the TSA Contact Center if you have any further questions or concerns.

Changes in atmospheric pressure when flying

Caution: Be prepared to check your glucose following amusement park rides and during flying or other situations with sudden changes or extremes of air pressure, altitude, or gravity. Though the Omnipod GO Pod is safe to use at atmospheric pressures typically found in airplane cabins during flight, the atmospheric pressure in an airplane cabin could change during flight, which may affect the Pod's insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight take-off and landing, could affect insulin delivery leading to possible low glucose or injury. If needed, follow your healthcare provider's treatment instructions.

Note: The Omnipod GO Pod is safe to use at atmospheric pressures typically found in airplane cabins during flight. The Pod can be used at atmospheric pressures as low as 700 hPa, which is lower than the typical pressure in airplane cabins.

4.7. Avoiding Low and High Glucose

You can avoid most risks related to using the Omnipod GO Pod by following the instructions in this *User Guide* for filling, applying, and using a Pod and by promptly treating any symptoms of low glucose. The easiest and most reliable way to avoid low and high glucose is to check your glucose daily or as recommended by your healthcare provider.

General Precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme highs or lows, or if highs or lows are occurring more often than usual.
- If you have technical problems with your Pod and cannot resolve them, call Customer Care immediately.

Warning: DO NOT wait to treat low glucose or symptoms of low glucose. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe low glucose, which can quickly lead to shock, coma, or death.

Low Glucose

Low glucose can occur even when a Pod is working properly. Never ignore the signs of low glucose, no matter how mild. If left untreated, severe low glucose can cause seizure or lead to unconsciousness. If you suspect that your glucose is low, check your glucose to confirm.

To treat low glucose

Any time your glucose is low, treat it immediately according to your healthcare provider's instructions. Contact your healthcare provider as needed for guidance.

Symptoms of low glucose

Never ignore the following symptoms, as they could be signs of low glucose:

- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling in the lips or tongue
- Anxiety

Tip: Hypoglycemia unawareness is a condition in which you do not realize when your glucose is low. If you are often unaware that your glucose is less-than-optimal, you may want to check your glucose more often.

Tip: Make sure your glucose is at least 100 mg/dL before driving or working with dangerous machinery or equipment. Low glucose may cause you to lose control of a car or dangerous equipment. Also, when you focus intently on a task, you may miss the symptoms of low glucose.

To avoid low glucose

- Work with your healthcare provider to establish individualized glucose target ranges and guidelines.
- Keep a fast-acting carbohydrate with you at all times to respond quickly to low glucose. Examples of fast-acting carbs are glucose tablets, hard candies, or juice.
- Teach your friends, family members, and colleagues to recognize the signs of low glucose, so they can help if you develop hypoglycemia unawareness or a severe adverse reaction.

Note: Carry medical identification and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

Again, glucose checks are the key to avoiding potential problems. Detecting low glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in avoiding low glucose.

Possible causes of low glucose	Suggested action
Incorrect Pod	Confirm that you have the correct Pod. Consult your healthcare provider if you think your insulin dose may need to change.
Prone to severe low glucose or hypoglycemia unawareness	Consult your healthcare provider about hypoglycemia (low glucose) unawareness and about changing prescribed amounts of insulin and other medications.
Unplanned physical activity	Carry fast-acting carbs, for example, glucose tablets.
Low carbohydrate intake prior to activity	Check glucose before activity. Consult your healthcare provider for guidance.

Possible causes of low glucose	Suggested action
Alcohol consumption	Check glucose, especially before going to bed. Consult your healthcare provider for guidance.

High Glucose

Warning: NEVER drive yourself to the emergency room if you need emergency medical care. Ask a friend or family member to take you to the emergency room or call an ambulance.

