



User Guide

Omnipod® 5 Automated Insulin Delivery System



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Controller Model: PDM-USA-H001-MG

Serial Number: _____

Controller FCC ID: 2ADINN5004L

Pod FCC ID: RBV-029 SAW Pod FCC ID: RBV-029C

Omnipod® 5 Automated Insulin Delivery System

Start Date: _____

Healthcare Provider			
Name			
Street Address			
City	State	Zip	
Phone			
Email			

Omnipod® Trainer			
Name			
Street Address			
City	State	Zip	
Phone			
Email			

Health Insurance			
Name			
Street Address			
City	State	Zip	
Phone			
Policy Number			

Pharmacy			
Name			
Street Address			
City	State	Zip	
Phone			
Email			

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Patent information at www.insulet.com/patents.

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BEFORE YOU BEGIN

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CHAPTER 1

Introduction

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1.1. Welcome to Your Omnipod® 5 System

The Omnipod® 5 System is the first wearable, on-body, tubeless, automated insulin delivery system. The Omnipod 5 System consists of a tubeless insulin Pod and the Omnipod® 5 App on an Insulet-provided Controller or installed on a compatible smartphone. The Omnipod 5 System works with the Dexcom G6® Continuous Glucose Monitoring System to continuously adapt and automatically deliver insulin according to your personal needs.

The Omnipod 5 System Features

- **Pod:** The Pod provides continuous subcutaneous insulin delivery. It may be worn for up to 3 days and can be filled with up to 200 units of U-100 rapid-acting insulin (minimum 85 units).
- **No tubing:** There is no tubing with the Pod allowing you to place the Pod almost anywhere you would give yourself an injection. The Pod is waterproof for depths up to 25 feet (7.6 meters) for up to 60 minutes (IP28).
- **Omnipod® 5 App:** The Omnipod 5 App allows you to select a basal profile, target glucose and bolus settings, activate and deactivate the Pod, connect with the Dexcom G6 Continuous Glucose Monitoring System, and select insulin delivery mode. The Omnipod 5 App comes installed on an Insulet-provided Controller or can be downloaded to a compatible smartphone. For a list of the latest compatible smartphones, please visit <https://omnipod.com/compatibility>.
- **Dexcom G6 Continuous Glucose Monitoring (CGM) System:** The Omnipod 5 System is designed to work with the Dexcom G6 which must be obtained separately. CGM values and trends from the Dexcom G6 are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode. The Dexcom G6 sensor must be started in the Dexcom app in order to use CGM values and trends in the Omnipod 5 System.
- **Pod Site tracker:** When activating a new Pod, the System provides the option to track the site on which you have applied a Pod. This allows you to reference past Pod sites when deciding where to place your next Pod.
- **Keeping Track of CGM and Insulin:** The Omnipod 5 System records up to 90 days of information, including basal delivery, bolus doses, carbohydrates, alarms, and glucose-related data. In Automated Mode, the system records automated insulin delivery and corresponding CGM values every 5 minutes. The Home screen features a CGM graph which allows for reference of your CGM values and displays some information about insulin delivery.

Omnipod 5 SmartBolus Calculator Features

- **SmartBolus Calculator:** If you are planning to eat or if your glucose is high, the SmartBolus Calculator can suggest a bolus amount of insulin based on your individual settings, entered values, and CGM value and trend when available. The SmartBolus Calculator allows for the immediate delivery of the bolus insulin in both Automated and Manual Mode. In Manual Mode, the SmartBolus Calculator also allows for an extended bolus. The extended bolus can be customized to deliver the bolus dose over a period of time.

Omnipod 5 SmartAdjust™ Technology Features

- **Two modes of operation:** The Omnipod 5 System provides the following modes of operation: Automated and Manual. The Omnipod 5 System enables you to switch between modes when required conditions are met. The System behaves differently depending on which mode you select.
 - **Automated Mode:** Each Pod contains SmartAdjust™ technology that adjusts insulin every 5 minutes to bring your glucose value to your customized glucose target, or Target Glucose.. The adjustment is based on a prediction of where your glucose will be 60 minutes in the future and considers your CGM value and trend, adaptive basal rate, and insulin that is still working in your body.
 - **Manual Mode:** The Omnipod 5 System delivers insulin based on user-defined Basal Programs. During Manual Mode, there is no automated adjustment of insulin delivery.
- **Dexcom G6 Continuous Glucose Monitoring (CGM) System:** The Omnipod 5 System is designed to work with the Dexcom G6 which must be obtained separately. CGM values and trends from the Dexcom G6 are used for automated insulin delivery in Automated Mode, as well as for bolus calculations in both Automated and Manual Mode. The Dexcom G6 sensor must be started in the Dexcom app in order to use CGM values and trends in the Omnipod 5 System.
- **Activity feature:** While in Automated Mode, you can enable the Activity feature in times when you need less insulin, for example, when you are getting ready to exercise. When the Activity feature is enabled, the system gives less insulin and aims for a Target Glucose of 150 mg/dL.
- **Keeping track of Automated Insulin:** In Automated Mode, the system records automated insulin delivery and corresponding CGM values every 5 minutes. The Home screen features a CGM graph which allows for reference of your CGM values and displays some information about insulin delivery, including automation status.

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1.2. About This *User Guide*

The purpose of this *User Guide* is to assist you with the features and functions of the Omnipod 5 System. It provides step-by-step instructions on how to properly operate the System, as well as important warnings and cautions to ensure your safety during use.

Note: This *User Guide* is intended for use only with the Insulet-provided Controller with the Omnipod 5 App, model PDM-USA-H001-MG, or the Omnipod 5 App on a compatible smartphone. To learn which version of the Insulet-provided Controller you have, turn it over. If you see "PDM-USA-H001-MG" on the back of the Controller, this is the correct *User Guide*. If you do not see it, call Customer Care. Using an incorrect *User Guide* can lead to improper use of the Omnipod 5 System.

Note: Screen images shown in this *User Guide* are examples only and are not suggestions for user settings. Always consult with your healthcare provider to determine the appropriate settings for you.

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.

1.3. 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 5 ACE Pump (Pod)** is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Omnipod 5 ACE Pump is intended for single patient, home use and requires a prescription.

SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. SmartAdjust technology is intended for the management of type 1 diabetes mellitus in persons 6 years of age and older. SmartAdjust technology is intended for single patient use and requires a prescription.

The **Omnipod 5 SmartBolus Calculator** is software intended for the management of diabetes in persons aged 6 and older requiring rapid-acting U-100 insulin. The Omnipod 5 SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value. The Omnipod 5 SmartBolus Calculator is intended for single patient, home use and requires a prescription.

