


Pod shown without the necessary adhesive.

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PT-002497

Controller FCC ID: 2ADINN5004L
Controller FCC ID: 2ADINN5004LR1
Pod FCC ID: RBV-029
Pod FCC ID: RBV-029C
Pod FCC ID: RBV-029D

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Omnipod® 5 Automated Insulin Delivery System Technical User Guide



Technical User Guide

for Insulet-provided Controller and Android smartphones

Omnipod® 5 Automated Insulin Delivery System



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REF PDM-H001-G-MG
Serial Number: _____
Controller FCC ID: 2ADINN5004L
Controller FCC ID: 2ADINN5004LR1
Pod FCC ID: RBV-029
Pod FCC ID: RBV-029C
Pod FCC ID: RBV-029D
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: www.insulet.com/patents

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BEFORE YOU BEGIN

1 Introduction

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CHAPTER 1

Introduction

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1 Introduction

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 or Dexcom G7 Continuous Glucose Monitoring Systems or the FreeStyle Libre 2 Plus Sensor 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 a compatible glucose Sensor, 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>.
- **Three compatible glucose Sensors:** The Omnipod 5 System is designed to work with either the Dexcom G6 or Dexcom G7 Continuous Glucose Monitoring (CGM) Systems or the FreeStyle Libre 2 Plus Sensor. Sensors must be obtained separately. Sensor glucose values and trends are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode.
 - The Dexcom G6 Transmitter must be connected and active within the Dexcom G6 App to send sensor glucose values to the Pod.
 - The Dexcom G7 Sensor must be connected and active within the Dexcom G7 App to send sensor glucose values to the Pod.
 - The FreeStyle Libre 2 Plus Sensor must be started by, connected, and active within the Omnipod 5 App on the Insulet-provided Controller to send sensor glucose values to the Pod.

- **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 Sensor Glucose 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 sensor glucose values every 5 minutes. The Home screen features a Sensor Graph which allows for reference of your sensor glucose 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 sensor glucose 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 sensor glucose 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.
- **Three compatible glucose Sensors:** The Omnipod 5 System is designed to work with either the Dexcom G6 or Dexcom G7

1 Introduction

Continuous Glucose Monitoring (CGM) Systems or the FreeStyle Libre 2 Plus Sensor. Sensors must be obtained separately. Sensor glucose values and trends are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode.

- The Dexcom G6 Transmitter must be connected and active within the Dexcom G6 App to send sensor glucose values to the Pod.
- The Dexcom G7 Sensor must be connected and active within the Dexcom G7 App to send sensor glucose values to the Pod.
- The FreeStyle Libre 2 Plus Sensor must be started by, connected, and active within the Omnipod 5 App on the Insulet-provided Controller to send sensor glucose values to the Pod.
- **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 sensor glucose values every 5 minutes. The Home screen features a Sensor Graph which allows for reference of your sensor glucose values and displays some information about insulin delivery, including automation status.

1.2 About This *Technical User Guide*

The purpose of this *Technical 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.

This *Technical User Guide* is intended for use only with:

- The Insulet-provided Controller with the Omnipod 5 App.
REF PDM-H001-G-XX
- 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-H001-G-XX" on the back of the Controller, this is the correct *Technical User Guide*. If you do not see it, contact Customer Care. Using an incorrect *Technical User Guide* can lead to improper use of the Omnipod 5 System.

Note: Screen images shown in this *Technical 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 *Technical 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 *Technical User Guide* is not a substitute for medical or healthcare advice, recommendations, and/or services from a qualified healthcare provider. This *Technical 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 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older. SmartAdjust™ technology is intended for single patient use and requires a prescription.

1 Introduction

The **SmartBolus Calculator** is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100 insulin. The 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 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 and using a Dexcom Sensor as it could lead to falsely elevated sensor glucose 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, Dexcom G6 Sensor and Transmitter, Dexcom G7 Sensor, and FreeStyle Libre 2 Plus 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 *Technical 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 *Technical User Guide* in any way in connection with your personal healthcare, related decisions, and treatment. This *Technical 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 *Technical 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 *Technical 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 hyperglycemia or hypoglycemia.

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.

1 Introduction

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" sensor glucose values and 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: 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 sensor glucose 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 sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor calibration (for Sensors requiring calibration, if necessary). ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose 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 *Technical User Guide*, contact your healthcare provider.

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

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

Warning: DO NOT use the Omnipod 5 System with the FreeStyle Libre 2 Plus Sensor if you are taking more than 1000 mg of ascorbic acid (Vitamin C) per day, a substance found in supplements like multivitamins or cold remedies such as Airborne® and Emergen-C®. Taking more than 1000 mg of Vitamin C per day may falsely raise your Sensor readings and result in over-delivery of insulin that could result in severe hypoglycemia. 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 181).

Warning: SmartAdjust technology should NOT be used by anyone under the age of 2 years old. SmartAdjust technology should also NOT be used in people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.

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 hyperglycemia. 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 Introduction

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 contact Customer Care for support.

Caution: ONLY use the Omnipod 5 System with authorized devices (Omnipod 5 App, Controller and Pod and Dexcom G6 or Dexcom G7 CGM). DO NOT attempt to use the Omnipod 5 System with unauthorized devices. Attempting to use the Omnipod 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 receiver with the Omnipod 5 System because the Omnipod 5 System is compatible only with the Dexcom G6 or Dexcom G7 App on a smartphone.

Caution: During the first 12 hours of use of a FreeStyle Libre 2 Plus Sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

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 Benefits

The benefits of the Omnipod 5 Automated Insulin Delivery System may include:

- Improved amount of time your glucose stays in range (70-180 mg/dL)
- Help with lowering and maintaining HbA1c
- Reduced feelings of diabetes distress related to eating, low glucose, and social perceptions
- Greater confidence in managing low glucose
- Improved quality of life related to managing diabetes

1 Introduction

Potential Risks

- The Omnipod 5 System uses sensor glucose values and trends to calculate insulin delivery. If the sensor glucose values are inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycemia or hyperglycemia.
- The Omnipod 5 System uses information and settings that you enter to calculate and adjust insulin delivery. If the information you enter is inaccurate, or if you don't give the System information about carbs and glucose, 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 in the cannula or dislodging of the cannula can interrupt insulin delivery. Glucose that does not decrease after a bolus, or other unexplained high glucose, are signs 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, the System could deliver an inaccurate dose of insulin which can lead to hypoglycemia or hyperglycemia.
- Infusion site complications like scar tissue and infection can make insulin delivery less effective. Glucose that does not decrease after a bolus, or other unexplained high glucose, is a sign of ineffective 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 *Technical User Guide*. The words "**Warning**" and "**Caution**" are displayed in red, bolded text.

The Omnipod 5 System is designed to work with either the Dexcom G6, Dexcom G7, or FreeStyle Libre 2 Plus Sensors.

- To use the Dexcom G6 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G6 Sensor, Transmitter, and Instructions for Use and download the Dexcom G6 App on your personal smartphone.
- To use the Dexcom G7 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G7 Sensor and Instructions for Use, and download the Dexcom G7 App on your personal smartphone.
- To use the FreeStyle Libre 2 Plus Sensor with the Omnipod 5 System, you will need to obtain FreeStyle Libre 2 Plus Sensors and the FreeStyle Libre 2 Plus Sensor Instructions for Use. If you are new to using a glucose sensor, continue using your BG meter until you are familiar with Sensor usage.

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

If you still have questions after reading this *Technical 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 9 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
- Glucose sensor supplies
 - Dexcom G6 or Dexcom G7 Continuous Glucose Monitor (CGM) System and supplies

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- FreeStyle Libre 2 Plus Sensors

- 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 235)

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

Omnipod 5 Pump
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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.

Important Safety Information

Omnipod 5 System

Warning: Device components including the Pod, Dexcom G6 Sensor and Transmitter, Dexcom G7 Sensor, and FreeStyle Libre 2 Plus Sensor may be affected by strong radiation or magnetic fields. Device components must be removed (and the Pod and 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 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.

Important Safety Information

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, contact 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.

Important Safety Information

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.

Important Safety Information

Warning: ALWAYS contact Customer Care if your Omnipod 5 System Controller is damaged and not working properly. If a Controller 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) "⚠ Blockage Detected" on page 181.

Glucose Monitoring

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

Important Safety Information

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 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 could lead to diabetic ketoacidosis (DKA), or death.

Warning: ALWAYS treat "LOW" or "HIGH" sensor glucose values and 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 sensor glucose 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.

Important Safety Information

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

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose 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 *Technical 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 contact 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 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.

Important Safety Information

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.

Important Safety Information

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.

Important Safety Information

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 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.

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 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 and adapter 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.

Important Safety Information

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 saving the setting change and before the app puts 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.

Important Safety Information

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 "27.5 Pod Communication Issues – "Try Again"" on page 458.

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 180).

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

Important Safety Information

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. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown.
- iPhone: Screen Time, Focus Mode, Hide App, Lock App.

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.

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CHAPTER 2

System Terminology and Navigation

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2 System Terminology and Navigation

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, sensor glucose 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 sensor glucose 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.
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 Sensor 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>Technical 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.
Hypoglycemia	Low glucose. A lower-than-normal level of glucose in the blood; generally below 70 mg/dL.

2 System Terminology and Navigation

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 Sensor 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.

Sensor Glucose Monitoring System	System to track glucose throughout the day and night, supplied by a third-party medical device manufacturer. Also known as Continuous Glucose Monitor (CGM).
Sensor	Component of a sensor glucose monitoring system that is inserted under the skin to measure glucose in interstitial fluid.
Transmitter	Component of a sensor glucose monitoring system that sends sensor glucose values to the Pod (Dexcom G6 only).
Sensor Glucose Value	Glucose measured by a Sensor. Sensor glucose values include trend, which indicates whether your glucose is going up, down, or remaining steady.
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 sensor glucose values from your Dexcom Sensor. Target Glucose can be set from 110–150 mg/dL in 10 mg/dL increments.
Units	How insulin is measured.

2 System Terminology and Navigation

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 *Technical 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.

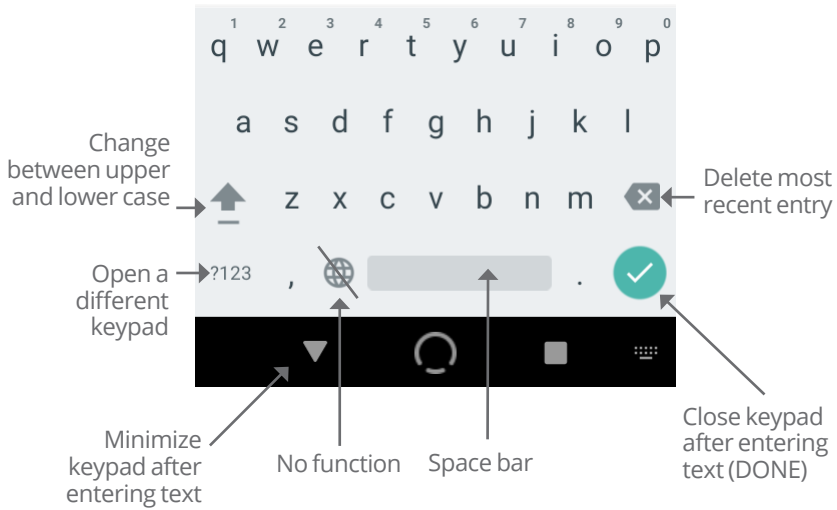
Screen time-out and brightness

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 141. 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

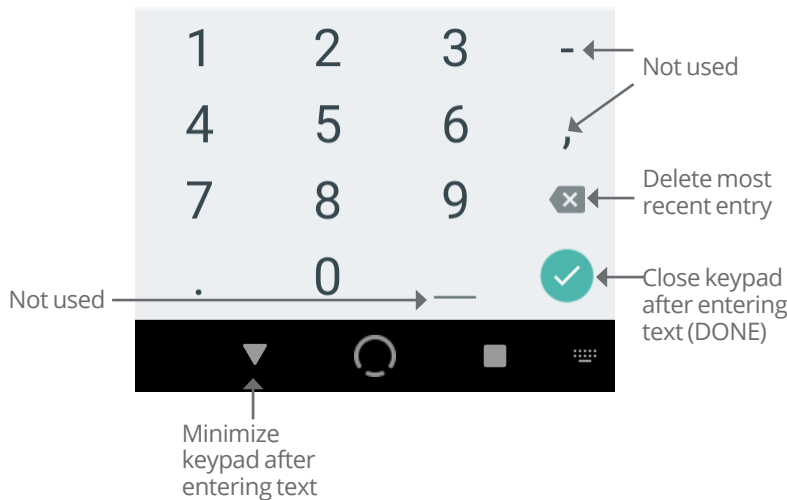
Tapping in an editable field can bring up a keypad or number pad.

Using a keypad



2 System Terminology and Navigation

Using a number pad



Using a scroll wheel



Basal Rate	
<input type="radio"/>	0.60 U/hr
<input type="radio"/>	0.65 U/hr
<input type="radio"/>	0.70 U/hr
<input checked="" type="radio"/>	0.75 U/hr
<input type="radio"/>	0.80 U/hr
<div>CANCEL DONE</div>	

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.



When your desired selection is shown, select the value by tapping the radio button to the side of the selection.

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.

Technical User Guide navigation shorthand

The *Technical 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**.

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CHAPTER 3

Omnipod 5 System Overview

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3.1 Omnipod 5 App and Sensor Communication

Communication between the parts of your Omnipod 5 System will be different depending on which Sensor you choose.

Omnipod 5 App and Dexcom G6 Communication

The Omnipod 5 System communicates with the Dexcom G6 or Dexcom G7 Continuous Glucose Monitoring (CGM) Systems.

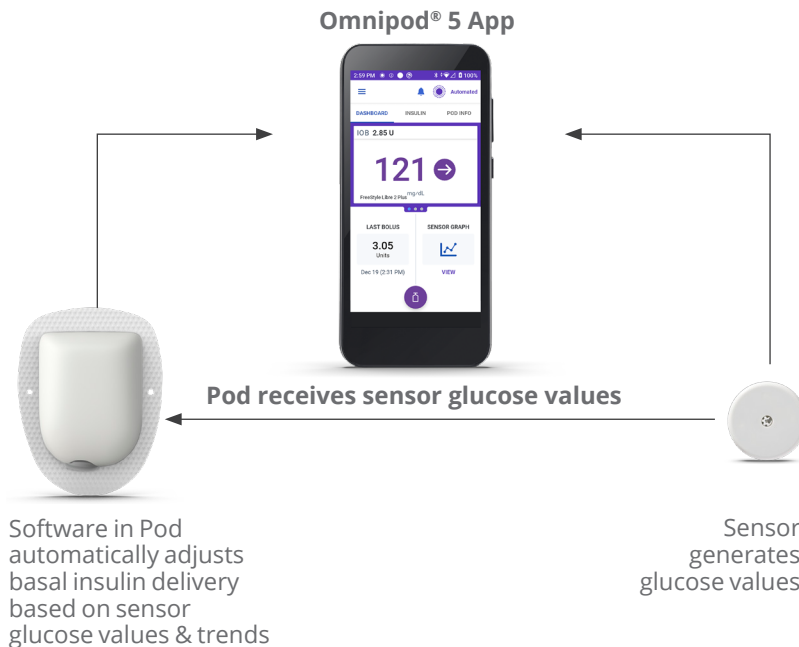
- The Pod delivers insulin to your body, receives commands from the Omnipod 5 App, receives sensor glucose values from the Dexcom Sensor, sends sensor glucose values to the Omnipod 5 App and automatically adjusts insulin delivery in Automated Mode.
- Your Dexcom Sensor sends sensor glucose values to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



Omnipod 5 App and FreeStyle Libre 2 Plus Sensor Communication

The Omnipod 5 System communicates with the FreeStyle Libre 2 Plus Sensor.

- The Pod delivers insulin to your body, receives commands from the Omnipod 5 App, receives sensor glucose values from the FreeStyle Libre 2 Plus Sensor, sends sensor glucose values to the Omnipod 5 App on the Insulet-provided Controller and automatically adjusts insulin delivery in Automated Mode.
- The FreeStyle Libre 2 Plus Sensor sends sensor glucose values to the Pod and to the Omnipod 5 App on the Insulet-provided Controller. For Sensor-specific information, refer to your FreeStyle Libre 2 Plus Sensor Instructions for Use.
- The Controller lets you control the Pod and Sensor using the Omnipod 5 App.
- The Omnipod 5 App activates the Pod, sends bolus commands to the Pod, receives insulin delivery and Sensor info from Pod when Pod is nearby, displays sensor glucose value & trend from the Pod, troubleshoots, adds a Sensor, and receives and displays information and alarms directly from the Sensor only when no Pod is active



3 Omnipod 5 System Overview

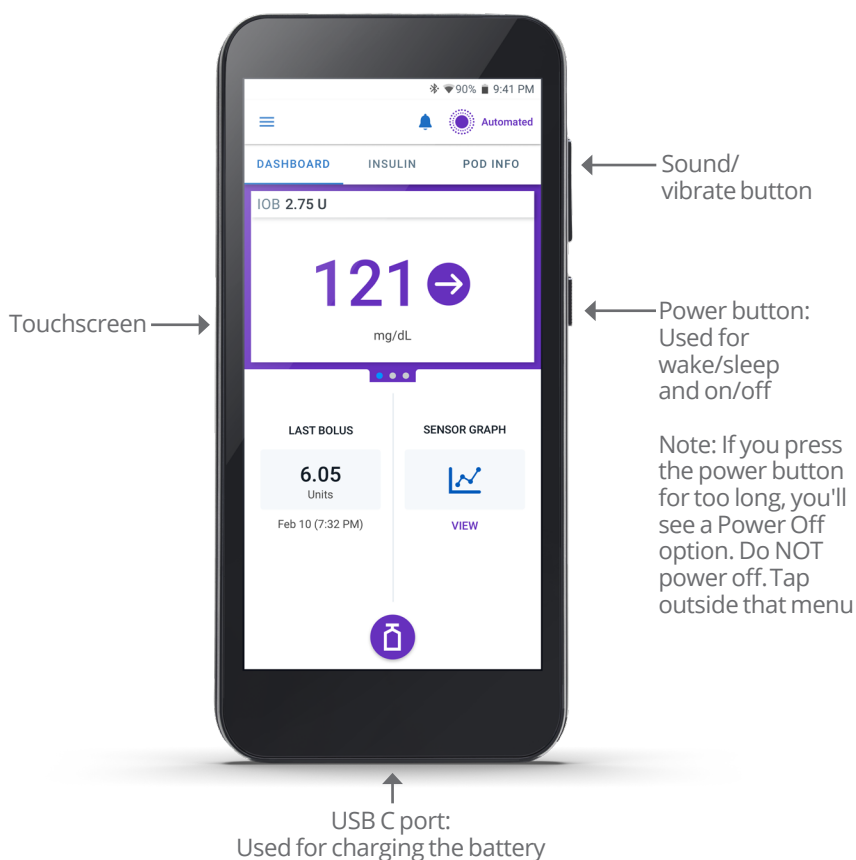
3.2 Omnipod 5 App

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.