To avoid high glucose and DKA

Check your glucose:

- At least once a day, or as advised by your healthcare provider
- If you feel nauseated or sick
- Whenever your glucose has been running unusually high or low
- If you suspect that your glucose is high or low
- As directed by your healthcare provider

Possible causes of high glucose	Suggested action
Expired insulin or insulin exposed to extreme temperatures	Remove the used Pod. Apply a new Pod filled from a new bottle of insulin.
Pod site in or near a scar or mole	Remove the used Pod. Apply a new Pod in a different location.
Infected Pod site	Remove the used Pod. Apply a new Pod in a different location and consult your healthcare provider.

Possible causes of high glucose	Suggested action
Dislodged cannula	Remove the used Pod. Apply a new Pod in a different location. **Note:** Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.
Empty Pod	Remove the used Pod. Apply a new Pod in a different location.
Incorrect Pod	Confirm that you are using the Pod prescribed to you. Consult your healthcare provider if you think your insulin dose may need to change.
Infection or illness or medication change	Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain or menstrual cycle or pregnancy	Consult your healthcare provider for guidance.

4.8. Handling Special Situations

Exercising, Playing Sports, or Working Hard

The Pod's adhesive keeps it securely in place for up to 3 days (72 hours). However, if necessary, several products are available to help with peeling adhesive tape. Ask your healthcare provider about these products.

Avoid getting body lotion, creams, or oils near the Pod site; these products may loosen the adhesive tape.

For some contact sports, if the Pod is in a location where it is likely to be knocked off, consider removing the Pod and placing a new one in a more protected location.

Pods are designed for one-time use. Do not attempt to reapply a Pod that has been removed.

If you will need to remove the Pod for a long period of time, ask your healthcare provider for steps you should take to continue managing your diabetes.

X-rays, MRIs, and CT Scans

The Pod can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

> **Warning:** The Pod may be affected by strong radiation or magnetic fields. The Pod must be removed and disposed of before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan. Exposure to X-ray, MRI, or CT treatment can damage the Pod. Check with your healthcare provider on Pod removal guidelines.

Surgery or Hospitalization

For scheduled surgeries or hospitalization, you should tell the physician/surgeon or hospital staff about your Pod. It may be necessary to remove it for certain procedures or treatments. You need to discuss this with your healthcare provider so you can prepare for these situations.

Chapter 5: Troubleshooting

Contents

5.1. Pod Issues

Issue	Possible Cause	What you can do
While filling the Pod, did not hear the 2 beep confirmation	Pod not filled with enough insulin.	If you filled the Pod, using all the insulin from the syringe that you filled to the "Fill Here" line, and you still do not hear 2 beeps, call Customer Care.
The adhesive tape around the Pod keeps lifting from the skin	If the area where you apply the Pod is not cleaned and dry, the adhesive tape may not stick well.	Make sure that the skin is cleaned and dry before applying the Pod. Avoid the use of moisturizers, oils, conditioners, sunscreen, or insect repellent around the site. If there is a lot of body hair, you may need to clip or shave the area 24 hours before applying a Pod there. Be sure to remove old adhesive residue from the skin.
Pod alarm sounding or solid red or blinking red Pod light showing	The Pod may stop working for many reasons, including these: • Pod expires • a blockage (occlusion) is detected • or an electrostatic discharge affects a circuit	The red Pod light means you should remove your Pod and replace it with a new one. In rare cases the Pod will sound a continuous tone, even after you remove it. In this case, you can disable the alarm. See page 48 for guidance.

Issue	Possible Cause	What you can do
Pod light off	During Pod setup After filling the Pod, it is normal for the Pod light to be off for a short time before it starts blinking Amber. If the Pod light stays off, it means the Pod is not working properly.	Do one of the following: • If the Amber light starts blinking soon after filling the Pod, apply the Pod to your body according to the instructions. • If the Pod light remains off for two or more minutes after the Pod was filled, discard your Pod and begin again with a new one.
	During Pod use The Pod you have been wearing has not been delivering insulin for an extended period of time. 4 hours passed since the Pod experienced a Hazard alarm, or 12 hours passed since the Pod expired.	Remove your Pod and replace it with a new one.