Contraindications

The Omnipod 5 System is NOT recommended for people who:

- are unable to monitor glucose as recommended by their healthcare provider
- are unable to maintain contact with their healthcare provider
- are unable to use the Omnipod 5 System according to instructions
- are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia
- do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders

Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components.

1.4. Compatible Insulins

The Omnipod 5 ACE Pump (Pod) is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.

SmartAdjust technology is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®

The Omnipod 5 SmartBolus Calculator is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®

1.5. General Warnings

Warning: Read all the instructions provided in this *User Guide* before using the Omnipod 5 System. Monitor your glucose with the guidance of your healthcare provider. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

Warning: DO NOT start to use your system or change your settings without adequate training and guidance from your healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia. Settings that impact insulin delivery mainly include: Pod Shut-Off, basal rate(s), Max Basal Rate, Max Bolus, Correction Factor(s), Insulin to Carb (IC) Ratio(s), Minimum Glucose for Calculations, Target Glucose and Correct Above, and Duration of Insulin Action.

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 5 System if you are unable or unwilling to use it as instructed by this *User Guide* and your healthcare provider. Failure to use this system as intended could result in over-delivery or under-delivery of insulin which can lead to hypoglycemia or hyperglycemia.

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

Warning: ALWAYS dispose of the Pod according to local waste disposal guidelines. The Pod is considered biohazardous after use and can potentially transmit infectious diseases.

Warning: DO NOT use SmartAdjust technology in pregnant women, critically ill patients, and those on dialysis. The safety of SmartAdjust technology has not been evaluated in these populations. Consult with your healthcare provider if any of these conditions apply to you before using SmartAdjust technology.

Warning: DO NOT use the Omnipod 5 System if you do not have adequate vision and/or hearing to recognize all functions of the Omnipod 5 System including alerts, alarms, and reminders according to instructions.

Warning: ONLY use rapid-acting U-100 NovoLog® (insulin aspart), Humalog® (insulin lispro), and Admelog® (insulin lispro) insulin in the Omnipod 5 System as they have been tested and found to be safe for use with this system. NovoLog,

Humalog, and Admelog are compatible with the Omnipod 5 System for use up to 72 hours (3 days). Follow your healthcare provider's directions for how often to replace the Pod.

Warning: AVOID administering insulin, such as by injection or inhalation, while wearing an active Pod as this could result in hypoglycemia. The Omnipod 5 System cannot track insulin that is administered outside of the system. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.

Warning: AVOID changing your SmartBolus Calculator settings before consulting with your healthcare provider. Incorrect changes could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia. Settings that impact bolus calculations mainly include: Max Bolus, Minimum Glucose for Calculations, Correct Above, Correction Factor(s), Insulin to Carb (IC) ratio(s), Duration of Insulin Action, and Target Glucose.

Warning: ALWAYS follow your healthcare provider's guidance on appropriate glucose monitoring to avoid hyperglycemia and hypoglycemia.

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

Warning: ALWAYS promptly treat hypoglycemia. Glucose at or below 55 mg/dL indicates significant hypoglycemia (very low glucose). If left untreated, this could lead to seizure, loss of consciousness or death. Follow your healthcare provider's recommendations for treatment.

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

Warning: DO NOT wait to treat hypoglycemia (low glucose) or symptoms of hypoglycemia. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe hypoglycemia, which can lead to seizure, loss of consciousness, or death.

Warning: ALWAYS promptly treat hyperglycemia (high glucose) according to your healthcare provider's recommendations. Symptoms of hyperglycemia include fatigue, thirst, excess urination, or blurry vision. If left untreated, hyperglycemia can lead to diabetic ketoacidosis (DKA), or death.

Warning: DO NOT wait to treat DKA. If left untreated, DKA can quickly lead to breathing difficulties, shock, coma, or death.

Warning: ALWAYS treat "LOW" or "HIGH" CGM values and "LO" or "HI" blood glucose readings according to your healthcare provider's recommendations. These values can indicate potentially serious conditions requiring immediate

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medical attention. If left untreated, these situations can quickly lead to diabetic ketoacidosis (DKA), 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: ALWAYS be aware of your current CGM value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your CGM values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low CGM values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *User Guide*, contact your healthcare provider.

Warning: ALWAYS make sure you are using the CGM per manufacturer's instructions. Do not extend the sensor wear beyond the recommended duration and do not wear a sensor that is past the labeled expiration date. The Omnipod 5 System relies on accurate, current CGM values to determine your insulin needs. Incorrect use of the CGM could result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia.

Warning: Do NOT use Omnipod 5 System if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom G6 CGM readings could be falsely elevated and could result in over-delivery of insulin which can lead to severe hypoglycemia.

Warning: ALWAYS respond to Hazard Alarms as soon as they occur. Pod Hazard Alarms indicate that insulin delivery has stopped. Failure to respond to a Hazard Alarm could result in under-delivery of insulin which can lead to hyperglycemia.

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin

which can lead to hyperglycemia or diabetic ketoacidosis (DKA) (see "⚠️ Blockage Detected" on page 163).

Warning: SmartAdjust technology should NOT be used by anyone under the age of 6 years old. SmartAdjust technology should also NOT be used in people who require less than 6 units of insulin per day as the safety of the technology has not been evaluated in this population.

Warning: DO NOT use the Omnipod 5 System at low atmospheric pressure (below 700hPA). 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 hypoglycemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycemia.

Warning: DO NOT use the Omnipod 5 System 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 or Omnipod 5 Controller, which can cause severe burns to the body.

Warning: DO NOT use the Omnipod 5 System 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 and Omnipod 5 Controller which could result in under-delivery of insulin which can lead to hyperglycemia.

1.6. General Precautions

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

Caution: DO NOT use any component of the Omnipod 5 System (smartphone, Controller, Pod) if you suspect damage after an unexpected event such as dropping or hitting on a hard surface. Using damaged components may put your health at risk as the system may not be working properly. If you are unsure if one or more of your components are damaged, stop using the system and call Customer Care for support.

Caution: ONLY use the Omnipod 5 System with authorized devices (Omnipod 5 App, Controller and Pod and Dexcom G6 CGM). DO NOT attempt to use the Omnipod 5 System with unauthorized devices. Attempting to use the Omnipod

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5 System with unauthorized devices could interrupt your insulin delivery and put your health and safety at risk.

Caution: Connect ONLY to trusted Wi-Fi networks with your Controller or smartphone. AVOID connecting to public Wi-Fi networks, such as those found in airports, coffee shops, etc, as these networks are not secure and could result in exposing your Controller or phone to malware. DO NOT connect to public Wi-Fi networks during first-time setup of your Omnipod 5 System.

Caution: ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to hyperglycemia. If another Pod is not available, use a different insulin delivery method.

