Omnipod® 5 System Technical User Guide for iPhone®

Omnipod® 5 Automated Insulin Delivery System

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Contacts and Important Information

Customer Care

1-800-591-3455 (24 hours/7 days)

From Outside the US: 1-978-600-7850
Customer Care Fax: 877-467-8538
Address: Insulet Corporation
100 Nagog Park, Acton MA 01720
Emergency Services: Dial 911 (USA only; not available in all communities)
Website: omnipod.com

Pod FCC ID: RBV-029
Pod FCC ID: RBV-029C
Omnipod 5 Automated Insulin Delivery System
Start Date: _____

Healthcare Provider
Name
Street Address
City State Zip
Phone
Email

Omnipod® Trainer
Name
Street Address
City State Zip
Phone
Email

Health Insurance
Name
Street Address
City State Zip
Phone
Policy Number

Pharmacy
Name
Street Address
City State Zip
Phone
Email

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Contents

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1

BEFORE YOU BEGIN

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CHAPTER 1

Introduction

Contents

1.1 Welcome to Your Omnipod® 5 System

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

The Omnipod 5 System Features

- **Pod:** The Pod provides continuous subcutaneous insulin delivery. It may be worn for up to 3 days and can be filled with up to 200 units of U-100 rapid-acting insulin (minimum 85 units).
- **No tubing:** There is no tubing with the Pod allowing you to place the Pod almost anywhere you would give yourself an injection. The Pod is waterproof for depths up to 25 feet (7.6 meters) for up to 60 minutes (IP28).
- **Omnipod® 5 App:** The Omnipod 5 App allows you to select a basal profile, Target Glucose and bolus settings, activate and deactivate the Pod, connect with the Dexcom G6 Continuous Glucose Monitoring System, and select insulin delivery mode. The Omnipod 5 App comes installed on an Insulet- provided Controller or can be downloaded to a compatible smartphone. For a list of the latest compatible smartphones and operating systems, please visit *https://omnipod.com/compatibility*.
- **Dexcom G6 Continuous Glucose Monitoring (CGM) System:** The Omnipod 5 System is designed to work with the Dexcom G6 which must be obtained separately. Sensor glucose values and trends from the Dexcom G6 are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode. The Dexcom G6 Sensor must be started in the Dexcom G6 app in order to use sensor glucose values and trends in the Omnipod 5 System.
- **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.

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.
- **Dexcom G6 Continuous Glucose Monitoring (CGM) System:** The Omnipod 5 System is designed to work with the Dexcom G6 which must be obtained separately. Sensor glucose values and trends from the Dexcom G6 are used for automated insulin delivery in Automated Mode, as well as for bolus calculations in both Automated and Manual Mode. The Dexcom G6 Sensor must be started in the Dexcom G6 app in order to use sensor glucose values and trends in the Omnipod 5 System.

- **Activity feature:** While in Automated Mode, you can use 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 for iPhone®

The purpose of this *Technical User Guide for iPhone®* is to assist you with the features and functions of the Omnipod 5 System when used with the Omnipod 5 App installed on a compatible iPhone. 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.

Please consult the full *Technical User Guide* for the complete list of features, troubleshooting steps, and important safety information related to System use with the Insulet-provided Controller or app for Android smartphone.

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.

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

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 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 for iPhone* 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 for iPhone* in any way in connection with your personal healthcare, related decisions, and treatment. This *Technical User Guide for iPhone* 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 for iPhone* 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 for iPhone* and your healthcare provider. Failure to use this system as intended could result in over-delivery or under-delivery of insulin which can lead to hypoglycemia or hyperglycemia.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Warning: ALWAYS treat "LOW" or "HIGH" 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 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.

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 the Omnipod 5 System with Dexcom G6 if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom G6 sensor glucose values could be falsely elevated and could result in over-delivery of insulin which can lead to severe hypoglycemia.

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

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not acting promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) (see "⚠ Blockage Detected" on page 158).

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 hypoglycemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycemia.

Warning: DO NOT use the Omnipod 5 System in oxygen rich environments (greater than 25% oxygen), which include home or surgical areas that use supplementary oxygen and hyperbaric chambers. Hyperbaric, or high pressure, chambers are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to oxygen rich environments could result in combustion of the Pod, 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 which could result in under-delivery of insulin which can lead to hyperglycemia.

1.6 General Precautions

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

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

Caution: ONLY use the Omnipod 5 System with authorized devices (Omnipod 5 App, Controller, Pod, and Dexcom G6). 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 or smartphone safe and within your control to ensure others cannot make changes to your insulin therapy. Do not share your screen lock security with anyone.

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

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

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

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

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

Potential Risks

- The Omnipod 5 System uses 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, 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 the Dexcom G6 CGM. To use the Dexcom G6 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G6 Sensor, Transmitter, and *Instructions for Use*, and download the Dexcom G6 app on your personal smartphone.

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

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

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

Emergency Kit

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

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

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

- Several new, sealed Omnipod 5 Pods
- A vial of rapid-acting U-100 insulin (see "1.5. General Warnings" on page 8 for insulins cleared for use in the Omnipod 5 Pod).
- Syringes or pens for injecting insulin
- Glucose tablets or another fast-acting source of carbohydrate
- Dexcom G6 Continuous Glucose Monitor (CGM) System and supplies
- Blood glucose test strips
- Blood glucose meter
- Ketone test strips
- Lancing device and lancets
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted.
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System.
- Phone numbers for your healthcare provider and/or physician in case of an emergency.
- Glucagon kit and written instructions for administering glucagon dosage if you are unconscious (see "15.4. Avoiding Lows, Highs, and Diabetic Ketoacidosis" on page 201).

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

OMNIPOD 5 PUMP FEATURES

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Omnipod 5 Pump Important Safety Information

Pump Warnings

Omnipod 5 System Settings and Training

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

Insulin

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

Warning: ALWAYS be prepared to inject insulin with an alternative method if insulin delivery from the Pod is interrupted. You are at increased risk for developing insulin delivery is interrupted because the Pod only uses rapid-acting U-100 insulin. Failure to have an alternative method of insulin delivery can lead to very high glucose or diabetic ketoacidosis (DKA). Ask your healthcare provider for instructions for handling interrupted insulin delivery.

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

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

Omnipod 5 System

Warning: Device components including the Pod, Transmitter, and 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.

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 alarm check, contact Customer Care *immediately. Continuing to use the Omnipod 5 System in these situations could put your health and safety at risk.*

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

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

Warning: DO NOT use the Omnipod 5 System at low atmospheric pressure (below 700hPA). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 10,000 feet (3,000 meters). Change in atmospheric pressure can also occur during take-off with air travel. Unintended insulin delivery can occur if there is expansion of tiny air bubbles that may exist inside the Pod. This can result in hypoglycemia. It is important to check your glucose frequently when flying to avoid prolonged hypoglycemia.

Warning: DO NOT use the Omnipod 5 System in oxygen rich environments (greater than 25% oxygen), which include home or surgical areas that use supplementary oxygen and hyperbaric chambers. Hyperbaric, or high pressure, chambers are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to oxygen rich environments can result in combustion of the Pod, 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 which could result in under- delivery of insulin which can lead to hyperglycemia.

Controller and Smartphone

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

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

Warning: ALWAYS contact Customer Care if your Omnipod 5 System Controller is damaged and not working properly. If a Controller 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 acting promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) (see "⚠ Blockage Detected" on "13.1 Types of Alarms and Notifications" on page 149).

Glucose Monitoring

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

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

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

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

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

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 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 in this *Technical User Guide for iPhone*, 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.

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 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 make sure you have a current record of your settings and a new Pod with supplies to use when restarting the app.

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

Pod

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

Caution: ALWAYS insert the fill syringe into the fill port and not into any other location on the Pod. Do not insert the fill syringe more than once into the fill port. Use only the fill syringe and needle that came with your Pod. The fill syringe is intended for single use only and should only be used with the Omnipod 5 System. Failure to follow the instructions above may result in damage to your Pod.

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

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

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

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

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

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

- Immediately remove the Pod and apply a new Pod at a different infusion site.
- Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.
- If you see blood in your cannula, check your glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected high glucose, change your Pod.

Caution: Use caution while cleaning the Pod on your body. Hold the Pod securely so the cannula does not kink and the Pod does not detach from your skin.

Caution: DO NOT use 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.

Smartphone

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

Caution: DO NOT stop the Omnipod 5 App in a way that stops it from running in the background (called force stopping) on your smartphone, and do not power off 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. If you do, your Pod will remain active, but you will not be able to control your Pod even if you re-install or re-open the App. You must remove the Pod in order to stop receiving insulin.

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

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

Communication

Caution: When there is no communication between the Pod and the Controller or smartphone, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode. Restoring communication is needed to see your system status, notifications, and to send new instructions to the Pod. To restore communication try bringing the Controller or smartphone within 5 feet (1.5 m) of the Pod. See "26.5. Pod Communication Issues – "Try Again"" on "26.5 Pod Communication Issues – "Try Again"" on page 356.

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 "Check alarms" on page 156).

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

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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.

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CHAPTER 2

System Navigation

Contents

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.

Term	Description
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 Transmitter to the Pod.
Controller	Omnipod 5 device, supplied by Insulet, that contains the Omnipod 5 App for use to control the Omnipod 5 System. A compatible personal smartphone may be used with the Omnipod 5 App installed instead of a Controller. Throughout the *Technical User Guide*, 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.

Term	Description
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 Transmitter 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.

Term	Description
Sensor	Component of a sensor glucose monitoring system that is inserted under the skin to measure glucose in interstitial fluid.
Sensor Glucose Monitoring System	System to track glucose throughout the day and night, supplied by a third-party medical device manufacturer.
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 G6. Target Glucose can be set from 110–150 mg/dL in 10 mg/dL increments.
Transmitter	Component of a sensor glucose monitoring system that sends sensor glucose values to the Pod.
Units	How insulin is measured.

2.2 Using the Touchscreen and Entering Information

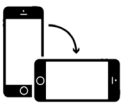
This section explains how to use the touchscreen on an iPhone, how to enter numbers or text into the Omnipod 5 App, and how this *Technical User Guide for iPhone* describes moving between Omnipod 5 App screens.

Touchscreen Basics

The Omnipod 5 App displays messages and options for you on your iPhone's touchscreen.

Tapping and swiping

The basic instructions for interacting with an iOS touchscreen are explained here. Refer to your iPhone instructions for a more complete list of gestures.

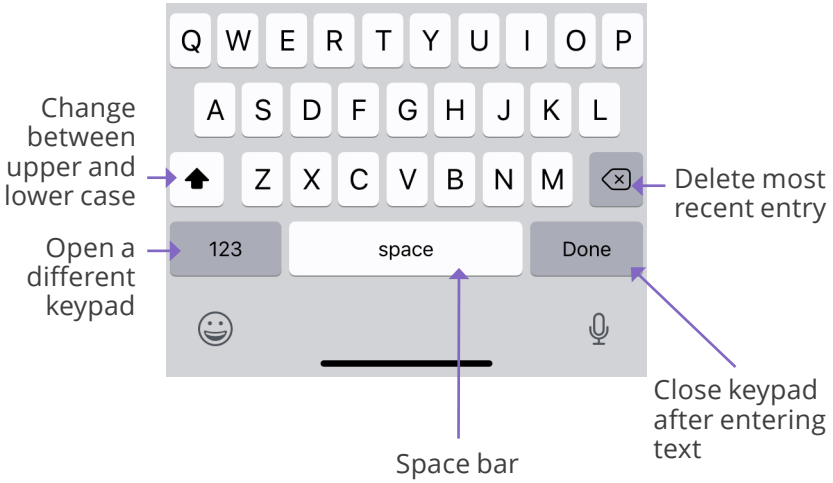
 Tap	Touch the screen, then lift your finger up.
 Swipe	Touch a starting point and move your finger up, down, left, or right. **Note:** Scrolling and swiping are related actions. When you swipe up, the screen display scrolls up to show items that are currently off-screen.
 Rotate	Rotate your iPhone from portrait (vertical) to landscape (horizontal) by turning the phone 90 degrees to the left or right. **Note:** Portrait Orientation Lock must be off for rotating to change the view. **Note:** A screen protector may decrease the touchscreen sensitivity.

Note: A screen protector may decrease the touchscreen sensitivity.

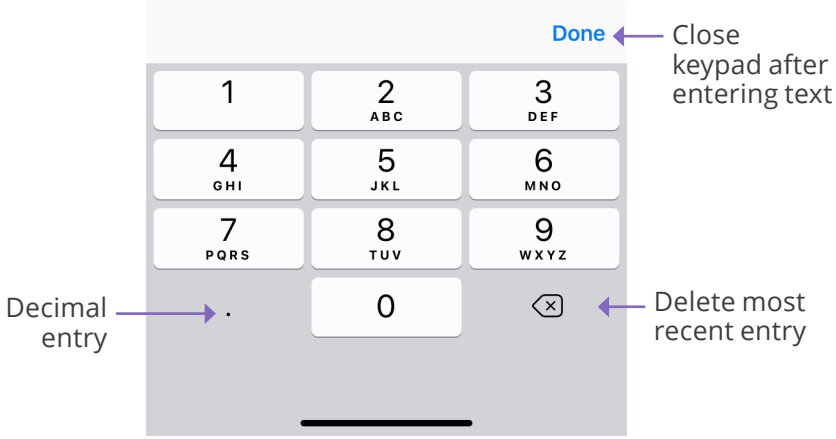
Entering Numbers and Text

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

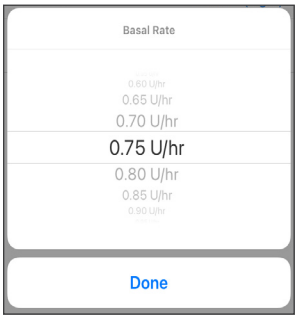
Using a keypad



Using a number pad



Using a scroll wheel



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

When your desired selection is shown in the center of the wheel, select the value by tapping **DONE**.

Selecting Items

Switches

Tap a switch to toggle the selection from one side to the other.

Switches allow you to toggle a feature on or off. The toggle is on the right side and green when a feature is on, and on the left and gray when a feature is off.

Navigation Buttons and Navigation Shorthand

Technical User Guide navigation shorthand

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

- **Menu** > **Pod** > **CHANGE POD**

  tells you to:

  1. Tap the Menu in the toolbar of the Home screen.
  2. Tap **Pod** to open the Pod screen.
  3. Tap **CHANGE POD**.

CHAPTER 3

Omnipod 5 System Overview

Contents

3.1 Omnipod 5 App and Dexcom Communication

The Omnipod 5 App

- On provided Controller or your compatible iPhone.
- Sends commands to the Pod.
- Displays glucose and insulin information from the Pod.
- Used to issue meal and correction boluses.

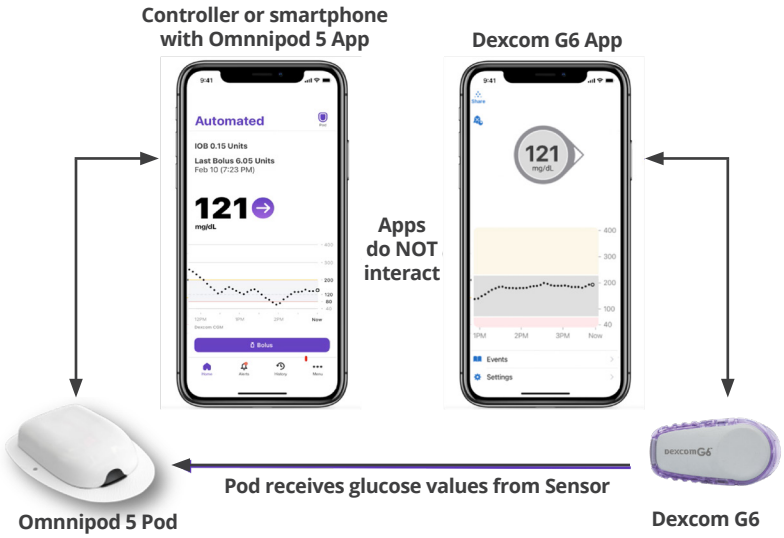
The Pod

- Delivers insulin to your body.
- Receives commands from the Omnipod 5 App.
- Receives sensor glucose values from the Dexcom G6 Sensor.
- Sends sensor glucose values to the Omnipod 5 App.
- Automatically adjusts insulin delivery in Automated Mode.

The Dexcom G6 Sensor

- Sends sensor glucose values to the Pod and to the Dexcom G6 app.
- Does not communicate directly with the Omnipod 5 App.
- Cannot communicate with Dexcom G6 receiver while paired with Pod.

  For Sensor-specific information, refer to your Dexcom G6 CGM System Instructions for Use.



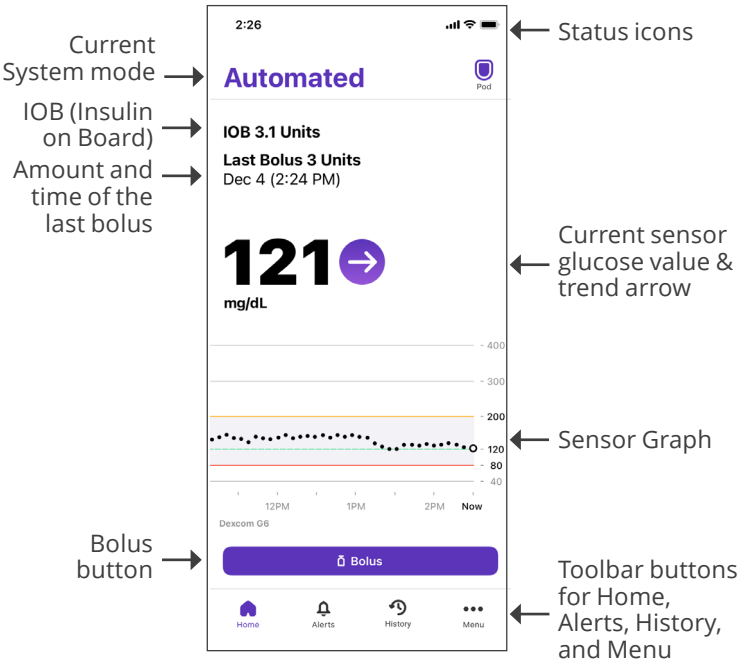
3.2 Omnipod 5 App

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.

This guide is intended for use with the Omnipod 5 App on an iPhone. If you intend to use the provided Controller or the App on an Android smartphone, consult the full *Omnipod 5 System Technical User Guide* at *https://www.omnipod.com/guides*.

3.3 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.



Use of Color in Omnipod 5

- **Purple**: In Automated Mode, most App features will be purple
- **Blue:** In Manual Mode, most App features will be blue
- **Green**: When the Activity feature is enabled, a green icon will display
- **Red** and **Yellow**: Highlight situations that need your attention, such as high and low glucose, System alarms, or an upcoming Pod change
- **Gray**: Used in situations where the System lacks information (such as Automated: Limited state) or for when a feature is temporarily unavailable

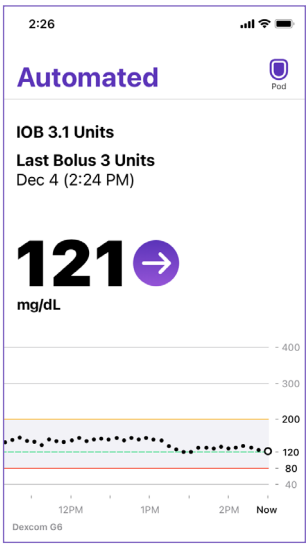
3.4 Status Icons

The top left corner of the Home screen displays a Mode Indicator to tell you whether your Omnipod 5 System is in Automated, Automated: Limited state, or Manual Mode.

In the top right corner, various status icons display that you can tap for information about your insulin.