5.2. Pod Complaints

If you have a problem with your Pod, contact Customer Care at 1-800-591-3455.

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Appendix

Pod Specifications

Size: 1.53" wide x 2.05" long x 0.57" high (3.9cm x 5.2cm x 1.45cm)

Weight (without insulin): 0.92 oz (26 grams)

Duration of use: up to 72 hours

Operating temperature range: Pod operating environment of 41°F to 104°F (5°C to 40°C).

Note: The Pod temperature equilibrates from 73°F to 100°F (23°C to 38°C) when worn on the body.

Startup temperature: above 50°F (10°C)

Storage temperature range: 32°F to 86°F (0°C to 30°C)

Transport temperature range: -13°F to 140°F (-25°C to 60°C)

Warm-up time 32°F to 68°F (0°C to 20°C): 7 minutes

Cooldown time: No time is required for cooldown from maximum storage temperature 86°F (30°C) to operating temperature.

Reservoir volume (deliverable): 180 units

Cannula insertion depth: 0.16-0.28 in (4-7 mm)

Depth of insulin infusion: ≥ 0.16 in (4 mm)

IP (Ingress Protection) rating for moisture and dust: IP28 (protected from touch by fingers and objects 12.5 millimeters or larger; protected from water to a depth of up to 25 feet (7.6 meters) for up to 60 minutes)

Insulin concentration: U-100

Alarm type:

Audible: Output: ≥ 45 db(A) at 1 meter

Visual: Output: tri-color LED (Red, Amber, Green)

Sterilizing agent: Sterilized using ethylene oxide

Operating relative humidity range: 20 to 85%, non-condensing

Storage relative humidity range: 20 to 85%, non-condensing

Transport relative humidity range: 10 to 90%, non-condensing

Operating atmospheric pressure: 700 hPa to 1060 hPa
Storage atmospheric pressure: 700 hPa to 1060 hPa
Transport atmospheric pressure: 700 hPa to 1060 hPa

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Type of protection against electric shock: Internally powered

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.05 U

Flow Capability: Prime rate: 0.05 unit per second
Basal: Factory pre-programmed rate by prescription as follows:

Omnipod GO 10 Units/Day Pod provides 10 U/day at 0.42 U/hr.

Omnipod GO 15 Units/Day Pod provides 15 U/day at 0.63 U/hr.

Omnipod GO 20 Units/Day Pod provides 20 U/day at 0.83 U/hr.

Omnipod GO 25 Units/Day Pod provides 25 U/day at 1.04 U/hr.

Omnipod GO 30 Units/Day Pod provides 30 U/day at 1.25 U/hr.

Omnipod GO 35 Units/Day Pod provides 35 U/day at 1.46 U/hr.

Omnipod GO 40 Units/Day Pod provides 40 U/day at 1.67 U/hr.

Basal Delivery accuracy (tested per IEC 60601-2-24): ± 5% over a 24-hour period.

Batteries service life: 84 hours

Accessories: Syringe and needle

Accessories service life: 1 hour

Accessories shelf life: 18 months

Mode of operation: Continuous use

Degree of safety of application in the presence of flammable anesthetic mixture with Air or with oxygen or Nitrous oxide: Not intended to be used in the presence of flammable anesthetic mixture with Air or with oxygen or Nitrous oxide.

Suitability for use in an Oxygen rich environment: Not intended for use in an Oxygen Rich Environment.

Protection from Over-infusion or Under-infusion

The Pod software monitors the infusion rate. If an error that would result in over- or under-infusion is detected and cannot be corrected, insulin delivery stops, an alarm sounds and the Pod light shows as solid red. See "3.4. When the Pod has Stopped: Alarms" on page 46 for more information about alarms.