Caution: DO NOT navigate away from the Omnipod 5 App while you are in the process of making changes to your insulin delivery settings. If you leave the App before you are able to save the setting change and before the App is able to put the setting change into effect, the system will continue to use your last saved settings. As a result, you may continue with therapy settings that you did not intend. If you are unsure about whether your changes were saved, review your settings.

Caution: ALWAYS keep your Controller safe and within your control to ensure others cannot make changes to your insulin therapy. Do not share your Controller screen lock security with anyone.

Caution: AVOID leaving your Controller or smartphone in a place that would prevent you from hearing alarms and notifications from your Omnipod 5 App. Delivery of insulin in Manual Mode or Automated Mode continues as programmed if you move away from your Controller or smartphone.

Caution: ALWAYS respond to Pod Expired, Low Pod Insulin, and Pod Shut-Off Advisory Alarms when they occur. These alarms escalate to Hazard Alarms if no action is taken. When Hazard Alarms occur, insulin delivery stops.

Caution: ALWAYS be aware of possible changes to your time zone when traveling. If you do not update your time zone, your insulin therapy will be delivered based on your old time zone which may cause disruptions in your insulin delivery schedule and inaccurate history logs. Talk to your healthcare provider about how to manage your insulin delivery while traveling between time zones.

Caution: You cannot use the Dexcom G6 receiver with the Omnipod 5 System because the Omnipod 5 System is compatible only with the G6 app on a smartphone.

Caution: ALWAYS check your glucose frequently during amusement park rides and flying or other situations where sudden changes or extremes of air pressure, altitude, or gravity may be occurring. Though the Omnipod 5 System is safe to use at atmospheric pressures typically found in airplane cabins during flight, the atmosphere pressure in an airplane cabin can 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, can affect insulin delivery, leading to possible hypoglycemia or injury. If needed, follow your healthcare provider's treatment instructions.

Potential Risks

- The Omnipod 5 System uses CGM values and trends to calculate insulin delivery. If the CGM values are inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycemia or hyperglycemia.
- 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 or air bubbles in the cannula, or dislodging of the cannula can affect insulin delivery. Glucose that does not decrease after a bolus, or other unexplained high glucose, are signs of a blockage (occlusion) and an interruption in insulin delivery.
- Hardware defects, software glitches, and Pod failures can cause an interruption in insulin delivery. A Pod failure can lead to hypoglycemia, hyperglycemia, or diabetic ketoacidosis. Keep your Omnipod 5 Controller and/or smartphone on and nearby to ensure you are notified of recent insulin delivery and important alarms and messages.

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.

The Omnipod 5 System is designed to work with the Dexcom G6 CGM. To use the Dexcom G6 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G6 sensor, transmitter, and *User Guide*, and download the Dexcom G6 app on your personal smartphone.

If you are new to using CGM, continue using your BG meter until you are familiar with CGM usage.

If you are currently using the system without the Dexcom G6 CGM, or if you are currently using the Dexcom G6 CGM, it is still very important that you review all instructions in this *User Guide* before using the system.

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

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.

Prepare an emergency kit to keep with you at all times. The kit should include:

- Several new, sealed Omnipod 5 Pods
- A vial of rapid-acting U-100 insulin (see "1.5. General Warnings" on page 8 for insulins cleared for use in the Omnipod 5 Pod)
- Syringes or pens for injecting insulin
- Glucose tablets or another fast-acting source of carbohydrate
- Dexcom G6 Continuous Glucose Monitor (CGM) System and supplies
- Blood glucose test strips
- Blood glucose meter
- Ketone test strips
- Lancing device and lancets
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System
- Phone numbers for your healthcare provider and/or physician in case of an emergency
- Glucagon kit and written instructions for administering glucagon dosage if you are unconscious (see "15.4. Avoiding Lows, Highs, and Diabetic Ketoacidosis" on page 216)

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.

OMNIPOD 5 PUMP FEATURES

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Omnipod 5 Pump Important Safety Information

Pump Warnings

Omnipod 5 System Settings and Training

Warning: DO NOT start to use your system or change your settings without adequate training and guidance from your healthcare provider. Initiating and adjusting settings incorrectly can result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia. Settings that impact insulin delivery mainly include: Pod Shut-Off, basal rate(s), Max Basal Rate, Max Bolus, Correction Factor(s), Insulin to Carb (IC) Ratio(s), Minimum Glucose for Calculations, Target Glucose and Correct Above, and Duration of Insulin Action.

Insulin

Warning: ONLY use rapid-acting U-100 NovoLog® (insulin aspart), Humalog® (insulin lispro), and Admelog® (insulin lispro) insulin in the Omnipod 5 System as they have been tested and found to be safe for use with this system. NovoLog, Humalog, and Admelog are compatible with the Omnipod 5 System for use up to 72 hours (3 days). Follow your healthcare provider's directions for how often to replace the Pod.

Warning: ALWAYS be prepared to inject insulin with an alternative method if insulin delivery from the Pod is interrupted. You are at increased

risk for developing hyperglycemia if insulin delivery is interrupted because the Pod only uses rapid-acting U-100 insulin. Failure to have an alternative method of insulin delivery can lead to very high glucose or diabetic ketoacidosis (DKA). Ask your healthcare provider for instructions for handling interrupted insulin delivery.

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

Warning: AVOID administering insulin, such as by injection or inhalation, while wearing an active Pod as this could result in hypoglycemia. The Omnipod 5 System cannot track insulin that is administered outside of the system. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.

Omnipod 5 System

Warning: Device components including the Pod, CGM transmitter, and CGM sensor may be affected by strong radiation or magnetic fields. Device components must be removed (and the Pod and CGM sensor should be disposed of) before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan (or any similar test or procedure). In addition, the Controller and

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smartphone should be placed outside of the procedure room. Exposure to X-ray, MRI, or CT, treatment can damage these components. Check with your healthcare provider on Pod removal guidelines.

Warning: DO NOT expose any Omnipod 5 System products or supplies to extreme temperatures as this results in them not functioning properly. Store all Omnipod 5 System products and supplies, including unopened Pods, in a cool, dry place.

Pod

Warning: Do NOT use 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.

Warning: ALWAYS dispose of the Pod according to local waste disposal guidelines. The Pod is considered biohazardous after use and can potentially transmit infectious diseases.

Warning: DO NOT allow small children access to small parts, such as the Pod and its accessories, including the 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: NEVER inject large bubbles or pockets of air when filling the Pod with insulin. Air in the system takes up space where insulin should be and can affect insulin delivery. Doing so could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

Warning: NEVER use a Pod if, while you are filling the Pod, you feel

significant resistance while 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 hyperglycemia.

Warning: 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 could lead to hyperglycemia.