Note: If you are using the FreeStyle Libre 2 Plus Sensor, you must use the provided Controller.

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 AutomatedMode 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 *Technical 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.

3 Omnipod 5 System Overview

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 *Technical User Guide*.

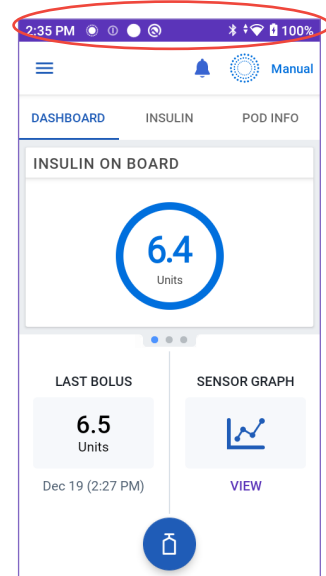
3.4 Status Bar

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 – Automated Mode
	Omnipod 5 status – Manual Mode
	Hazard Alarm
	Advisory Alarm
	Action Item notification
	Reminder
	Vibrate/Mute
	Airplane mode ON
	Bluetooth wireless technology setting ON
	Cellular connectivity
	Wi-Fi



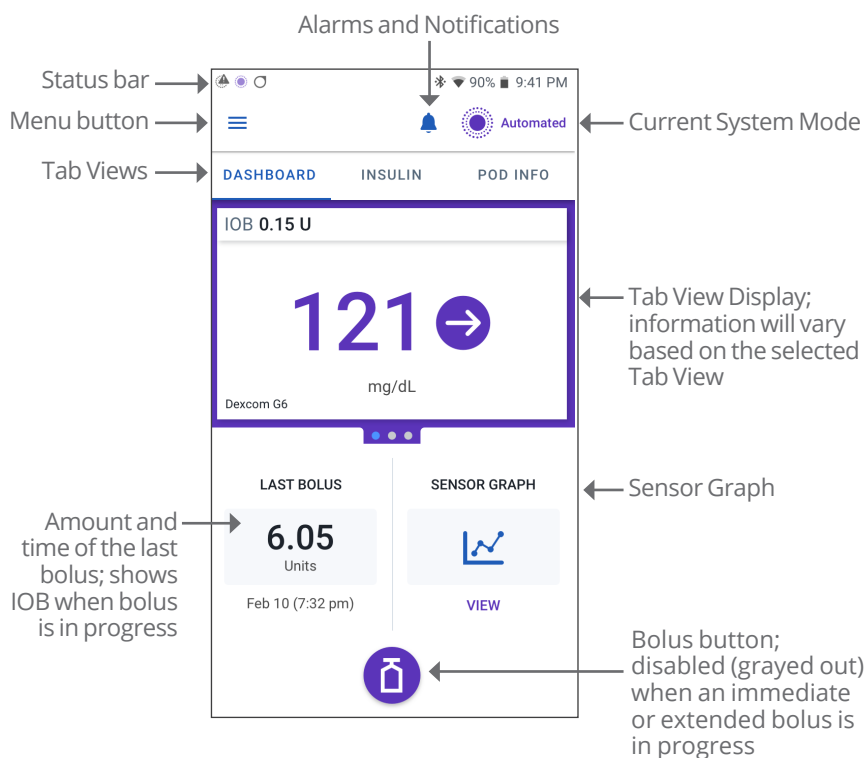
Note: Swipe down from the status bar for more details on what's currently displayed on the status bar. Then, swipe up to close.

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

3 Omnipod 5 System Overview

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 "17.9 Delivering an Immediate Bolus" on page 267).

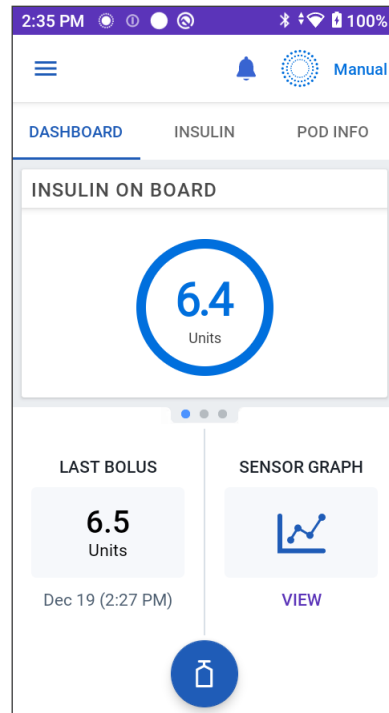
DASHBOARD Tab

The **DASHBOARD** tab displays the following information.

Note: The **DASHBOARD** tab shows different content if a Sensor or Transmitter is paired to the Omnipod 5 App.

Without paired Sensor or Transmitter

- **INSULIN ON BOARD (IOB):** value displays when IOB is available.
- **INSULIN ON BOARD (IOB):** displays as dashes when IOB is unavailable or there is no Pod communication. Tap **MORE INFORMATION** for possible reasons.



3 Omnipod 5 System Overview

With paired Sensor or Transmitter

- **INSULIN ON BOARD (IOB)**
- **Sensor glucose value** (with trend arrow): when a sensor glucose value is available. See "19.5 Sensor Glucose Trend Arrows" on page 307.
- **Sensor glucose value** (without arrow): when Sensor supplies a sensor glucose value but is unable to report sensor glucose trend.
- **HIGH:** when sensor glucose value received from your Sensor is greater than 400 mg/dL.
- **LOW:** when sensor glucose value received from your Sensor is less than 40 mg/dL.

The **DASHBOARD** tab also displays information related to potential Sensor communication issues. See page 308 for more information.

A progress bar appears when a bolus is in progress (see "16.3 Tracking the Progress of a Bolus" on page 254).



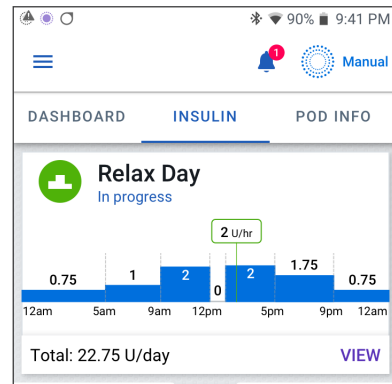
INSULIN Tab

The **INSULIN** tab label changes to **ACTIVITY** when the Activity feature is enabled in Automated Mode or to **TEMP ON** when a temp basal is running in Manual Mode.

Manual Mode

By default, in Manual Mode, the **INSULIN** tab shows the name and graph of the user-defined Basal Program. A label below the Basal Program's name indicates whether the listed Basal Program is:

- In progress—This program is running on the active Pod.
- Paused—This program will resume when you start insulin delivery.
- Current—There is no active Pod. This program will be sent to your next Pod during activation.



When there is a Basal Program in progress, a green vertical line marks the current time. The numbers above the graph indicate the basal rate for each time segment.

The total daily amount of basal insulin in Manual Mode is shown beneath the graph. This total is the amount of insulin that the Basal Program in progress is scheduled to deliver in a 24-hour period. This total does not account for temp basals or boluses.

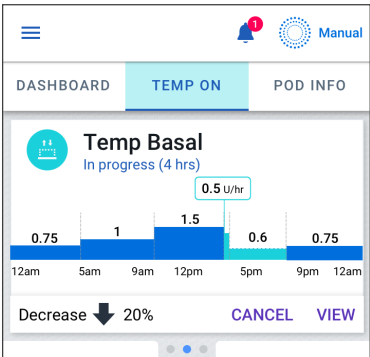
To see the total amount of insulin that your Pod has actually delivered, including temp basals and boluses, see "Browsing Your History and Records" on page 149.

Tap **VIEW** to see details about other Basal Programs.

3 Omnipod 5 System Overview

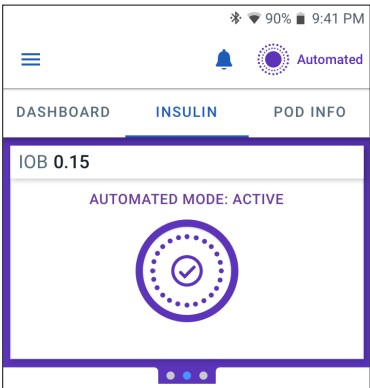
Temp basal

When a temp basal is running, the **INSULIN** tab label changes to **TEMP ON** and is highlighted in light blue. It displays the temp basal graph and allows you to cancel the temp basal. See "7.1 About Temporary Basal Rates" on page 120.



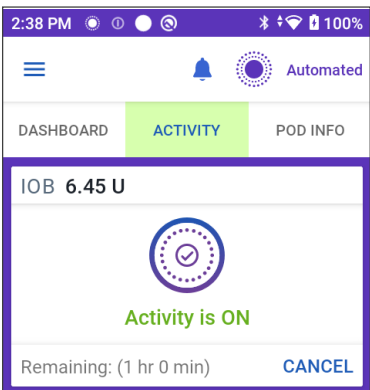
Automated Mode

In Automated Mode, the **INSULIN** tab shows **AUTOMATED MODE: ACTIVE** and displays **LAST BOLUS** and **SENSOR INFO**. For more information on using Automated Mode, see "22.1 About Automated Mode" on page 372.



Activity feature

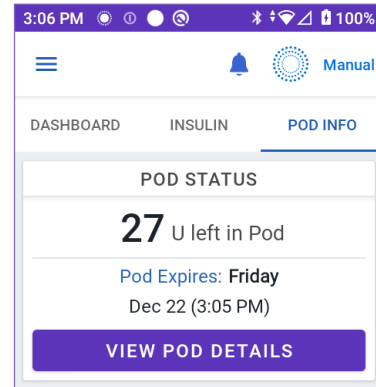
In Automated Mode, when the Activity feature is enabled, the **INSULIN** tab label changes to **ACTIVITY**, highlighted in green, and shows **Activity is ON**. See "24.1 About the Activity Feature" on page 388 for more information.



POD INFO Tab

The **POD INFO** tab shows whether there is an active Pod, and, if so, how much insulin is left in the Pod and when the Pod will expire.

If the Omnipod 5 App cannot communicate with an active Pod, the **POD INFO** tab shows "**No Pod Communication.**" Tap **MORE INFORMATION** for details.



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 "27.5 Pod Communication Issues – "Try Again"" on page 458.

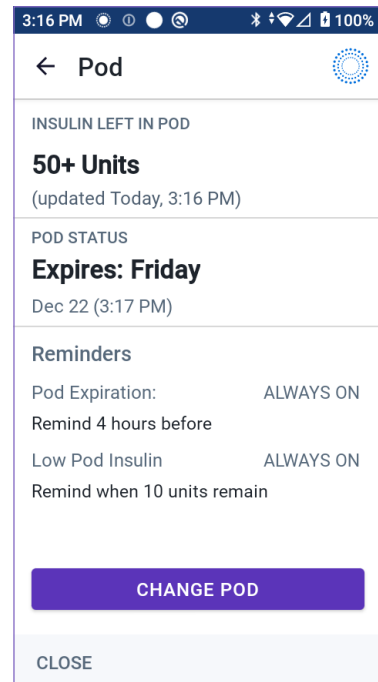
If there is no active Pod, the **POD INFO** tab shows "**No Active Pod.**" To set up a new Pod, see "Activating and Changing Your Pod" on page 93.

If there is an active Pod, tap **VIEW POD DETAILS** to bring up a screen that lets you deactivate or change your Pod.

The **VIEW POD DETAILS** screen shows:

- Amount of insulin in the Pod
- Time of the last communication between the Omnipod 5 App and Pod
- Date and time of the Pod's expiration
- Reminders
- A **CHANGE POD** button

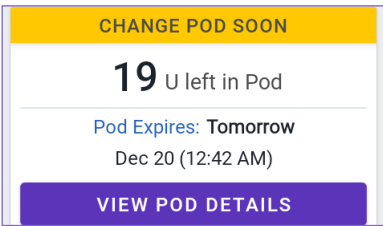
Tip: You can also access this screen by tapping **Menu button** (☰) > **Pod**.



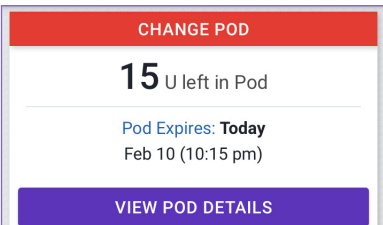
3 Omnipod 5 System Overview

POD INFO banners

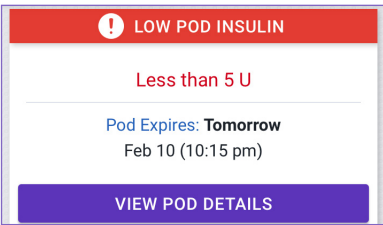
When your Pod will expire soon, a yellow **CHANGE POD SOON** banner appears on the **POD INFO** tab. The yellow banner appears 12 hours before Pod expiration or at the time of your Pod expiration reminder, whichever is earlier.



At 6 hours before Pod expiration, a red **CHANGE POD** banner appears on the **POD INFO** tab.



When less than 5 units of insulin remain in the Pod, a red **LOW POD INSULIN** banner appears on the **POD INFO** tab. If the Pod will expire soon **and** there are less than 5 units of insulin in the Pod, the red **LOW POD INSULIN** banner is displayed on the **POD INFO** tab.



Note: If you change the time zone, the Pod expiration time is adjusted to match the new time zone selection.

Bolus Information and Button

The lower left section of the Home screen displays bolus information. The Bolus button is at the bottom.

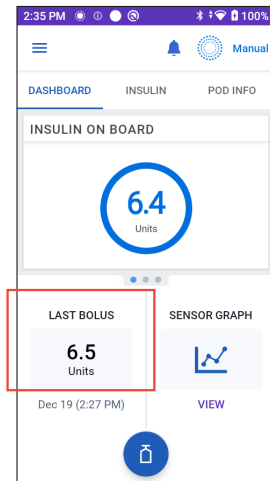
Between boluses

When a bolus is not being delivered, the section is labeled **LAST BOLUS** and shows the amount and time of the most recent bolus.

During a bolus

When a bolus is being delivered, the last bolus information is replaced by an estimate of the insulin on board (IOB):

- During an immediate bolus, the IOB estimate is updated every second.
- During an extended bolus, the IOB estimate is updated based on:
 - Previous boluses
 - Amount of insulin already delivered from the ongoing bolus
 - Amount of insulin projected to be delivered within the time period defined by your Duration of Insulin Action setting



Bolus information if there is no Pod communication

If the Pod is out of range of the Controller or smartphone running the Omnipod 5 App and cannot confirm the recent bolus amount, an estimated bolus amount is shown. Once the Pod is in range again and the bolus delivery is confirmed, the confirmed bolus amount is shown.

Estimated and unconfirmed bolus amounts

The Omnipod 5 App estimates bolus amounts during an ongoing bolus and when the Pod is out of range. A gray icon (ⓘ) marks estimated bolus amounts. A yellow icon (⚠) marks unconfirmed bolus amounts (see "When the Pod has not confirmed a bolus delivery" on page 160).

Bolus button


The Bolus button provides access to the SmartBolus Calculator. The Bolus button is not available while an immediate or extended bolus is being delivered, or when there is no active Pod.



3 Omnipod 5 System Overview

3.6 Home Screen Main Menu

The Main Menu on the Home screen lets you access most of the Omnipod 5 App's functions. To access the Main Menu:

- Tap the Menu button () in the upper left corner of the Home screen.
- or
- Place your finger on the far left side of the Omnipod 5 App and swipe right across the screen. Swipe left to hide the Menu.

Tap an option on the Menu to bring up the related screen.

Tip: The Menu extends beyond the bottom of the screen. Swipe up or down to see all parts of the Menu.

The menu options available to you vary according to the current mode: Manual or Automated. Menu options in gray are disabled based on current mode or settings.