Blockage (occlusion) detection

A blockage (occlusion) is an interruption in insulin delivery from the Pod. A blockage may result from blocked tubing, Pod malfunction, or from using old or inactive insulin. If the Omnipod GO Pod detects a blockage, it sounds a hazard alarm and its Pod light turns red to tell you to change your Pod.

A blockage (occlusion) hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts blockage detection for three different situations when using U-100 insulin. For example, if the Pod's cannula becomes blocked while using a 25 U/day Pod, 5.5 hours may pass before the Pod sounds a hazard alarm.

	Time between blockage (occlusion) and Pod alarm	
Basal	**Typical time**	**Maximum time**
10 U/day	8.5 hr	12.5 hr
25 U/day	3.5 hr	5.5 hr
40 U/day	2.5 hr	3.5 hr

If a blockage spontaneously clears up, a volume of insulin could be released. That volume would not exceed the volume of the pre-programmed insulin intended for delivery.

Essential performance

The Pod will maintain the following functional performance to avoid under or over infusion:

- Insulin delivery accuracy
- Occlusion detection
- Protection against unintended bolus upon release of an occlusion
- An audible and visible alarm at termination of insulin delivery due to the following:
  - Pod functional failure
  - Empty reservoir
  - Occlusion
  - Pod expiration

Performance Characteristics

The Omnipod GO Pod delivers continuous basal insulin. The following accuracy data was collected on basal delivery in laboratory studies performed by Insulet.

Delivery performance characterization

Insulin Delivery: To assess insulin delivery accuracy, 12 Pods were tested by delivering at low, medium, and high basal rates (10, 25, and 40 U/day). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warm-up period.

For each time period, the tables show the following:

- Row 1: the volume of insulin requested
- Row 2: the median volume that was delivered as measured by the scale
- Row 3: the minimum and maximum volume delivered
- Row 4: the minimum and maximum error as a percentage of the intended insulin rate

The graph below each table shows the minimum and maximum observed errors within the flow accuracy data for any given time period up to 25 hours. In other words, for a given duration of wear, the graph shows you the worst potential error in insulin delivery you could expect.

For the following table and graph, the measurements were made using a Pod with a preset insulin rate of 10 U/day at a low operating temperature. The overall mean percentage flow error was 0.90%.

Low Basal Rate Delivery Performance (10 U/day)				
Row #	**Basal Duration**	**1 hour**	**6 hours**	**12 hours**
1	**Number of units requested**	**0.42 U**	**2.50 U**	**5.00 U**
2	**Amount Delivered (median)**	0.42 U	2.53 U	5.05 U
3	**Amount Delivered [min, max]**	[0.14, 0.64]	[1.72, 3.09]	[3.83, 5.18]
4	**Error % [min, max]**	[-67%, 55%]	[-31%, 24%]	[-23%, 3.6%]

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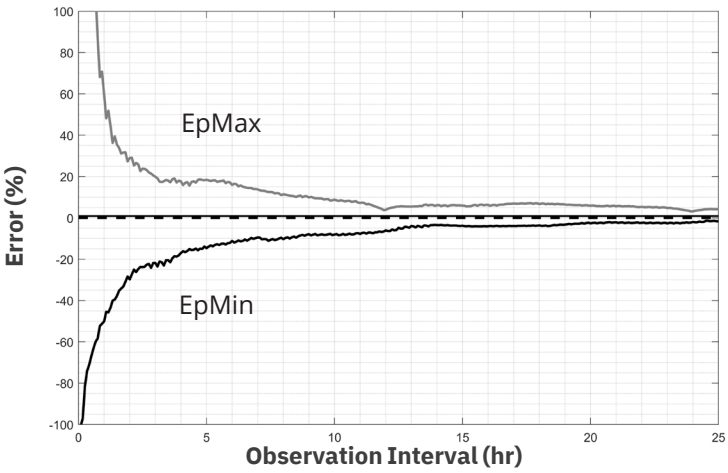