Icon definitions:

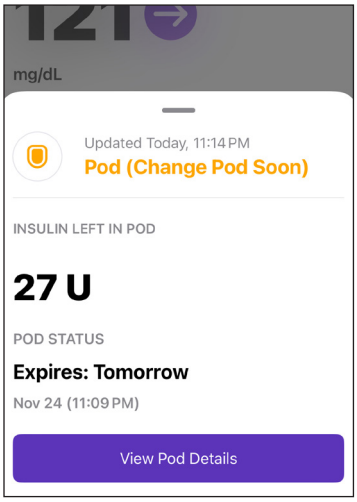
	Pod Icon – Automated Mode
	Pod Icon – Manual Mode
	Pod Icon – Change Pod soon
	Pod Icon – Low Pod Insulin
	Pod Icon – No active Pod
	Basal Program active (Manual)
	Temp Basal active (Manual)
	Activity is on (Automated)

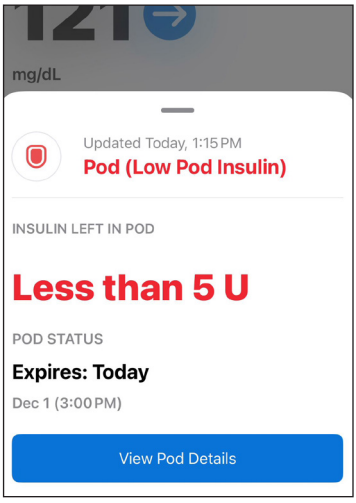


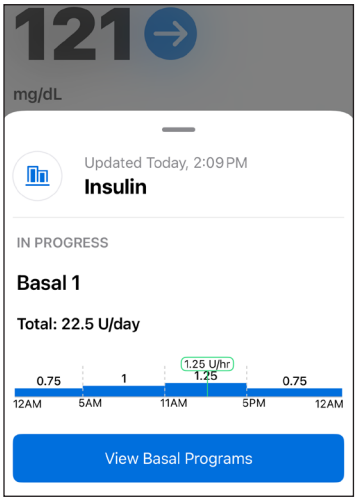
Tapping these icons will bring up a status sheet with more information about:

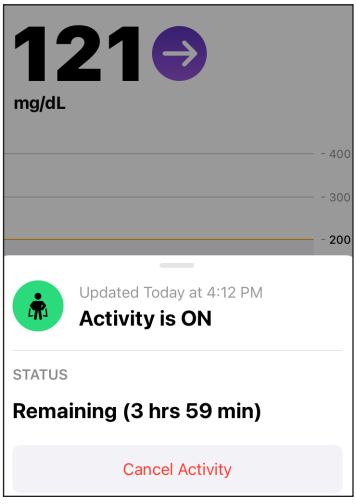
- the time or insulin remaining in your Pod
- details about your current Basal Program or temp basal (Manual Mode)
- or the time remaining on your Activity feature (Automated Mode)

In many cases, you can use these status sheets as a shortcut for actions available in the menu, such as canceling Temp Basal or the Activity feature.

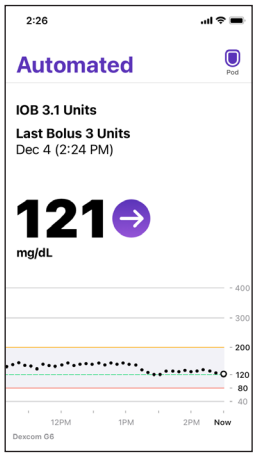






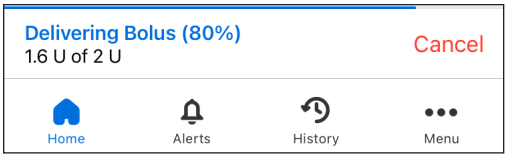


3.5 Bolus Information and Button



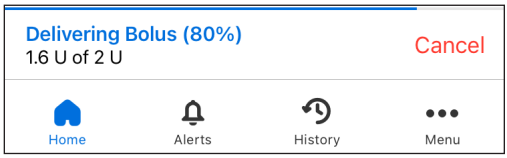
The upper left section of the Home screen displays bolus information. The Bolus button is at the bottom.

- During an immediate bolus, the IOB estimate is updated every second.
- Bolus progress displays above the toolbar at the bottom of the Home screen.



Note: When a bolus is in progress, some areas of the App are unavailable. You can navigate to History, but you cannot make therapy changes or start a new bolus.

- 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

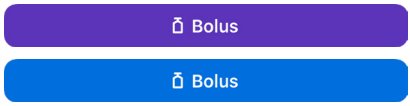
If the Pod is out of range of the iPhone running the Omnipod 5 App and cannot confirm the recent bolus amount, an estimated bolus amount is shown. Once the Pod is in range again and the bolus delivery is confirmed, the confirmed bolus amount is shown.

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 139).

Bolus button

The Bolus button at the bottom of the Home screen 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. The bolus button is purple while in Automated mode and blue while in Manual mode.

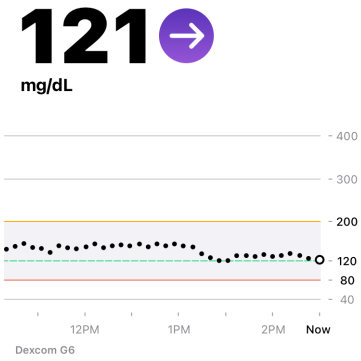


3.6 Sensor Value and Trend

The center of the Home screen displays information about your glucose. When you have a paired Transmitter and active Sensor, your sensor glucose value, trend arrow, and Sensor graph will show here.

Sensor Value Color Key

The sensor glucose value and trend arrow will change color depending on your Glucose Goal Range.



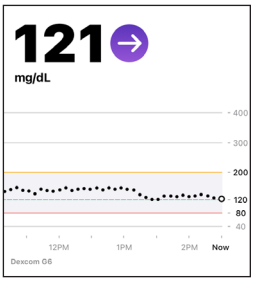
- Sensor glucose value within Glucose Goal Range (Manual)
- Sensor glucose value within Glucose Goal Range (Automated)
- Sensor glucose value below Glucose Goal Range (Automated & Manual)
- Sensor glucose value above Glucose Goal Range (Automated & Manual)

Note: A sensor glucose value will not be displayed if in Limited or No Pod Communication states.

3.7 Sensor Graph

When you have a paired Transmitter and active Sensor, your sensor glucose value, trend arrow, your Sensor graph will show the last few hours of glucose information from your paired Sensor.

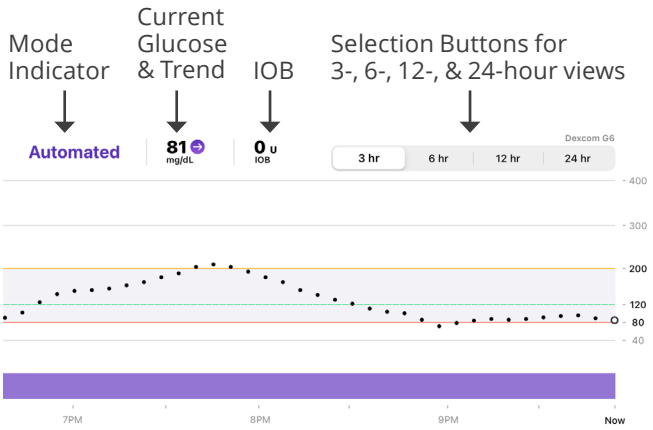
Tapping the Sensor graph allows you to cycle through views of 3-, 6-, 12-, and 24-hours.



When you rotate the phone into a landscape view (horizontally), the graph will expand to fill the whole screen and show you additional information.

The landscape view of the Sensor graph shows you the following across the top of the screen:

- mode indicator
- current glucose and trend
- IOB
- selection buttons for 3-, 6-, 12-, and 24-hour views

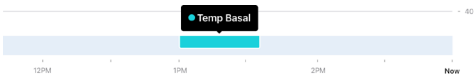


Note: Portrait Orientation Lock must be off for rotating to change the view.

The bottom of the landscape view shows information about the mode that Omnipod 5 was operating in during that time period. Tap any element on the graph for more information.

- Manual Mode (blue)

- Temp Basal (aqua)



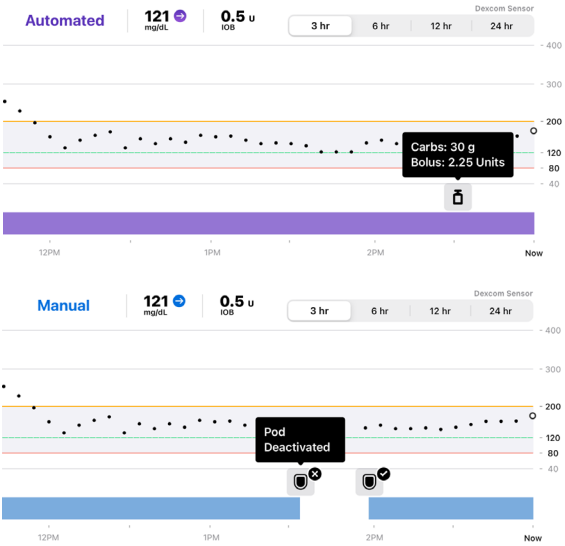
- Automated Mode (purple)

- Automated Mode: Limited (gray)

- Activity Feature (green)

- Automated Delivery Restriction (yellow)
- Insulin Paused (red)

This view also shows information about your boluses and Pod activations and deactivations. Tap any element on the graph for more information.

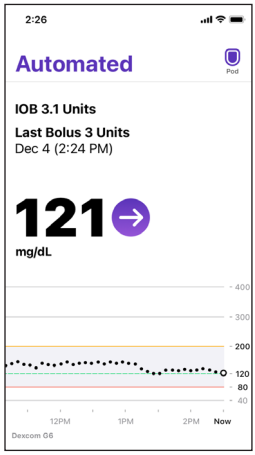


3.8 Toolbar

The bottom of the Home screen displays a toolbar with four buttons to help you navigate your Omnipod 5 System.

The four toolbar buttons are:

Home	Home
Alerts	Alerts (with no active alerts)
Alerts (3)	Alerts (with active alerts)
History	History
Menu	Menu



Tapping these buttons will open additional screens of the App where you can:

- view and resolve alarms and notifications
- view details about your recent insulin delivery history
- access the menu for settings and device maintenance

Note: The toolbar button will be filled in with color to indicate your current App screen, in purple or blue depending on your mode.

3.9 Home Screen Main Menu

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

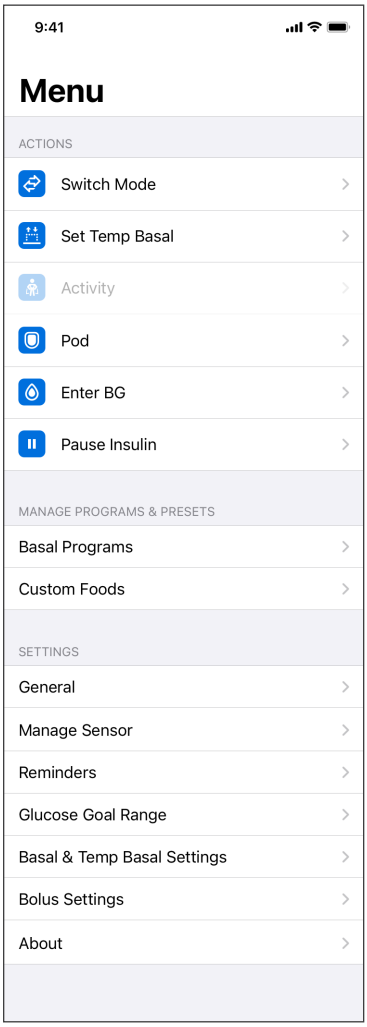
➢ Tap the Menu in the toolbar.

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

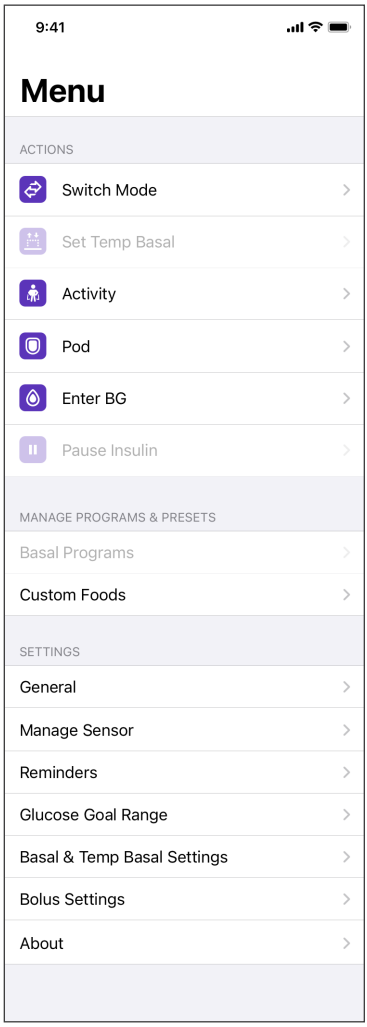
Tip: The Menu extends beyond the bottom of the screen. Swipe up or down to see all parts of the Menu.

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

Manual Mode



Automated Mode



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

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	√	√
Enter BG	√	√
Start or Pause Insulin	√	
Manage Programs & Presets		
Basal Programs	√	
Custom Foods	√	√
Settings		
General	√	√
Manage Sensor	√	√
Glucose Goal Range	√	√
Basal & Temp Basal Settings	√	
Bolus Settings	√	√
Reminders	√	√
About	√	√

About screen

The About screen displays details about your Omnipod 5 System, such as the Omnipod 5 App version number, Customer Care contact information, the Pod version number, the time of the most recent Omnipod 5 App-Pod communication, the time of the most recent sync to Insulet Cloud, and other legal information.

3.10 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, and do not power off 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: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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 System on your iPhone require Critical Alerts permission, Notifications, and Notifications permission to be turned on to ensure you always receive important safety alarms. You cannot use the App until Critical Alerts permission is provided and Notifications and Notifications permissions are turned on.

The Omnipod 5 App can deliver Omnipod 5 notifications and confirmations 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 and Action Item Notifications.

Alarms

Alarms require your immediate attention (see "Pod alarms" on page 151). 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 "13.8 Action Item Notification List" on page 172) are 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.

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.
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 Transmitter serial number (SN)	View Transmitter serial number (SN)
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 Item Notifications" on page 149 for a detailed list of alarms and notifications.	

Identifying System modes

The mode indicator shows Omnipod 5 System's current operating mode. It displays in the upper left-hand corner of the Home screen.

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 on Your iPhone

Contents

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 Dexcom G6 Sensor.

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

For training information about your Dexcom G6, refer to your *Dexcom G6 CGM System 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 for the Controller
- *Omnipod 5 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 G6 CGM System and supplies must be obtained from Dexcom or an authorized distributor. Refer to the *Dexcom G6 CGM System Instructions for Use*.

Items needed for your training

- Your Controller and iPhone with Omnipod 5 App and charger
- Your Dexcom G6 Transmitter and Sensor
- Your Dexcom G6 app on your iPhone
- Two Pods
- *User Guide for iPhone*
- Access to this *Technical User Guide for iPhone*
- 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 and iPhone are charged before training begins. You will sign in to the Controller even if you intend to use only your iPhone. The Insulet-provided Controller should be charged only with the provided wall adapter and cable.
For additional instructions on charging your Controller, consult Chapter 14 of the full *Omnipod 5 System Technical User Guide*, available at *https://www.omnipod.com/guides*.

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.

Users New to Omnipod 5

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 and operating systems at *omnipod.com/compatibility*.

If you choose to use the Controller provided by Insulet, please refer to the full Omnipod 5 *Technical User Guide* at *https://www.omnipod.com/guides*. This *Technical User Guide for iPhone* does not cover use of the Controller beyond setup.

If you choose to use the Omnipod 5 App on your iPhone, 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: After you have signed in to 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.

You'll be presented with a short in-app learning experience to introduce you to the differences between the Controller and the iPhone App.

Existing Omnipod 5 Users Moving to iPhone from the Insulet-provided Controller or Android Smartphone App

If you choose to move from the Controller or Android app to the Omnipod 5 App on your iPhone, you can sign in to the iPhone app with your Omnipod ID without additional interaction with your Controller.

You'll be presented with a short in-app learning experience to introduce you to some important new features and/or differences between the Controller and the iPhone App.

Treat the iPhone App experience as though it is a completely new Controller.

- **New Setup:** Your settings must be re-entered. They are stored on your previous device and will not transfer over. It is recommended that you copy all your settings from your previous device and double-check each as you re-enter it.
- **New Pod:** You will need to deactivate and remove your old Pod and activate a new Pod. Your old Pod cannot connect to two Apps at one time. Your Dexcom G6 Transmitter will need to connect to your new Pod to enter Automated Mode.
- **New Adaptivity:** Adaptivity will start over with your first Pod on the iPhone System. Your adaptive settings are stored on your previous device and will not transfer over. Remember that there may be an adjustment period for the first few Pods.

4.4 Turning On and Signing In to Your 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 175 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.Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:

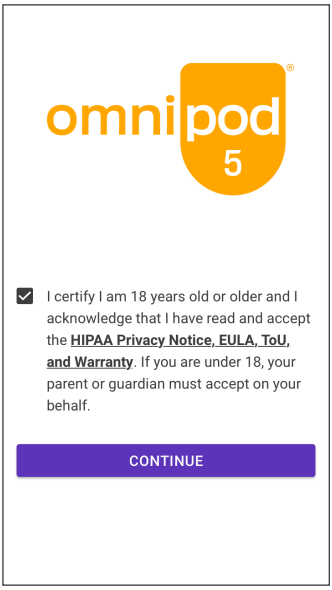
4. Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:

   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.**

The username and password are case-sensitive.

Setting Up Training

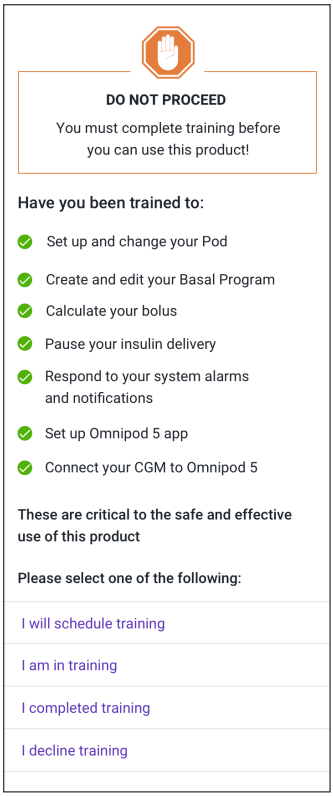
After signing into the Controller, you will be prompted to schedule or confirm training for the Omnipod 5 System.

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 sign into the Omnipod 5 App on your smartphone. If you intend to use your smartphone for the Omnipod 5 App, you do not need to continue with any further Controller setup at this time.

4.5 General Settings on Your iPhone

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.

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.

If you choose to use the Omnipod 5 App on your iPhone, 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 iPhone for the Omnipod 5 App and have not yet signed into your Insulet-provided Controller, see “4.3. Choosing a Controller or smartphone" on page 60 and “4.5. General Settings on Insulet-provided Controller” on page 62

If you are an existing Omnipod 5 user setting up the iPhone App for the first time, see “Existing Omnipod 5 Users Moving to iPhone from the Insulet-provided Controller or Android smartphone App” in “Chapter 4.3. Choosing a Controller or smartphone” on page 60.

Using the Omnipod 5 app on Your iPhone

If you use your iPhone, you will need to download the Omnipod 5 App from the App Store®.

Caution: DO NOT install apps on your iPhone 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., App Store). 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 the App Store on your iPhone 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.

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.

Noter: ALWAYS check that your iPhone 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 iPhone 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 iPhone storage.

Required iPhone settings

The Omnipod 5 System relies on some of your iPhone's settings to function. If these settings are not correctly set, the App will navigate you to your iPhone'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 iPhone, find the Settings app and tap to open.

Required Setting	iPhone Settings menu location	ON or OFF
Allow Notifications	"Notifications > Omnipod 5 App"	ON
Allow Critical Alerts	"Notifications > Omnipod 5 App"	ON
Bluetooth	"Bluetooth"	ON
Date & Time: Set Automatically	"General > Date & Time"	ON
Face ID & Passcode	"Face ID & Passcode"	ON
Sounds & Haptics	"Sounds and Haptics"	ON

Recommended iPhone 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 iPhone's settings menu to enable the setting.

Note: Use of Wi-Fi is required during first-time setup.