The below table shows menu options and their availability in each mode:

Menu Options	Manual Mode	Automated Mode
Frequent Tasks		
Switch Mode	✓	✓
Set Temp Basal	✓	
Activity		✓
Pod	✓	✓
Manage Sensor	✓	✓
Enter BG	✓	✓
Pause Insulin	✓	
Manage Programs & Presets		
Basal Programs	✓	
Custom Foods	✓	✓
History		
History Detail	✓	✓
Notifications	✓	✓
Settings		
General	✓	✓
Reminders	✓	✓

Menu Options	Manual Mode	Automated Mode
Glucose Goal Range	✓	✓
Basal & Temp Basal	✓	
Bolus	✓	✓

About screen

The About screen displays details about your Omnipod 5 System, such as the Omnipod 5 App version number, the Customer Care contact information, the Controller serial number (if viewing on the Controller), the Pod version number, the time of the most recent Omnipod 5 App-Pod communication, and other Controller and legal information.

3.7 Notifications and Messages

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 from 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: 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. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown
- iPhone: Screen Time, Focus Mode, Hide App, Lock App

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 see the Alarm or Notification displayed on the Omnipod 5 App.

Note: The Omnipod 5 App on your smartphone requires Do Not Disturb permission and Notifications to be turned ON to ensure

3 Omnipod 5 System Overview

you always receive important safety alarms. You cannot use the app until Do Not Disturb permission is provided and Notifications is turned ON.


The Omnipod 5 App can deliver Omnipod 5 notifications and confirmation messages.


Omnipod 5 Notifications

Notifications display in order of importance and then based on the order they were received, with the most recent first. Hazard Alarms are most important, followed by Advisory Alarms, Action Item Notifications, and lastly, Reminders.

Alarms

Alarms require your immediate attention (see page 178). If you ignore an alarm, you could develop hypoglycemia or hyperglycemia. When an alarm occurs, the Pod will beep and the Omnipod 5 App will beep or vibrate if sound/vibrate is on.


Hazard Alarms () alert you to a problem with your insulin delivery, Pod, or Omnipod 5 App that requires immediate attention to resolve. Hazard Alarms are accompanied by a continuous tone from the Pod and tone/vibration from the Controller or smartphone running the Omnipod 5 App. Hazard Alarms interrupt anything else the Omnipod 5 App is doing except another Hazard Alarm. For example, a Hazard Alarm is issued if the Pod runs out of insulin.

Advisory Alarms () alert you to some aspect of the Omnipod 5 App or Pod that will need your attention in the near future. For example, if the level of insulin in your Pod is getting low, the Omnipod 5 App issues an Advisory Alarm.

Action Item notifications

Action item notifications (see page 194) are for technical System tasks that should be responded to as soon as possible. Action item notifications are related to changes you may have made to your Omnipod 5 App that could affect safe use of the system. For example, a **Turn on Bluetooth** action item means Bluetooth wireless technology has been shut off and your App is no longer communicating with your Pod.

Reminder notifications

Reminder notifications () remind you about diabetes management actions you may want to perform (see "13.10 Reminder Notifications List" on page 217).

Status

Status notifications appear on the lock screen and display the current system mode and IOB, when available.

Confirmation Messages

In some situations, the Omnipod 5 App will display a green banner at the bottom of the screen that confirms the status of an action. The confirmation message disappears after several seconds.

Tip: Swipe to the right on the message to dismiss it sooner.

If an instruction is not successful, the Omnipod 5 App displays a communication error message (see "Frequently Asked Questions and Troubleshooting" on page 439).

3.8 Manual and Automated Mode Overview

Available tasks in each mode

The following table defines the tasks that can be performed in Manual Mode and Automated Mode.

	Manual Mode	Automated Mode
How it works		
Basal Insulin Delivery	Insulin is delivered according to the Active Basal Program.	Insulin is delivered and adjusted automatically based on sensor glucose values and prediction.
Bolus Insulin Delivery	Insulin is delivered using the SmartBolus Calculator or entered manually.	Insulin is delivered using the SmartBolus Calculator or entered manually.
Connected Sensor	Not required. If connected, sensor glucose values displayed, stored in history, and available for use in SmartBolus Calculator.	Required. Sensor glucose values used for automated insulin delivery, displayed, stored in history, and available for use in SmartBolus Calculator.

3 Omnipod 5 System Overview





	Manual Mode	Automated Mode
What you can do		
Basal Programs	Edit, create new, activate Basal Programs (Does not impact Automated Mode).	Edit Target Glucose to impact automated insulin delivery. Cannot modify Basal Programs in Automated Mode.
Basal Insulin Delivery	Start and cancel Temp Basal Rate	Start and cancel the Activity feature
SmartBolus Calculator Settings	Edit Bolus Settings	Edit Bolus Settings
Bolus Insulin Delivery	Deliver, and cancel Immediate and Extended Boluses	Deliver and cancel Immediate Boluses

	Manual Mode	Automated Mode
What you can do		
Pod Changes	Activate and Deactivate Pods	Deactivate Pods Once deactivated, the system switches to Manual Mode. Pod activation occurs in Manual Mode (after activation, prompt to switch to Automated Mode is displayed)
Manage Sensor	View, and modify Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number Switch between Sensor brands and models (between Pod changes) Start or delete a FreeStyle Libre 2 Plus Sensor, view wear duration, and configure alarm settings	View Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number View FreeStyle Libre 2 Plus Sensor wear duration and configure alarms
Pause and Start Insulin	Manually pause insulin for a specified duration of up to 2 hours. Manually Start insulin.	System automatically pauses automated insulin delivery based on sensor glucose value/prediction. Switch to Manual Mode to manually pause insulin delivery.
History Details	Review History Details	Review History Details
BG Entry	Enter blood glucose readings to save in History Details	Enter blood glucose readings to save in History Details
How you will be notified	See "Alarms, Action and Reminder Notifications" on page 169 for a detailed list of alarms and notifications.	

3 Omnipod 5 System Overview

Identifying System modes

The mode indicator shows Omnipod 5 System's current operating mode.

Graphic	Description
 --	Displays when there is no Pod communication or no active Pod.
 Automated	Displays when the Omnipod 5 System is in Automated Mode and the Pod is providing automated insulin delivery.
 Limited	Displays when the Omnipod 5 System is in Automated Mode: Limited state. The most common reason is that the Pod is not receiving sensor glucose values. In response, the system is delivering basal insulin based on a calculation of user-entered settings and past insulin delivery. Check your Sensor to make sure it is functioning. The position of the Pod and Sensor may also be contributing to the loss of connectivity between the devices.
 Manual	Displays when the Omnipod 5 System is in Manual Mode and delivering the active Basal Program.

CHAPTER 4

Setting Up Your Omnipod 5 Application

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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.

4.1 Setting Up Your Account

To use Omnipod 5, you need to sign in to omnipod.com to enter your therapy and insurance information and schedule your training. If you already have an Omnipod account, use the same Omnipod ID and password.

If you need to create an Omnipod ID:

1. Navigate to <https://omnipod.com/setup>
2. Follow the on-screen instructions to set up your account.

4.2 Preparing for Your Training

If you are a first-time Omnipod user, you may need to meet with your Omnipod 5 Trainer to set up your Omnipod 5 App, first Pod, and your Sensor.

To get a head start on learning about the Omnipod 5 System, review this *Technical User Guide*.

Note: For training information about your Dexcom Sensor, refer to your *Dexcom CGM System Instructions for Use*.

Note: For training information about your FreeStyle Libre 2 Plus Sensor, refer to your *FreeStyle Libre 2 Plus Instructions for Use*.

Omnipod 5 Intro Kit contents

Your initial shipment contains the items you need to begin using the Omnipod 5 System.

The Insulet-provided Omnipod 5 Intro Kit contains:

- Omnipod 5 Controller and Pods
- USB charging cable and adapter
- *User Guide*

After you unpack the shipment, use the "Contents" label on the side of the box to make sure you have everything.

The Dexcom System and supplies must be obtained from Dexcom or an authorized distributor. Refer to the *Dexcom CGM System Instructions for Use*.

The FreeStyle Libre 2 Plus Sensor and supplies must be obtained from Abbott Diabetes Care or an authorized distributor. Refer to the *FreeStyle Libre 2 Plus Sensor Instructions for Use*.

Items needed for your training

- Your Controller or smartphone with Omnipod 5 App and charging cable and adapter
- Your glucose Sensor supplies:
 - For Dexcom G6, your Dexcom G6 Sensor, Transmitter, and Dexcom G6 App
 - For Dexcom G7, your Dexcom G7 Sensor and Dexcom G7 App
 - For FreeStyle Libre 2 Plus, your FreeStyle Libre 2 Plus Sensor
- Two Pods
- The *Technical User Guide* and/or *User Guide*
- BG meter
- Test strips and a lancing device (available from many pharmacies)
- Vial of rapid-acting U-100 insulin (See page 8 for information about the approved types of insulin to use with the Pod)
- Alcohol prep swabs
- Instructions from your healthcare provider with Omnipod 5 App settings tailored to your needs. These settings include Basal Program, Insulin to Carb Ratio, Correction Factor, Target Glucose, and Duration of Insulin Action.

Note: Ensure that your Controller is charged before training begins. To charge your Controller, see "Charging the Battery" on page 226.

4 Setting Up Your Omnipod 5 Application

4.3 Choosing a Controller or Smartphone

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 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.

Before setting up your Omnipod 5 System, decide whether you want to use the Insulet-provided Controller or a compatible personal smartphone for the Omnipod 5 App. You can find a list of compatible smartphones at omnipod.com/compatibility.

If you plan to use the Omnipod 5 App for iPhone, review the *Omnipod 5 User Guide for iPhone* at <http://www.omnipod.com/guides>

If you choose to use the Omnipod 5 App on your smartphone, you will need to sign into the Insulet-provided Controller first to confirm that your healthcare provider has prescribed the use of the Omnipod 5 System. After signing into the Controller and confirming prescription and training requirements, you will be able to sign into the Omnipod 5 App on your smartphone and continue setting up the Omnipod 5 System.

Settings and history are stored on the device (Omnipod 5 Controller or smartphone) that you choose.

Note: Once you have signed into the Controller with your Omnipod ID, you will not be able to sign in using a different Omnipod ID. For example, when resetting a Controller, you will need to use the original Omnipod ID to sign in again and begin setting up your device.

Note: If you are using the FreeStyle Libre 2 Plus Sensor with Omnipod 5, you must use the Insulet-provided Controller and not a smartphone.

4.4 General Settings on Insulet-provided Controller

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.

Note: Tapping the back arrow on the screen returns you to the previous screen. However, tapping the **CANCEL** button in any of these setup steps takes you to the first screen of each section and erases any entries in that section. A pop-up screen warns you that you could lose these entries.

Turning On and Signing in to Your Controller

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.

1. Press and hold the Power button on the right side until the device manufacturer logo appears.
2. Select your language.
3. The Controller runs through a series of checks. If prompted, allow permissions and connect to Wi-Fi. See page 197 for more details.

Note: The SIM Card on your Omnipod 5 Controller enables data to be sent and received via the AT&T wireless network when your Controller is not connected to a Wi-Fi network. If you stop using the Omnipod 5 App over a cellular network on your Controller, Insulet may deactivate the SIM Card. Please note that the Controller is still functional using Wi-Fi. If you return to using the Omnipod 5 App on your Controller after a significant period of time, please contact Customer Care to request SIM card reactivation for full coverage via both cellular network and Wi-Fi. Upon request, the SIM card is reactivated.

4 Setting Up Your Omnipod 5 Application

4. Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:

- a. Tap the **HIPAA Privacy Notice, EULA, ToU, and Warranty** link to read the Omnipod 5 System's legal notices and privacy policy. Then tap **AGREE**.

A checkmark is added to the checkbox to indicate agreement.


- b. Tap **CONTINUE**.

Note: If you are under 18, your parent or guardian must accept for you.

5. Sign in with your Omnipod ID:

- a. Enter your username.
- b. Enter your password.
- c. Tap **SIGN IN**.

Note: The username and password are case-sensitive.



☒ I certify I am 18 years old or older and I acknowledge that I have read and accept the **HIPAA Privacy Notice, EULA, ToU, and Warranty**. If you are under 18, your parent or guardian must accept on your behalf.

CONTINUE

Setting Up Training


After signing into the Controller, you will be prompted to schedule or confirm training for the Omnipod 5 System. Training is critical to the safe and effective use of the Omnipod 5 System.

- Review the training options provided and tap the option that applies to you.

After tapping the training option:

- If you tap **I will schedule training:**
 - You will be provided 3 options to schedule training. Once completed, tap **OK**.
- If you tap **I am in training or I completed training:**
 1. Read the terms and conditions and tap the checkbox to agree.
 2. Tap **CONTINUE**.
- If you tap **I decline training:**
 1. Read the terms and conditions and tap the checkbox to agree.
 2. Tap **CONTINUE**.

After signing into your Controller, you may continue setting up your Omnipod 5 System on your Controller, or sign into the Omnipod 5 App on your smartphone. If you intend to use your smartphone for the Omnipod 5 App, continue to "4.5 General Settings on Your Smartphone" on page 75. You do not need to continue with any further Controller setup at this time.



DO NOT PROCEED

You must complete training before you can use this product!

Have you been trained to:

- ✓ Set up and change your Pod
- ✓ Create and edit your Basal Program
- ✓ Calculate your bolus
- ✓ Pause your insulin delivery
- ✓ Respond to your system alarms and notifications
- ✓ Set up Omnipod 5
- ✓ Connect your Sensor to Omnipod 5

These are critical to the safe and effective use of this product

Please select one of the following:

I will schedule training

I am in training

I completed training

I decline training

4 Setting Up Your Omnipod 5 Application

Setting Up Your Controller

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.

Personalize your Controller

Follow the steps below to personalize your Controller.

1. Enter a personalized screen message (at least two characters), tap **Done**, then tap **CONTINUE**.

A screen appears showing several background images.

2. Swipe right or left to see more images. Tap on your preferred image, then tap **CONTINUE**.

Note: When you wake up your Controller, you will see your personalized screen message and background image. Always confirm that the Controller is yours before using it.

Setting the PIN on your Controller

To protect against unintended use or screen touches, you must create a 4-digit personal identification number or PIN.

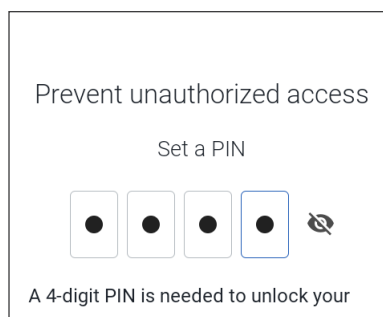
To set a PIN:

1. Choose 4 numbers to be your PIN. You will use this PIN every time you wake up your Controller. You may want to record the PIN in a safe place.

Tip: To keep the PIN visible, tap the eye icon located to the right of the PIN entry fields. To hide the number, tap the eye icon again.

2. Tap a field to display the number pad. Enter your 4-digit PIN. Tap **Done**.
3. Enter the same 4 numbers again to confirm your PIN. Tap **Done**.

If the second PIN entry does not match the first, you must repeat the above steps.



Enabling Notifications and Sound on Your Controller

1. Read the message explaining the importance of enabling Omnipod 5 App notifications. You cannot enter or use the app if you turn notifications off.

➤ Tap **I UNDERSTAND**.

Notifications

To use the Omnipod 5 app, keep Notifications on. Notifications alert you when an issue needs your attention. You cannot use the app if you turn off Notifications.

I UNDERSTAND

2. Read the message explaining the importance of enabling sound on your Omnipod 5 App. If you do not have sound enabled, you may miss important messages.

➤ Tap **I UNDERSTAND**.

If you do silence your device, the Omnipod 5 App will still be able to sound for important alerts and alarms, such as Urgent Low glucose. Your Pod will not be silenced.

Sound

Avoid setting your controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms or notifications from your Omnipod 5 App.

The Pod will still sound, and you will be able to see the alarm or notification in the App.

I UNDERSTAND

4.5 General Settings on Your Smartphone

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.

Note: Tapping the back arrow on the screen returns you to the previous screen. However, tapping the **CANCEL** button in any of these setup steps takes you to the first screen of each section and

4 Setting Up Your Omnipod 5 Application

erases any entries in that section. A pop-up screen warns you that you could lose these entries.

If you choose to use the Omnipod 5 App on your smartphone, you will need to sign into the Insulet-provided Controller first to confirm that your healthcare provider has prescribed the use of the Omnipod 5 System. After signing into the Controller and confirming prescription and training requirements, you will be able to sign into the Omnipod 5 App on your smartphone and continue setting up the Omnipod 5 System.

If you intend to use your smartphone for the Omnipod 5 App and have not yet signed into your Insulet-provided Controller, see "Setting Up Your Omnipod 5 Application" on page 67.

Using the Omnipod 5 App on Your Smartphone

If you use your smartphone, you will need to download the Omnipod 5 App from Google Play.

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). If you do not know what an App is, do not install it, regardless of the source.

It is not advised to install any App from a source other than Google Play on your smartphone that is running the Omnipod 5 App. Doing so may put you at risk of unintentionally installing malware on your device.

Malware, or "malicious software" from unknown third-parties, is designed to damage your device and/or read your private information. Unknown apps and unknown downloads are the most common method for spreading malware. Malware could prevent the Omnipod 5 System from functioning as intended, causing over-delivery or under-delivery of insulin, which could lead to hypoglycemia or hyperglycemia.

The Omnipod 5 App performs a check to ensure that your device is not rooted or jailbroken. If the Omnipod 5 App determines your device is, you will be blocked from Omnipod 5 App use.


If you believe you may have an app installed from a third-party source, take steps to delete that app. If you believe you may have malware on your device, discontinue use of your Omnipod 5 System and use an alternate means of insulin delivery until you can resolve. Delete any apps installed from a third-party source, restore your phone to factory default settings, and contact Insulet Customer Care.