For the following table and graph, the measurements were made using a Pod with a preset insulin rate of 25 U/day at a low operating temperature. The overall mean percentage flow error was 0.21%

Medium Basal Rate Delivery Performance (25 U/day)				
Row #	**Basal Duration**	**1 hour**	**6 hours**	**12 hours**
1	**Number of units requested**	**1.04 U**	**6.25 U**	**12.50 U**
2	**Amount Delivered (median)**	1.07 U	6.34 U	12.59 U
3	**Amount Delivered [min, max]**	[0.46, 1.54]	[5.09, 6.88]	[11.31, 13.39]
4	**Error % [min, max]**	[-56%, 47%]	[-18%, 10%]	[-9.5%, 7.1%]

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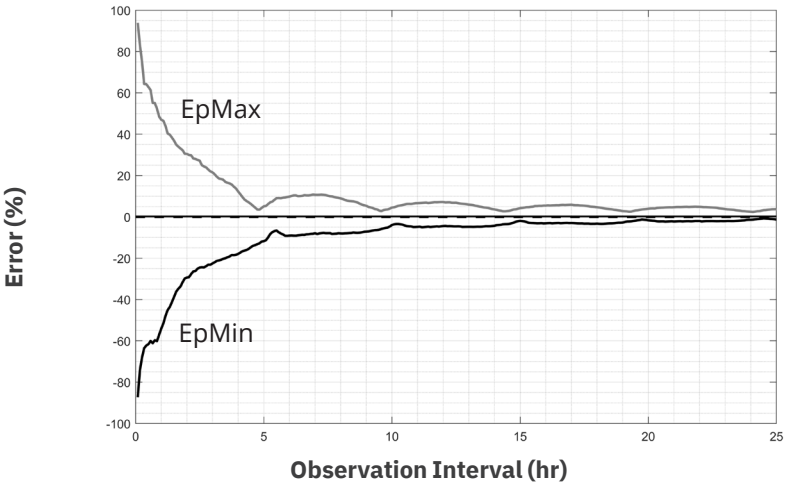
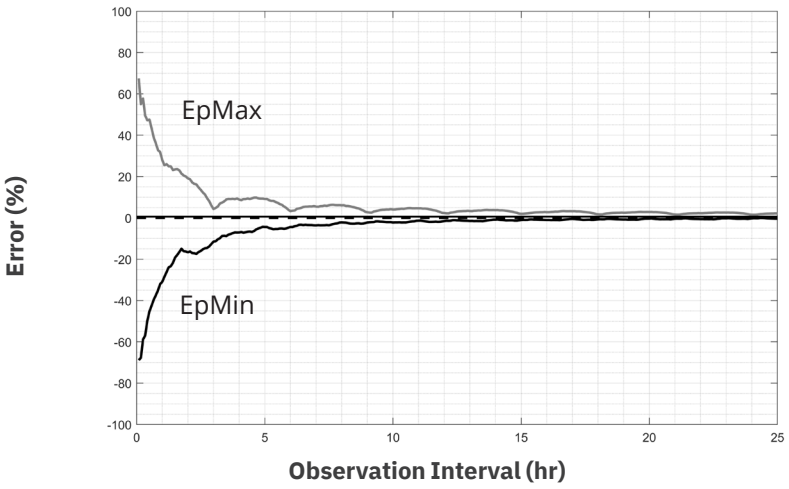


For the following table and graph, the measurements were made using a Pod with a preset insulin rate of 40 U/day at a low operating temperature. The overall mean percentage flow error was 0.58%.