Recommended Setting	iPhone Settings menu location	ON or OFF
Wi-Fi	"Wi-Fi"	ON

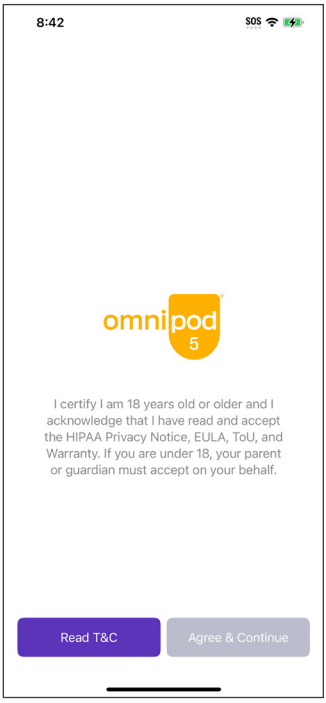
Caution: DO NOT enable any app development settings on your iPhone. Enabling these settings may cause issues with the Omnipod 5 App and prevent normal app operation.

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

Signing in to the Omnipod 5 App on Your iPhone

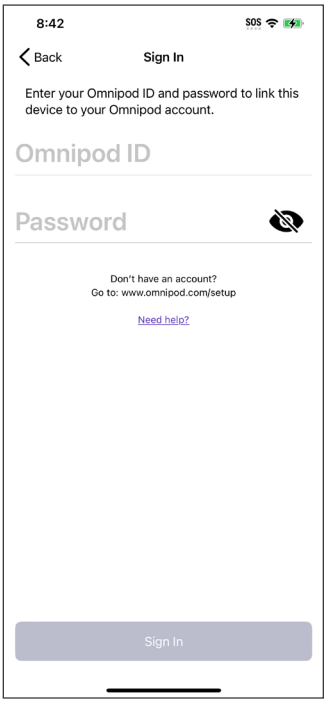
1. Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:
   a. Tap **Read T&C** to read the Omnipod 5 System's legal notices and privacy policy.
   b. Tap **Agree & Continue**.

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



2. 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.



In-App Learning Video

You will be presented with a short in-app learning experience to introduce you to the key differences between the Controller and the iPhone App.

This video covers:

- Differences of the Home screen
- Differences of Navigation
- Introduction of Custom Foods

You must complete this video to proceed with setup of the Omnipod 5 App for iPhone.

Note: This short video does NOT replace the full and complete System training available to you through an Omnipod 5 Trainer, the training modules at *http://www.omnipodID.com*, or the video tutorials on the Omnipod website.

Setting Your Omnipod 5 App Security on Your iPhone

Use of the Omnipod 5 App on your iPhone 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 app. Tap the Settings app to open it. Tap Face ID & Passcode to personalize these settings.

If someone other than you uses or has regular access to your iPhone (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 Passcode (or other selected security method) each time you access the Omnipod 5 App.

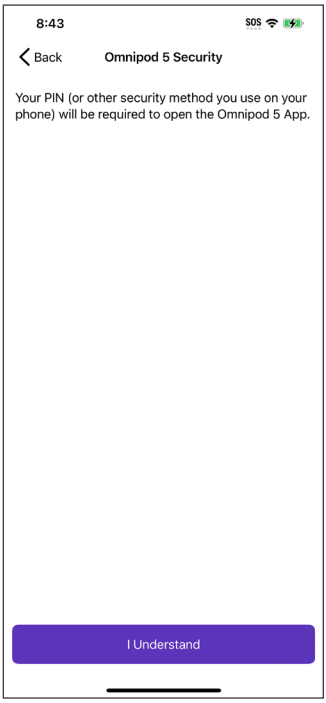
Omnipod 5 Security cannot be turned off.

After you've signed in to the Omnipod 5 App on your iPhone 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 iPhone, 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 iPhone's Settings. Tap **Face ID & Passcode**. 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**.
   - ➢ Follow the prompt to enter your security method.

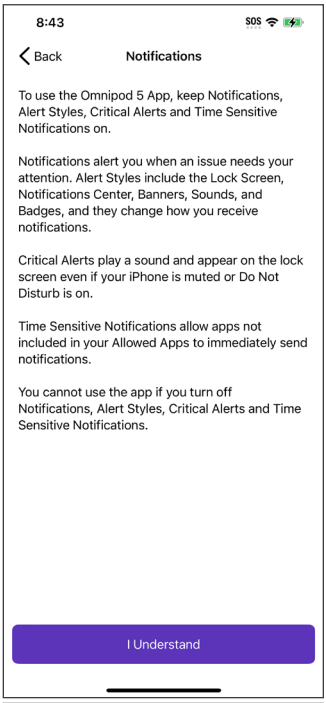


Enabling Notifications and Sound on Your Smartphone

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**.

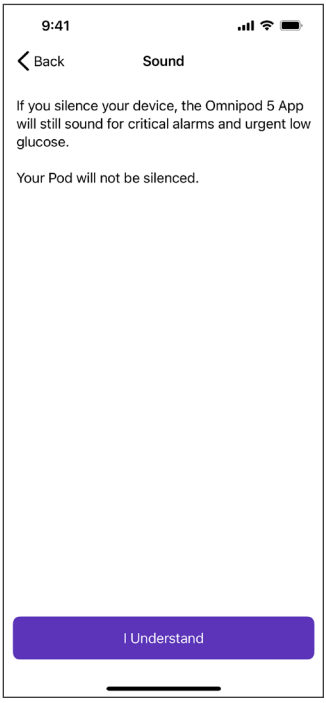
Follow the prompt to enter your security method.



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 alerts and alarms, such as Urgent Low glucose. Your Pod will not be silenced.



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.

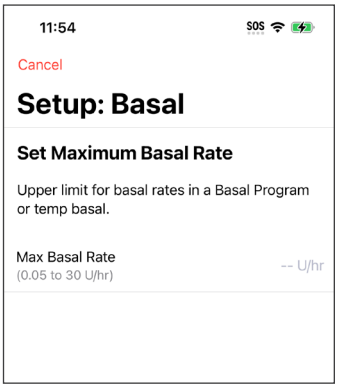
Next, you will set basal settings, which will be used to deliver basal insulin while in Manual Mode.

➢ Tap **Set Up Profile**

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 **Done** to select it.
3. Tap **Next**.

Note: You can adjust your Maximum Basal Rate later if your needs change. See "Maximum Basal Rate" on page 131.

Create a Basal Program

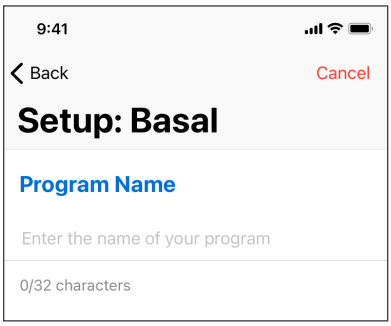
The next step is to create a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Basal Programs" on page 103.

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

Name the Basal Program

Enter the name of your program.

1. To set the name, tap the Program Name field and enter the new name.
2. Tap **Done** to close the keypad.
3. Tap **Next**.



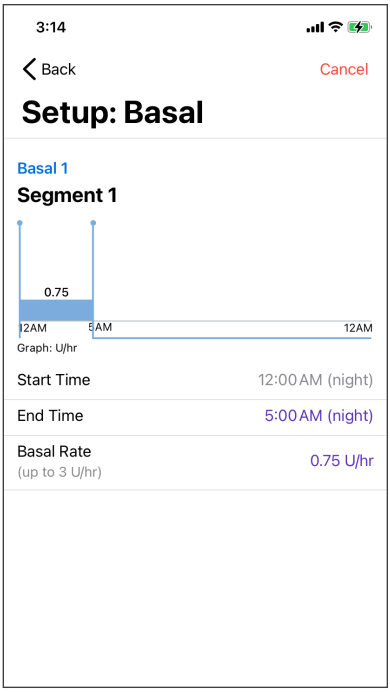
Define the Segments

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.

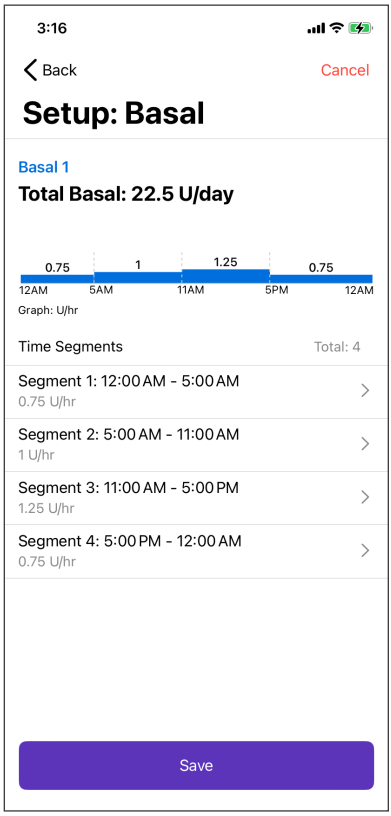
   Note: The Maximum Basal Rate that you entered earlier is displayed under the Basal Rate text. You cannot enter a basal rate greater than this number.

   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



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.
   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.

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.

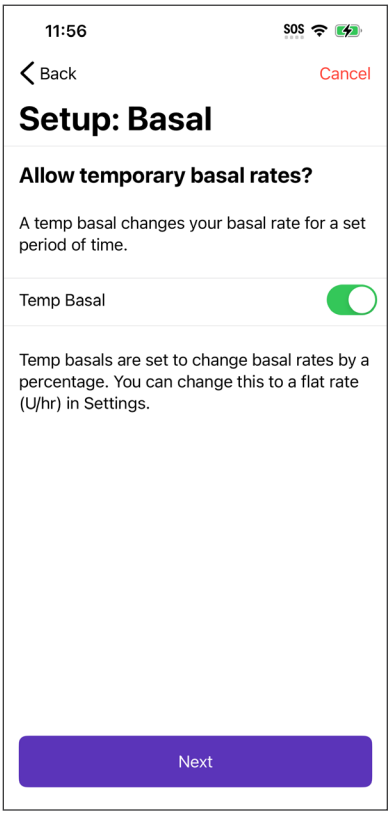
Note: To create additional Basal Programs after setup is complete, start at page 103 and begin steps again.

Temporary Basal Configuration

For a description of temporary basal rates, also called temp basals, see page 108.

Note: Temp basal is available in Manual Mode only.

1. If you want the ability to use temp basals, tap the switch to the on position. The switch is in the on position when it is on the right and is green.
   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 132.
2. Tap **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 234 for more information).

1. Tap 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

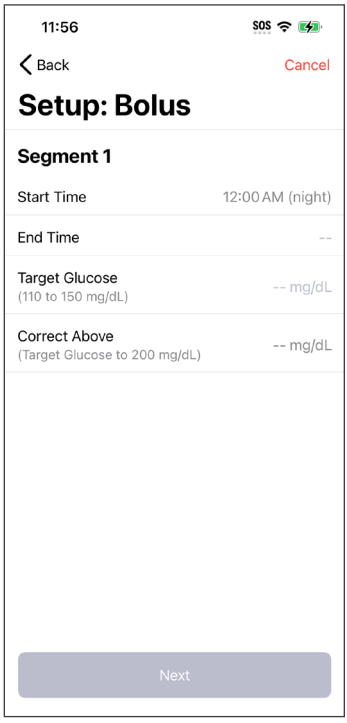
Target Glucose and Correct Above values are used in both Automated and Manual Modes.

- 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.

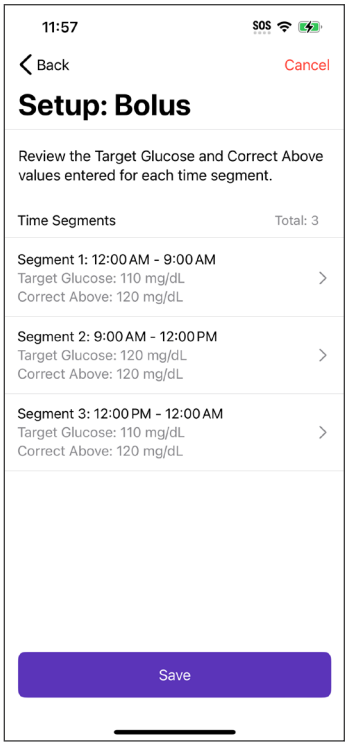
Define the Segments

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**.
5. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.



6. Review the segments for the full 24-hour profile.
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**.



Insulin to Carb (IC) Ratio

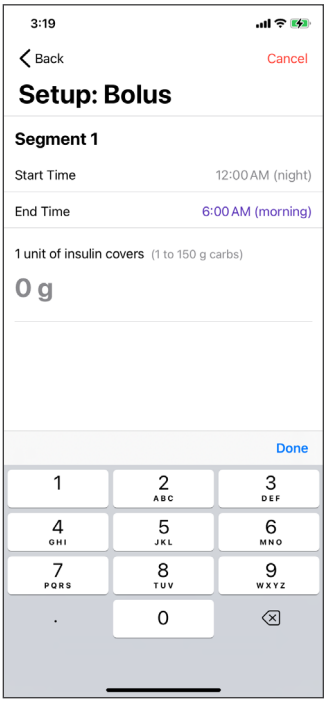
Your Insulin to Carbohydrate Ratio, or "IC Ratio," defines how many carbohydrates are covered by one unit of insulin.

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.

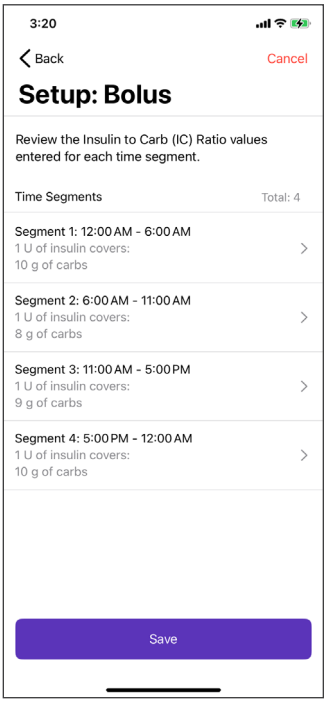
➢ Tap Next on the Set Insulin to Carb (IC) Ratio description screen to move to the Insulin to Carb Ratio segment screen.

Define the Segments

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



Correction Factor

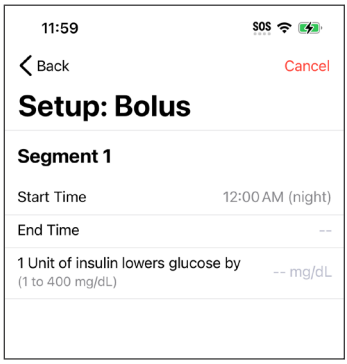
Your Correction Factor defines how much one unit of insulin lowers your glucose. For example, if your Correction Factor is 50, one unit of insulin lowers your glucose by 50 mg/dL.

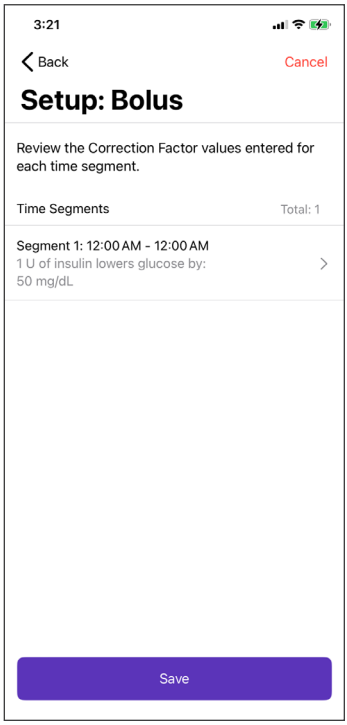
The SmartBolus Calculator uses the Correction Factor to calculate the correction portion of a suggested bolus. You can create up to eight Correction Factor segments per day.

➢ Tap Next on the Set Correction Factors description screen to move to the segment screen.

Define the Segments

1. Tap the End Time field and specify an end time for the segment.
2. Tap the 1 U 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**.

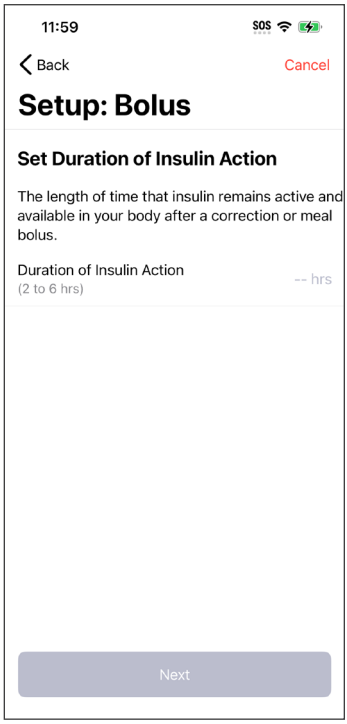




Duration of Insulin Action

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).

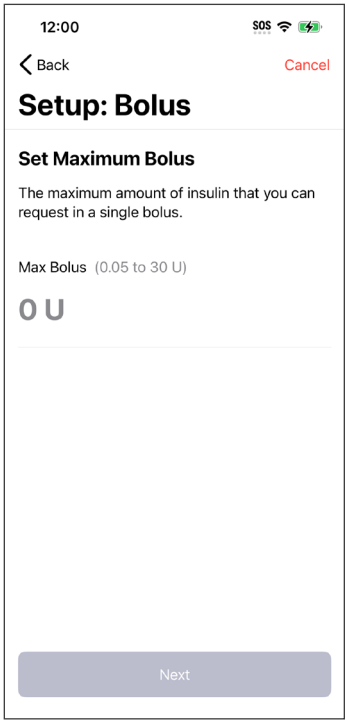
1. Tap the Duration of Insulin Action field and scroll to select your Duration of Insulin Action.
2. Tap **NEXT**.



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**.

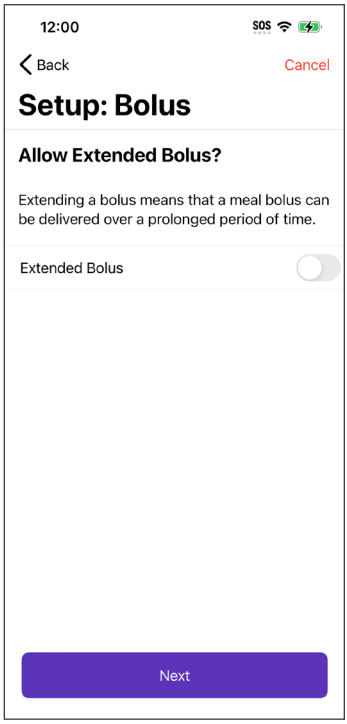


Extended Bolus

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: xtended bolus is available in Manual Mode only.

1. To turn the Extended Bolus feature on, tap the switch to the on position. The switch is in the on position when it is on the right and is green.
2. Tap **Next**.



4.8 Your App Setup is Complete

Congratulations! Omnipod 5 App setup is complete.

When you are ready to activate your first Pod, go to "5.1. Beginning the Pod Activation Process" on page 84.

After successfully activating the Pod, you will be prompted to connect your Sensor to the Omnipod 5 System. See "Connecting Sensor to the Pod" on page 270.

4.9 Saving Your Settings for Reference

Caution: DO NOT reset the Omnipod 5 App 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, 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. 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 screenshots 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 between using the Controller and using the Omnipod 5 App on your iPhone.
- Delete the Omnipod 5 App from your iPhone.

CHAPTER 5

Activating and Changing Your Pod

Contents

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.

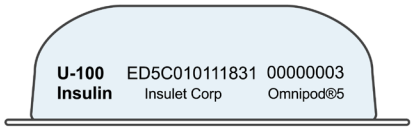
Caution: ALWAYS rotate insulin infusion sites to help prevent infusion site complications like scar tissue and infection. Rotating insulin infusion sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption.