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.

Note: ALWAYS check that your smartphone has at least 150 MB of free storage space for the Omnipod 5 App to work and save important information regarding your insulin therapy. If your smartphone does not have enough free space, you will not be able to use the Omnipod 5 App and you will be prompted to free up smartphone storage.

Required smartphone settings

The Omnipod 5 System relies on some of your smartphone’s settings to function. If these settings are not correctly set, the app will navigate you to your smartphone’s settings menu, and you will not be able to use the app until the setting is correctly enabled or disabled.

Follow the setting requirements below to ensure the Omnipod 5 System works as intended. To change your settings on an Android phone, find the Settings App, and then tap the gear icon() labeled Settings.

Required Setting	Android Settings menu location	ON or OFF
Bluetooth	“Connections” or “Connected devices”	ON
Automatic date and time	“General management” or “System”	ON
Battery optimization	“Battery and device care” or “Battery”	OFF
Location	“Location”	ON (required during Pod activation)
Smartphone security	“Biometrics and security” or “Security and screen lock”	ON
Notifications	“Notifications” or “apps & notifications”	ON
Permission to override Do Not Disturb	“Do not disturb permission”	ON



4 Setting Up Your Omnipod 5 Application

Recommended smartphone settings

Follow the recommended settings below to improve your experience using the Omnipod 5 System. If these settings are not set as recommended, the app will periodically alert you and give you the option to navigate to your smartphone's settings menu to enable the setting.

Recommended Setting	Android Settings menu location	ON or OFF
Location	"Location"	ON (recommended for daily use)
Network connectivity (Wi-Fi or cellular)	"Connections" or "Network & internet"	ON

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.

Tip: To see notifications without unlocking your smartphone, make sure your smartphone settings allow Omnipod 5 App notifications to show on your Lock Screen.

Signing in to the Omnipod 5 App on Your Smartphone


1. Select your language.
2. Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:

- a. Tap the **HIPAA Privacy Notice, EULA, ToU, and Warranty** link to read the Omnipod 5 System's legal notices and privacy policy. Then tap **AGREE**.

A checkmark is added to the checkbox to indicate agreement.

- b. Tap **CONTINUE**.

Note: If you are under 18, your parent or guardian must accept for you.



☒ I certify I am 18 years old or older and I acknowledge that I have read and accept the **HIPAA Privacy Notice, EULA, ToU, and Warranty**. If you are under 18, your parent or guardian must accept on your behalf.

CONTINUE

3. Sign in with your Omnipod ID:

- a. Enter your username.
- b. Enter your password.
- c. Tap **SIGN IN**.

Note: The username and password are case-sensitive.

Setting Your Omnipod 5 App Security (on Your Smartphone)

Use of the Omnipod 5 App on your phone requires that you select a screen lock type and set security options on your phone to protect against unintended use and accidental therapy changes. This feature can be enabled from your phone's Settings. From the Home screen, swipe up and tap Settings to access Settings.

If someone other than you uses or has regular access to your phone (e.g., your child, partner, roommate), they may unintentionally access the Omnipod 5 App, which could result in unintended changes to your therapy. Changes to your therapy can result in over-delivery or under-delivery of insulin, which could lead to hypoglycemia and hyperglycemia.

To prevent unintended access, the Omnipod 5 App will require you to enter your phone's PIN (or other selected security method) each time you access the Omnipod 5 App.

Omnipod 5 Security cannot be turned off.

After you've signed in to the Omnipod 5 App on your smartphone for the first time, the Security screen will appear.

1. Read the **Lock Screen Security** screen.

➤ Tap **I UNDERSTAND**.

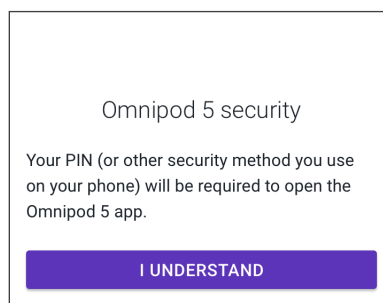
If you do not have a security method on your smartphone, you will be prompted to create one to continue setting up your Omnipod 5 App.

1. Tap **SET UP SECURITY** to continue.

2. You will be taken to your smartphone's screen lock settings screen. Select your desired security method and complete security setup.

3. After you successfully set your security method, you will see the **Omnipod 5 Security** screen on the Omnipod 5 App.

➤ Tap **I UNDERSTAND**.



4 Setting Up Your Omnipod 5 Application

Enabling Additional Settings on Your Smartphone

Use of Omnipod 5 on your smartphone requires certain settings to be enabled on your smartphone.

Setup screens will guide you through the specific settings for your smartphone's operating system.

Tap **I UNDERSTAND** to acknowledge each screen.

If you change these settings later, you may not be able to use your Omnipod 5 App until you change them back. The Omnipod 5 App checks for required settings and will notify you if it finds a problem with your settings.

4.6 Basal Settings

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.

Next, you will set basal settings which will be used to deliver basal insulin while in Manual Mode.

1. Tap **SET UP PROFILE**.
2. Tap the arrow (➤) on the Basal screen to move to the next screen.

Set Maximum Basal Rate

The Maximum Basal Rate sets the upper limit of any basal insulin rate you can use while in Manual Mode.

- 1. Tap the **Max Basal Rate** field.
- 2. Scroll to your desired Maximum Basal Rate. When the correct number is in the center of the scroll wheel, tap the number to select it.

Tip: Alternatively, tapping outside of the scroll wheel selects the value in the center of the scroll wheel.

- 3. Tap **NEXT**.

Note: You can adjust your Maximum Basal Rate later, if your needs change. See "Maximum Basal Rate" on page 148.

← Setup: Basal

Set Maximum Basal Rate

Upper limit for basal rates in a Basal Program or temp basal.

(You can adjust this rate later if your needs change)

Max Basal Rate

(0.05 to 30 U/hr)

U/hr

Create a Basal Program

The next step is to create a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Basal Programs" on page 113.

- Tap **NEXT** on the Create Basal Program description screen to continue.

Name the Basal Program

The default name for the Basal Program is **Basal 1**.

- 1. To change the name, tap the **Program Name** field and enter the new name, then tap **Done**.
- 2. Tap **NEXT**.

← Setup: Basal

Program Name

Basal 1



4 Setting Up Your Omnipod 5 Application

Define the segments

You can create up to 24 segments within your midnight to midnight Basal Program. The **Start Time** for the first segment is always 12:00 AM.

1. Tap the **End Time** field and scroll to select the desired end time.
2. Tap the **Basal Rate** field and scroll to select the basal rate for the segment.

Note: The Maximum Basal Rate that you entered earlier is displayed under the **Basal Rate** text. You cannot enter a basal rate greater than this number.

Note: The two vertical blue lines on the graph near the top of the screen show the start and end time for the basal segment. The selected basal rate for the segment is shown between the two vertical lines.

3. Check the values of your start and end times and the basal rate. Then tap **NEXT**.
4. If the Basal Program does not cover 12:00 AM-12:00 AM, you must add additional segments. Repeat steps 1–3 as needed until your final segment ends at midnight.

← Setup: Basal

Weekday: Segment 1 Graph: U/hr

12am 12am

Start 12:00 AM End -- --

Night

Basal Rate (up to 30 U/hr)

-- -- U/hr

CANCEL NEXT

Review the Basal Program

The next screen summarizes the start and end times, and basal rate for each segment of the Basal Program.

1. Tap CONTINUE to review your Basal Program.

2. Check that the graph and the individual segment values are correct.

The total daily amount of basal insulin to be delivered by this Basal Program is listed below the graph.

3. To change an end time or basal rate for a segment:
 - a. Tap the row containing the segment you would like to change.
 - b. Tap the **End Time** field and enter the new end time for the segment.
 - c. Tap the **Basal Rate** field and enter the desired basal rate.
 - d. Tap **NEXT**.
 - e. Set the end time and basal rate for any following segments, as needed.

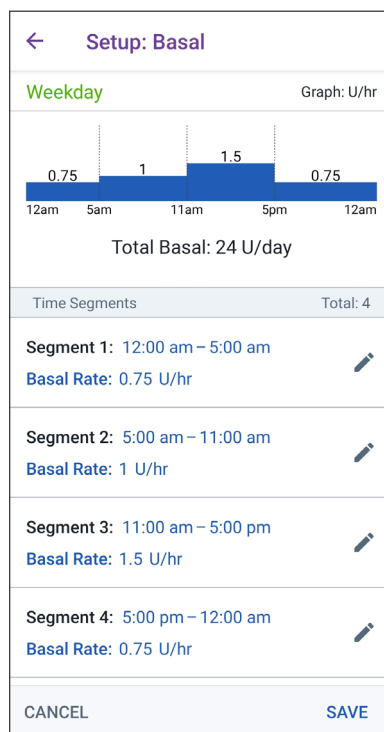
4. When the Basal Program is correct, tap **SAVE**.

5. To add a new segment:

- a. Tap the row containing the start time of the new segment.
- b. Tap the **End Time** field and enter the start time of the new segment as the end time of this segment.
- c. Change the basal rate, if necessary.
- d. Tap **NEXT**.
- e. Set the end time and basal rate for any following segments, as needed.

6. To delete a segment:

- a. Note the end time of the segment you want to delete.
- b. Tap the segment before the segment you want to delete.



4 Setting Up Your Omnipod 5 Application

- c. Tap the **End Time** field and enter the end time of the segment you want to delete. This 'overwrites' the segment you want to delete.
 - d. Tap **NEXT**.
 - e. Set the end time and basal rate for any following segments, as needed.
7. When the Basal Program is correct, tap **SAVE**.

Note: If the basal rate for a segment is 0 U/hr, the Omnipod 5 App displays a message calling this to your attention. Tap **OK** if the 0 U/hr rate is correct. Otherwise, tap **CANCEL** and edit the segment with the 0 U/hr rate.

Note: To create additional Basal Programs after setup is complete, start at page 115 and begin steps again.

Temporary Basal Configuration

For a description of temporary basal rates, also called temp basals, see page 119.

Note: Temp basal is available in Manual Mode only.

1. If you want the ability to use temp basals, tap the toggle to the ON position. The toggle is in the ON position when it is on the right and is blue.

If you turn temp basals on, percentages are used by default. To specify temp basal as a flat rate (U/hr), see "Temp Basal" on page 148.

2. Tap **NEXT**.

← Setup: Basal

Allow temporary basal rates?

A temp basal changes your basal rate for a set period of time.

Temp Basal ☒ On

Temp basals are set to change basal rates by a percentage. You can change this to a flat rate (U/hr) in Settings.

CANCEL NEXT

4.7 Bolus Settings

Next, you will set Bolus Settings that will be used to calculate a bolus in the SmartBolus Calculator. You can adjust your bolus settings later, if your needs change (see "17.11 Bolus Settings" on page 270 for more information).

1. Tap the arrow (➤) on the Bolus screen to move to the Target Glucose & Correct Above description screen.
2. Tap **NEXT** to move to the segment screen.

Target Glucose and Correct Above Values

Target Glucose and Correct Above values are used in both Automated and Manual Modes.

- In Automated Mode, your insulin delivery will be adjusted automatically to bring your glucose towards your Target Glucose value.
- In both Automated and Manual Modes, the SmartBolus Calculator aims to bring your glucose to the Target Glucose value. The SmartBolus Calculator delivers a correction bolus if the current glucose value is higher than the Correct Above value.

Define the segments

You can establish up to eight different blood glucose targets for different times of day. To set Target Glucose and Correct Above values for each segment:

1. Tap the **End Time** field and specify an end time for the segment.
2. Tap the **Target Glucose** field and specify the Target Glucose for that segment.
3. Tap the **Correct Above** field and specify the Correct Above value for that segment.
4. Review and tap **NEXT**.

←

Setup: Bolus

Segment 1

Start

End

12:00 AM

-

9:00 AM

Night

Morning

Target Glucose

(110 to 150 mg/dL)

110 mg/dL

Correct Above

(Target Glucose to 200 mg/dL)


120 mg/dL

CANCEL



NEXT

4 Setting Up Your Omnipod 5 Application

- Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
- Review the segments for the full 24-hour profile.
- To change any of the entries:
 - Tap the row containing the entry to be changed and enter the corrected value.
 - Review and correct as needed any remaining segments.
- When the segments and values are correct, tap **SAVE**.

 **Setup: Bolus**

Review the Target Glucose and Correct Above values entered for each time segment.

Time Segments	Total: 3
Segment 1: 12:00 AM – 9:00 AM	
Target Glucose: 110 mg/dL 	
Correct Above: 120 mg/dL	
Segment 2: 9:00 AM – 12:00 PM	
Target Glucose: 120 mg/dL 	
Correct Above: 120 mg/dL	
Segment 3: 12:00 PM – 12:00 AM	
CANCEL	SAVE

Insulin to Carb (IC) Ratio


Your Insulin to Carbohydrate Ratio, or "IC Ratio," defines how many carbohydrates are covered by one unit of insulin.

The SmartBolus Calculator uses the IC Ratio to calculate the meal portion of a suggested bolus. You can create up to eight IC Ratio segments per day.

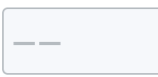
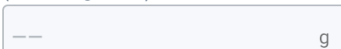
- Tap **NEXT** on the Set Insulin to Carb (IC) Ratio description screen to move to the Insulin to Carb Ratio segment screen.

Define the segments

- Tap the **End Time** field and specify an end time for the segment.
- Tap the **1 Unit of insulin covers** field and specify the IC Ratio value for the segment.
- Tap **DONE** to close the number pad.
- Review and tap **NEXT**.

 **Setup: Bolus**

Segment 1

Start	End
12:00 AM	
Night	
1 Unit of insulin covers (1 to 150 g carbs)	
 g	

- 5. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
- 6. Review your 24-hour IC Ratio segments.
- 7. To change any of the entries:
 - a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
- 8. When the segments and values are correct, tap **SAVE**.

← Setup: Bolus

Review the Insulin to Carb (IC) Ratio values entered for each time segment.

Time Segments	Total: 4
<div>Segment 1: 12:00 AM – 6:00 AM</div> <div>1 U of insulin covers: 10 g of carbs</div>	
<div>Segment 2: 6:00 AM – 11:00 AM</div> <div>1 U of insulin covers: 8 g of carbs</div>	
<div>Segment 3: 11:00 AM – 5:00 PM</div> <div>1 U of insulin covers: 9 g of carbs</div>	
<div>Segment 4: 5:00 PM – 12:00 AM</div> <div>1 U of insulin covers: 10 g of carbs</div>	
CANCEL	SAVE

Correction Factor

Your Correction Factor defines how much one unit of insulin lowers your glucose. For example, if your Correction Factor is 50, one unit of insulin lowers your glucose by 50 mg/dL.


The SmartBolus Calculator uses the Correction Factor to calculate the correction portion of a suggested bolus. You can create up to eight Correction Factor segments per day.

- Tap **NEXT** on the Set Correction Factors description screen to move to the segment screen.

4 Setting Up Your Omnipod 5 Application

Define the segments

1. Tap the **End Time** field and specify an end time for the segment.
2. Tap the **1 Unit of insulin lowers glucose by** field and specify the Correction Factor for this segment.
3. Review and tap **NEXT**.
4. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
5. Review the segments for the full 24-hour profile.
6. To change any of the entries:
 - a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
7. When the segments and values are correct, tap **SAVE**.

 **Setup: Bolus**

Segment 1


Start

End





12:00 AM -

Night

1 Unit of insulin lowers glucose by
(1 to 400 mg/dL)

 **Setup: Bolus**

Review the Correction Factor values entered for each time segment.

Time segments	Total: 4
Segment 1: 12:00 am - 5:00 am 1 U of insulin lowers glucose by: 55 mg/dL	
Segment 2: 5:00 am - 9:00 am 1 U of insulin lowers glucose by: 40 mg/dL	
Segment 3: 9:00 am - 12:00 pm 1 U of insulin lowers glucose by: 47 mg/dL	
Segment 4: 12:00 pm - 12:00 am 1 U of insulin lowers glucose by: 55 mg/dL	

CANCEL

SAVE

Duration of Insulin Action

The Duration of Insulin Action is the length of time that insulin stays active in your body. The SmartBolus Calculator uses this setting to determine how much insulin remains in your body from previous boluses (called insulin on board or IOB).

- 1. Tap the **Duration of Insulin Action** field and scroll to select your Duration of Insulin Action.
- 2. Tap **NEXT**.

← Setup: Bolus

Set Duration of Insulin Action

The length of time that insulin remains active and available in your body after a correction or meal bolus.

Duration of Insulin Action

(2 to 6 hrs)

— —

hrs

CANCEL

NEXT

Maximum Bolus

The Omnipod 5 App will not let you request a bolus above the Maximum Bolus setting. You will see a message if the SmartBolus Calculator calculates a bolus that is above this amount.

- 1. Tap the **Max Bolus** field and enter your Maximum Bolus. Tap **DONE** to close the number pad.
- 2. Tap **NEXT**.

← Setup: Bolus

Set Maximum Bolus

The maximum amount of insulin that you can request in a single bolus.

Max Bolus

(0.05 to 30 U)

— —

U

89

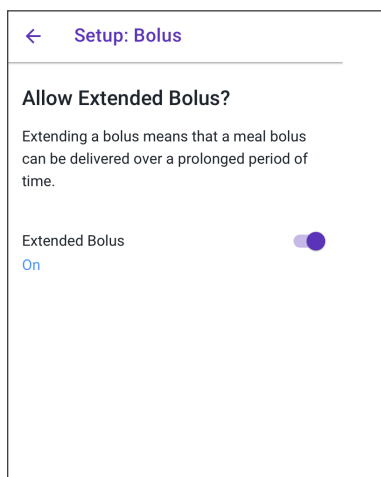
4 Setting Up Your Omnipod 5 Application

Extended Bolus

Extending a bolus allows you to give a portion of the bolus dose at the beginning of the meal with the remainder of the bolus dose dripped over a chosen period of time.