High Basal Rate Delivery Performance (40 U/day)				
Row #	**Basal Duration**	**1 hour**	**6 hours**	**12 hours**
1	**Number of units requested**	**1.67 U**	**10.00 U**	**20.00 U**
2	**Volume Delivered (median)**	1.73 U	10.09 U	20.19 U
3	**Amount Delivered [min, max]**	[0.99, 2.28]	[9.09, 10.37]	[19.13, 20.47]
4	**Error % [min, max]**	[-41%, 37%]	[-9.1%, 3.7%]	[-4.3%, 2.4%]



Symbols

The following symbols appear on the Omnipod GO Pod's packaging:

Symbol	Meaning
	Single use only
	Consult accompanying documents
	Sterilized using ethylene oxide
	Date of manufacture
	Batch code
	Use by date
	Reference number
IP28	Submersible: Waterproof up to 25 feet (7.6 meters) for up to 60 minutes
	Pod
	Do not dispose with household waste
	Single Patient Multiple Use
	Electronic Instructions for Use

Symbol	Meaning
	MR unsafe
	Do not use if package is damaged
	Type BF applied part
	Manufacturer
Rx ONLY	Prescription only
	Storage temperature, Operational temperature
	Storage relative humidity, Operational relative humidity
	Storage atmospheric pressure, Operational atmospheric pressure
	Non-pyrogenic fluid path
	Proof of product compliance to North American safety standards
	Single Sterile Barrier System
	Compatible with U-100 insulin only

Omnipod GO Pod Notice Concerning Interference

Caution: DO NOT make changes or modifications to any component of the Omnipod GO Pod. Tampering with the Pod can revoke your right to operate it.

This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with the instructions may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If the equipment does cause harmful interference to radio and television reception, the user is encouraged to try to correct the interference by one of the following measures:

- Move or relocate the Omnipod GO Pod.
- Increase the separation between the Omnipod GO Pod and the other device that is emitting or receiving interference.
- Consult the dealer or an experienced radio/TV technician for help.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod GO Pod. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod GO Pod fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

Be careful when you use the Omnipod GO Pod close to other electrical equipment because potential electromagnetic or other interference could occur and affect the Pod or the other equipment. Try to minimize this interference by not using the equipment near the Pod.

If you can't avoid being close to equipment, such as in work environments, be sure to observe the Pod to verify normal operation in this area.

The Omnipod GO Pod complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2: 2014 + AMD1: 2020.

Caution: DO NOT use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 12 inches (30 cm) to the Omnipod GO Pod, as degradation of the performance of this equipment could result.

One exception is that if you use a wearable device, you should check that device's user guide. If it says the device uses Bluetooth Wireless Technology, then follow that user guide's instructions about how close you can place it to other devices.

Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
RF Emissions CISPR 11	Group 1, Class B	The Pod is suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity

The Pod is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the Pod.

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.

Electromagnetic Immunity			
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod GO Pod.

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communication equipment. The frequencies and services listed in the table are representative examples in various locations where the Pod may be used.

Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380–390	TETRA 400	Pulse modulation b)18Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800. ODEM 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	G GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2450-2570	Bluetooth WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	0.2	0.3	9

5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9

a) For some services, only the uplink frequencies are included
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.

This table lists the immunity levels at specific test frequencies for Proximity Magnetic Fields Range of 9kHz to 13.56 MHz.

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1 kHz	65 c)
13.56 MHz	Pulse modulation b)	7.5 c)

a) This test is applicable only to ME equipment and ME systems in a HOME HEALTHCARE ENVIRONMENT.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) RMS before modulation is applied.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. In order to assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

Security Information

Insulet's cybersecurity program includes security assessments, simulated attacks on systems, vulnerability management and tracking data about current or potential cyber attacks. Active during the design process and beyond, the cybersecurity program uses models to predict and prevent problems. Insulet conducts many annual reviews and audits to ensure policies and standards remain effective. If you notice any evidence of product tampering, contact Customer Care.

Customer's Bill of Rights

Mission Statement

Insulet Corporation is dedicated to designing, developing, and distributing products that provide superior treatment options and lifelong health benefits for people with diabetes.

Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod GO Pod.