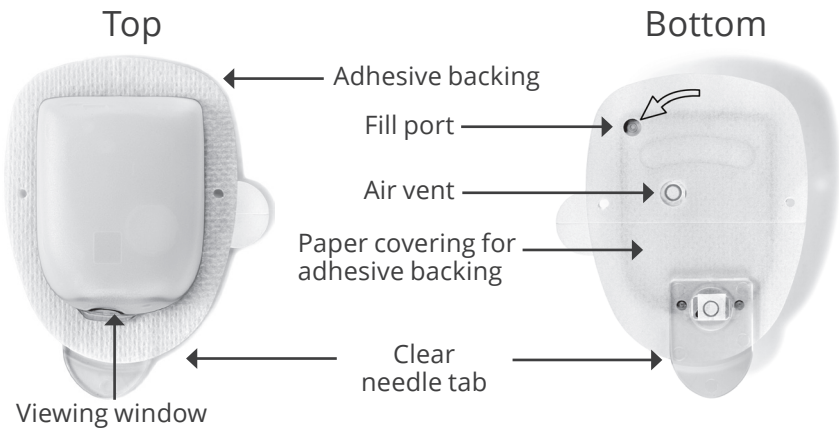
After initial Omnipod 5 app setup, you will activate your first Pod. Your Pod should be changed at least once every 48 to 72 hours (2 to 3 days) or after delivering 200 units of insulin. Consult with your healthcare provider to determine if you should change your Pod more often.

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.
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.

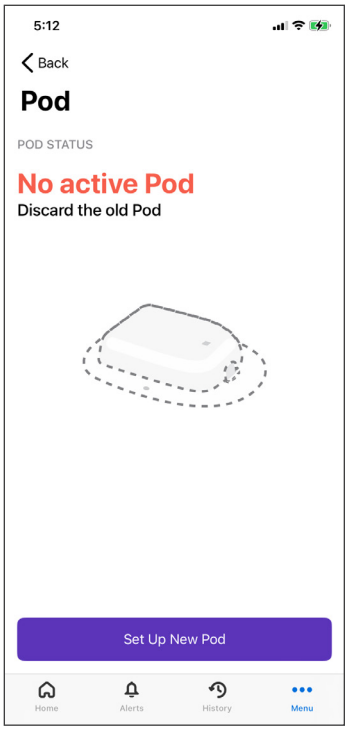
Confirm that you are using an Omnipod 5 Pod prior to beginning Pod activation. Look for the Omnipod 5 logo on the Pod tray lid and the words “Omnipod 5®” on your Pod.





5.2 Setting Up a New Pod

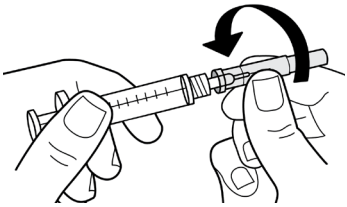
1. Navigate to: Menu > Pod or tap the Pod status icon.
2. Tap **SET UP NEW POD**.



5.3 Fill the Syringe with Insulin

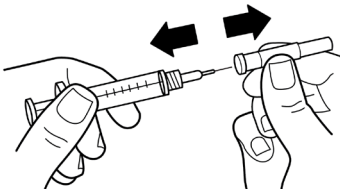
Warning: NEVER inject large bubbles or pockets of air when filling the Pod with insulin. Air in the system takes up space where insulin should be and can affect insulin delivery. Doing so could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

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.

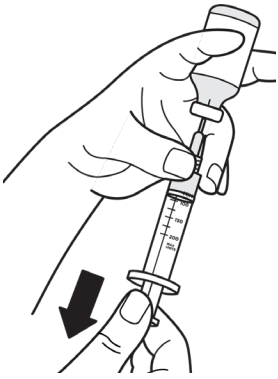
Pull apart



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. Draw air into the fill syringe up to the amount of insulin you want.

   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.

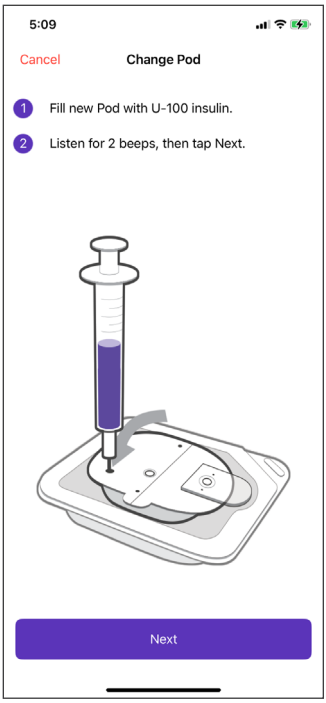
5.4 Filling, Activating, Applying, and Starting the Pod

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.

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. 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):

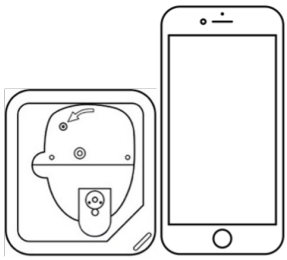
4. Be sure to completely empty the fill syringe, even after hearing the two beeps.

   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 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



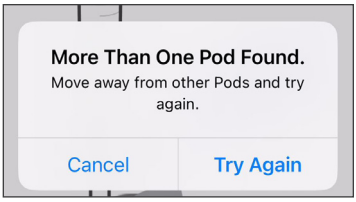
To activate the Pod:

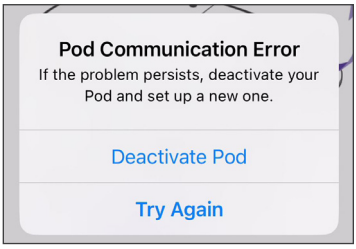
1. Place your iPhone next to the Pod so they are touching. The Pod should be in its plastic tray during this process.

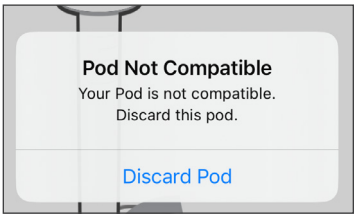
   Note: ALWAYS ensure that no other Pods are being activated within 20 feet (6 m) of your Omnipod 5 App before filling a Pod. If the App detects more than one Pod, you will not be able to proceed.

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 at least 20 feet (6 m) 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.
- 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 358.

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:

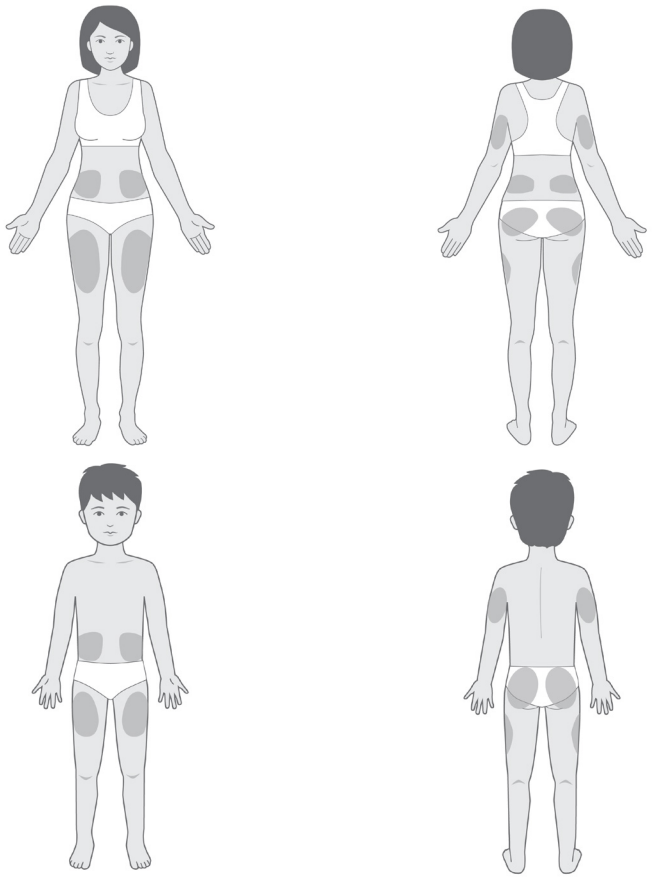
Guidelines for Pod site selection

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

- Place at least 3 inches (8 cm) from your Sensor site, as indicated in your *Dexcom G6 System Instructions for Use*.
- Place within line of sight of the Sensor for the best connectivity. See "19.2. Sensor Placement" on page 263.

  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



Prepare the infusion site

To reduce the risk of infection at the infusion site:

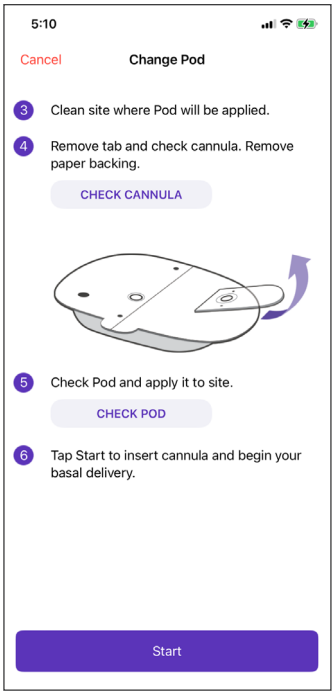
1. Wash your hands with soap and water.
2. Wash your selected infusion site with soap and water.

   Note: Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare provider how to treat any skin irritation.
3. Dry the infusion site with a clean towel.
4. 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.
5. 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.

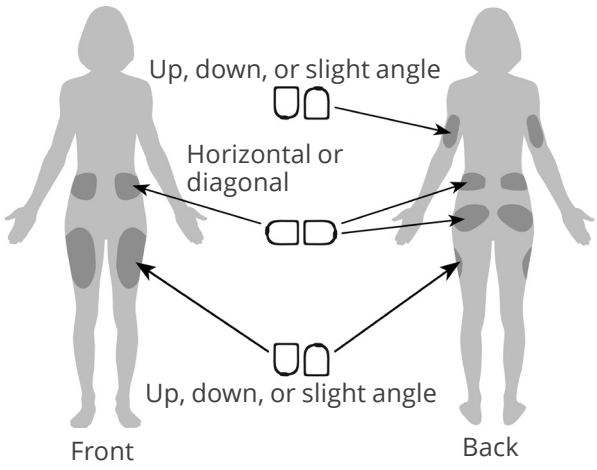
Apply the Pod

Tap **check Pod** and apply it to site (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.
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 at least 3 inches (8 cm) from and 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. See "19.2. Sensor Placement" on page 263.

     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.

Start 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.

Start 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.

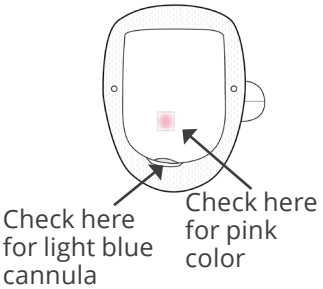
5.5 Checking Your Infusion Site

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. 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 156).

5.6 Switching to Automated Mode

An active Pod and Transmitter serial number (SN) are required to switch to Automated Mode. If you have a Transmitter (SN) 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 "22.1. Switching from Manual Mode to Automated Mode" on page 290.

After switching to Automated Mode, you may see Automated Mode: Limited until sensor glucose values are available. See "21.5. About Automated Mode: Limited" on page 284.

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.

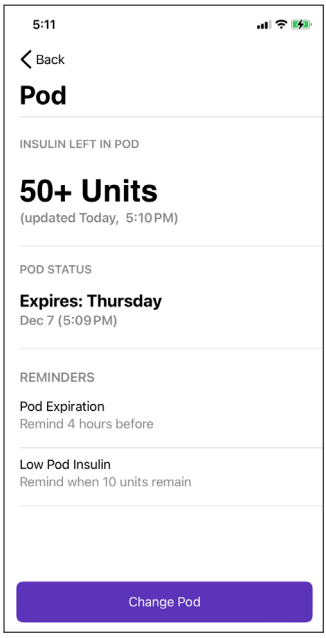
Caution: NEVER reuse the Pod or fill syringe or try to use a fill syringe that did not come with your Pod. Always dispose of the used Pod and fill syringe according to local disposal guidelines. Only use a new Pod with included fill syringe with each Pod change. Always carry supplies to perform a Pod 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:
   Tap the Pod status icon or
   Tap **Menu** > **Pod**.
2. Tap **Change Pod**, then tap **Deactivate**. If a temp basal, extended bolus, or the Activity feature was enabled, it is canceled now.

   If you see a communication error message, see "Error when activating a Pod" on page 358.

   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 Transmitter serial number (SN) entered in to the Omnipod 5 App.



3. Remove the deactivated Pod from your body:
   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 98).

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: 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.

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 192.
- To learn about the Pod alarms, see page 149.
- To learn how to silence a Pod alarm (see "13.9. Silencing Unresolved Alarms" on page 188).
- To understand the Pod's informational and notification beeps, including which beeps are optional, see "13.11. Reminder Notifications List" on page 190 and "13.4. Informational Sounds and Vibrations" on page 152.
- To understand how to handle situations where the Omnipod 5 App cannot communicate with your Pod, see "26.5. Pod Communication Issues – "Try Again"" on page 356.
- If you receive a “No Pod Communication" error:
    - To find the last time the Omnipod 5 App successfully communicated with the Pod, tap the Pod status icon.
    - If you are unable to restore communication with the Pod and want to change to a new Pod, navigate to: Menu > Pod > Change Pod.

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CHAPTER 6

Basal Programs

Contents

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 111.
- Switch to Manual Mode if currently using Automated Mode. See "22.2. Switching from Automated Mode to Manual Mode" on page 292.

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*.

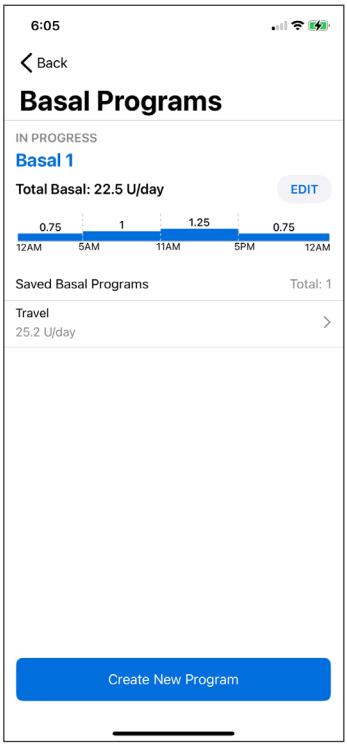
6.2 Reviewing All Basal Programs

To review all Basal Programs:

1. Navigate to the list of Basal Programs:

   Menu > **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 < Back to close that graph.

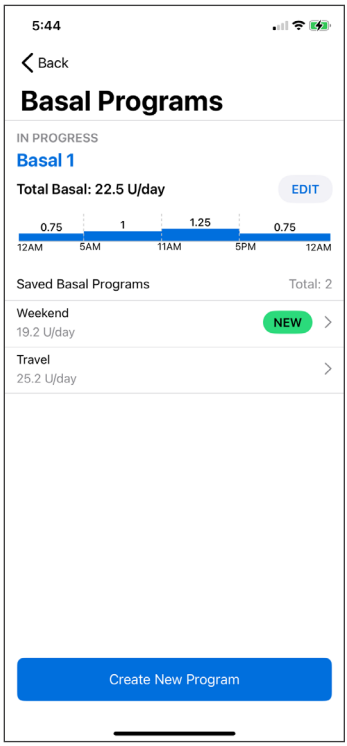


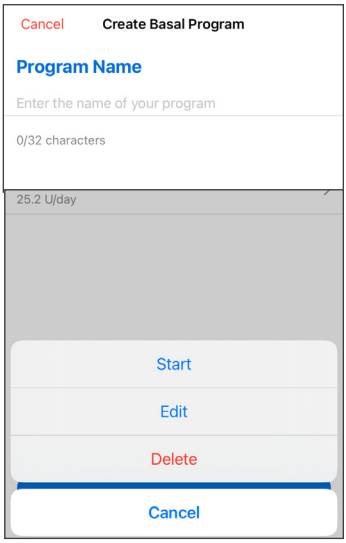
6.3 Creating New Basal Programs

To create a new Basal Program:

1. Tap **Menu** > **Basal Programs**.
2. Tap **Create New Program**.

   Note: If you already have 12 Basal Programs, Create New Program does not appear. If necessary, you can delete an existing Basal Program. See "6.5. Deleting a Basal Program" on page 104.
3. Enter a name for your new Program and tap **Next**. Tap **Done** to close the keypad.
4. Define each basal segment of your new program as you did in "4.6 Basal Programs" on page 71 when you set your first default Program. Each segment requires an end time and a basal rate.
5. When all segments have been defined and your Basal Program is complete, tap **Save**.
6. You will see a green icon that reads NEW next to your new Program.
7. If you have an active Pod and you want to use the new Basal Program now, tap the new Program, and tap **Start** to start using the new Basal Program.
8. 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. Tap **Menu** > **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** above the graph of the program in progress. Then tap **Pause Insulin**.
   - To edit a saved Basal Program, tap the Basal Program you want to edit. Then tap **Edit**.
3. To rename the Basal Program, tap the Program Name field and enter the new name.
4. Tap **Done**.
5. Tap **Next**.
6. When all edits have been made and your Basal Program is complete, tap **Save**.
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. Tap **Menu** > **Basal Programs**
2. Tap 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. Tap **Menu** > **Basal Programs**. A list of Basal Programs appears with the Program in progress at the top.
2. Tap on the Basal Program you want to switch to. Then tap **Start**. Tap **Start** again.

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 your 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.

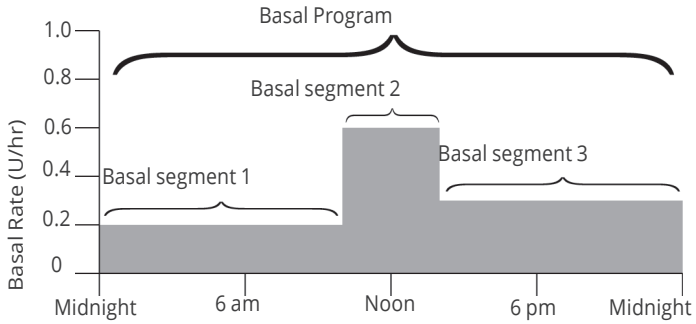
Manual Mode Basal Programs

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.

This figure shows a Basal Program with three basal segments that deliver 7.4 U total in a 24-hour period.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 103).

CHAPTER 7

Temporary Basal Rates

Contents

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 132.

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.

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

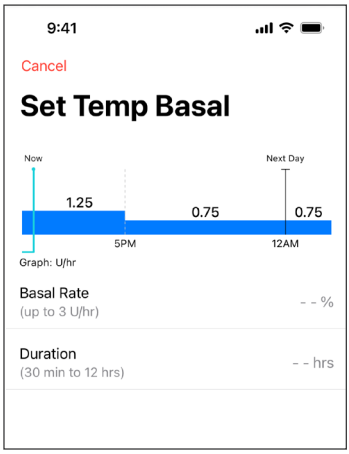
- Temp basal setting must be on. If it is off, see "10.3. Basal and Temp Basal Settings" on page 132.
- If the Omnipod 5 System is currently in Automated Mode, switch to Manual Mode. See "22.2. Switching from Automated Mode to Manual Mode" on page 290.

7.2 Starting a Temp Basal

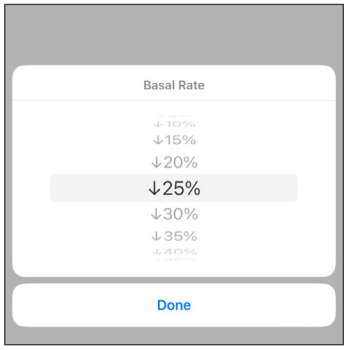
Note: You cannot start or cancel a temp basal during an immediate bolus, but you can start or cancel a temp basal while an extended bolus is in progress.

1. To start a temp basal:

   Menu > **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.

3. Tap **Done**

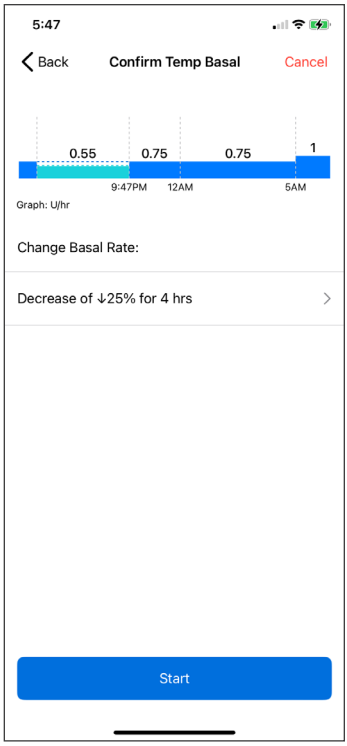
   Note: To change whether temp basals are configured as percent (%) or U/hr, see "10.3. Basal and Temp Basal Settings" on page 132.