Note: Extended bolus is available in Manual Mode only.

1. Toggle the Extended Bolus button to turn the extended bolus feature **ON** or **OFF**.
2. Tap **NEXT**.



4.8 Your App Setup is Complete

Congratulations! Omnipod 5 App setup is complete.

When you are ready to connect your Sensor to the Omnipod 5 System. See Chapters 19, 20, and 21 for instructions on connecting your Sensor to the System.

When you are ready to activate your first Pod, go to "5.1 Beginning the Pod Activation Process" on page 94.

4.9 Saving Your Settings for Reference

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: 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 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: 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.

Before you begin using your Omnipod 5 App, write down or take photos of all your settings and keep them in a secure location that you can reference in the future. This list will be helpful if you ever need to go through the setup process again and re-enter your insulin therapy settings.

You will lose all your insulin therapy settings and insulin history if you do any of the actions listed below:

- Get a new Controller.
- Reset your Controller.
- Switch from using the Controller to using the Omnipod 5 App on your smartphone.
- Reset the Omnipod 5 App on your smartphone.
- Clear the Omnipod 5 App data on your smartphone.
- Delete the Omnipod 5 App from your smartphone.

Tip: Use the pages at the end of this *Technical User Guide* to write down all of your settings. This list will be helpful if you ever need to replace your Controller or re-install the Omnipod 5 App.

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CHAPTER 5

Activating and Changing Your Pod

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5 Activating and Changing Your Pod

5.1 Beginning the Pod Activation Process

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.

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: 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 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.

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: 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: 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 contact Customer Care for support.

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.

After initial Omnipod 5 App setup, you will activate your first Pod. Your Pod should be changed at least once every 48 to 72 hours (2 to 3 days) or after delivering 200 units of insulin. Consult with your healthcare provider to determine if you should change your Pod more often.

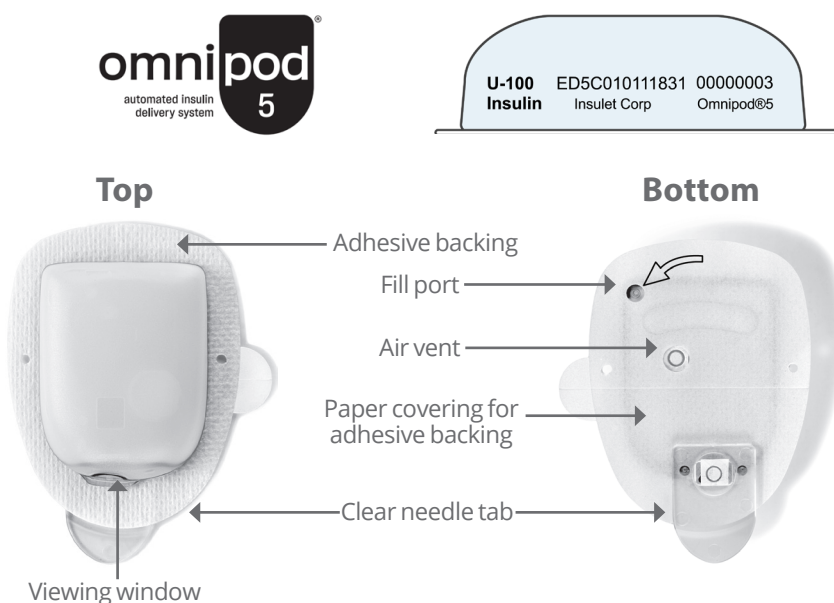
Before activating a Pod, do the following:

1. Gather the necessary supplies:
 - A vial of rapid-acting U-100 insulin cleared for use in the Omnipod 5 System. See "1.4 Compatible Insulins" on page 8 for a list of the approved insulin types that can be used with the Omnipod 5 System
 - An unopened Omnipod 5 Pod
 - Alcohol prep swabs
 - Controller or smartphone with Omnipod 5 App
2. Wash your hands before starting and keep them clean throughout the Pod change process.

5 Activating and Changing Your Pod

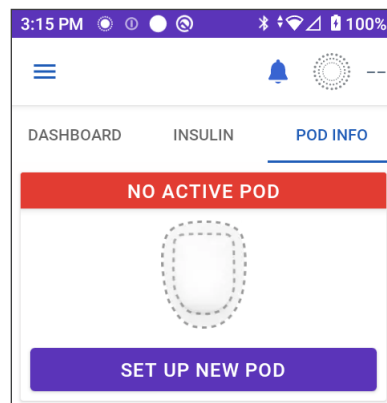
3. Check the insulin for signs of deterioration according to the manufacturer's instructions for use.
4. Check the Pod's packaging for damage. If undamaged, open it and inspect the Pod for signs of damage.
5. If the insulin or Pod is below 50°F (10°C), allow it to warm up to room temperature before proceeding.

Confirm that you are using an Omnipod 5 Pod prior to beginning Pod activation. Look for the Omnipod 5 logo on the Pod tray lid and the words "Omnipod 5®" on your Pod. Check the Pod tray lid and Pod box for compatibility with the Sensor you will use with Omnipod 5.



5.2 Setting Up a New Pod

1. Navigate to:
Menu button (≡) > Pod
or
Home > POD INFO
2. Tap **SET UP NEW POD**.



Turn on location access

If you are using the Omnipod 5 App on your smartphone, location permission must be allowed and location setting must be turned on to activate a Pod. If you deny the permission or turn off the setting, you will be prompted to turn it on to activate a Pod.

- If your location setting is off, tap **CONTINUE** and turn on your location setting.
- If your location access has been denied previously, or you are setting up your first Pod, you will be prompted to allow the Omnipod 5 App to access your location. Tap **CONTINUE** and allow access.

Note: If you have previously selected "Deny & don't ask again," you will need to tap **APP INFO** to allow the permission in your smartphone settings.

Allow location access during Pod activation

Omnipod 5 needs location access to activate a Pod.

Go to App Info > Permissions, and **Allow** location access.

[CANCEL](#) [APP INFO](#)

Allow location access during Pod activation

Omnipod 5 needs location access to activate a Pod.

Allow location access.

[CANCEL](#) [CONTINUE](#)

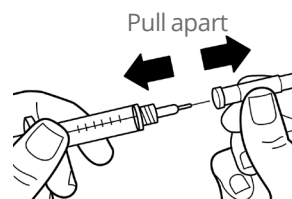
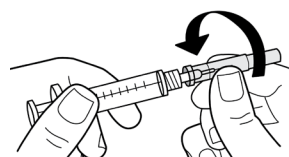
5 Activating and Changing Your Pod

5.3 Fill the Syringe with Insulin

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.

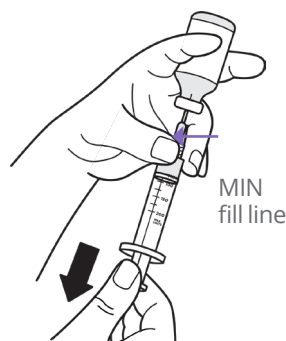
The next step is to fill the syringe that came with the Pod (the "fill syringe") with insulin:

1. Use an alcohol prep swab to clean the top of the insulin vial.
2. Securely twist the fill needle onto the fill syringe.
3. Pull outward to remove the protective cap from the needle.
4. Determine how much insulin you will put into the Pod. For example, to use the Pod for 72 hours, determine how much insulin you will use over the next 72 hours. Your healthcare provider can help you determine the correct amount.



Note: The Pod requires a minimum of 85 units of U-100 insulin to begin operation. The Pod can deliver up to 200 units of U-100 insulin.

5. Draw air into the fill syringe up to the amount of insulin you want.
6. Insert the needle into the insulin vial and inject the air. Injecting air makes it easier to withdraw insulin from the vial.
7. Turn the vial of U-100 insulin and the fill syringe upside down. Pull down on the plunger to withdraw the desired amount of insulin from the vial into the fill syringe.
 - Fill the syringe at least to the MIN (minimum) fill line.
 - To fill the Pod with enough insulin to deliver 200 units, pull the plunger down until it stops. This will be below the 200 mark.



8. With the needle still in the vial, flick the side of the syringe with your fingertip to dislodge any air bubbles so they collect at the top of the syringe. Then push in the plunger to expel any air bubbles out of the syringe and into the insulin vial. Pull down on the plunger again, if necessary, to refill the fill syringe to the desired amount of insulin.
9. Remove the needle from the vial.

5.4 Filling, Activating, Applying, and Starting the Pod

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: 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.

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.

5 Activating and Changing Your Pod

Fill the Pod with Insulin

To fill the Pod with insulin (screen step 1)

1. Locate the arrow on the underside of the Pod. The arrow points to the insulin fill port.

Tip: You can leave the Pod in its tray during filling and activating.

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

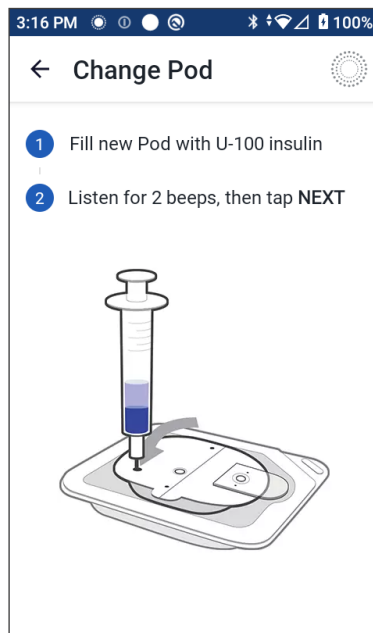
Listen for two beeps from the Pod during the filling process (screen step 2):

4. Be sure to completely empty the fill syringe, even after hearing the two beeps.

Note: The Pod must contain a minimum of 85 units of insulin to function. The Pod beeps twice after it has been filled with 85 units of insulin. If you filled the Pod with more than 85 units and still do not hear the two beeps, contact Customer Care.

Note: After filling the Pod, continue to the next step immediately. If two hours pass before activating the filled Pod, the Pod becomes unusable.

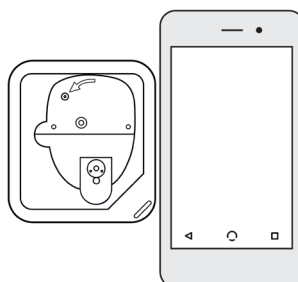
5. Remove the needle from the insulin fill port. The port is self-sealing; insulin will not leak after the needle is removed.
6. Discard the fill needle in a sharps container.



Activate the Pod

To activate the Pod:

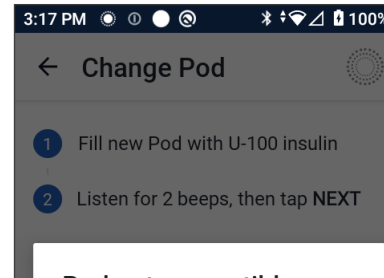
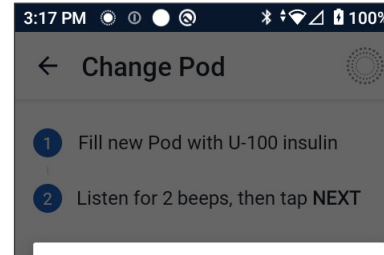
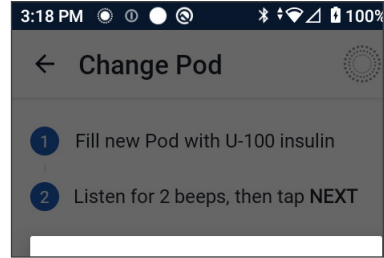
1. Place the Controller or smartphone running the Omnipod 5 App next to the Pod so they are touching. The Pod should be in its plastic tray during this process.



Note: ALWAYS ensure that no other Pods are being activated near your Omnipod 5 App before filling a Pod.

2. Tap **NEXT**.

- If more than one, non-paired, filled Omnipod 5 Pod is in range, the Omnipod 5 App informs you of this and prevents you from completing activation. Move away from any other filled Omnipod 5 Pod and tap **TRY AGAIN**.
- Only Omnipod 5 Pods are compatible with the Omnipod 5 System. If you try to use an older Pod that cannot communicate with the system, the Omnipod 5 App informs you of this and prevents you from completing activation. Tap **DISCARD POD** and restart Pod activation with an Omnipod 5 Pod.
- If the Omnipod 5 App is able to communicate with the Pod but detects an incompatible Pod, the Omnipod 5 App informs you of this and prevents you from completing activation. Tap **DISCARD POD** and restart Pod activation with an Omnipod 5 Pod.



3. Listen for the tone from the Omnipod 5 App that indicates the Pod is activated and ready to be applied.

Note: After activating a Pod, the Omnipod 5 App should always be able to communicate with a Pod that is up to 5 feet (1.5 meters) away. Depending on the location, the Omnipod 5 App may be able to communicate with a Pod that is as much as 50 feet (15 meters) away.

Note: After activating, the Pod beeps every 5 minutes until you apply it. If you do not apply it and do not begin insulin delivery within 60 minutes after activating, the Pod becomes unusable.

If you see a communication error message when you attempt to activate your Pod, and you are not using an older Pod, see "Error when activating a Pod" on page 461.

5 Activating and Changing Your Pod

Prepare the Pod Site

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.

Select the Pod infusion site (screen step **3**):

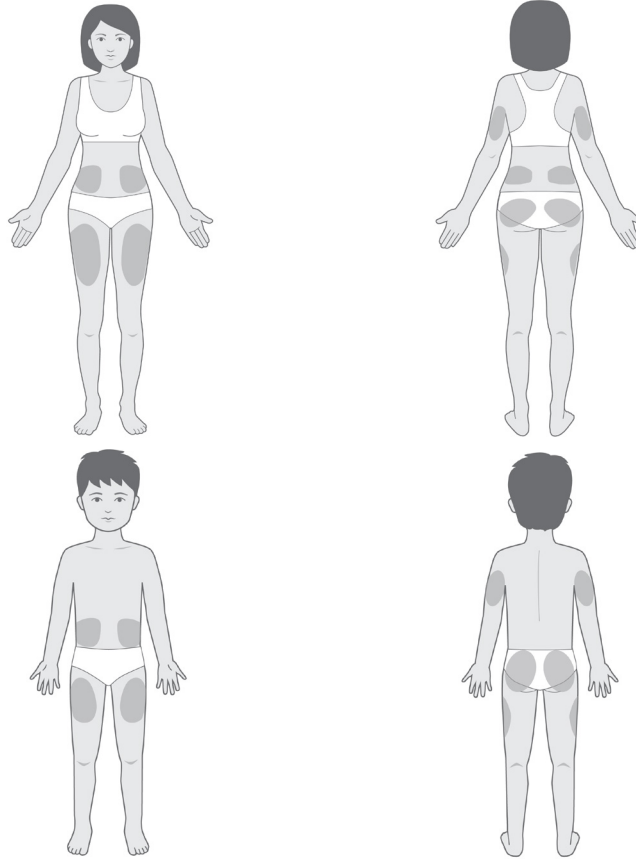
Guidelines for Pod site selection

Discuss suitable Pod placement sites with your healthcare provider using the following guidelines:

- Place your Pod and Sensor as indicated in the Instructions for Use for your compatible Sensor.
 - at least 3 inches (8 cm) apart for your Dexcom Sensor
 - at least 1 inch (2.5 cm) apart for your FreeStyle Libre 2 Plus Sensor
- Place within line of sight of the Sensor for the best connectivity. See "19.2 Dexcom Sensor Placement" on page 303. See "21.2 FreeStyle Libre 2 Plus Sensor Application and Placement" on page 331.

Note: Line of sight means that the Pod and Sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.
- Ideal sites have a layer of fatty tissue.
- Ideal sites offer easy access and viewing.
- The site should be at least 1 inch (2.5 cm) away from the previous site to avoid skin irritation.
- The site should be at least 2 inches (5 cm) away from your navel.
- Avoid sites where belts, waistbands, or tight clothing may rub against or dislodge the Pod.
- Avoid sites where the Pod will be affected by folds of skin.
- Avoid placing the Pod over a mole, tattoo, or scar, where insulin absorption may be reduced.
- Avoid areas of the skin with an active infection.

Pod site examples

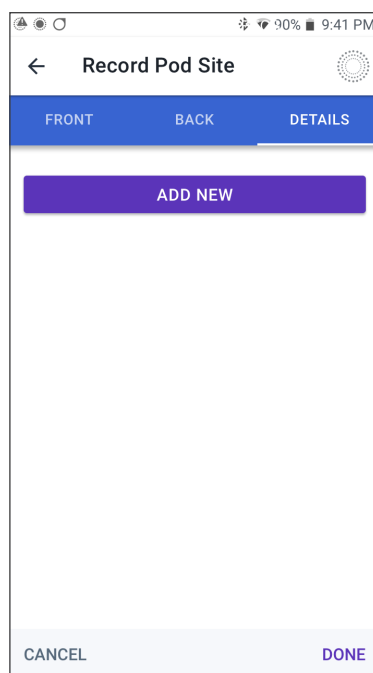
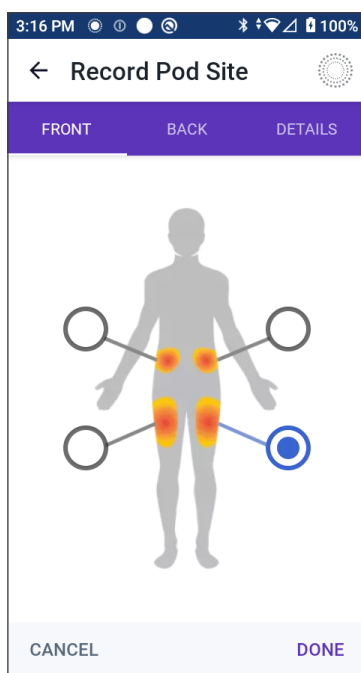


Pod site map (optional)

The Pod site map is an optional feature that helps you track your current and recent Pod site locations.