Warning: ALWAYS check the infusion site often to make sure the cannula is properly inserted and secured to the Pod. Verify that there is no wetness or scent of insulin, which may indicate that the cannula has dislodged. An improperly inserted, loose, or dislodged cannula could result in under-delivery of insulin which can lead to hyperglycemia.

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

Warning: DO NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that is not deactivated properly can continue to deliver insulin as programmed, putting you at risk of over-delivery of insulin, which can lead to hypoglycemia.

Warning: DO NOT continue using an activated Pod that fails to beep during a diagnostic test. The Pod should be changed immediately. If the

Omnipod 5 App fails to beep during a diagnostic test, call Customer Care immediately. Continuing to use the Omnipod 5 System in these situations may put your health and safety at risk.

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 to extreme temperatures and may also affect the insulin inside the Pod which could lead to hyperglycemia.

Warning: Do NOT expose your Pod to water at depths greater than 25 feet (7.6 meters) or for longer than 60 minutes because damage to the Pod can occur. This could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

Warning: DO NOT use the Omnipod 5 System at low atmospheric pressure (below 700hPA). 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 hypoglycemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycemia.

Warning: DO NOT use the Omnipod 5 System 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 can result in combustion of the Pod or Omnipod 5 Controller, which can cause severe burns to the body.

Warning: DO NOT use the Omnipod 5 System 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 and Omnipod 5 Controller which could result in under-delivery of insulin which can lead to hyperglycemia.

Controller and Smartphone

Warning: ALWAYS identify the Omnipod 5 App as yours before using it. Using someone else's Omnipod 5 App can result in incorrect insulin delivery for both of you.

Warning: ALWAYS keep your Omnipod 5 App secure and within your control to ensure others cannot make changes to your insulin therapy which can lead to hypoglycemia or hyperglycemia. Do not share your Controller PIN or your smartphone screen lock security with anyone.

Warning: ALWAYS contact Customer Care if your Omnipod 5 System Controller is damaged and not working properly. If a Controller

Important Safety Information

replacement is needed, ALWAYS consult with your healthcare provider to get instructions on using other backup insulin delivery methods, like insulin injections. Make sure to check your glucose frequently.

Warning: You will NOT be able to use the Omnipod 5 App if:

- You have not installed a required update to the Omnipod 5 App
- An update for the Omnipod 5 App is not yet available to fix a known issue
- Your smartphone device is no longer compatible with use of the Omnipod 5 App
- The operating system of your smartphone has not yet been tested for safety by Insulet

Use the Insulet-provided Controller or a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery could result in the over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

Alarms

Warning: You must use the Omnipod 5 App within 15 minutes of the onset of the Pod Shut-Off advisory alarm. If you do not respond to this alarm within this time, the Omnipod 5 App and Pod sound a hazard alarm and your Pod stops delivering insulin which can lead to hyperglycemia.

Warning: ALWAYS respond to Hazard Alarms as soon as they occur. Pod Hazard Alarms indicate that insulin delivery has stopped. Failure to respond to a Hazard Alarm could

result in under-delivery of insulin which can lead to hyperglycemia.

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) ((see"  Blockage Detected" on page 163).

Glucose Monitoring

Warning: ALWAYS follow your healthcare provider's guidance on appropriate glucose monitoring to avoid hyperglycemia and hypoglycemia.

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

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

Warning: DO NOT wait to treat hypoglycemia (low glucose) or symptoms of hyperglycemia. Even if

you cannot check your glucose, waiting to treat symptoms could lead to severe hypoglycemia, which can lead to seizure, loss of consciousness, or death.

Warning: ALWAYS promptly treat hyperglycemia (high glucose) according to your healthcare provider's recommendations. Symptoms of hyperglycemia include fatigue, thirst, excess urination, or blurry vision. If left untreated, hyperglycemia could lead to diabetic ketoacidosis (DKA), or death.

Warning: ALWAYS treat "LOW" or "HIGH" CGM values and "LO" or "HI" blood glucose readings according to your healthcare provider's recommendations. These values can indicate potentially serious conditions requiring immediate medical attention. If left untreated, these situations can quickly lead to diabetic ketoacidosis (DKA), shock, coma, or death.

Warning: ALWAYS be aware of your current CGM value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your CGM values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia,

seizure, loss of consciousness or death.

- Erroneously low CGM values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *User Guide*, contact your healthcare provider.

Pump Precautions

Omnipod 5 System

Caution: DO NOT use any component of the Omnipod 5 System (smartphone, Controller, Pod) if you suspect damage after an unexpected event such as dropping or hitting on a hard surface. Using damaged components may put your health at risk as the system may not be working properly. If you are unsure if one or more of your components are damaged, stop using the system and call Customer Care for support.

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

Caution: ALWAYS make sure your battery has adequate charge prior to installing a software update.

Caution: If you decide later to switch between the Controller and your smartphone, you will need to start setup again on the new device. New setup requires entry of all your personalized settings. Consult with

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your healthcare provider if you are unsure about how to set up the new device. If you are wearing a Pod and need to switch devices, you will need to deactivate your Pod and activate a new one, since the Pod cannot communicate with two devices at one time. If possible, wait to switch between devices until a scheduled Pod change.

Caution: ALWAYS check your glucose frequently during amusement park rides and flying or other situations where sudden changes or extremes of air pressure, altitude, or gravity may be occurring. Though the Omnipod 5 System is safe to use at atmospheric pressures typically found in airplane cabins during flight, the atmosphere pressure in an airplane cabin can 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, can affect insulin delivery, leading to possible hypoglycemia or injury. If needed, follow your healthcare provider's treatment instructions.

Caution: ALWAYS check your glucose frequently when you use very low basal rates. Checking your glucose frequently can alert you to the presence of a blockage (occlusion). Blockages can result in hyperglycemia.

Caution: ALWAYS tap START INSULIN to start insulin delivery after a pause period has ended during Manual Mode use. Insulin delivery does not automatically start after a pause. If you do not start insulin delivery, you could develop hyperglycemia.

Caution: ALWAYS be aware of possible changes to your time zone when traveling. If you do not update your time zone, your insulin therapy will be delivered based on your old time zone which may cause disruptions in your insulin delivery schedule and inaccurate history logs. Talk to your healthcare provider about how to manage your insulin delivery while traveling between time zones.

Caution: DO NOT reset the Omnipod 5 App or clear the app data before checking with your healthcare provider. This will erase all of your settings, Adaptive Basal Rate, and history, and require you to change your active Pod. Before resetting or clearing app data, make sure you have a current record of your settings and a new Pod with supplies to use when restarting the app.

Caution: AVOID storing Omnipod 5 System components and supplies in a place where children, pets, or pests may access. Unintended access could result in damage to system parts or impact their sterility.