   Note: The scroll wheel will not scroll above your Maximum Basal Rate. To adjust your Maximum Basal Rate, see "Maximum Basal Rate" on page 131.

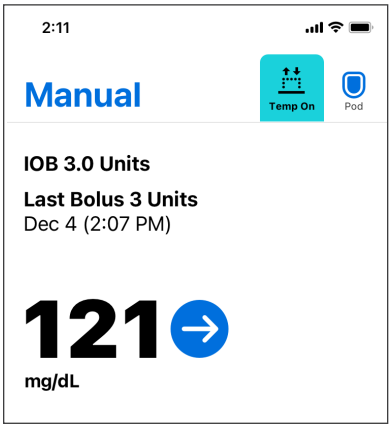
   Tip: You can turn off insulin delivery for the duration of the temp basal by setting a decrease of 100% or setting the temp basal to 0 U/hr. For more information, see "7.4. Temporary Basal Rates Delivery" on page 111.

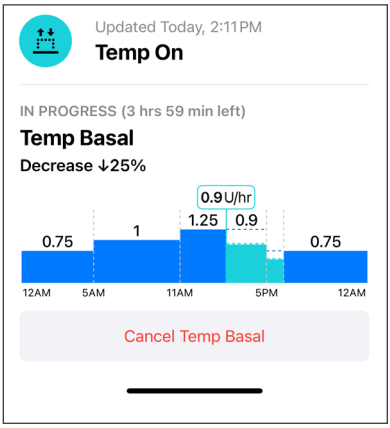
4. Tap the Duration field and scroll to the desired temp basal duration (between 30 minutes and 12 hours). Tap **Done**.

5. 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.
6. Tap **Confirm**.
7. Review the temp basal details. If corrections are needed, tap on the row to change. Then enter your corrections and confirm them.
8. To start the temp basal, tap **Start**. Then tap **Start** again.



After the temp basal starts, the Home screen will show a Temp Basal status icon that you can tap for more details or if you want to Cancel it early.





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 and tap the Temp Basal status icon.
2. Tap **Cancel Temp Basal**.
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.

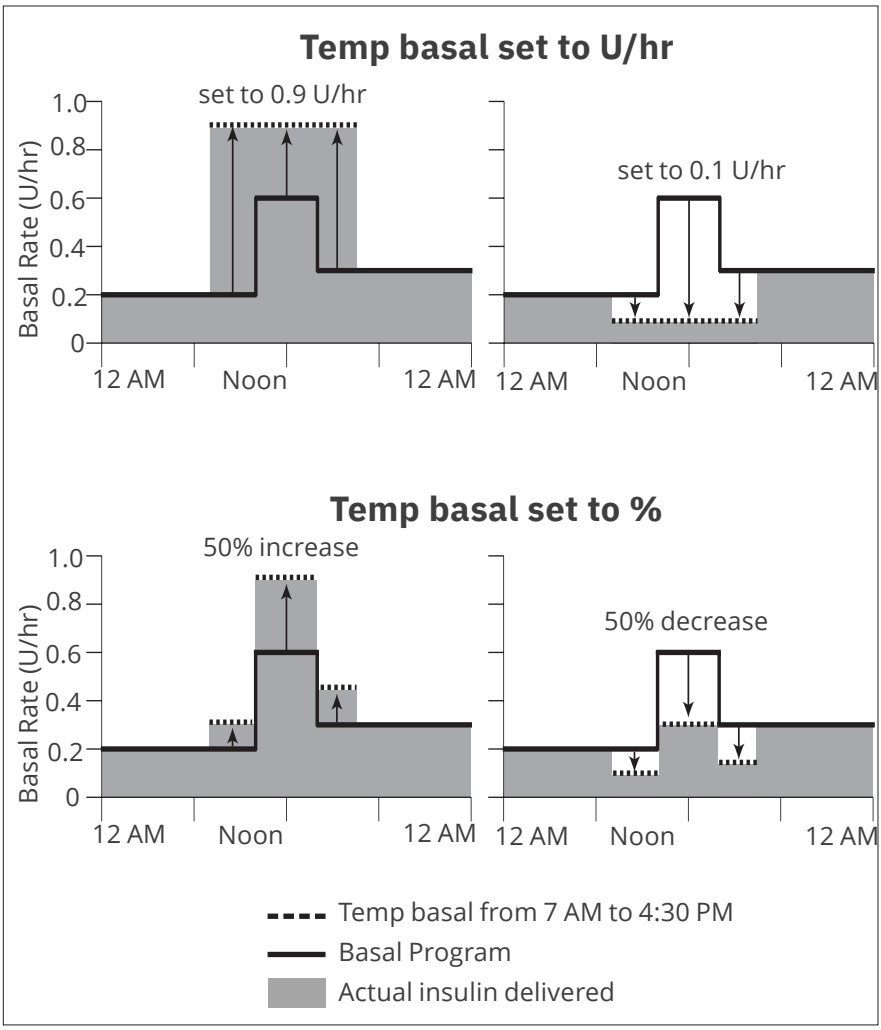
Temp basals can last from 30 minutes to 12 hours. At the end of the specified time, the Pod automatically goes back to the programmed basal rate.

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 x 50%=0.10	0.20 + 0.10 = 0.30
10:00 am–2:00 pm	0.60	0.60 x 50%=0.30	0.60 + 0.30 = 0.90
2:00 pm–4:30 pm	0.30	0.30 x 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.

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

Contents

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 201.
- You are experiencing symptoms of hyperglycemia. See "Symptoms of hyperglycemia (high glucose)" on page 205.
- You are experiencing symptoms that are not consistent with your sensor glucose values.
- 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 > **Enter BG**
3. Manually enter or edit a blood glucose value as follows:
   a. Tap the BG field.
   b. Enter and confirm your blood glucose reading using the number pad.
   c. Tap **Done** 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. Tap **Save** to save the blood glucose reading in the history records.

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

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.

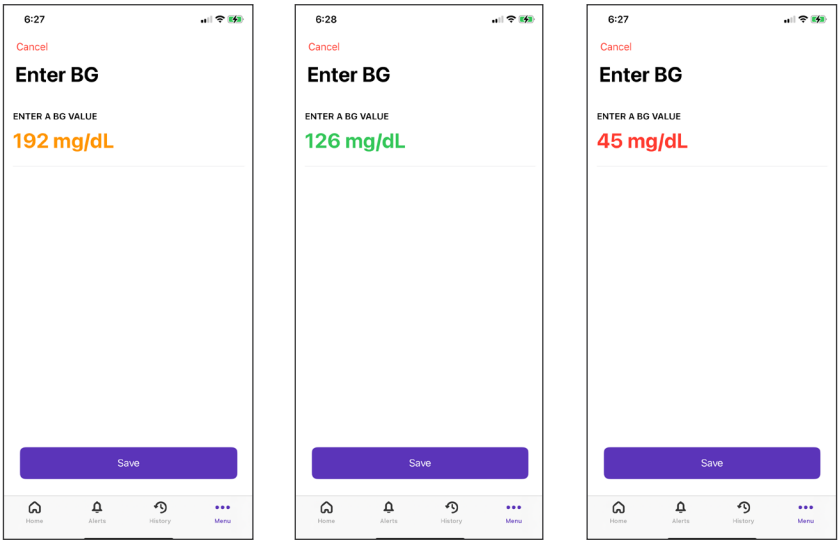
Glucose reading	Screen display
Above 600 mg/dL or HIGH	HIGH
20-600 mg/dL	<blood glucose reading>
0-19 mg/dL or LOW	LOW

How Blood Glucose Readings are Displayed

The Omnipod 5 App displays the blood glucose reading with a corresponding color. The colors are:

- 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 137.



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CHAPTER 9

Pausing and Starting Insulin Delivery

Contents

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 123.

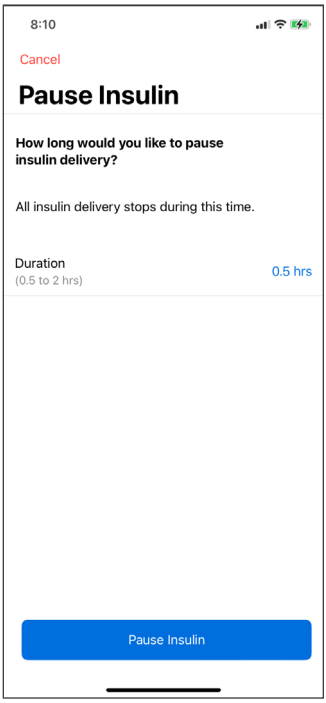
Before you begin, do the following:

➢ You must be in Manual Mode to pause insulin. If you are currently using Automated Mode, see "22.2. Switching from Automated Mode to Manual Mode" on page 292.

Pause insulin delivery

To pause insulin delivery:

1. Navigate to:
   Menu > **Pause Insulin**
2. Tap the Duration 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. Tap **Done**.
3. Tap **Pause Insulin**.
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."

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."	Status icons on Home screen now show only "Basal," not "Temp Basal"
Beeps while insulin is paused	Every 15 min	At the beginning and every 60 min
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** > **Start Insulin**	Home: Temp Basal icon > **Cancel**

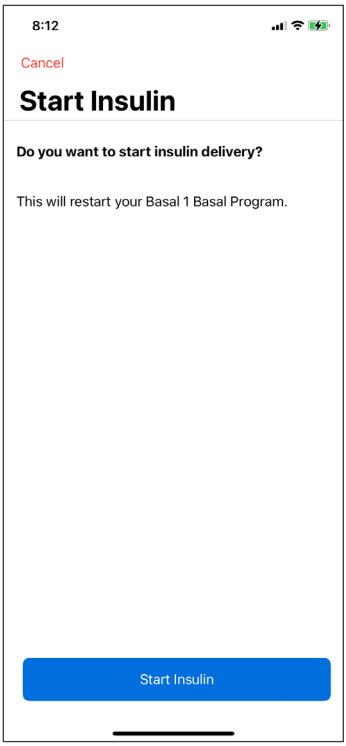
9.3 Starting Insulin Delivery

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.

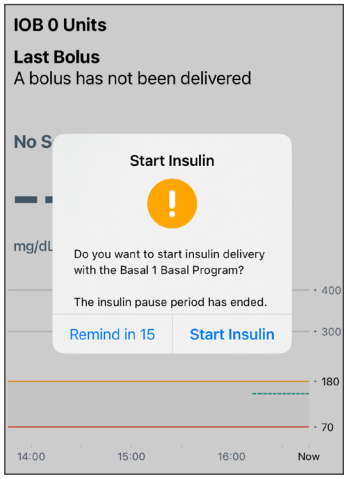


Start insulin delivery after the pause period ends

➢ 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.



CHAPTER 10

Changing Settings

Contents

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. See the full system Omnipod 5 Technical User Guide for instructions for the Controller.

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

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: Check that Bluetooth is enabled after you turn ON Airplane mode on your iPhone.

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 iPhone:

1. Navigate to your iPhone Settings.
2. Tap the Airplane Mode toggle to turn Airplane Mode ON or OFF.

Time Change

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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.

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
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

Automatic Date and Time

Your device time zone is the time displayed outside of the Omnipod 5 App on your iPhone. Automatic Date and Time can be turned on or off in your iPhone settings.

To turn Automatic Date and Time Zone on or off:

1. Navigate in your iPhone's Settings to: **Menu** > **General** >**Date & Time** > **Set Automatically**.
2. Tap the switch to turn Set Automatically on. The switch is in the on position when it is on the right and is green.

   Note: Using the Omnipod 5 App on your smartphone requires you to have Set Automatically on.

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. 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 > **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 resume insulin delivery. Tap **DONE**

10.2 Reminder Settings

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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.

Reminder notifications bring attention to various diabetes management actions you may want to take (see "13.11. Reminder Notifications List" on page 190 and "13.3. Sounds and Vibrations" on page 151).

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.

To set the timing of the Pod Expiration reminder:

1. Navigate to: **Menu** > **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**. Then tap **Done.**

At the selected time, the Pod beeps. The Omnipod 5 App displays a message and your smartphone beeps/vibrates.

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** > **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**. Then tap **Done**.

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** >**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. Tap **Done**.

   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

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** >**Reminders.**

2. Tap the **Confidence Reminders** switch 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** >**Reminders**
2. Scroll as needed and tap the **Program Reminders** switch 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.

10.3 Basal and Temp Basal Settings

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

Note: These settings apply only 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** > **Basal & Temp Basal Settings** > **Max Basal Rate**.
2. Tap the Max Basal Rate field and enter the new value for your Maximum Basal Rate. Tap **Done**.
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** > **Basal & Temp Basal Settings**.
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

Contents

11.1 About Your Recent History

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:

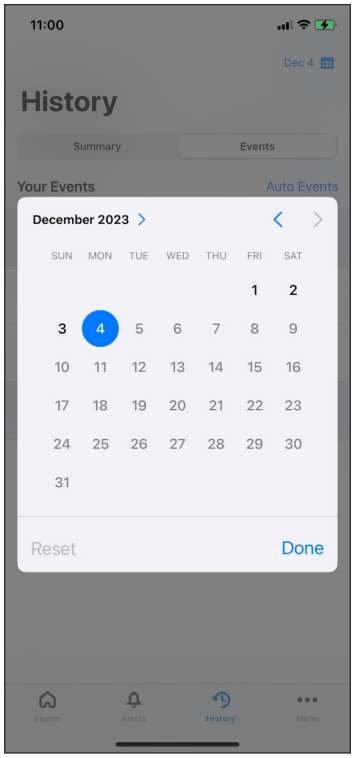
- History screens: The Summary screen shows glucose and insulin & carb history. The Events screen shows glucose entries, Pod events, and Auto Events. Tap the History button on the Home screen toolbar to view History.
- History of alarms and notifications can be viewed on the Alerts screen. Tap the Alerts button on the Home screen toolbar to view a history of Alerts.

11.2 Summary

Tap the History button on the toolbar to reach the History screen. The default view will show your Summary.

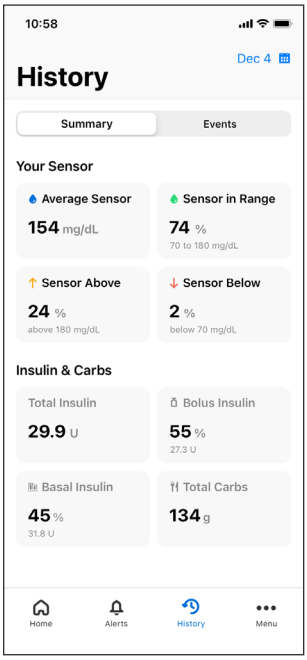
To select a different date for your Summary view:

- Tap the blue calendar icon at the top of the screen.
- Select the date you want to view.
- Tap **Done**.



The Summary highlights your daily glucose history, insulin use, and entered carbs.

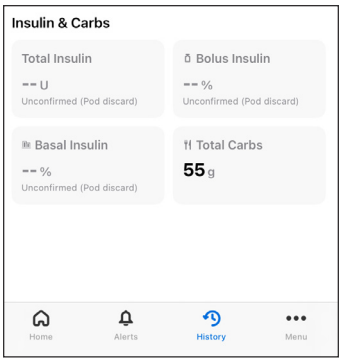
Summary item	Description
Your Sensor	
Average Sensor	Average of sensor glucose values for the day.
Sensor in Range	Percentage of sensor glucose values within your Glucose Goal Range.
Sensor Above	Percentage of sensor glucose values above your Glucose Goal Range.
Sensor Below	Percentage of sensor glucose values below your Glucose Goal Range.
Row 2 – Insulin & Carbs	
Total Insulin	Total insulin (basal + bolus) delivered for the day.
Bolus Insulin	Percentage of the total insulin that was delivered through bolus(es) along with the number of units of bolus insulin delivered.
Basal Insulin	Percentage of the total insulin that was delivered as basal along with the number of units of basal insulin delivered. Basal insulin includes delivery based on your Basal Program while in Manual Mode, and any automated deliveries received while in Automated Mode.
Total Carbs	Sum of meal carbohydrates (in grams) that were used in bolus delivery calculations for the given day.



Note: Percentages may not add to 100 due to rounding.

When insulin delivery is unconfirmed

After delivering a bolus or basal dose of insulin, the Pod sends a confirmation to the Omnipod 5 app once completed. If a bolus, basal, or total insulin delivery has not been confirmed, the summary will be grayed out.



11.3 Calculations for History Summaries

This section lists the calculations for the summary data shown on the History screens.

Glucose Summaries

The calculations used for the glucose summaries include sensor glucose values (including HIGH and LOW values) and exclude manually-entered readings.

Item	Calculation
Row 1	
Average Sensor	$= \frac{\text{Sum of all sensor glucose values}}{\text{Total number of sensor glucose values}}$ **Note:** HIGH sensor glucose values are included as 401 and LOW sensor glucose values as 39.
Sensor in Range	$= \frac{\text{Qty of sensor glucose values within Glucose Goal Range}}{\text{Total number of sensor glucose values}} \times 100$
Sensor Above	$= \frac{\text{Qty of sensor glucose values above Glucose Goal Range upper limit}}{\text{Total number of sensor glucose values}} \times 100$
Sensor Below	$= \frac{\text{Qty of sensor glucose values below Glucose Goal Range lower limit}}{\text{Total number of sensor glucose values}} \times 100$

Glucose Goal Range

The goal of using the Omnipod 5 System is to keep your glucose within your Glucose Goal Range. You define this range by setting the upper and lower limits. The Sensor Graph and the Enter BG screen use the Glucose Goal Range to determine which glucose readings are within your goal and which are above or below your goal.

Note: The Glucose Goal Range does not impact insulin delivery. To set the upper and lower limit of your Glucose Goal Range:

1. Navigate to: Menu button > Glucose Goal Range.
2. Set the limits of the Glucose Goal Range:
   a. Tap the Upper Limit field and enter the desired value.
   b. Tap the Lower Limit field and enter the desired value.
3. Tap **Save**.

Insulin Delivery Summaries

Bolus insulin calculations include:

- SmartBolus Calculator boluses
- Manual boluses.
- Any partial bolus amounts delivered from immediate or extended boluses that were canceled that the Pod can confirm.

Basal insulin calculations include:

- Basal adjustments from SmartAdjust technology (Automated Mode).
- Basal Programs (Manual Mode).
- Any adjustments for temp basals, pause periods, or times without an active Pod.

When your Omnipod 5 System has not received updates from the Pod about confirmed insulin delivery, the insulin delivery calculations are estimates based on the scheduled insulin delivery.

Summary item	Calculation
Row 2	
Total Insulin	= Sum of basal and bolus insulin delivered.
Basal Insulin	= Amount of basal insulin delivered in Manual Mode and all automated insulin deliveries in Automated Mode.
Bolus Insulin	= Amount of bolus insulin delivered.
Total Carbs	= Total grams of carbs entered into the SmartBolus Calculator.

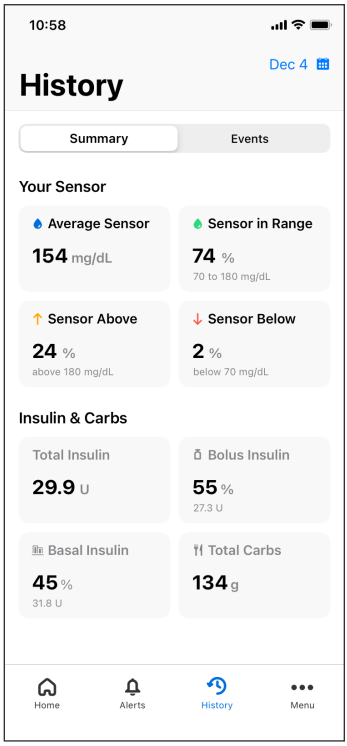
11.4 Events

Tap the Events button at the top of the History screen for the Events view.

The Events view shows individual records listed by time of day.

Tip: Tap any row to display more details about that event.

Tip: Tap < Back to return to the Events screen.