1. Tap **RECORD POD SITE** to bring up the Record Pod Site screen.
2. Tap the **FRONT** or **BACK** tab to select an area of your body for your Pod. To help you avoid recent Pod sites, the screen shows the two most recent dates that each site was selected.
3. Tap a circle to indicate the location on your body where you will place your new Pod. A blue dot appears inside the selected circle. Tap again to deselect the location.
4. Tap the **DETAILS** tab to add a detail about the placement of this Pod. For example, you could add a detail that says "Facing up" or "Facing down" to describe the Pod's orientation.

5 Activating and Changing Your Pod



- To add a new detail, tap **ADD NEW** and type in the new detail. Tap **ADD** when done. The new detail is added to the list.
- Select a detail for the new Pod by tapping the circle next to that detail. You may only add one detail for each Pod. Tap again to deselect the detail.

Note: To delete a site detail, tap the  next to the detail.

- Tap **DONE** when finished to return to the Change Pod screen.

Prepare the infusion site

To reduce the risk of infection at the infusion site:

- Wash your hands with soap and water.
- Wash your selected infusion site with soap and water.
Note: Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare provider how to treat any skin irritation.
- Dry the infusion site with a clean towel.
- Use an alcohol prep swab to disinfect the infusion site. Start at the center of the site and gently rub outward in a circular motion.
- Let the infusion site air-dry thoroughly. Do not blow on the site to dry it.

Remove the Pod's Tab

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.

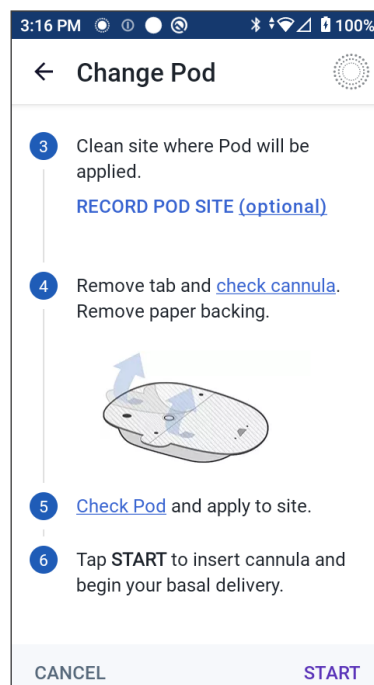
Remove the Pod's tab (screen step 4):

1. Turn the Pod so the tab is up and facing you.
2. Place your thumb on the bottom (flat edge) of the tab and pull the tab upwards. The tab snaps off. Throw the tab away.

When you remove the tab, a drop of insulin may be visible at the end of the cannula or in the well.

3. If any of the following apply, tap **CANCEL**, and then dispose of the Pod and begin again with a new Pod:
 - The Pod is accidentally dropped, as this could mean the Pod is no longer sterile.
 - The Pod or its adhesive pad is wet, dirty, or damaged.
 - The cannula extends beyond the adhesive backing when the tab is removed.

4. Using the pull tabs, remove the white paper backing covering the adhesive pad. Be careful not to remove the adhesive pad itself. Do not allow the adhesive to fold back on itself.



Apply the Pod

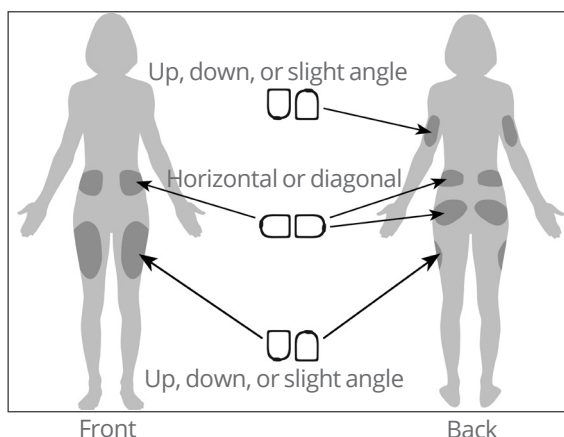
Inspect and apply the Pod (screen step 5):

1. Examine the Pod. Tap **CANCEL** and dispose of the Pod if the adhesive pad is folded, torn, or damaged, and begin again with a new Pod.

5 Activating and Changing Your Pod

2. Orient the Pod so it is:

- Horizontal or diagonal on your abdomen, hip, lower back, or buttocks
- Up and down or at a slight angle on your upper arm or thigh
- For optimal connectivity, the



Pod should be placed within line of sight to the Sensor. The Bluetooth connection between the Sensor and the Pod does not travel well through the body. Keeping both devices within line of sight allows for consistent Sensor communication with the Pod.

Note: Line of sight means that the Pod and Sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.

3. Apply the Pod to the selected infusion site, pressing down firmly to secure the Pod to your skin.

The adhesive is designed for one-time use. After a Pod is placed on your body, you cannot move that Pod to another infusion site.

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

Begin Insulin Delivery

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.

Begin insulin delivery (screen step **6**):

1. If you applied the Pod to a lean area, squeeze the skin around the Pod.
2. Tap **START** to insert the cannula.

Confirm Pod is securely attached

1. Confirm that the Pod is securely attached to your body, then tap **YES**.
2. If you are squeezing your skin, stop squeezing when the Omnipod 5 App asks if the cannula is properly inserted.

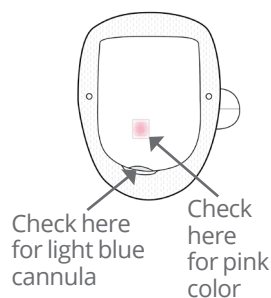
5.5 Checking Your Infusion Site

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 attempt to 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 hypoglycemia or hyperglycemia.

Following insertion of the cannula, check the Pod and infusion site:

1. Look through the viewing window on the edge of the Pod to verify that the cannula is inserted into the skin. The cannula is tinted light blue.
2. Verify that there is a pink color on top of Pod. This is an additional check that the cannula was inserted.
3. Verify that there is no wetness or scent of insulin at the infusion site. The presence of either may indicate that the cannula has dislodged.
4. If the cannula is not properly inserted, tap **NO**. Then tap **DEACTIVATE POD**. Restart the process with a new Pod.



5 Activating and Changing Your Pod

5. If the cannula is properly inserted, tap **YES**.

Pod setup is complete. The screen shows details about the active Pod and a list of reminders.

Once the cannula is inserted, the Pod automatically fills the cannula with insulin. The Pod then begins delivering the basal rate of insulin according to the Basal Program in progress.

The cannula can be inserted only once with each Pod.

6. Review the list of active reminders, then tap **CLOSE**.

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 180).

5.6 Switching to Automated Mode

An active Pod and saved Sensor information are required to switch to Automated Mode. If you have saved Sensor information entered in the Omnipod 5 App, you will be prompted to switch to Automated Mode after activating your Pod.

To switch to Automated Mode:

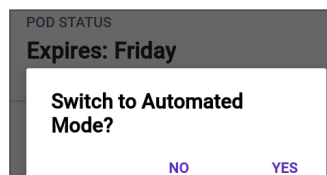
- Tap **YES**

To continue in Manual Mode:

- Tap **NO**

You can switch from Manual Mode to Automated Mode at a later time. See "23.1 Switching from Manual Mode to Automated Mode" on page 384.

Note: After switching to Automated Mode, you may see Automated Mode: Limited until sensor glucose values are available. See "22.5 About Automated Mode: Limited" on page 379.



5.7 Deactivating an Active Pod

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.

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.

To deactivate and remove an active Pod:

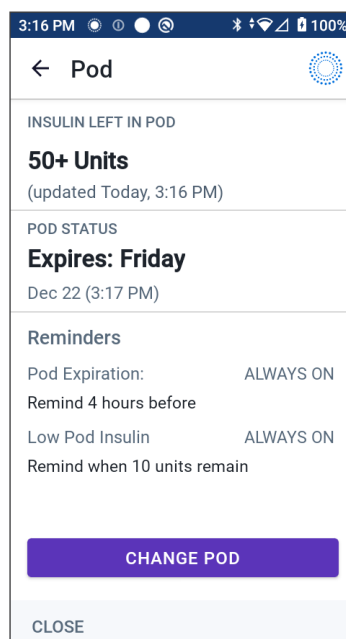
1. Navigate to the Pod change screen:
Home > POD INFO tab > VIEW POD DETAILS
or
Menu button (≡) > Pod
2. Tap **CHANGE POD**, then tap **DEACTIVATE POD**.

If a temp basal, extended bolus, or the Activity feature was in progress, it is canceled now.

If you see a communication error message, see "Error when activating a Pod" on page 461.

When you deactivate your Pod, the system exits Automated Mode. When the new Pod is activated, the system will be in Manual Mode; however, you will be prompted to enter Automated Mode if you have a Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number entered in to the Omnipod 5 App.

3. Remove the deactivated Pod from your body:



5 Activating and Changing Your Pod

- a. 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.

- b. Use soap and water to remove any adhesive that remains on the skin, or, if necessary, use an adhesive remover.
 - c. Check the infusion site for signs of infection (see "Avoiding Infusion Site Infections" on page 111).
 - d. Dispose of the used Pod according to local waste disposal regulations.
4. To activate a new Pod, tap **SET UP NEW POD**.

5.8 More Information about Pod Use

Avoiding Infusion Site Infections

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: 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 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 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.

Check the infusion site at least once a day:

- Be aware of signs of infection, including pain, swelling, redness, discharge, or heat at the infusion site. If you suspect an infection, immediately remove the Pod and apply a new Pod in a different location. Then contact your healthcare provider.

If you observe any problems with the Pod, deactivate the Pod and activate a new one.

5 Activating and Changing Your Pod

Additional Information

Tip: 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.

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

- To learn about caring for your Pod, see "14.1 Pod and Insulin Storage and Care" on page 220.
- To learn about the Pod alarms, see page 169.
- To learn how to silence a Pod alarm (see "13.8 Silencing Unresolved Alarms" on page 215).
- To understand the Pod's informational and notification beeps, including which beeps are optional, see "13.10 Reminder Notifications List" on page 217 and "13.3 Informational Sounds and Vibrations" on page 176.
- To understand how to handle situations where the Omnipod 5 App cannot communicate with your Pod, see "27.5 Pod Communication Issues – "Try Again"" on page 458.
- If the Home: **POD INFO** tab says "No Pod Communication:"
 - To find the last time the Omnipod 5 App successfully communicated with the Pod, navigate to:
Menu button (≡) > Pod.
 - If you are unable to restore communication with the Pod and want to change to a new Pod, navigate to:
Menu button (≡) > Pod > CHANGE POD.

CHAPTER 6

Basal Programs

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6 Basal Programs

6.1 About Basal Programs

While in Manual Mode, Basal Programs are used to deliver a steady amount of insulin throughout the day. This is known as your basal insulin. Different days can have different routines. The Omnipod 5 System lets you create different Basal Programs for your different routines. For example, you may use one Basal Program on weekdays and a different one on weekends.

Before you create or change a Basal Program, do the following:

- Cancel your temp basal if it is running. See "7.3 Canceling a Temp Basal" on page 123.
- Switch to Manual Mode if currently using Automated Mode. See "23.2 Switching from Automated Mode to Manual Mode" on page 386.

Tip: Write a list of the basal segments to guide you through entering the values for each segment. You can write this list on the pages at the end of this *Technical User Guide*.

6.2 Reviewing All Basal Programs

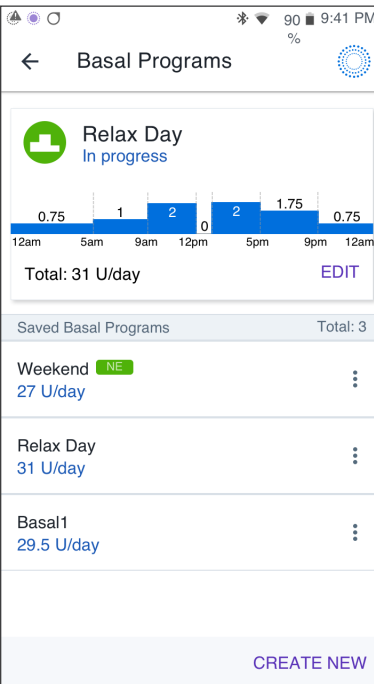
To review all Basal Programs:

1. Navigate to the list of Basal Programs:

Menu button (≡) > Basal Programs

A list of Basal Programs appears with the Basal Program in progress at the top.

2. Scroll up or down as needed to see additional Basal Programs.
3. Tap on the name of a saved Basal Program to see its graph and basal rates. Tap outside the graph to close that graph.



6.3 Creating New Basal Programs

To create a new Basal Program:

1. Navigate to the Create Basal Program screen:

Menu button (≡) > Basal Programs

2. Tap **CREATE NEW**.

Note: If you already have 12 Basal Programs, **CREATE NEW** does not appear. If necessary, you can delete an existing Basal Program. See "6.5 Deleting a Basal Program" on page 116.

3. See "Create a Basal Program" on page 81 to continue creating your new Basal Program.
4. If you have an active Pod and you want to use the new Basal Program now, tap **START** to start using the new Basal Program. If you do not want to use the new Basal Program now, tap **NOT NOW**.

6.4 Editing a Basal Program

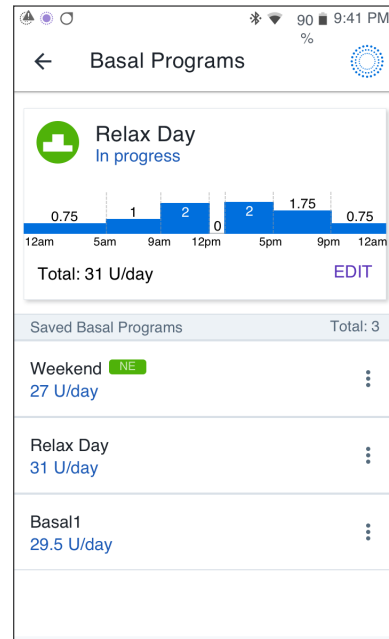
To edit a Basal Program:

1. Navigate to the list of Basal Programs:

Menu button (≡) > Basal Programs

2. Select the Basal Program you want to edit. Scroll up or down as necessary to locate the Basal Program.

- To edit the Basal Program in progress, tap **EDIT** beneath the graph of the program in progress. Then tap **PAUSE INSULIN**.
- To edit a saved Basal Program, tap the Options button (⋮) next to the Basal Program you want to edit. Then tap **Edit**.



6 Basal Programs

3. To rename the Basal Program, tap the **Program Name** field and enter the new name.
4. Tap **DONE**.
5. Tap **NEXT**.
6. See steps 2–7 of "6.2 Reviewing All Basal Programs" on page 114 to continue editing your Basal Program.
7. To activate the newly edited Basal Program:
 - If you edited the Basal Program in progress, tap **START INSULIN**.
 - If you edited a saved Basal Program and want to start it, tap **START**.
8. If you do not want to start the newly edited Basal Program, tap **NOT NOW**.

6.5 Deleting a Basal Program

You can only delete a Basal Program that is not in progress. To delete a Basal Program:

1. Navigate to the list of Basal Programs:
Menu button (≡) > Basal Programs
2. Tap the Options button (⋮) next to the Basal Program you want to delete.
3. Tap **Delete**.
4. Tap **DELETE** to confirm deletion of the Basal Program.

Note: Always make sure you are deleting the correct Basal Program. Once deleted, the action cannot be undone and you will have to recreate the Basal Program if needed.

6.6 Switching to a Different Basal Program

To switch to a different Basal Program:

1. Navigate to: **Menu button (≡) > Basal Programs**.
A list of Basal Programs appears with the Basal Program in progress at the top.

2. Select a different Basal Program in one of the following ways:
 - To see a graph of a saved Basal Program prior to activating it, tap on the name of that Basal Program. Then tap **START**.
Tip: Double-tap the graph to see an expanded view of the Basal Program. Swipe left and right to view basal rates for later or earlier times.
 - Tap the Options button (⋮) to the right of a saved Basal Program, then tap **START**.
3. Tap **START** again to start the newly selected Basal Program.

6.7 Basal Insulin Delivery

Even without eating, our bodies need a small, constant supply of insulin for normal daily living, which is referred to as "basal" insulin. In people without diabetes, the pancreas continuously delivers this basal insulin. For people using the Omnipod 5 System, the Pod can mimic a pancreas of a person without diabetes by delivering basal insulin continuously as you wear the Pod.

About half of a person's total daily insulin (TDI) dose typically comes from basal insulin delivery; the other half typically comes from bolus doses.

In the Omnipod 5 System, basal delivery occurs differently depending on which of the two modes you are operating in: Manual or Automated.

Manual Mode Basal Programs

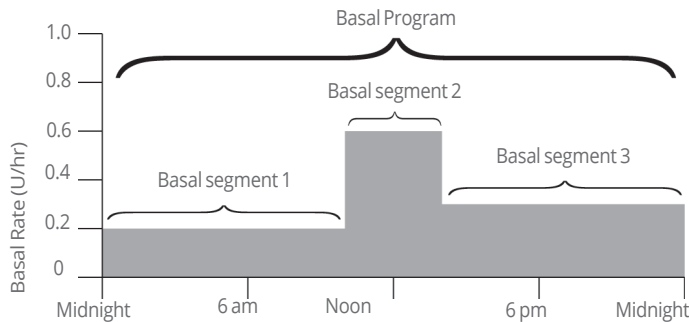
A basal rate is the number of units of insulin delivered per hour.