Pod

Caution: DO NOT use a Pod if the sterile packaging is open or damaged, the Pod has been dropped after removal from the package, or the Pod is expired as the Pod may not work properly and increase your risk of infection.

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 only be used with the Omnipod 5 System. Failure to follow the instructions above may result in damage to your Pod.

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 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.

Caution: ALWAYS follow these steps in preparing your 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 vial with an alcohol prep swab.
- Clean your infusion 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 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 cannula has inserted. Blockages (occlusions) may result if you do not use this technique for lean areas.

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

Caution: ALWAYS check for signs of infection often. If an infusion site shows signs of infection:

- Immediately remove the Pod and apply a new Pod at a different infusion 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 more frequently to ensure insulin delivery has not been affected. If you experience unexpected high glucose, change your Pod.

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 detach from your skin.

Caution: DO NOT use strong detergents or solvents such as cleaning solutions, aerosol sunscreen, or aerosol bug spray on your Pod. The use of such items can irritate the infusion site or damage the Pod.

Controller

Caution: AVOID turning Automatic Time Zone OFF on the Controller. If you turn Automatic Time Zone OFF, your Controller will not be able to detect when your device time zone and insulin delivery time zone do not match. Delivering insulin based on a different time zone than your local time may cause errors in insulin delivery and data logging, which can lead to hypoglycemia or hyperglycemia.

Caution: ALWAYS plug in and charge your Controller when you see the low battery message. If the battery charge

Important Safety Information

becomes critically low, the Controller turns itself off, and you will not receive a low battery hazard alarm. Without the use of the Controller, you will not be able to make changes to your insulin delivery, which could result in the over-delivery or under-delivery of insulin that can lead to hypoglycemia or hyperglycemia.

Caution: DO NOT expose your Controller battery to high heat [$>86^{\circ}\text{F}$ ($>30^{\circ}\text{C}$) during storage and $>104^{\circ}\text{F}$ ($>40^{\circ}\text{C}$) during use]. Do not puncture, crush, or apply pressure to your battery. Failure to follow these instructions could result in an explosion, fire, electric shock, damage to the Controller or battery, or battery leakage.

Caution: DO NOT expose your Controller to extreme temperatures while in storage or during use. Extreme heat or cold can cause the Controller to malfunction. Extreme heat is defined as $>86^{\circ}\text{F}$ (30°C) during storage and $>104^{\circ}\text{F}$ (40°C) during use. Extreme cold is defined as $<32^{\circ}\text{F}$ (0°C) during storage and $<41^{\circ}\text{F}$ (5°C) during use.

Caution: Use ONLY the USB charging cable that you received in the box with your Controller. AVOID using alternative charging cables or other accessories, as they may damage the Controller or affect the way it charges in the future. If you must use a different cable, use only cables less than or equal to 4 feet (1.2 meters) in length.

Caution: DO NOT place the Controller in or near water because the Controller is not waterproof. Failure to do so could result in damage to the Controller.

Caution: DO NOT use solvents to clean your Controller. DO NOT immerse your Controller in water as it is not waterproof. The use of solvents or immersion in water could result in damage to the Controller.

Caution: DO NOT allow debris or liquid to get into the USB port, speaker, sound/vibrate button, or Power button while cleaning the Controller. Failure to do so could result in damage to the Controller.

Smartphone

Caution: DO NOT navigate away from the Omnipod 5 App while you are in the process of making changes to your insulin delivery settings. If you leave the App before you are able to save the setting change and before the App is able to put the setting change into effect, the system will continue to use your last saved settings. As a result, you may continue with therapy settings that you did not intend. If you are unsure about whether your changes were saved, review your settings.

Caution: DO NOT stop the Omnipod 5 App in a way that stops it from running in the background (called force stopping) on your smartphone. The Omnipod 5 App must be open or be running in the background in order to display and sound alarms on the smartphone. If the App is not running, you could miss important alarms and notifications on the smartphone. If you do not hear alarms and notifications from your smartphone, you might not make the changes you need to make to your therapy in a timely manner. Your Pod will continue to operate and sound alarms. In addition, if you stop the Omnipod 5 App while sending commands to the Pod, the command

can be interrupted and may not be completed.

Caution: DO NOT delete the Omnipod 5 App while you have an active Pod, and DO NOT clear the Omnipod 5 App data. If you do, your Pod will remain active, but you will not be able to control your Pod even if you re-install or re-open the App. You must remove the Pod in order to stop receiving insulin.

Caution: DO NOT attempt to use the Omnipod 5 App on a smartphone device with unauthorized modifications. If you do, you will not be able to use the Omnipod 5 App.

Caution: DO NOT install apps on your smartphone from untrusted sources. These apps may contain malware that may impact use of the Omnipod 5 App. Install apps only from trusted sources (i.e. Google Play).

Caution: DO NOT enable any app development settings on your smartphone. Enabling these settings may cause issues with the Omnipod 5 App and prevent normal app operation.

Communication

Caution: When there is no communication between the Pod and the Controller or smartphone, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode. Restoring communication is needed to see your system status, notifications, and to send new instructions to the Pod. To restore communication try bringing the Controller or smartphone within 5 feet (1.5 m) of the Pod. See

"26.5. Pod Communication Issues – "Try Again"" on page 337.

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 any part of the Omnipod 5 System, as it may impact the communication between your smartphone or Controller and your Pod.

Alarms and Sound

Caution: ALWAYS respond to Pod Expiration, Low Pod Insulin, and Pod Shut- Off Advisory Alarms when they occur. These alarms escalate to Hazard Alarms if no action is taken. When Hazard Alarms occur, insulin delivery stops.

Caution: Permanently silencing a Pod alarm requires the Pod to be removed from your body. Once removed and discarded, promptly activate a new Pod to avoid going too long without insulin, which could lead to hyperglycemia.

Caution: ALWAYS check the alarm function when you change the Pod if you suspect any issue with the Pod's sounds to ensure you don't miss important alarms during use (see "Check alarms" on page 161).

Caution: ALWAYS make sure you can hear alarms and notifications when paired to alternative audio devices (e.g. Bluetooth speaker, headphones).

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App, such as Digital Wellbeing for

Android tools that limit sounds and notifications. If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able to see the Alarm or Notification displayed on the Omnipod 5 App. See "13.3. Sounds and Vibrations" on page 157 to learn how to manage sounds and vibrations.