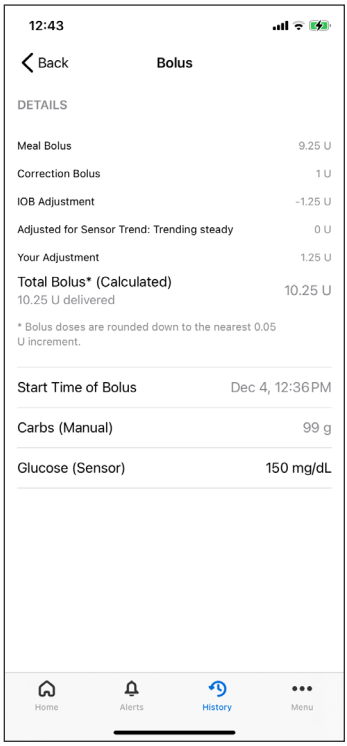


Bolus Details

Immediate and extended boluses

Tapping a row with a bolus entry allows you to view the record to show additional details about the bolus, including:

- Whether the bolus was calculated by the SmartBolus Calculator or it was a manual bolus.
- The amount originally scheduled for delivery if you canceled an immediate bolus.
- For an extended bolus, the amount delivered now and extended, and the percentage (%) of the meal bolus delivered now and extended.
- If a bolus is ongoing, unconfirmed, or lost, how much of the bolus has been confirmed.



Extended bolus events

- Extended Bolus started marks the time when the immediate bolus finishes and the extended bolus starts. In addition to the start time of the bolus, the banner lists the number of units extended and the duration of the extension.
- Extended Bolus completed marks the end of the extended bolus.
- Extended Bolus canceled marks the cancellation of an extended bolus and states the confirmed amount of the bolus that was delivered before cancellation.

When the Pod has not confirmed a bolus delivery

After you confirm the amount of a bolus that you want to be delivered, a bolus instruction is sent to your Pod. When the Pod completes delivery, it sends a confirmation to the Omnipod 5 app that the bolus was delivered.

Before the Omnipod 5 app receives confirmation from the Pod that the bolus has been delivered, the Omnipod 5 app estimates the amount delivered. Events indicate when a bolus is estimated.

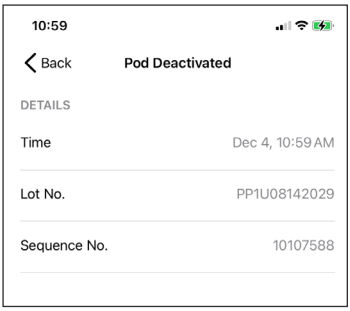
In most cases, after the iPhone running the Omnipod 5 App and Pod are back in range, the Pod confirms the bolus delivery. However, in rare cases, the Pod is unable to confirm bolus delivery due to a communication error. If you tap the Discard Pod option in this situation, the System mark the bolus as “unconfirmed."

If a Pod is discarded with an unconfirmed bolus, the basal and total insulin amounts for that day are also marked as unconfirmed. The listed bolus amount includes the amount that was scheduled for delivery up until the Pod was discarded.

Note: If you have an unconfirmed bolus, the SmartBolus Calculator is disabled for the duration of insulin action.

Pod Details

Details about activation and deactivation (or discarding) of each Pod are shown as Events. Tapping a Pod Event displays the Pod's lot number and sequence number.



Carbs Details

Bolus events indicate whether carbs were manually entered or from Custom Foods.

Basal Rate Details

Activity feature

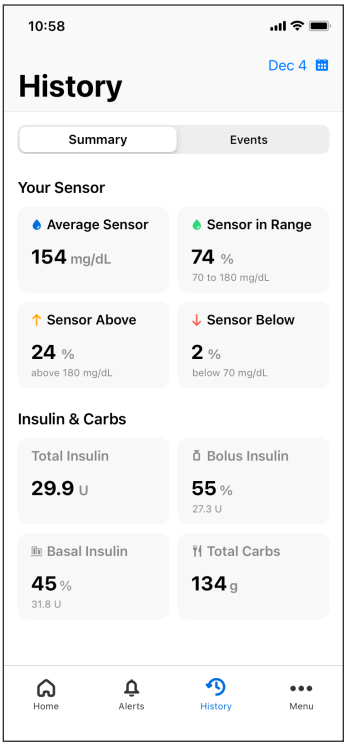
Events indicate the start, end, or cancellation of the Activity feature.

Basal Programs

Events indicate the start of a Basal Program and the restart of a Basal Program at the end of a temp basal or insulin pause period.

Temp basals

Events indicate the start, end, or cancellation of a temp basal in Manual Mode.



If a temp basal was defined as a percentage (%) of the Basal Program in progress, the banner displays the percent increase or decrease as well as the duration. If a temp basal was defined as a flat basal rate (U/hr), the banner displays the temp basal rate and the duration.

If a temp basal was canceled, the Temp Basal started Event contains the scheduled duration, and the Temp Basal canceled Event contains the actual duration.

Basal rate at midnight

The first entry for each day is an Event displaying the status of the basal insulin delivery at midnight. If a Basal Program, temp basal, or use of the Activity feature was carried over from the day before, the Event indicates that this is a continued program. If insulin was paused at midnight, the Event states this.

Insulin Paused and Started Details

An **Insulin Delivery Paused** Event indicates the time an insulin paused period began.

An **Insulin Delivery Started** Event indicates the time insulin delivery was restarted.

Time Change Details

A Time zone changed Event appears if you change your insulin delivery time zone.

After the time zone change has occurred, new Events will reflect your new time zone.

Note: Events recorded before your time zone changed will show in your prior time zone.

Auto Events

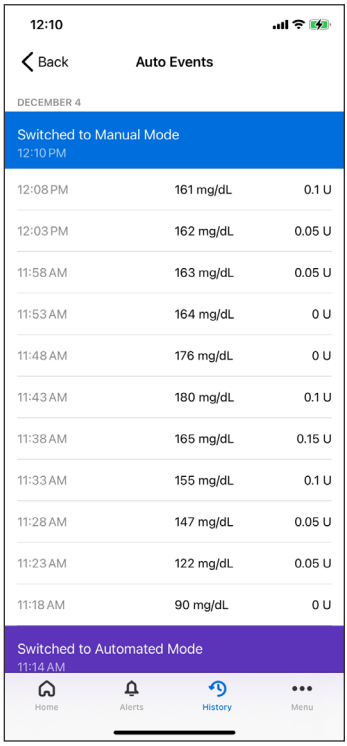
Tap **Auto Events** on the Events screen.

Auto Events show the total amount of automated insulin delivered every 5 minutes while in Automated Mode.

This view shows all automated insulin, both your baseline adaptive basal rate and any adjustment up or down due to your sensor glucose value, trend, and 60-minute prediction. The values will always be small. (Remember that a basal rate of 0.60 U/hr would be like getting 0.05 U every 5 minutes.)

Note: Your sensor glucose value informs how much insulin the System will deliver in the next 5-minute time period. For example, if your sensor glucose value at 11:00 dropped to 58 mg/dL, SmartAdjust technology will not deliver a microbolus at 11:05.

Auto Events will not show basal insulin delivered in Manual Mode.



CHAPTER 12

Managing Software Updates

Contents

12.1 Omnipod 5 App Updates for iPhone

The Omnipod 5 App offers updates through the App Store. You will be notified when an update is available for download. You will not be able to navigate in the Omnipod 5 App during an update, but your insulin therapy will not be impacted. The Pod continues delivering insulin and will re-establish connection with the Omnipod 5 App after the update is complete.

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

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.

Automatic Updates Enabled

If you have Automatic Updates enabled on your phone, the Omnipod 5 app updates will be downloaded and installed automatically through the App Store. If an automatic update occurs, the Omnipod 5 app informs you that an update was successfully completed when you open the App.

For more information on how to enable automatic updates, see your smartphone's user manual.

Automatic Updates Disabled

To download and install an Omnipod 5 app update on your smartphone:

1. Ensure your phone battery is charged to above 15%.
2. If prompted when using the app, select Update Now.

After the update is complete and the Omnipod 5 App is reopened, a confirmation screen displays to inform you that the update was completed successfully.

If the update is not considered required, you may select Not Now to delay the update to a later time; however, it is recommended that you update the Omnipod 5 App as soon as the update is available. If you choose to postpone an optional update to a later time, you can manually update the Omnipod 5 App at any time. After 72 hours have passed, you will receive a notification every 24 hours reminding you to update your Omnipod 5 app.

To manually update your Omnipod 5 app:

1. Ensure your phone battery is charged to above 15%.
2. Navigate to the App Store.
3. Tap **Update** next to the Omnipod 5 app.

Once the update is complete and the Omnipod 5 App is reopened, a confirmation screen displays to inform you that the update was completed successfully.

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CHAPTER 13

Alarms, Action and Reminder Notifications

Contents

13.1 Types of Alarms and Notifications

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, and do not power off your smartphone. The Omnipod 5 App must be open or be running in the background in order to display and sound alarms on the iPhone. 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 iPhone, 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 prevent you from hearing alarms and notifications from your Omnipod 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 iPhone requires Critical Alerts permission and Notifications to be turned on to ensure you always receive important safety alarms. You cannot use the App until Critical Alerts permission is provided and Notifications is turned on.

The Omnipod 5 System generates the following types of alarms and notifications.

- **Alarms**:
  - **Hazard alarms** are high-priority alarms that indicate a serious problem has occurred, and you may need to remove your Pod. Hazard Alarms will repeat every15 minutes until acknowledged. The audible alarm on the Pod will continue until acknowledged in the Omnipod 5 App. See "13.6. Hazard Alarm List" on page 157.

    In general, only one hazard alarm can occur at a time. In the unlikely event that a Pod and Omnipod 5 App hazard alarm occur simultaneously, the hazard alarm that most recently

occurred will be displayed first on the Omnipod 5 App. Any Pod hazard alarms will be sounded on the Pod.

- **Advisory alarms** are low-priority alarms that indicate that a situation exists that needs your attention. Advisory alarms will repeat every 15 minutes until acknowledged (see Alarm tables for additional details) and continue on the Pod until acknowledged in the Omnipod 5 App. See "13.7. Advisory Alarm List" on page 167.

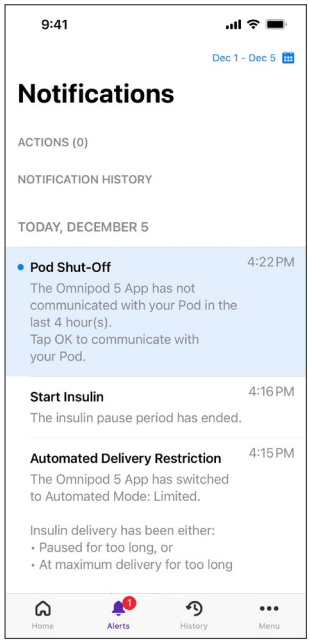
- **Notifications:**
  - **Action Item notifications** are tasks that need your attention. See "13.8. Action Item Notification List" on page 172.
  - **Reminder notifications** remind you about an action that you may want to perform. See "13.11. Reminder Notifications List" on page 190.
  - **Communication error** messages display when the Omnipod 5 App is unable to communicate with the Pod. See "26.5. Pod Communication Issues – "Try Again"" on page 356.

For Dexcom G6 alarm information, see the *Dexcom G6 CGM System Instructions for Use.*

13.2 Alarms and Notifications Screen

To review past alarms and notifications:

1. Tap **Alerts** ( ) in the toolbar. Messages from today are displayed first, with newest at the top of the screen and oldest at the bottom of the screen.
2. To display a specific date range, tap the date range in the upper right-hand corner.
   a. Tap the starting date on the calendar. Note: Tap the arrow to view an earlier month.
   b. Tap the ending date for the date range.
   c. Tap **Done**.
3. When finished, tap Home ( ) to return to the Home screen.



13.3 Sounds and Vibrations

The Omnipod 5 System uses sounds and vibrations to attract your attention to an alarm or notification.

> **Caution:** AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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 System on your iPhone requires Critical Alerts permission and Notifications and Notifications permission to be turned on to ensure you always receive important safety alarms. You cannot use the App until Critical Alerts permission is provided and Notifications and Notifications permission are turned on.

Tip: To test the sounds and vibrations, see "Check alarms" on page 156.

Pod alarms

The Pod sounds a tone when it detects a problem that can affect insulin delivery.

- Pod hazard alarms are continuous tones broken up periodically by a set of beeps.
- Pod advisory alarms and notifications are intermittent beeps, which periodically repeat until you acknowledge them.

Omnipod 5 App alarms

Omnipod 5 App alarm sounds are dependent on your iPhone sound settings, for example, silent or vibrate setting.

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

Navigate to your Omnipod 5 App settings to ensure that all Omnipod 5 App notifications are enabled to produce a visual notification and audible sound. See "4.5. General Settings on Your iPhone" on page 64 for more information on how to adjust your iPhone sound or vibration settings.

Note: When paired to an alternative Bluetooth device to project sound, such as headphones or speakers, alarms/alerts/notifications may sound on your iPhone or on the Bluetooth accessory. Each accessory is different. Test yours prior to use to ensure alarms/alerts/notifications are audible. See "Check alarms" on page 156.

13.4 Informational Sounds and Vibrations

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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.

Caution: 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 System on your iPhone require Critical Alerts permission, Notifications, and Notifications permission to be turned on to ensure you always receive important safety alarms. You cannot use the App until Critical Alerts permission is provided and Notifications and Notifications permissions are turned on.

The Pod and the Omnipod 5 App can provide informational sounds (tones, beeps) or vibrations to let you know that normal activity between the Pod and the Omnipod 5 App is occurring as expected. See the tables below for descriptions of informational sounds you will encounter during use.

Confidence reminders

Cause	Omnipod 5 App	Pod
Tones or vibrations let you know that your temp basals and boluses are working as expected. These reminders are on by default.	Tone/vibration at the start of a temp basal, bolus, or extended bolus.	Beeps once at the end of a temp basal, bolus, or extended bolus.

Note: Confidence reminders and program reminders cause the Omnipod 5 App or Pod to beep at the beginning and end of boluses and temp basals, and also once an hour during an extended bolus or temp basal. For more information, see "Confidence Reminders" on page 130.

Program reminders

Cause	Omnipod 5 App	Pod
Beeps remind you that you have a temp basal or extended bolus running. These reminders are on by default.	No tone/vibration	Beeps once every 60 minutes while a temp basal or extended bolus is running.

Basal Program changes

Cause	Omnipod 5 App	Pod
Tones or vibrations inform you of changes to your Basal Program. You cannot turn these off.	Tone/vibration when a Basal Program is activated, edited, paused, or started.	Beeps once every 15 minutes after the pause period has ended.

Canceling temp basals and boluses

Cause	Omnipod 5 App	Pod
Tone informs you that the temp basal or bolus has been successfully canceled. You cannot turn these off.	No tone/vibration	Beeps once when you cancel a temp basal, bolus, or extended bolus.

Pod activation / Pod deactivation

Cause	Omnipod 5 App	Pod
Tones or vibrations occur at various times during the Pod activation process to indicate progress. You cannot turn these off	Tone/vibration when the Pod and Omnipod 5 App are successfully paired. Sounds tone/vibrates twice when the Pod is successfully deactivated.	Beeps twice when it has been filled with the minimum amount of insulin needed for activation (see page 89). Beginning 10 minutes after the Pod is filled with insulin, beeps every five minutes until insulin delivery has started.

13.5 Responding to Alarms

Caution: AVOID leaving your iPhone 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 iPhone.

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevent you from hearing alarms and notifications from your Omnipod 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 System on your iPhone require Critical Alerts permission, Notifications, and Notifications permission to be turned on to ensure you always receive important safety alarms. You

cannot use the App until Critical Alerts permission is provided and Notifications and Notifications permissions are turned on.

To respond to a hazard alarm or advisory alarm:

1. Wake up your iPhone. The Lock screen shows an alarm message along with the hazard alarm ( ) icon or advisory alarm ( ) icon.
2. After unlocking your Omnipod 5 App, follow the on-screen instructions or see the individual alarm details starting on page 157.

   Note: You can use your Omnipod 5 System even if you acknowledge but do not address an advisory alarm immediately. However, you must acknowledge a hazard alarm before you can use your Omnipod 5 System.

   Tip: Tip: If you follow the Omnipod 5 App's instructions and are still not able to silence a hazard alarm, see "13.9. Silencing Unresolved Alarms" on page 188.

   Note: If a temp basal or extended bolus is running when a Pod hazard alarm occurs, the Omnipod 5 App informs you that it was canceled.

Timing of Pod Alarms on the Omnipod 5 App

If the Pod is sounding a hazard alarm, the Pod sends a signal to your Omnipod 5 App.

- If your iPhone running the Omnipod 5 App is in range and awake within 2 minutes of the Pod's initial alarm sound, your Omnipod 5 App also sounds an alarm and displays the alarm message.
- If your iPhone running the Omnipod 5 App is out of range of the Pod, your Omnipod 5 App cannot receive any communication from the Pod. Therefore, if you hear a Pod alarm or notification, bring your iPhone in range of the Pod, and wake up your Omnipod 5 App. Within 2 minutes, your Omnipod 5 App sounds the alarm and displays the alarm message.

Diagnostics

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 could put your health and safety at risk.

Check alarms

Before you begin, switch to Manual Mode if currently using Automated Mode. See "22.2. Switching from Automated Mode to Manual Mode" on page 290.

Note: Your iPhone sound settings must be on to hear a tone on the Omnipod 5 App.

To verify that your Omnipod 5 App and Pod's alarm functions are working properly, test them as follows:

1. Tap **Menu** and scroll to **Menu** > **General** > **Check Alarms**.
2. If you have an active Pod, tap Pause Insulin, and tap **YES**.
3. Tap **Check Alarms** to initiate the alarm check.
4. Listen and feel: Your iPhone running the Omnipod 5 App beeps or vibrates three times. If you are wearing a Pod, the Pod beeps several times and sounds the alarm tone for several seconds.
5. If the Pod did not beep, tap **NO**. Then either tap **Check Alarms** Again to retry testing the alarms or change your Pod.
6. If the Omnipod 5 System did not alarm as expected, tap **NO**. Then either tap **Check Alarms Again** to retry testing the alarms or contact Customer Care.
7. If the beeps or vibrations worked properly, tap **YES**. If you paused insulin to check the alarms, tap **YES** to start insulin delivery.

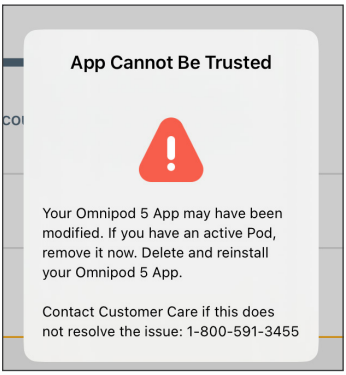
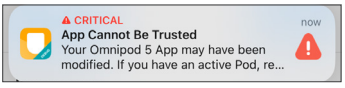
13.6 Hazard Alarm List

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.

Hazard alarms make you aware of serious situations. Always respond to a hazard alarm immediately. Some alarm messages give you a unique number called a reference number. Give that number to Customer Care if you contact them about that alarm.

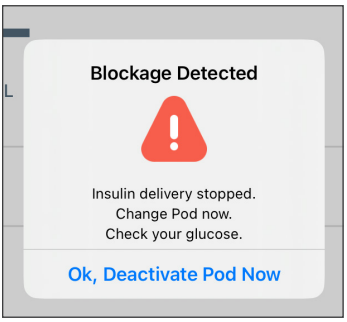
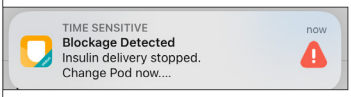
App Cannot Be Trusted

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

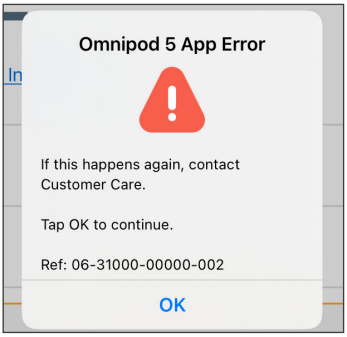
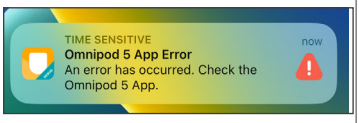
Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Your Omnipod 5 App has been modified and is not safe to use. **Pod sound:** None **iPhone sound or vibration:** - 30 second tone - Standard iPhone vibration - No repetition **What to do:** 1. Remove your Pod if you have an active Pod. 2. Delete and reinstall the Omnipod 5 App.
Lock Screen: 	

Blockage Detected

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

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** A blockage (occlusion) was detected from the blocked cannula, a Pod malfunction, or from using old or inactive insulin, which has stopped insulin delivery.
	Pod sound: Continuous tone
	iPhone sound or vibration: • 30 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged
Lock Screen: 	**What to do:** 1. Tap **OK, Deactivate Pod Now**. 2. Change your Pod. 3. Check your blood glucose.