A basal segment defines the time of day during which a given basal rate is delivered.

A collection of basal segments covering a midnight-to-midnight period is called a "Basal Program." In other words, a Basal Program describes the rate of insulin delivery throughout an entire 24-hour period.

6 Basal Programs

This figure shows a Basal Program with three basal segments that deliver 7.4 U total in a 24 hour period.



Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver more or less insulin at certain times of the day. For example, you could deliver a lower rate of insulin during the night and a higher rate during the day.

In order to create the Basal Program shown in the example above, the following basal segments are programmed into the Omnipod 5 app:

Segment	Basal rate	
1: Midnight–10:00 am	0.20 U/hr	Between midnight and 10:00 am, the Pod delivers 0.20 units of insulin per hour.
2: 10:00 am–2:00 pm	0.60 U/hr	Between 10:00 am and 2:00 pm, the Pod delivers 0.60 units of insulin per hour.
3: 2:00 pm–midnight	0.30 U/hr	Between 2:00 pm and midnight, the Pod delivers 0.30 units of insulin per hour.

You may have different routines on different days of the week; for example, your weekend routine may differ from your weekday routine. To handle these predictable changes in your routine, you can create up to 12 different Basal Programs (see "6.3 Creating New Basal Programs" on page 115).

CHAPTER 7

Temporary Basal Rates

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7 Temporary Basal Rates

7.1 About Temporary Basal Rates

When in Manual Mode, you can use a temporary basal rate, or “temp basal,” to handle a temporary change in your routine. For example, a temp basal can be used when you are exercising or when you are sick. When a temp basal ends, the Pod will start delivering the scheduled Basal Program.

To turn ON or OFF the ability to start temp basals, or to change between specifying the temp basal as a percentage or in U/hr, see page 148.

Tip: By default, the Omnipod 5 App or Pod sounds a tone at the beginning and end of a temp basal and every 60 minutes while a temp basal is running. To turn these ON or OFF, see "13.2 Sounds and Vibrations" on page 174.

Before you create or change a temporary basal rate, do the following:

- Temp basal setting must be **ON**. If it is **OFF**, see "10.3 Basal and Temp Basal Settings" on page 148.
- If the Omnipod 5 System is currently in Automated Mode, switch to Manual Mode. See "23.2 Switching from Automated Mode to Manual Mode" on page 386.

7.2 Starting a Temp Basal

Note: You cannot start or cancel a temp basal during an immediate bolus, but you can start or cancel a temp basal while an extended bolus is in progress.

To start a temp basal:

1. Navigate to:
Menu button (☰) > Set Temp Basal
 The screen shows a graph of the Basal Program in progress.
2. Tap the **Basal Rate** field and scroll to the desired change in the basal rate:
 - If using a percent (%) change
 An UP ARROW (⬆) indicates **increasing** the basal rate above that of the Basal Program in progress.
 A DOWN ARROW (⬇) indicates **decreasing** the basal rate below that of the Basal Program in progress.
 - If using a flat rate (U/hr), scroll to select the basal rate for the entire temp basal period.

Note: To change whether temp basals are configured as percent (%) or U/hr, see "10.3 Basal and Temp Basal Settings" on page 148.

Note: The scroll wheel will not scroll above your Maximum Basal Rate. To adjust your Maximum Basal Rate, see "Maximum Basal Rate" on page 148.

Tip: You can turn OFF insulin delivery for the duration of the temp basal by setting a decrease of 100% or setting the temp basal to 0 U/hr. For more information, see "Temp basal limitations" on page 125 and "7.4 Temporary Basal Rates Delivery" on page 123.

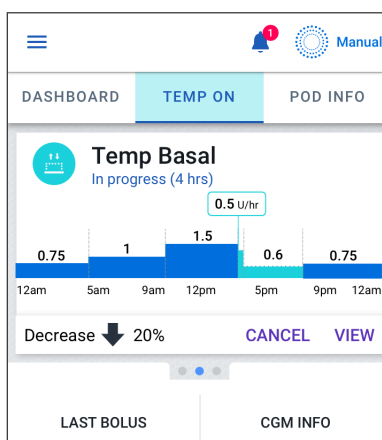
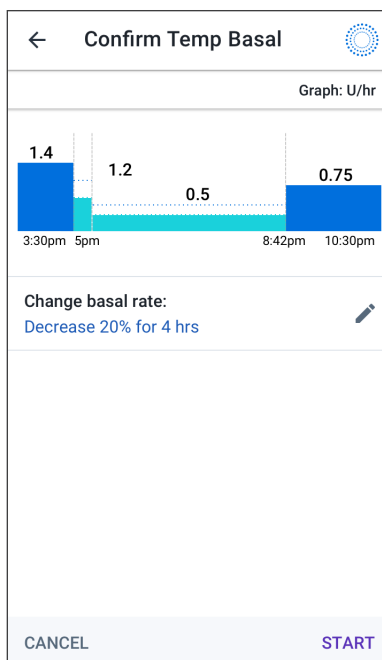
3. Tap the **Duration** field and scroll to the desired temp basal duration (between 30 minutes and 12 hours).

7 Temporary Basal Rates

4. Examine the temp basal graph at the top of the screen. The proposed temp basal is displayed over the Basal Program in progress.
 - The lighter blue shaded area shows the proposed temp basal rate for each segment.
 - If you set a decrease, the Basal Program in progress is shown as a horizontal dotted line.
5. Tap **CONFIRM** to continue.
6. Review the temp basal details. If corrections are needed, tap on the row to change. Then enter your corrections and confirm them.
7. To start the temp basal, tap **START**. Then tap **START** again.

Once the temp basal starts, the Home screen's **INSULIN** tab is highlighted in light blue and is renamed to **TEMP ON** which indicates that the temp basal is in progress. The **TEMP ON** tab now shows that the temp basal is in progress, what the basal rate change is, and how much time remains.

At the end of the temp basal time period, the Pod will go back to delivering the scheduled Basal Program.



7.3 Canceling a Temp Basal

A temp basal stops automatically at the end of its time period and the last scheduled Basal Program starts.

To cancel a temp basal before the end of its time period:

1. Navigate to the Home screen's **TEMP ON** tab.
2. Tap **CANCEL**.
3. Tap **YES** to confirm cancellation. The Omnipod 5 App cancels the temp basal and starts the last scheduled Basal Program.

7.4 Temporary Basal Rates Delivery

A temp basal lets you override the currently running Basal Program by setting a different basal rate for a predetermined period of time. This feature is only available in Manual Mode.

For example, if you are going cross-country skiing for several hours, you could set a temp basal to lower your basal rate during and after your exercise (see "Temporary Basal Rates" on page 119).

Temp basals can last from 30 minutes to 12 hours. At the end of the specified time, the Pod automatically goes back to the programmed basal rate.

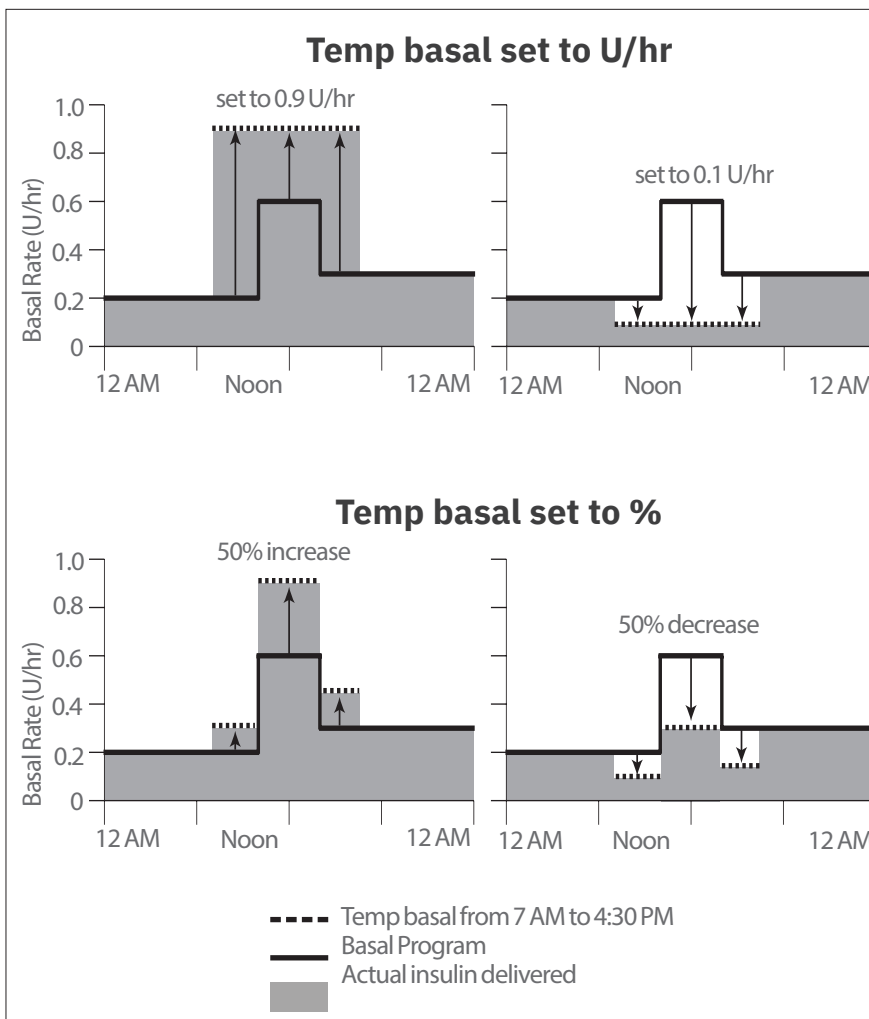
7 Temporary Basal Rates

Temp basal settings: Units per hour (U/hr) or percent (%)

Temp basals can be set using percent (%) or units per hour (U/hr).

Setting temp basals to units per hour (U/hr) means that the Pod delivers insulin at a flat rate for the duration of the temp basal. In other words, the details of the currently scheduled Basal Program are ignored during these temp basals.

Setting temp basals to percent (%) means insulin delivery follows the pattern defined by the currently scheduled Basal Program but increases or decreases the insulin delivery by the specified percentage. For example, a 50% increase raises the Basal Program's insulin delivery by 50%, while a 50% decrease lowers the Basal Program's insulin delivery by 50%.



The calculations for the 50% increase temp basal in the example above figure are:

Segment boundaries*	Basal rate of Basal Program (U/hr)	50% increase (U/hr)	Resulting temp basal rate: (U/hr)
Midnight–7:00 am	0.20		
7:00 am–10:00 am	0.20	$0.20 \times 50\% = 0.10$	$0.20 + 0.10 = 0.30$
10:00 am–2:00 pm	0.60	$0.60 \times 50\% = 0.30$	$0.60 + 0.30 = 0.90$
2:00 pm–4:30 pm	0.30	$0.30 \times 50\% = 0.15$	$0.30 + 0.15 = 0.45$
4:30 pm–midnight	0.30		

* Segments are defined by the currently scheduled Basal Program.

Temp basal limitations

Prohibited temp basals: You cannot set a temp basal of 0%, as there would be no change from the Basal Program in progress.

Maximum temp basal:

- When using percent (%), you can set the temp basal up to 95% more than your Basal Program in progress's rate with the following exception: You cannot set a temp basal that would go above your Maximum Basal Rate during any time segment covered by the temp basal duration.
- When using a flat rate (U/hr), you cannot set a temp basal above your Maximum Basal Rate.

Temp basals that turn off basal insulin delivery: When using percent (%), if you set a decrease that results in a flow of less than 0.05 U/hr for a segment, the Omnipod 5 App informs you that you will receive 0 U/hr of insulin for one or more segments.

If the temp basal is long enough, you will eventually receive some insulin. This is because the Pod delivers insulin in 0.05 U pulses.

For example, if the flow rate for a basal segment is 0.10 U/hr and you create a temp basal with a 60% decrease for:

- One hour, the resulting flow rate of 0.04 U/hr results in no insulin being delivered for the one-hour duration of the temp basal.
- Two hours, the resulting flow rate of 0.04 U/hr results in the delivery of 0 U insulin in the first hour and 0.05 U insulin in the second hour.

7 Temporary Basal Rates

- You can set a temp basal to turn off basal insulin delivery for a set period of time by using a 100% decrease or a flat rate of 0 U/hr. The Pod beeps at the start and end of a temp basal period of no basal insulin. You can still deliver boluses when using a temp basal to turn off basal insulin delivery.

Tip: Using a temp basal to turn off basal insulin delivery is useful if you want your Basal Program to automatically start when the temp basal ends.

CHAPTER 8

Blood Glucose Readings

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8 Blood Glucose Readings

8.1 About Blood Glucose Readings

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

The Omnipod 5 System receives regular glucose values from the Sensor when you have connected the Sensor to an active Pod. Once connected, sensor glucose values are displayed and can be used in the Omnipod 5 App in both Manual and Automated Modes. There may be times when you need to check your blood glucose using a separate BG meter. You may want to check your blood glucose if:

- You are experiencing symptoms of hypoglycemia. See "Symptoms of hypoglycemia (low glucose)" on page 236.
- You are experiencing symptoms of hyperglycemia. See "Symptoms of hyperglycemia (high glucose)" on page 240.
- You are experiencing symptoms that are not consistent with your sensor glucose values.
- You use a Dexcom G6 Sensor, and your Sensor requires calibration. For more information, refer to your *Dexcom G6 CGM System Instructions for Use*.
- You are not using a Sensor to monitor glucose.
- Your healthcare provider advises you to do so.

8.2 Entering Your Blood Glucose Reading

To enter your blood glucose reading:

1. Check your blood glucose following your BG meter's instructions for use.
2. Go to the Enter BG screen on your Omnipod 5 App:
Menu button (≡) > Enter BG
 Or from the SmartBolus Calculator, tap the **GLUCOSE** field.
3. Manually enter or edit a blood glucose value as follows:
 - a. Enter and confirm your blood glucose reading using the number pad.
 - b. Tap the check mark to close the number pad.

Note: When you enter a blood glucose reading above 600 mg/dL, the Omnipod 5 App stores it as "**HIGH**". When you enter a blood glucose reading below 20 mg/dL, the Omnipod 5 App stores it as "**LOW**".

4. After the blood glucose reading is entered, do one of the following:
 - Tap **ADD TO CALCULATOR** to save and enter the blood glucose reading into the SmartBolus Calculator.
Note: Until a blood glucose reading has been entered, or if insulin is paused, **ADD TO CALCULATOR** is disabled.
 - Tap **SAVE** to save the blood glucose reading in the history records. If you accessed this screen from the SmartBolus Calculator, **SAVE** does not appear.
 - Tap **CANCEL**, then **YES**, to exit the screen without saving the blood glucose reading.

The Omnipod 5 App records the current time as the time of the blood glucose reading.

8 Blood Glucose Readings

8.3 High and Low Blood Glucose Readings

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 and 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 could 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 could 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" sensor glucose values and 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.

If the blood glucose reading is HIGH or above 600 mg/dL, the Omnipod 5 App records "HIGH" in the history. This indicates severe hyperglycemia (high glucose). If the blood glucose reading is LOW or below 20 mg/dL, the Omnipod 5 App records "LOW" in the history. This indicates severe hypoglycemia (low glucose).

The Omnipod 5 App indicates high and low blood glucose readings as follows.

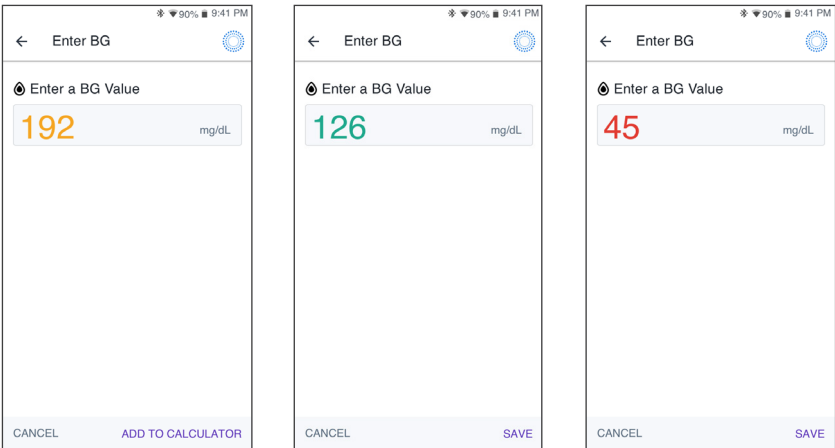
Glucose reading	Screen display
Above 600 mg/dL or HIGH	HIGH
20–600 mg/dL	<blood glucose reading>
0–19 mg/dL or LOW	LOW

How Blood Glucose Readings are Displayed

The Omnipod 5 App displays the blood glucose reading with color. The text color is:

- Yellow if your blood glucose is above your Glucose Goal Range
- Green if your blood glucose is within your Glucose Goal Range
- Red if your blood glucose is below your Glucose Goal Range

To change your Glucose Goal Range, see page 158.



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CHAPTER 9

Pausing and Starting Insulin Delivery

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9 Pausing and Starting Insulin Delivery

9.1 Pausing Insulin Delivery

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.

Sometimes you may need to pause insulin delivery briefly. For example, you must pause insulin delivery prior to editing a Basal Program in progress or changing the time zone. The Omnipod 5 System lets you pause all insulin delivery for up to two hours.