CHAPTER 2

System Terminology and Navigation

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2.1. Terminology

Term	Description
Activation	The process of waking up a Pod and setting up exclusive communication with the Omnipod 5 App that woke it up.
Adaptive basal rate	Insulin delivery, in units per hour, that is calculated by SmartAdjust™ technology to aim your glucose to your target. This amount changes over time based on your insulin delivery history.
Advisory Alarm	An alarm that alerts you to some aspect of the Omnipod 5 System that will need your attention in the near future, such as a low amount of insulin remaining in your Pod.
Automated Mode	An insulin delivery method that uses your insulin delivery history, CGM value and trend to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values using a customizable glucose target, or Target Glucose.
Automated Mode: Limited	Automated insulin delivery used when CGM values are not available. Insulin delivery is based on your settings and recent history.
Basal insulin	A small amount of insulin that is delivered throughout the day and night to help keep glucose stable.
Basal Program	Insulin delivery schedule used to deliver insulin in Manual Mode. Also considered in some instances for Automated Mode
Basal rate	The number of units of insulin delivered in one hour (U/hr).
BG	Blood Glucose
Bolus insulin	A dose of insulin delivered for meals with carbohydrates and/or to correct a high glucose.
Cannula	A small, thin tube inserted under the skin that the Pod uses to deliver insulin.
Carbs (carbohydrates)	Sugars and starches that are consumed and the body breaks down into glucose.

CGM (Continuous Glucose Monitor)	System to track glucose throughout the day and night, supplied by a third-party medical device manufacturer.
CGM sensor	Component of a CGM that is inserted under the skin to measure glucose in interstitial fluid.
CGM transmitter	Component of a CGM that sends CGM values to the Pod.
CGM value	Glucose measured by a CGM. CGM values include trend, which indicates whether your glucose is going up, down, or remaining steady.
Connecting	In Omnipod 5, "connecting" refers to setting up wireless communication between system components. Omnipod 5 uses Bluetooth® wireless technology to communicate with your Pod and from the CGM transmitter to the Pod.
Controller	Omnipod 5 device, supplied by Insulet, that contains the Omnipod 5 App for use to control the Omnipod 5 System. A compatible personal smartphone may be used with the Omnipod 5 App installed instead of a Controller. Throughout the <i>User Guide</i> , the term Controller refers to the handheld Insulet-provided device.
Deactivate	Preferred method for shutting down the Pod. Deactivation turns off insulin delivery in the Pod and allows the Omnipod 5 App to activate a new Pod.
Device	In Omnipod 5, "device" refers to the smartphone or Omnipod 5 Controller used to control the Omnipod 5 App.
Discard Pod	When a communication problem prevents you from deactivating a Pod, the DISCARD option allows Omnipod 5 to activate a new Pod without shutting down the active Pod. Always remove a "discarded" Pod from your body, as it may still be delivering insulin.
Hazard Alarm	An alarm that alerts you to a problem with the Omnipod 5 System that needs your immediate attention, such as a disruption to your insulin delivery.
Hyperglycemia	High glucose. A higher-than-normal level of glucose in the blood; generally above 250 mg/dL.

2 System Terminology and Navigation

Hypoglycemia	Low glucose. A lower-than-normal level of 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 hypoglycemia.
Infusion site	The place on the body where a Pod's cannula is inserted to deliver insulin.
Insulin on board (IOB)	Insulin that is still active (available to lower glucose) in the body.
Ketoacidosis (Diabetic ketoacidosis, or DKA)	Diabetic ketoacidosis (DKA) is a serious condition in which extremely high 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.
Ketones	Acidic by-products that result from the breakdown of fat for energy. The presence of ketones indicates that the body is using stored fat (instead of glucose) for energy.
Line of sight	How to wear the Pod and CGM on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.
Manual bolus	A bolus amount chosen by you (not calculated by the SmartBolus Calculator).
Manual Mode	Insulin delivery method that delivers insulin amounts according to the basal rates in your Basal Program.
Microbolus	A small amount of insulin calculated by SmartAdjust technology delivered automatically by the Pod every 5 minutes during Automated Mode.
Omnipod 5 Application (App)	Software on the Controller or smartphone that is the primary user interface of the Omnipod 5 System.
SmartAdjust™ technology	Pod software used to calculate automated insulin delivery, as often as every 5 minutes to bring your glucose to your customized glucose target, or Target Glucose.

Target Glucose	The user-customizable glucose target used by both SmartAdjust technology and the Omnipod 5 SmartBolus Calculator to calculate how much insulin you need based on both your manually entered blood glucose readings and the CGM values from your Dexcom G6. Target Glucose can be set from 110–150 mg/dL in 10 mg/dL increments.
Units	How insulin is measured.

2.2. Using the Touchscreen and Entering Information

This section explains how to use the touchscreen, how to enter numbers or text into the Omnipod 5 App, and how this *User Guide* describes moving between Omnipod 5 App screens.

Note: If you are using your smartphone with the Omnipod 5 App, images in this section may differ from your smartphone.

Touchscreen Basics

The Omnipod 5 App displays messages and options for you on its touchscreen.

Tapping and swiping

The basic instructions for interacting with the touchscreen are explained here.

	Tap	Touch the screen, then lift your finger up.
	Swipe	Touch a starting point and move your finger up, down, left, or right. Note: Scrolling and swiping are related actions. When you swipe up, the screen display scrolls up to show items that are currently off-screen.

Note: A screen protector may decrease the touchscreen sensitivity.

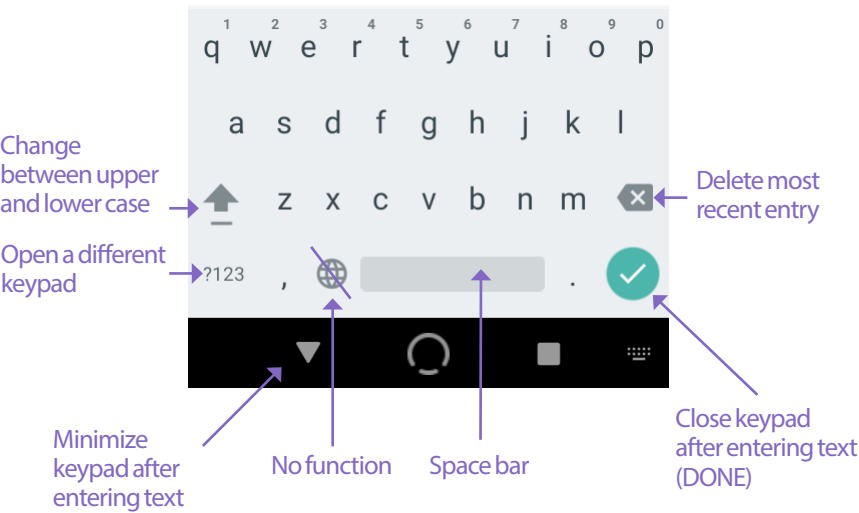
Screen time-out and brightness

The screen on the Controller turns black, called "timing-out", after a period of inactivity. To control the screen time-out and brightness settings, see "Screen Display" on page 125. The screen dims 6-10 seconds before it times out. If the screen dims, tap the screen to prevent it from timing out.