Omnipod 5 App Error

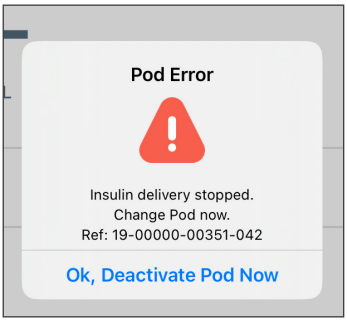
Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** An unexpected error is detected in the Omnipod 5 App. **Note:** If your Omnipod App stops and restarts on its own, you may notice the app flashing white before this screen appears.
	Pod sound: None
	iPhone sound or vibration: • 30 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged.
Lock Screen:  	**What to do:** 1. Tap **OK** to acknowledge or silence the alarm. **Note:** Depending on the cause of this error, the Controller may restart after you tap OK. Whether or not that happens, continue with the following steps. 2. Contact Customer Care immediately. 3. Check your blood glucose.

Omnipod 5 Memory Corruption

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** An unexpected error is detected in the Omnipod 5 App.
	Pod sound: None
	iPhone sound or vibration: • 30 second tone • Standard iPhone vibration • Vibration and tone repeat every 15 minutes until acknowledged.
Lock Screen: 	**What to do:** 1. Tap **OK** to acknowledge the alarm and reset the Omnipod 5 App. 2. Remove your Pod. 3. Contact Customer Care immediately. 4. Check your blood glucose.

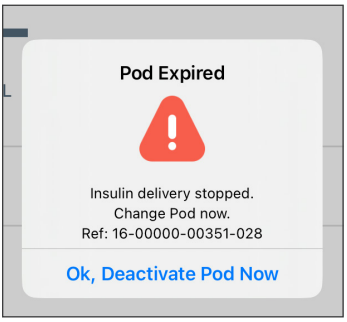
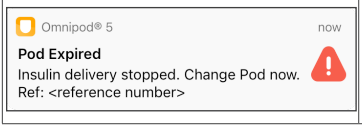
Pod Error

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.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Why it occurs: The Pod detects an unexpected error and insulin delivery has stopped.
	Pod sound: Continuous tone
	iPhone sound or vibration: • 30 second tone • Standard iPhone vibration • Vibration and tone repeat every 15 minutes until acknowledged.
Lock Screen: 	**What to do:** 1. Tap **OK, Deactivate Pod Now**. 2. Change your Pod. 3. Check your blood glucose.

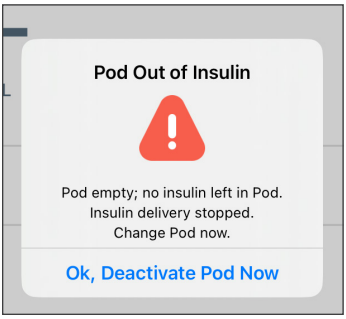
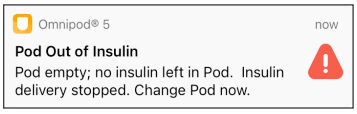
Pod Expired

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.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Why it occurs: The Pod has reached the end of its operating life, and insulin delivery has stopped.
	Pod sound: Continuous tone
	iPhone sound or vibration: • 30 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged.
Lock Screen: 	**What to do:** 1. Tap **OK, Deactivate Pod Now**. 2. Change your Pod. 3. Check your blood glucose.

Pod Out of Insulin

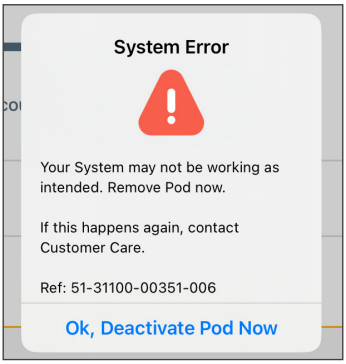
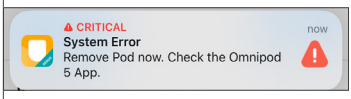
Caution: ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to hyperglycemia. If another Pod is not available, use a different insulin delivery method.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** The Pod's insulin reservoir is empty, and insulin delivery has stopped. **Pod sound:** Continuous tone **iPhone sound or vibration:** • 30 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged. **What to do:** 1. Tap **OK, Deactivate Pod Now**. 2. Change your Pod. 3. Check your blood glucose.
Lock Screen: 	

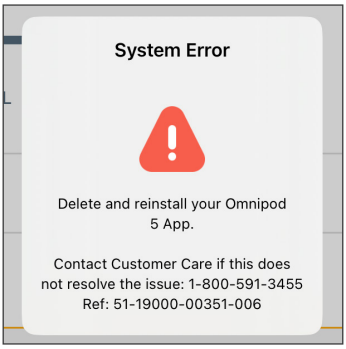
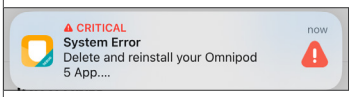
Pod Shut-Off

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.

System Error

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** An unexpected error is detected in the Pod or the Omnipod 5 app. **Pod sound:** None **iPhone sound or vibration:** • 30 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged. **What to do:** 1. Tap **OK, Deactivate Pod Now**. 2. Remove your Pod. 3. Contact Customer Care immediately. 4. Check your blood glucose.
Lock Screen: 	

System Error (Cloud)

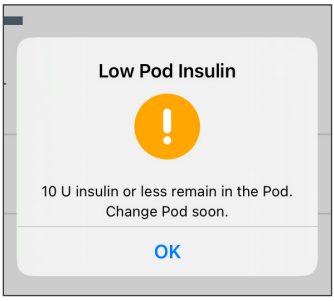
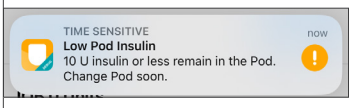
<table>
<tr><th>Screen Alert</th><th>Description</th></tr>
<tr><td>Omnipod 5 App:
 
</td><td>Why it occurs: An unexpected error is detected in the Pod or the Omnipod 5 app.</td></tr>
<tr><td rowspan="3">Lock Screen:
 
</td><td>Pod sound: None</td></tr>
<tr><td>iPhone sound or vibration:
• 30 second tone
• Standard iPhone vibration
• Vibration or tone repeat every 15 minutes until acknowledged.</td></tr>
<tr><td>What to do:
1. Delete and reinstall the Omnipod 5 App.
2. Contact Customer Care if this does not resolve the issue.</td></tr>
</table>

13.7 Advisory Alarm List

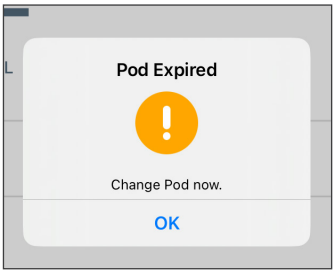
Caution: ALWAYS respond to Pod Expired, Low Pod Insulin, and Pod Shut-Off Advisory Alarms when they occur. These alarms escalate to Hazard Alarms if no action is taken. When Hazard Alarms occur, insulin delivery stops.

Advisory alarms inform you of a situation that needs your attention in the near future.

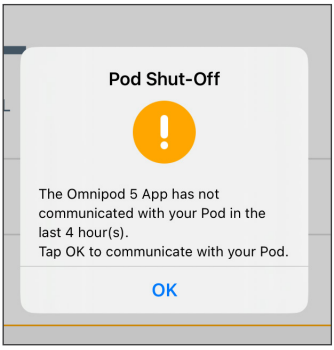
Low Pod Insulin

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** The amount of insulin in the Pod is below the value specified in your settings.
	Pod sound: • 8 beep tone pattern • Tone pattern sounds once every 3 minutes for 60 minutes.
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged.
Lock Screen:  	**What to do:** 1. Tap OK. 2. Change your Pod.
Note: This escalates to the Pod Out of Insulin hazard alarm if ignored. **Note:** To change this value, see "Low Pod Insulin" on page 129.	

Pod Expired

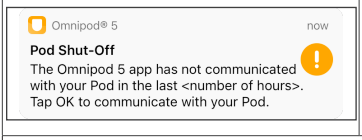
<table>
<tr><th>Screen Alert</th><th>Description</th></tr>
<tr><td rowspan="3">Omnipod 5 App:
 
</td><td>Why it occurs: Your Pod will stop delivering insulin soon.</td></tr>
<tr><td>Pod sound:
• 8 beep tone
• Tone issued once every 60 minutes starting after 72 hours of Pod life.
• After 79 hours of Pod life, tone is issued once every 5 minutes.</td></tr>
<tr><td>iPhone sound or vibration:
• 3 second tone
• Standard iPhone vibration
• Vibration or tone repeat every 15 minutes until acknowledged.</td></tr>
<tr><td>Lock Screen:
 
</td><td>What to do:
1. Tap OK.
2. Change your Pod.</td></tr>
<tr><td colspan="2">Note: After acknowledgment or if ignored, the alarm will repeat when there is 1 hour left of Pod life.
Note: This escalates to the Pod Expired hazard alarm if ignored.</td></tr>
</table>

Pod Shut-Off

<table>
<tr><th>Screen Alert</th><th>Description</th></tr>
<tr><td>Omnipod 5 App:
 
</td><td>Why it occurs: You have reached the Pod Shut-Off time you set. The Pod will stop delivering soon if you do not respond to this alarm.

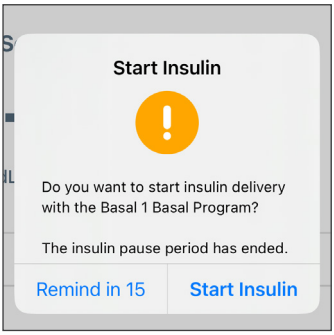
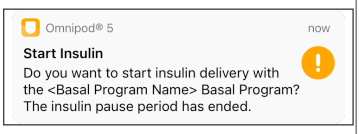
Pod sound:
• 6 beep tone
• Once every minute for 15 minutes

iPhone sound or vibration:
• 3 second tone
• Standard iPhone vibration
• Vibration or tone repeat every 15 minutes until acknowledged.

What to do:
➢ Tap OK to reset the Pod Shut-Off timer.</td></tr>
<tr><td>Lock Screen:
 
</td><td></td></tr>
<tr><td colspan="2">Note: To enable or disable the Pod Shut-Off feature or to change the countdown period, see "Pod Shut-Off" on page 169.</td></tr>
</table>

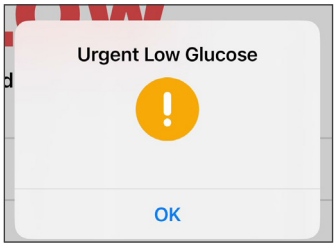
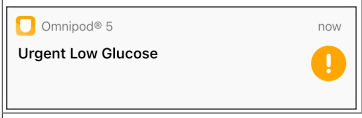
Start Insulin

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.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** The time period that you specified to pause insulin has passed. If you do not start insulin delivery, you could develop hyperglycemia.
	Pod sound: • 8 beep tone • Tone sounds once every minutes for 3 minutes. • Repeats every 15 minutes until acknowledged. **Note:** User will be notified up to only 8 times if Pod is out of range of the iPhone.
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged.
Lock Screen: 	**What to do:** Do one of the following: • If you want to start insulin with the Basal Program, tap Start Insulin. • If you want to keep insulin paused, tap Remind in 15.

Urgent Low Glucose

Warning: ALWAYS promptly treat low glucose. 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.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Your glucose is at or below 55 mg/dL, according to what your Sensor sent to the Omnipod 5 app.
	Pod sound: • 4 beep tone • Repeats every 5 minutes that sensor glucose value is urgently low.
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • Vibration or tone repeat every 15 minutes until acknowledged.
Lock Screen: 	**What to do:** ➢ Tap **OK** to acknowledge the alarm.

Note: This Advisory Alarm will only stop repeating after a glucose value of 56 mg/dL or greater is received. You may silence this Advisory Alarm for 30 minutes by acknowledging the on-screen message.

Note: After the initial Advisory Alarm is acknowledged, the Advisory Alarm will occur again if sensor glucose values are still below 55 mg/dL after 30 minutes.

Note: Use a blood glucose meter to confirm your blood glucose reading. Treat low glucose as needed.

Note: The Urgent Low Glucose Advisory Alarm has to do directly with your body's current glucose, while other alarms have to do with the Pod or Omnipod 5 App state.

13.8 Action Item Notification List

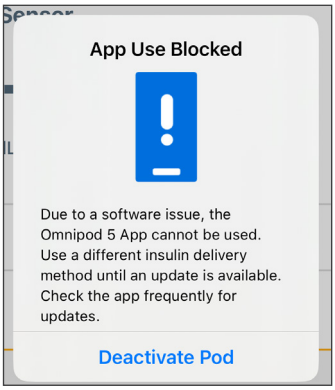
Action Item notifications are technical System tasks that need your attention.

App Use Blocked

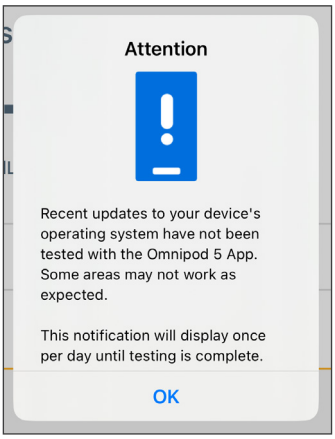
Warning: You will NOT be able to use the Omnipod 5 App if:

- 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 iPhone is no longer compatible with use of the Omnipod 5 App.
- The operating system (iOS version) of your iPhone 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 over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

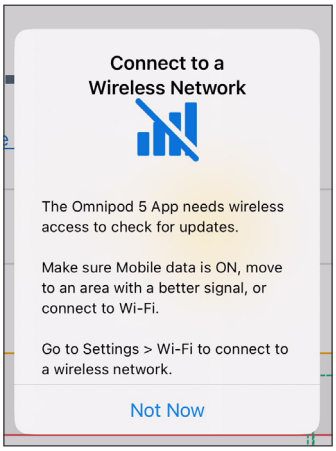
Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** The installed version of the Omnipod 5 App is no longer supported for use. You will not be able to use the App until an update becomes available. This message may appear whether you have an active Pod or not.
	Pod sound: None
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • No repetition
	What to do: 1. If you have an active Pod, tap Deactivate Pod. (This option only appears if you have an active Pod.) 2. Check your Omnipod 5 App for available updated notifications frequently. When you see a notification for an available App update, follow the instructions to install the update.

Attention

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** Your smartphone's operating system has not been completely tested for use with the Omnipod 5 System. **Pod sound:** None **iPhone sound or vibration**: • 3 second tone • Standard iPhone vibration • No repetition **What to do:** ➢ Tap **OK**. You may continue using the Omnipod 5 App on your iPhone, as essential functions should not be affected. The notification will display once per day until testing is complete. If you notice any unexpected effects on your screen or otherwise have concerns about the way your Omnipod 5 System is working, contact Customer Care. For a list of compatible operating systems, go to *https://www.omnipod.com/ compatibility*

Connect to a Wireless Network

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.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Your Omnipod 5 App has not connected to Insulet's network for 7 or more days. **Pod sound:** None **iPhone sound or vibration:** • 3 second tone • Standard iPhone vibration • No repetition **What to do:** ➢ Tap **WI-FI SETTINGS** when prompted. Connect to a Wi-Fi network.
Tip: When you are connected to a network, your Omnipod 5 App is notified about software updates when you need them. **Tip:** If Wi-Fi is not available, move to an area with a better cellular signal.	

Daylight Saving Time Change

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.

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** The Omnipod 5 App has detected that Daylight Saving Time has started or ended. **Pod sound:** None **iPhone sound or vibration:** • 3 second tone • Standard iPhone vibration • No repetition **What to do:** ➢ Tap **Update** to update your insulin delivery time. Or: ➢ Tap **Not Now** to continue using your current insulin delivery time.
Note: Correct time is essential for correct insulin delivery and history records. If you tap Not Now, you can find this Action Item notification in your Alerts History and every 24 hours you will be reminded to update.	

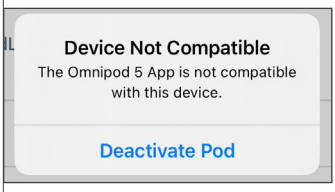
Device Not Compatible

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 iPhone is no longer compatible with use of the Omnipod 5 App.
- The operating system (iOS version) of your iPhone 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 over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

Note: If you get this message while using the Controller, contact Customer Care.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Your iPhone is incompatible with the Omnipod 5 System, and an update will not fix the problem. **Pod sound:** None **iPhone sound or vibration**: • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. If you have an active Pod, tap Deactivate Pod. (This option only appears if you have an active Pod.) 2. Find out if your iPhone is on the compatible device list here: *https://www.omnipod.com/compatibility*

Not Enough Storage

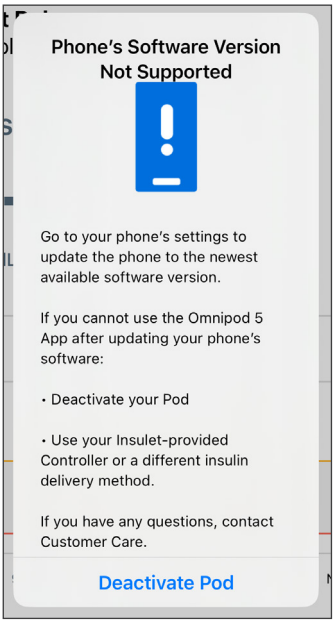
Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** You do not have enough available storage for the Omnipod 5 App to run on your iPhone. Your iPhone must have enough storage space for the Omnipod 5 App to work and save important information about your insulin therapy.
	Pod sound: None
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • No repetition
	What to do: 1. Go to your iPhone Settings. 2. Tap **General**. 3. Tap **iPhone Storage**. 4. Clear up storage by deleting files such as photos and videos, or by deleting other apps that you are not using.
Note: If you do not delete enough files, you will see this Action Item Notification again.	

OS Not Compatible

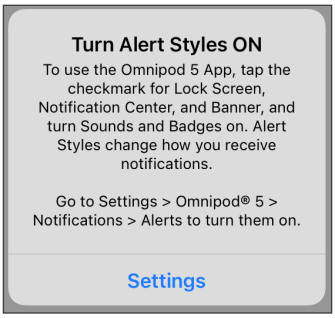
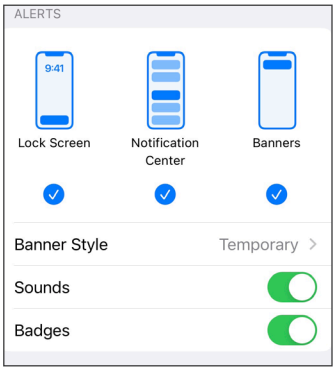
Warning: You will NOT be able to use the Omnipod 5 App if:

- 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 iPhone is no longer compatible with use of the Omnipod 5 App.
- The operating system (iOS version) of your iPhone has not yet been tested for safety by Insulet.