Compliance

The Omnipod GO Insulin Delivery Device is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

Inquiries

Representatives are available to answer product-related inquiries 24 hours per day at our toll free number, 1-800-591-3455 (from outside the United States, 1-978-600-7850). For all other questions, concerns, or complaints, please contact us between the hours of 8:30am and 6:00pm Eastern Time, Monday through Friday, at 1-800-591-3455 (from outside the United States, 1-978-600-7850). We will respond immediately whenever possible; some issues may take up to 14 days to resolve.

CHAP Accredited

Insulet Corporation has been accredited by the Community Health Accreditation Program (CHAP) since 2007. To learn more about CHAP or to communicate concerns that you have been unable to resolve directly with the company, please visit www.chapinc.org or call CHAP at 1-800-656-9656.

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.
2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.
3. Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice later in this section.
4. Receive a timely response to your request for service.
5. Receive continued service.
6. Select the medical equipment supplier of your choice.
7. Make informed decisions regarding your care planning.
8. Understand what services will be provided to you.
9. Obtain an explanation of charges, including policy for payment.
10. Agree to or refuse any part of the plan of service or plan of care.
11. Voice complaints without fear of termination of service or other reprisals.
12. Have your communication needs met.

You have the responsibility to:

1. Ask questions about any part of the plan of service or plan of care that you do not understand.
2. Use the equipment for the purpose for which it was prescribed, following instructions provided for use, handling care, safety and cleaning.
3. Supply Insulet Corporation with insurance information necessary to obtain payment for services.
4. Be accountable for charges not covered by your insurance. You are responsible for settlement in full of your account.
5. Notify us immediately of:
    a. Equipment failure, damage or need of supplies.
    b. Any change in your prescription or physician.
    c. Any change or loss in insurance coverage.
    d. Any change of address or telephone number, whether permanent or temporary.

Warranty

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE OMNIPOD GO POD (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod GO Pods

Subject to this Limited Express Warranty, Insulet warrants to you, the original purchaser of the Omnipod GO Pod, that, if Insulet determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod GO Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e. occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet of the claim).

This eighteen (18) month and seventy-two (72) hour warranty period applies only to new Pods and, in the event a Pod is replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Pod under this Limited Express Warranty, the warranty coverage for the replacement Pod shall expire either eighteen (18) months from the manufacture date of the original Pod or seventy-two (72) hours from the time of activation of the original Pod, whichever occurs first.

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Insulet of the claimed defect with the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). You may also be required to verify the date of purchase of the Pod, the manufacture date of the Pod and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet refers you to a third party, you must obtain a prior authorization and return the Pod to Insulet. The Pod must be properly packaged and returned to Insulet according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a prior authorization, Insulet will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the Pod to Insulet under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet, except those performed or provided by third parties to which you were explicitly referred by Insulet.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, Insulet may require that you provide a valid proof of purchase, manufacture or activation. Your failure to provide a

valid proof of purchase, manufacture or activation, as determined by Insulet, may result in the denial of coverage under this Limited Express Warranty.

Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental or other transfer of the Pod to any other person or entity.

This Limited Express Warranty will apply only if the Pod at issue has been used in accordance with the *Omnipod GO Insulin Delivery Device User Guide* and/or other written instructions provided by Insulet. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE POD HAS BEEN:

- Altered, changed or modified by any person or entity other than Insulet;
- Opened, serviced or repaired by any person or entity other than Insulet;
- Damaged by an act of God or other "force majeure" like event;
- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage;
- Damaged by wear and tear, causes unrelated to defective materials or workmanship or other circumstances outside of the reasonable control of Insulet.

This Limited Express Warranty does not apply to test strips, batteries that are not provided by Insulet, other accessories, or related products provided by third parties (e.g., data management tools, CGMs).

This Limited Express Warranty does not extend to design defects (i.e. claims that the Pod should have been designed in a different way).