For the difference between pausing insulin delivery using the pause feature or the temp basal feature, see "9.2 Methods to Temporarily Pause Insulin Delivery in Manual Mode" on page 135.

Before you begin, do the following:

- You must be in Manual Mode to pause insulin. If you are currently using Automated Mode, see "23.2 Switching from Automated Mode to Manual Mode" on page 386.

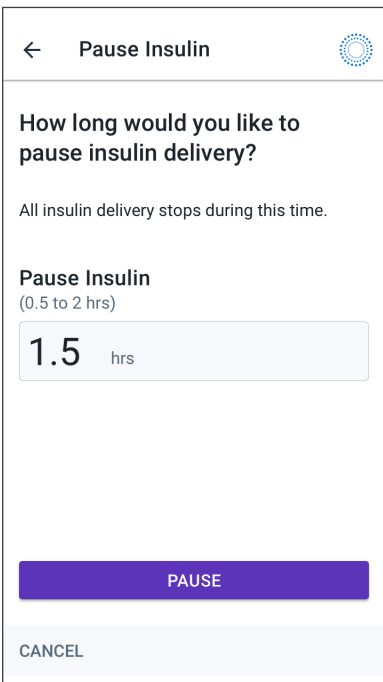
Pause insulin delivery

To pause insulin delivery:

1. Navigate to: **Menu button (≡)**
> **Pause Insulin**
2. Tap the **Pause Insulin** field. Scroll to specify how long to pause insulin. The paused time can last 0.5 hour, 1 hour, 1.5 hours, or 2 hours.
3. Tap **PAUSE**.
4. Tap **YES** to confirm that you want to pause all insulin delivery.

All basal insulin delivery is paused.

The Home screen displays a yellow banner stating that "Insulin delivery is paused."



← Pause Insulin

How long would you like to pause insulin delivery?

All insulin delivery stops during this time.

Pause Insulin
(0.5 to 2 hrs)

1.5 hrs

PAUSE

CANCEL

Note: The Pod beeps every 15 minutes throughout the pause period. At the end of the pause period, insulin delivery does not automatically start. The Pod and Omnipod 5 App notify you every minute for 3 minutes, and repeat this notification every 15 minutes until you have started insulin delivery.

9.2 Methods to Temporarily Pause Insulin Delivery in Manual Mode

There may be times when you want to pause all insulin delivery, or at least all basal insulin delivery, for a period of time. If you do not want to deactivate your current Pod, you can request a temporary halt of insulin delivery as follows:

- Pause insulin delivery.
- Set a temp basal to turn off insulin delivery.

The following table compares these options for pausing insulin delivery.

	Pause insulin	Temp basal of 0 U/hr
Effect on basal and bolus insulin delivery	No basal delivery No bolus delivery	No basal delivery Boluses allowed
Minimum duration for pausing insulin	30 min	30 min
Maximum duration for pausing insulin	2 hrs	12 hrs
Insulin delivery starts automatically	No	Yes
Screen display at the end of the specified duration	"Start insulin. The insulin pause period has ended."	The middle tab of Home screen now shows "Basal," not "Temp Basal"
Beeps while insulin is paused	Every 15 min	At the beginning and every 60 min

9 Pausing and Starting Insulin Delivery

	Pause insulin	Temp basal of 0 U/hr
Beeps at the end of the specified duration	Every 15 min until you tap Start	One beep, then insulin starts automatically
Must be used when	Editing a Basal Program in progress Changing the time zone Testing alarm and vibrate feature	Use is never required
How to cancel the pause	Menu button (≡) > Start Insulin	Home: Temp Basal tab > CANCEL

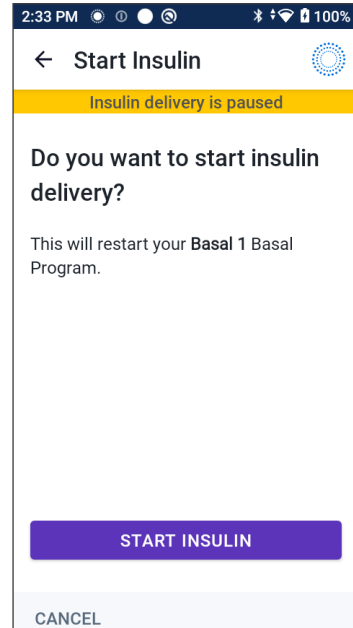
9.3 Starting Insulin Delivery

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.

Start insulin delivery before the pause period ends

1. Navigate to:
Menu button (≡)
> Start Insulin
2. Tap **START INSULIN** to confirm restarting the Basal Program scheduled for the current time.

The Omnipod 5 App beeps to confirm that insulin delivery has started.

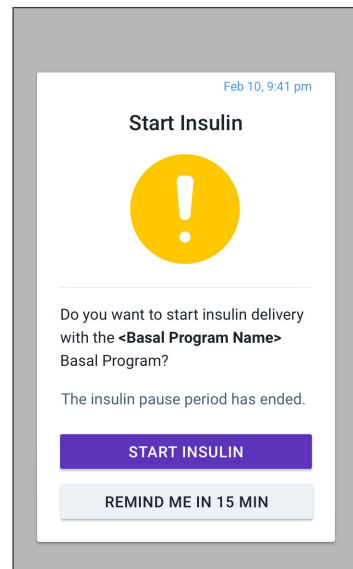


Start insulin delivery after the pause period ends

- Tap **START INSULIN** to start insulin delivery.

The Omnipod 5 App starts the Basal Program that is scheduled for the current time and beeps to alert you that insulin delivery has started.

If you do not start insulin delivery immediately, this screen reappears and the Omnipod 5 App and Pod beep every 15 minutes until insulin delivery is started.



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CHAPTER 10

Changing Settings

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10 Changing Settings

10.1 General Settings

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.

Some settings differ between the Insulet-provided Controller with the Omnipod 5 App and the Omnipod 5 App on your smartphone.

If you are using the Controller, settings allow you to change your network connectivity, screen display settings, lock screen settings, and time zones. You can also check alarms and reset the Controller.

If you are using your smartphone, settings allow you to change your insulin delivery time zone. You can also check alarms and reset the App.

Network Connectivity

Airplane Mode is a device setting that turns off cellular and Wi-Fi network connectivity. Airplane Mode can be turned ON or OFF.

Note: Though the Omnipod 5 System does not require constant network connectivity, frequent connectivity (either cellular or Wi-Fi) is needed for optimal use of the system, such as if you typically share your glucose data with a care partner. Consider re-enabling Wi-Fi after turning on Airplane Mode for optimal system use.

Note: On the Controller, Bluetooth connectivity is not affected. If you are using your smartphone, make sure to check that Bluetooth is enabled after you turn ON Airplane mode.

Note: ALWAYS keep the Bluetooth setting ON. If you turn this setting OFF, you will not be able to use the Omnipod 5 App.

Airplane mode

To turn Airplane Mode ON or OFF on the Controller:

1. Navigate to:
Menu button (≡) > Settings > General.
2. Tap the **Airplane Mode** toggle to turn Airplane Mode ON or OFF.

Screen Display

Use the screen display settings to control the screen time-out and brightness.

Screen time-out

The Controller screen turns black if you have not used it for the specified amount of time in order to preserve battery power. To change the amount of time:

1. Navigate to:
Menu button (≡) > Settings > General > Screen Time-Out
2. Tap a desired amount of time to select it.
Tip: A shorter screen time-out extends the battery charge.
3. Tap **SAVE**.

Screen brightness

To adjust the brightness of the screen on the Controller:

1. Navigate to:
Menu button (≡) > Settings > General > Brightness.
2. Place your finger on the blue dot of the slider. Slide your finger to the right to increase the screen brightness. Slide your finger to the left to decrease the screen brightness.
Tip: Lower screen brightness extends the battery charge.

Lock Screen

You can edit your Controller's Lock screen message, background image, and PIN, which help ensure that you are using the correct Controller.

Lock screen message

To change your Lock screen message:

1. Navigate to:
Menu button (≡) > Settings > General > Message.
2. Tap the Lock screen message field and enter the message you want the Controller to display when you turn it ON.
3. Tap **SAVE**.

10 Changing Settings

Lock screen background

To change the background image on the Lock screen:

1. Navigate to:
Menu button (≡) > Settings > General > Background.
2. Tap the background image you want to use.
3. Tap **SAVE**.

PIN

To change your personal identification number or PIN:

1. Navigate to:
Menu button (≡) > Settings > General > PIN.
2. Enter your current PIN.
3. Enter the new four-digit PIN.
Tip: Tap the eye icon to display or hide the PIN.
4. Tap **Done** to accept the PIN.
5. Re-enter the new PIN, and then tap **Done**.

Note: To change your PIN, you must have cellular or Wi-Fi connectivity.

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

Time Change

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 could cause errors in insulin delivery and data logging, which could lead to hypoglycemia or hyperglycemia.

A time change occurs when you are traveling to a different time zone or for daylight savings time. To help you manage time changes your device's time zone is separate from your insulin delivery time zone as described in the table below.

Omnipod 5 App on:	Device Time Zone	Insulin Delivery Time Zone	Automatic Time Zone Setting: ON/OFF
Controller	Time shown on your Controller (status bar, lock screen)	Time shown in the Omnipod 5 App, insulin delivery is based on App time	Recommended ON
Smartphone	Time shown on your smartphone (status bar, lock screen)	Time shown in the Omnipod 5 App, insulin delivery is based on App time	Required ON

Device time zone

Your device time zone is the time displayed outside of the Omnipod 5 App on the status bar and the lock screen. Your device time will update automatically when you travel to a new time zone or for Daylight Saving Time when you have the Automatic Time Zone setting ON. It is recommended that you keep your Automatic Time Zone setting ON so your device time zone will always be your local time zone.

To turn Automatic Time Zone ON or OFF:

1. Navigate to:
Menu button (≡) > Settings > General > Time Zone.
2. If you have an active Pod, tap **PAUSE INSULIN** and tap **YES**.
3. Tap **Device Automatic Time Zone**.
4. Tap the toggle to turn Automatic Time Zone detection ON or OFF
Tip: Blue color means the setting is ON. Gray means the setting is OFF.
5. When the device's Automatic Time Zone is OFF, you have access to the Controller time zone.
6. To change the time zone of the Controller, tap **SELECT TIME ZONE** and select the desired time zone from the list.

Note: Using the Omnipod 5 App on your smartphone requires you to have the Automatic time setting ON.

10 Changing Settings

Insulin delivery time zone

Your insulin delivery time zone is the time displayed in the Omnipod 5 App and only changes when you change it yourself. This is the time zone that your insulin delivery is based on. When you have the Automatic Time Zone setting ON, the Omnipod 5 App detects when your device time zone and insulin delivery time zone do not match and will notify you. For example, when you travel outside of the country, your Omnipod 5 App will ask you if you would like to update your insulin delivery time zone to your new local time.

You may want to change your insulin delivery time zone, for example, if you are preparing to travel to a new time zone.

To change your insulin delivery time zone:

1. In Manual Mode, navigate to: **Menu button (≡) > Settings > General > Insulin Delivery Time Zone.**
2. If you have an active Pod, tap **PAUSE INSULIN** and tap **YES**.
3. Select the desired time zone and tap **SAVE** and then tap **CONFIRM**.
4. Tap **YES** to restart insulin delivery.

Language

To change your preferred language:

1. Navigate to:
Menu button (≡) > Settings > General > Language.
2. Select the language you would like to use for your Omnipod 5 App.
3. Tap **SAVE**.
4. The screen will flash briefly. The App will relaunch in the selected language. Changing the language will NOT reset your settings, history, or adaptivity.

Reset

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.

If you need to reset the Omnipod 5 App on your Controller or smartphone, which will clear all your settings and history, follow these steps.

1. Navigate to **Menu button (≡) > Settings > General > Reset.**
2. If you have an active Pod, deactivate and remove your Pod.
Note: While a Pod will continue delivering insulin into your body after an App reset, you will not be able to reconnect to this Pod to deliver a bolus or deactivate it later. Remove it and be ready to activate a new Pod.
3. Tap **Clear all data.**
4. Tap **CONFIRM.**
5. You will need to complete first-time setup again. Follow the steps in Chapter 4 to set up your Omnipod 5 App.

10.2 Reminder Settings

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. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown
- iPhone: Screen Time, Focus Mode, Hide App, Lock App

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.

Reminder notifications bring attention to various diabetes management actions you may want to take (see "13.10 Reminder Notifications List" on page 217 and "13.2 Sounds and Vibrations" on page 174).

10 Changing Settings

Pod Expiration

The Pod Expiration reminder tells you when the Pod is nearing its expiration so you can plan to change your Pod at a convenient time. You can set this notification to appear from 1 to 24 hours before the Pod expires. At the selected time, the Pod beeps. The Omnipod 5 App displays a message and the Controller or smartphone beeps/vibrates.

To set the timing of the Pod Expiration reminder:

1. Navigate to:
Menu button (≡) > Settings > Reminders > Pod Expiration.
2. Tap the **Pod Expiration** field and select how long before your Pod expires that you would like to be notified.
3. Tap **SAVE**.

Low Pod Insulin

An Advisory Alarm from the Pod and Omnipod 5 App sounds when the insulin level in your Pod drops below the low Pod insulin setting. This setting can range from 10 to 50 units.

To set the insulin level for the Low Pod Insulin Advisory Alarm:

1. Navigate to:
Menu button (≡) > Settings > Reminders > Low Pod Insulin.
2. Tap the **Low Pod Insulin** field and select the level of Pod insulin at which you would like to be notified.
3. Tap **SAVE**.

Pod Shut-Off

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.

If the Pod Shut-Off feature is ON, the Pod automatically deactivates if you do not use the Omnipod 5 App within the defined time. Consult your healthcare provider prior to changing the Pod Shut-Off setting.

To enable or disable Pod Shut-Off:

1. Navigate to:
Menu button (≡) > Settings > Reminders > Pod Shut-Off.
2. Tap the **Pod Shut-Off** toggle to enable or disable the Pod Shut-Off feature.
3. If Pod Shut-Off is enabled, tap the **Inactivity Timer** field and select the length of time for the countdown timer. This setting can range from 1 to 24 hours.

Example: If you choose 10 hours, you must wake up your Omnipod 5 App and unlock it at least once every 10 hours, day and night, to prevent the Pod Shut-Off alarm.

4. Tap **SAVE**.

Confidence Reminders

When confidence reminders are ON, you will hear a tone at the start and end of each bolus, extended bolus, or temp basal:

- The Omnipod 5 App beeps at the start.
- The Pod beeps at the end.

Confidence reminders are especially useful when you are getting familiar with your Omnipod 5 System and want additional confirmation that an insulin delivery command went through. To turn confidence reminders ON or OFF:

1. Navigate to: **Menu button (≡) > Settings > Reminders.**
2. Tap the **Confidence Reminders** toggle to turn confidence reminders ON or OFF.

Note: You cannot turn OFF beeps that occur at the start of a temp basal set to deliver no (zero) insulin.

Program Reminders

When program reminders are ON, the Pod beeps every 60 minutes while a temp basal or extended bolus is in progress. To turn program reminders ON or OFF:

1. Navigate to: **Menu button (≡) > Settings > Reminders.**
2. Scroll as needed and tap the **Program Reminders** toggle to turn program reminders ON or OFF.

Note: You cannot turn OFF beeps that occur during a temp basal set to deliver no (zero) insulin.

10 Changing Settings

10.3 Basal and Temp Basal Settings

The following sections describe how to change settings that control basal insulin delivery.

Note: These settings only apply when using Manual Mode.

Maximum Basal Rate

The Maximum Basal Rate defines an upper limit for any basal rate used in your Basal Programs and temp basals during Manual Mode only. Consult your healthcare provider before changing this setting.

To change your Maximum Basal Rate:

1. Navigate to: **Menu button (≡) > Settings > Basal & Temp Basal > Max Basal Rate.**
2. Tap the **Max Basal Rate** field and enter the new value for your Maximum Basal Rate.
3. Tap **SAVE.**

Note: You cannot set a Maximum Basal Rate that is lower than the highest basal rate of an existing Basal Program or currently running temp basal.

Temp Basal

To turn ON or OFF the ability to set temp basals:

1. Navigate to:
Menu button (≡) > Settings > Basal & Temp Basal.
2. To enable or disable the ability to set temporary basal rates (temp basals), tap the toggle ON or OFF.
3. To change between using percent (%) or flat rate (U/hr) temp basals:
 - a. Tap **Temp Basal.**
 - b. Select the desired method for setting a temp basal:
 - Tap **Percent (%)** to modify the Basal Program in progress by a set percentage increase or decrease.
 - Tap **Flat Rate (U/hr)** to replace the Basal Program in progress with a fixed basal rate for the specified duration.
 - c. Tap **SAVE.**

CHAPTER 11

Browsing Your History and Records

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11 Browsing Your History and Records

11.1 About Your Recent History and Past Records

The Omnipod 5 App can store 90 days of history records. Once the memory is full, new records begin to replace the oldest records. You can browse but not edit the information in your records.

Your records are displayed on:

- Sensor Graph (recent)
- History Detail screens, which show insulin, glucose, carbohydrate, Pod events, and Auto Events
- History of alarms and notifications can be viewed on the Notification screen.

11.2 Viewing the Sensor Graph

The Sensor Graph can be viewed from the Home screen in both Manual Mode and Automated Mode.

To view the Sensor Graph:

- On the lower right part of the Home screen, tap **VIEW**.

To exit the Sensor Graph:

- Tap the **(X)** located in the top right corner of the graph.