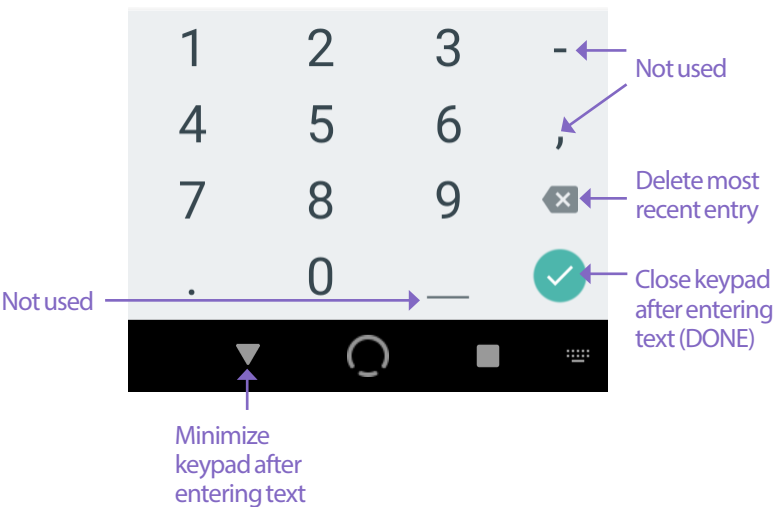
Entering Numbers and Text

Tapping in an editable field can bring up a keypad or number pad.

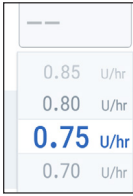
Using a keypad



Using a numberpad



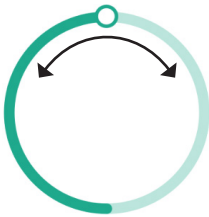
Using a scroll wheel



Tapping an editable field can bring up a scroll wheel. Place your finger on the scroll wheel. Swipe up or down to select your desired value. The faster you move your finger, the faster the wheel will scroll.

When your desired selection is shown in the center of the wheel, select the value by tapping it or by tapping outside the scroll wheel.

Using a slider



Use sliders to select a value from a scale. Place your finger on the small open circle and move your finger until your desired value is displayed. Move your finger along the circle to move the slider. Move your finger clockwise for a larger number and counterclockwise for a smaller number. Lift your finger when the desired value is displayed.

Selecting, Adding, and Deleting Items

Toggles

-  Tap a toggle to change the selection from one side to the other.
-  Toggles allow you to turn a feature ON or OFF. The toggle is on the right side and purple when a feature is ON, and on the left and gray when a feature is OFF.

Add and delete buttons

-  A plus symbol in a circle indicates that you can add an item to a list. Tap the plus symbol to add the item to the list.
-  A red x in a circle indicates that you can remove an item from a list. To remove the item, tap the red x.

Navigation Buttons and Navigation Shorthand

Options button



The Options button (⋮) appears on the right side of certain lists. Tapping the Options button brings up a list of options

relevant to the item on that row.

User Guide navigation shorthand

The *User Guide* uses the ">" symbol to indicate navigating from one screen to another. For example:

- Menu button (≡) > Pod > CHANGE POD

tells you to:

1. Tap the Menu button (≡) in the upper left of the Home screen.
2. Tap Pod to open the Pod screen.
3. Tap CHANGE POD.

CHAPTER 3

Omnipod 5 System Overview

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3.1. Omnipod 5 App and Dexcom Communication

The Omnipod 5 System communicates with the Dexcom G6 Continuous Glucose Monitoring (CGM) System.

- The Pod delivers insulin to your body, receives commands from the Omnipod 5 App, receives CGM values from Dexcom CGM transmitter, sends CGM values to the Omnipod 5 App and automatically adjusts insulin delivery in Automated Mode.
- Your Dexcom G6 transmitter sends CGM values to the Pod and to the Dexcom G6 app. The Omnipod 5 App does not communicate directly with the Dexcom G6 app. For CGM-specific information, refer to your *Dexcom G6 CGM System User Guide*.
- The Controller or a compatible smartphone lets you control the Pod using the Omnipod 5 App.

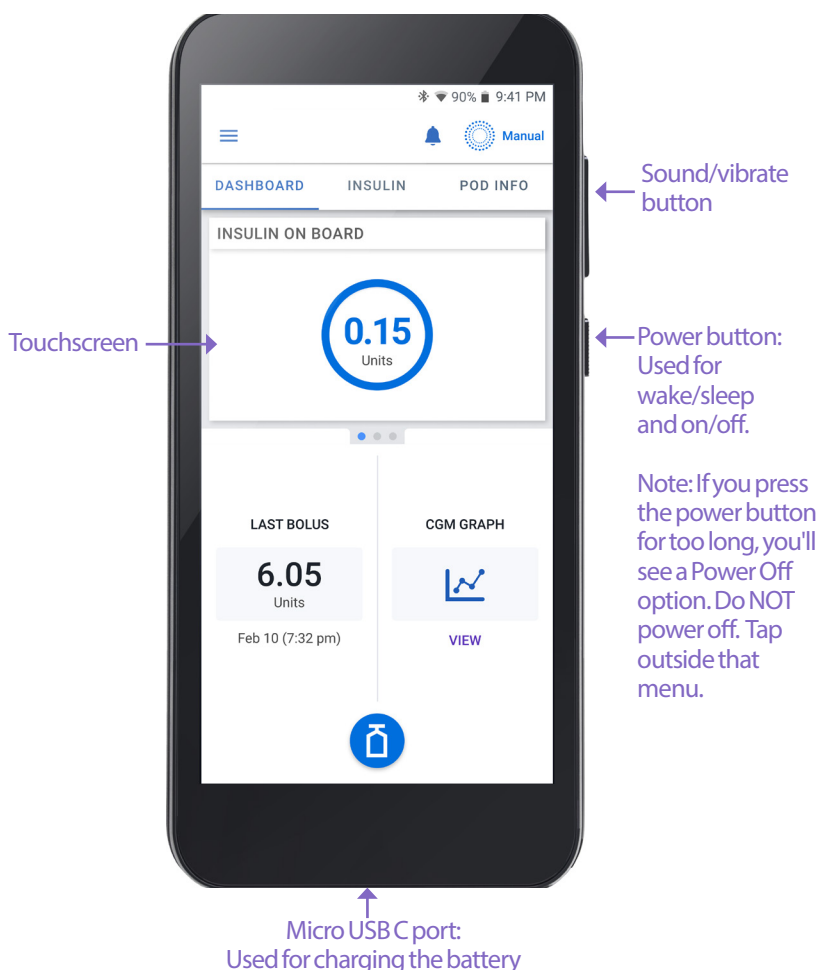


3.2. Omnipod 5 App

You use the Omnipod 5 App to control and monitor the Pod's operations using Bluetooth® wireless technology. You can use the provided Controller or a compatible smartphone with the Omnipod 5 App.