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

REPAIR OR REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE POD IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF INSULET. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE SO LONG AS INSULET IS WILLING AND ABLE TO REPAIR OR REPLACE A POD WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER PRESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

Important Additional Provisions

INSULET CORPORATION DOES NOT WARRANT THE SUITABILITY OF THE OMNIPOD GO POD FOR ANY SPECIFIC PERSON AS HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction. The above Limited Express Warranty applies only to the Pods that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. INSULET CORPORATION'S LIABILITY IN SUCH JURISDICTIONS SHALL BE LIMITED TO THE MAXIMUM EXTENT PERMITTED BY LAW. SUCH LIMITATIONS SHALL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING: ANY IMPLIED WARRANTIES THAT CANNOT BE DISCLAIMED UNDER THE LAW OF A PARTICULAR JURISDICTION ARE LIMITED, TO THE EXTENT ALLOWED BY LAW, TO THE TIME PERIOD COVERED BY THE ABOVE LIMITED EXPRESS WARRANTY, OR TO THE APPLICABLE TIME PERIOD PROVIDED BY LAW, WHICHEVER PERIOD IS SHORTER.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in an Omnipod GO Pod. No employee, agent or other representative of Insulet or any other party is authorized to make any product warranty or agreement applicable to an Omnipod GO Pod in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod GO Pod please return any Omnipod GO Pods to Insulet in exchange for a full refund. Failure to return such Omnipod GO Pod products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

This notice of privacy practices (the "HIPAA Privacy Notice") describes how we may use and disclose your Medical Information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act, and all regulations issued thereunder ("HIPAA"). It also describes your rights to access and control your Medical Information. As used herein, "Medical Information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. Most uses

or disclosures of your Medical Information constituting psychotherapy notes will be made only after receiving your written authorization. We will not use or disclose your Medical Information for purposes of marketing, except as permitted by law and/or outlined in this HIPAA Privacy Notice. We will not sell your Medical Information, without first obtaining your written authorization. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations where we may use or disclose your Medical Information without your prior written authorization, as described further below:

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided By Us

Treatment, Payment and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

Appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

Family, Friends and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will

be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is

necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities, or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.

Inmates: We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and good order of the correctional institution.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Non-identifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a
request to review your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment, payment or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. Except as otherwise provided in this HIPAA Privacy Notice, we are not required to agree to a restriction that you may request. We are required to agree to your request to restrict disclosure of your Medical Information to a health plan if (i) the disclosure is to carry out payment or healthcare operations and is not otherwise required by law; and (ii) your Medical Information pertains solely to a healthcare item or service for which you or someone (other than the health plan) on your behalf, has paid us in full. If we agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications From Us By Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer at

https://www.omnipod.com/privacyrequest

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, for notification purposes, for national security or intelligence purposes, to correctional institutions or law enforcement officials, or as part of a limited data set. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under applicable law. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

You Have The Right to Obtain a Copy of this HIPAA Privacy Notice: You have the right to obtain a paper copy of this HIPAA Privacy Notice from us, upon request, even if you have agreed to accept this notice electronically. If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request at

https://www.omnipod.com/privacyrequest

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our legal duties and privacy practices with respect to Medical Information, and to notify you if there is a breach resulting in disclosure of your unsecured Medical Information.

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our website at

https://www.omnipod.com.

If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request at

https://www.omnipod.com/privacyrequest

What To Do If You Have a Problem or Question

If you are unable to use the online privacy request form, you may obtain assistance by calling our toll-free number: 1-800-591-3455.

If you have any further questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us in writing or by phone at:

Insulet Corporation
Attn: Privacy Officer
Email: privacy@insulet.com

(866) 941-0155

Our mailing address is:

100 Nagog Park
Acton, MA 01720

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by

calling (877) 696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

Revision Dates: April 1, 2009, September 20, 2013, April 22, 2014, September 2, 2014, and September 15, 2022.

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Acton, MA 01720
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omnipod.com

Pod shown without the necessary adhesive.

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