Caution: AVOID leaving your Controller or smartphone in a place that would prevent you from hearing alarms and notifications from your Omnipod 5 App. Delivery of insulin in Manual Mode or Automated Mode continues as programmed if you move away from your Controller or smartphone.

The Omnipod 5 Controller



3.3. Lock Screen and Security

Warning: ALWAYS identify the Omnipod 5 App as yours before using it. Using someone else's Omnipod 5 App can result in incorrect insulin delivery for both of you.

Warning: ALWAYS keep your smartphone or Controller safe and within your control to ensure others cannot make changes to your insulin therapy. Unintended changes to your insulin delivery could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia. Be careful who you share your Controller PIN or your smartphone screen lock security with.

Omnipod 5 App Security on Your Controller

After you set up your provided Controller, the Lock and PIN screens appear whenever you wake up your Controller.

The Lock screen displays:

- Your selected background image
- Today's date and time
- Your customized message
- The current system mode
- The amount of insulin on board
- Any alarm or notification messages

Unlock your Controller

In the remainder of this *User Guide*, instructions to "wake up" or "unlock" the Controller mean to do the following:

1. Press and release the Power button.
2. Unlock the Lock screen by either swiping left to right or by swiping up from the bottom. The PIN screen appears.
3. Enter your 4-digit PIN.
4. Tap OK. The Home screen or your most recent screen appears.

Lock your Controller

To lock your Controller when you are finished using it:

- Press the Power button briefly. This locks the Controller by putting it to sleep.

Note: Keep your Controller in a safe, accessible location.

Caution: ONLY press the Power button on the Controller for less than 1 second or you may accidentally turn the power off. If the Controller displays a message asking if you would like to "Power Off", tap outside the message to cancel the message. If you accidentally power off your Controller, you can miss important notifications and alarms from the Omnipod 5 App. If you do not hear alarms and notifications from your Controller, you might not make the changes you need to make to your insulin therapy in a timely manner. The Pod will alarm regardless of whether the state of the Controller is On or Off.

Forgot your PIN?

If you have problems with your PIN, contact Customer Care. For contact information, see the Customer Care card at the front of this *User Guide*.

3.4. Status Bar

At the top of the screen is a status bar that shows icons for both the Omnipod 5 App and your Controller or smartphone. The following icons will display when applicable:

- Omnipod 5 Status icon
- Battery level
- Battery charging indication
- Current time

Status bar icon definitions:

 Omnipod 5 status (system mode and IOB) – Automated Mode

 Omnipod 5 status (system mode and IOB) – Manual Mode

 Hazard alarm

 Advisory alarm

 Action Item notification

 Reminder

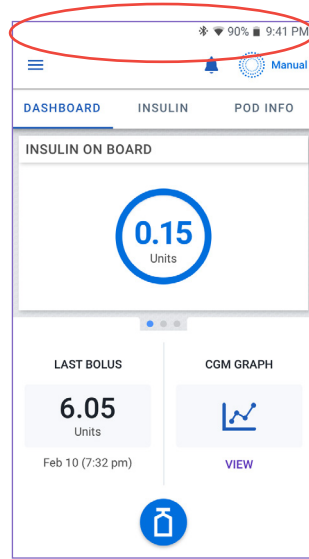
 Vibrate/Mute

 Airplane mode ON

 Bluetooth wireless technology setting ON

 Cellular connectivity

 Wi-Fi

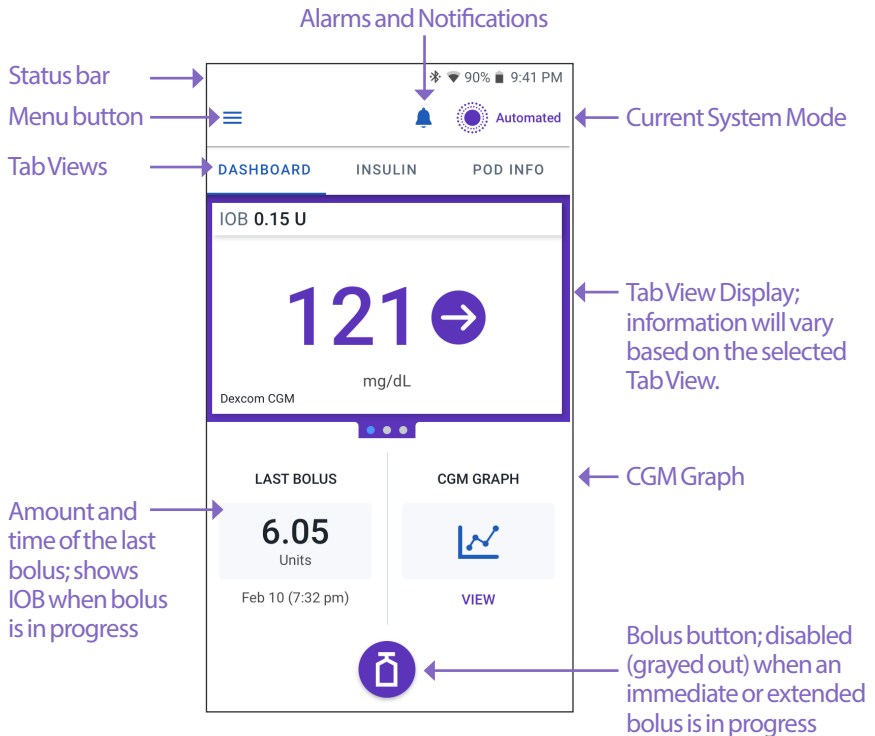


Note: Swipe down from the status bar for more details on what's currently displayed on the status bar. Then, swipe up to close.

Note: Device-specific icons such as Wi-Fi and vibrate/mute may vary in appearance.

3.5. Home Screen

This section introduces you to what you may see on the Omnipod 5 App Home screen. Different information will display depending on which system mode is activated.



The Home screen tab view that you select determines what information displays on the screen. To change the information displayed:

- Tap DASHBOARD, INSULIN, or POD INFO.
- Swipe right or left in the middle portion of the screen (directly below the Home screen tabs) to move between tab views.
- If an immediate bolus is in progress, a bolus progress bar and a button to cancel the bolus are shown on the Home screen. The three tabs are not visible if an immediate bolus is running. (See "17.6. Delivering an Immediate Bolus" on page 245).