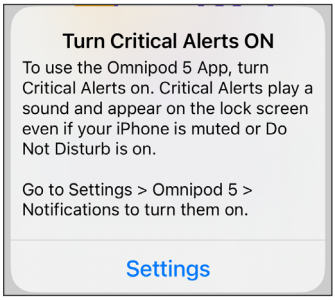
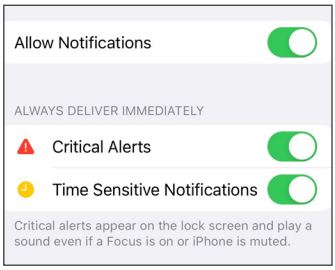
Use the Insulet-provided Controller or a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery can result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** The Omnipod 5 App cannot be used on your iPhone's current operating system (OS). You will not be able to use the app until an update becomes available. This message may appear whether you have an active Pod or not. **Pod sound:** None **iPhone sound or vibration:** • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. Check your Omnipod 5 App frequently to see when Insulet has approved App use on the current OS your iPhone is operating on. For a list of compatible operating systems, go to *https://www.omnipod.com/compatibility.*

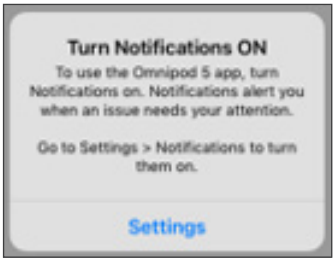
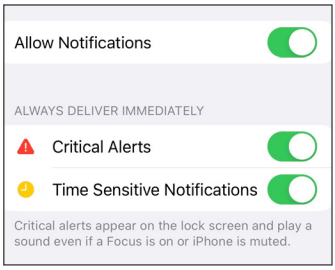
Turn Alert Styles On

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** Alert Styles for the Omnipod 5 App have been turned off. **Pod sound:** None **iPhone sound or vibration:** • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. Go to your iPhone Settings screen. 2. Scroll to find Omnipod 5 and tap to open the App's settings. 3. Tap **Notifications**. 4. Scroll to the area marked Alerts.  5. Tap the checkbox for each of the Alert Styles to turn them on: Lock Screen, Notification Center, and Banners. 6. Toggle both Sounds and Badges on.
Note: The Omnipod 5 App on your iPhone requires Alert Styles to be turned on to ensure you always receive important safety alarms.	

Turn Critical Alerts On

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** Critical Alerts access for the Omnipod 5 App has been turned off. **Pod sound:** None **iPhone sound or vibration:** • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. Go to your iPhone Settings screen. 2. Scroll to find Omnipod 5 and tap to open the App's settings. 3. Tap **Notifications**. 4. Toggle the switch on to allow Critical Alerts. 
Note: The Omnipod 5 App on your iPhone requires Critical Alerts permission to be turned on to ensure you always receive important safety alarms.	

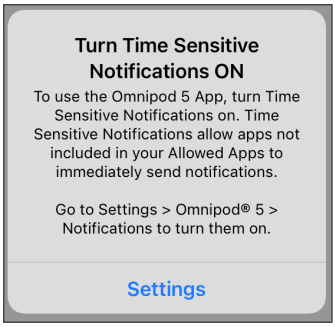
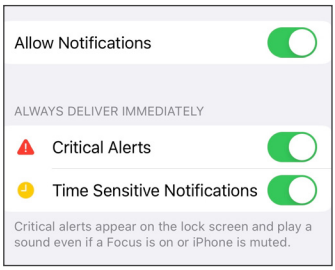
Turn Notifications ON

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** Notifications access for the Omnipod 5 App has been turned off.
	Pod sound: None
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • No repetition
	What to do: 1. Go to your iPhone Settings. 2. Scroll to find Omnipod 5 and tap to open the App's settings. 3. Tap **Notifications**. 4. Toggle the switch on to Allow Notifications. 
Note: The Omnipod 5 App on your iPhone requires Notifications permission to be turned on to ensure you always receive important safety alarms.	

Turn ON Automatic Date and Time

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** You have turned off Automatic Date and Time in your iPhone settings. The Omnipod 5 App has many therapy-related actions that depend on time. Automatic Date and Time is a setting on your smartphone that ensures the accuracy of your time.
	Pod sound: None
	iPhone sound or vibration: • 3 second tone • Standard iPhone vibration • No repetition
	What to do: 1. Go to your iPhone Settings. 2. Tap **General**. 3. Tap **Date & Time**. 4. Toggle the switch on to Set Automatically.

Turn Time Sensitive Notifications On

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** Time Sensitive Notifications access for the Omnipod 5 App has been turned off. **Pod sound:** None **iPhone sound or vibration**: • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. Go to your iPhone Settings. 2. Scroll to find Omnipod 5 and tap to open the App's settings. 3. Tap **Notifications**. 4. Toggle the switch on to allow Time Sensitive Notifications. 
Note: The Omnipod 5 App on your iPhone requires Time Sensitive Notifications to be turned on to ensure you always receive important safety alarms.	

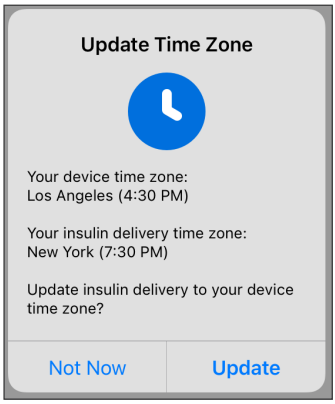
Update Omnipod 5 - App No Longer Supported

Screen Alert	Description
Omnipod 5 App:  	**Why it occurs:** The Omnipod 5 App version you are currently using is obsolete and no longer supported. **Pod sound:** None **iPhone sound or vibration**: • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. Tap **Update Now**. Your battery power must be above 15% before updating. 2. If you do not have enough battery power, charge your battery before continuing. You will see that the update is in progress. 3. When you see the message that the update was successful, tap OK.

Update Omnipod 5 - Software Update

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** An Omnipod 5 App software update is available. **Pod sound:** None **iPhone sound or vibration:** • 3 second tone • Standard iPhone vibration • No repetition **What to do:** 1. Tap **Update Now**. Your battery power must be above 15% before updating. 2. If you do not have enough battery power, charge your battery before continuing. 3. When you see the message that the update was successful, tap OK.
Note: If the update is critical (required), you will not have the option to dismiss the notification. If you tap Not Now, you can find this Action notification in your Alerts History.	

Update Time Zone

<table>
<tr><th>Screen Alert</th><th>Description</th></tr>
<tr><td rowspan="3">Omnipod 5 App:
 
</td><td>Why it occurs: Your iPhone time zone does not match the Omnipod 5 App insulin delivery time zone.</td></tr>
<tr><td>Pod sound: None</td></tr>
<tr><td>iPhone sound or vibration:
• 3 second tone
• Standard iPhone vibration
• No repetition</td></tr>
<tr><td colspan="2">What to do:
1. Tap Update when prompted to update your insulin delivery time zone.
2. If you are in Automated Mode, follow the on-screen instructions to switch to Manual Mode and pause insulin delivery.
3. After the time zone is updated, you may start insulin delivery and return to Automated Mode.</td></tr>
<tr><td colspan="2">Note: Correct time is essential for correct insulin delivery and history records. If you tap Not Now, you can find this Action notification in your Alerts History and every 24 hours you will be reminded to update.</td></tr>
</table>

13.9 Silencing Unresolved Alarms

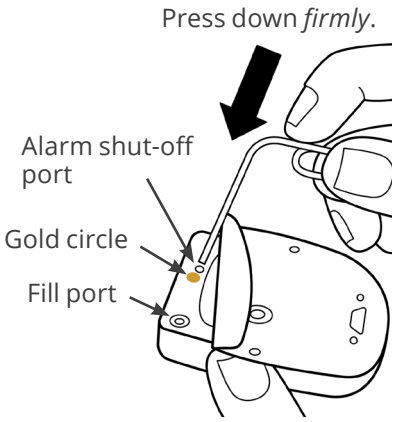
You can silence Pod or Omnipod 5 App alarms by acknowledging the alarm screen displayed on your Omnipod 5 App. If the alarm continues, follow the directions in this section.

Pod Alarm

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.

To permanently silence a Pod alarm:

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



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

13.10 Responding to Reminder Notifications

Reminder notifications remind you about actions you may want to perform.

Finding out about reminder notifications

To alert you to a notification, the Pod sounds a 3-beep tone, and the Omnipod 5 App either sounds a tone or vibrates (see "13.3. Sounds and Vibrations" on page 151). When you hear a sound or feel a vibration, check your Omnipod 5 App for a message.

Note: Program reminders, confidence reminders, and some informational signals do not have an accompanying message.

If your Omnipod 5 App is asleep when you hear or feel a notification, wake it up. The Lock screen shows the reminder notification icon and the notification message.

- If there are multiple messages, the most recent message is shown at the top of the list, with additional messages grouped below it.

Note: The Omnipod 5 App on your iPhone requires Critical Alerts permission and notifications to be turned on to ensure you always receive important safety alarms. You cannot use the App until Critical Alerts permission is provided and notifications is turned on.

If you are using your Omnipod 5 App when a notification is triggered, the notification message appears at the top of the screen. To remove the message from the screen:

- Do nothing. The message disappears after several seconds and is saved as a new message.
- Swipe up to remove the message immediately and save it as a new message.

Acknowledging reminder notifications

Note: Waking up your Omnipod 5 app and using it does not automatically acknowledge or silence notifications.

All new notifications are included in the Notifications & Alarms count (3) in the red circle over the Alerts button in the toolbar.

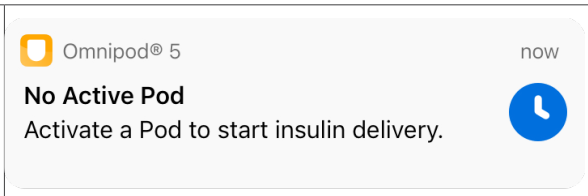
To acknowledge the notification:

1. Wake up your Omnipod 5 app.
2. Tap the Alerts button (3) to bring up the notifications & Alarms screen.
3. Scroll down the screen, if necessary, to see any additional notifications with blue icons.
4. Tapping the notifications acknowledges the alert and clears the red badge.

Reminder Notifications List

Reminder notifications remind you about various actions you may want to perform.

No Active Pod

Screen Displayed	
Cause	Reminds you to activate a new Pod to begin basal insulin delivery.
Pod sound:	None
iPhone sound and vibration:	Repeats twice, 15 minutes after initial notification unless acknowledged.
What to do	Unlock the Omnipod 5 app. Activate a new Pod.

CHAPTER 14

Taking Care of Your Pod

Contents

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.

The Omnipod 5 Automated Insulin Delivery System has no user-serviceable parts. If you require assistance operating or maintaining the Omnipod 5 System, contact Customer Care.

14.1 Pod and Insulin Storage and Care

This section describes proper care of your Pod.

Pod and Insulin Storage

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

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

Pods and the Environment

Avoid extreme temperatures

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

The Pod's operating temperature has been tested and found to operate safely between 41°F and 104°F (between 5°C and 40°C). Under normal circumstances, your body temperature keeps the Pod within a range of 73°F and 98.6°F (23°C and 37°C).

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

If you remove your Pod to avoid exposing it to extreme temperatures, remember to check your glucose frequently.

Note: Check with your healthcare provider for guidelines if you plan on not using a Pod for extended periods.

Note: heck the labeling for your rapid-acting insulin, as maximum insulin exposure temperatures may vary between insulins.

Water and your Pod

> **Warning:** DO NOT expose your Pod to water at depths greater than 25 feet (7.6 meters) or for longer than 60 minutes 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.

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

Cleaning Your Pod

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

> **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.

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CHAPTER 15

Living with Diabetes

Contents

15.1 Infusion Site Checks

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.

At least once a day, use the Pod's viewing window to inspect the infusion site. Check the site for:

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

Tip: Consider making infusion site checks a part of your daily routine, like showering or brushing your teeth.

15.2 Being Aware of Your Glucose

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 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.

When you routinely view your sensor glucose values and/or check your glucose, you can better identify when you need to make a treatment decision or troubleshoot an issue. If you are not wearing a Sensor, it is advisable to check your blood glucose at least 4–6 times per day (when you wake up, before each meal, and before going to bed).

Check your glucose:

- Whenever you feel nauseated or sick
- Before driving a car
- Whenever your glucose has been running unusually high or low
- If you suspect that your glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

When using a Sensor, if your sensor glucose values are different than what you expect based on how you feel, then check your blood glucose using a BG meter to verify your sensor glucose value's

accuracy. For example, if you feel shaky and sweaty, which usually means your glucose is very low, but your sensor glucose value shows as in your acceptable range, you should confirm by checking with your BG meter.

If your blood glucose readings are verified too low or too high, consider treatment.

A sensor calibration may also be needed; consult your compatible *Dexcom G6 CGM System Instructions for Use* for more information.

15.3 Traveling and Vacations

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

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

Keep Supplies Accessible

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

- Your Controller or your smartphone with the Omnipod 5 App
- Extra Pods
- An emergency kit
- Vials of insulin (cargo area temperatures may affect insulin)
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System
- Prescriptions for all medications
- Medications and supplies with their original prescription label

  Note: Generic medications may be easier to find than brand names outside your country.
- Snacks and hypoglycemia treatment, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of your physician and of a physician at your final destination

Note: For information about the recommended glucose sensing supplies to carry, see your *Dexcom G6 CGM System Instructions for Use.*

Note: Keep your emergency kit with you during trips or vacations (see "If you still have questions after reading this *Technical User Guide for iPhone*®, contact Customer Care 24 hours a day, 7 days a week." on page 15). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

Tip: When you travel outside the country or for long periods of time, be sure to take extra Pod supplies. Prior to departure, contact Customer Care to inquire about additional Omnipod 5 System supplies for your trip.

Plan for Changing Time Zones

If you're planning a vacation or business trip to a different time zone, you may need to adjust Basal Programs that you would typically follow while in Manual Mode. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct Basal Program can be more challenging. Your healthcare provider can help with these adjustments.

Airports and Flying

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

Airport security

Prepare for your travel:

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

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

To prevent contamination or damage to your supplies, you should be asked at the security checkpoint to display, handle, and repack your own supplies during the visual inspection process. Any medication and/or associated supplies that cannot be cleared visually must be submitted for X-ray screening.

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

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

Note: For information about passing glucose sensor equipment through airport X-ray machines, see your *Dexcom G6 CGM System Instructions for Use*.

Flying and airplane mode

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.

The Omnipod 5 System sends and receives information from the Pod using Bluetooth wireless technology. Before flying, check your airline's policy regarding the use of Personal Medical Electronic Devices that communicate using Bluetooth technology.

If the use of a Personal Medical Electronic Device using Bluetooth technology is allowed, set your Omnipod 5 App to airplane mode while on the airplane (see page 125). The Bluetooth setting remains enabled in the iPhone's Airplane Mode so you can communicate with your Pod.

Note: The Omnipod 5 System is safe to use at atmospheric pressures typically found in airplane cabins during flight. The Omnipod 5 System can be used at atmospheric pressures as low as 700 hPa, which is lower than the typical pressure in airplane cabins.

15.4 Avoiding Lows, Highs, and Diabetic Ketoacidosis

You can avoid most risks related to using the Omnipod 5 System by following the instructions in this *Technical User Guide* and by promptly treating symptoms of hypoglycemia (low glucose), hyperglycemia (high glucose), or diabetic ketoacidosis (DKA) according to your healthcare provider's instructions. The easiest and most reliable way to avoid these conditions is to check your glucose often.

General Precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme high glucose or low glucose, or if high glucose or low glucose are occurring more often than usual.
- If you have technical problems with your Omnipod 5 System and cannot resolve them, contact Customer Care immediately.

Hypoglycemia (Low Glucose)

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.

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

Symptoms of hypoglycemia (low glucose)

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

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

Tip: Hypoglycemia unawareness is a condition in which you do not realize when your glucose is low. If you are prone to hypoglycemia unawareness, you may want to use the Omnipod 5 System's blood glucose reminder and check your glucose more frequently (see "Insulin infusion (U)" on page 217).

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

Tip: Teach people you trust (like family members and close friends) how to administer glucagon dosage. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.

To avoid hypoglycemia (low glucose)

- Work with your healthcare provider to establish individualized Target Glucose settings and guidelines.
- Keep a fast-acting carbohydrate with you at all times to respond quickly to low glucose. Examples of fast-acting carbs are glucose tablets, hard candies, or juice.
- Teach your friends, family members, and colleagues to recognize the signs of hypoglycemia so they can help if you develop hypoglycemia unawareness or a severe adverse reaction.
- Keep a glucagon kit with your emergency supplies. Teach friends and family members how to administer a glucagon dosage in case you have severe hypoglycemia and become unconscious.

  Periodically check the expiration date of your glucagon kit to make sure it has not expired.

Note: Always carry medical identification (such as an emergency wallet card) and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

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

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

Possible causes of hypoglycemia	Suggested action
Incorrect Basal Program (Manual Mode)	Confirm that the correct Basal Program is active. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too large	Take bolus with food. Check blood glucose before giving a meal bolus. If necessary, adjust the bolus. Check the bolus size and timing. Do not overcorrect for post-meal glucose. Check carb intake. Consult your healthcare provider for guidance.
Incorrect Target Glucose level or incorrect Correction Factor or incorrect IC Ratio	Consult your healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia or hypoglycemia unawareness	Consult your healthcare provider about hypoglycemia unawareness and about raising Target Glucose.
Unplanned physical activity	Consult with your healthcare provider about using Temp Basal (Manual Mode) or the Activity feature (Automated Mode).
Prolonged or intense exercise	Adjust insulin delivery as instructed by your healthcare provider. Check glucose before, during, and after activity and treat as necessary. **Note:** Effects of exercise can last several hours—even a full day—after activity ends. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal (Manual Mode) or the Activity feature (Automated Mode) to avoid hypoglycemia.

Possible causes of hypoglycemia	Suggested action
Low carbohydrate intake prior to activity	Check glucose before activity. Consult your healthcare provider for guidance.
Alcohol consumption	Check glucose frequently, especially before going to bed. Consult your healthcare provider for guidance.

To treat hypoglycemia (low glucose)

Any time your glucose is low, treat it immediately according to your healthcare provider's instructions. Your healthcare provider might recommend that you treat hypoglycemia with a different amount of carbs during Automated Mode compared to Manual Mode. Check your glucose every 15 minutes while you are treating to make sure you don't overtreat the condition and cause glucose levels to rise too high. Contact your healthcare provider as needed for guidance.

Hyperglycemia (High Glucose)

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 158).

Pods use rapid-acting insulin, which has a shorter duration than long-acting insulin, so you have no long-acting insulin in your body when using the Omnipod 5 System. If a blockage (interruption of insulin delivery from the Pod, or occlusion) occurs, your glucose can rise rapidly.

Tip: Hyperglycemia symptoms can be confusing. Always check your glucose before you treat for hyperglycemia.

Symptoms of hyperglycemia (high glucose)

Never ignore the following symptoms, as they could be a sign of hyperglycemia:

- Fatigue
- Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

To avoid hyperglycemia (high glucose)

Check your glucose:

- At least 4–6 times a day (when you wake up, before each meal, and before going to bed); unless you are using a continuous glucose monitoring system
- If you feel nauseated or sick
- Before driving a car
- Whenever your glucose has been running unusually high or low
- If you suspect that your glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

Possible causes of hyperglycemia	Suggested action
Expired insulin or insulin exposed to extreme temperatures	Deactivate and remove the used Pod. Apply a new Pod filled from a new vial of insulin.
Infusion site in or near a scar or mole	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Infected infusion site	Deactivate and remove the used Pod. Apply a new Pod in a different location and consult your healthcare provider.

Possible causes of hyperglycemia	Suggested action
Dislodged cannula	Deactivate and remove the used Pod. Apply a new Pod in a different location. **Note:** Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.
Empty Pod	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Incorrect Basal Program (Manual Mode)	Confirm that the correct Basal Program is active. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too small	Check carb intake. Take bolus with or before eating food rather than after. Check glucose before giving meal bolus. If necessary, adjust bolus. Consult your healthcare provider for guidance.
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type. Consult your healthcare provider about using the extended bolus option.
Less activity than usual	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal (Manual Mode).
Glucose greater than 250 mg/dL (with ketones present) before exercise	Do not exercise when ketones are present. **Note:** Glucose increases with exercise when ketones are present. Consult your healthcare provider for guidance.
Infection or illness or medication change	See "Sick Days" on page 209. Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain or menstrual cycle or pregnancy	Consult your healthcare provider for guidance.

Possible causes of hyperglycemia	Suggested action
Blockage (occlusion)	Deactivate and remove the used Pod. Apply a new Pod in a different location.

To Treat Hyperglycemia (High Glucose)

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

Always check your glucose frequently while treating hyperglycemia. You don't want to over-treat the condition and cause your glucose to drop too low.

1. Check your glucose. The result will help you to find out how much insulin is needed to return your glucose to your glucose goal.
2. If your glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check your glucose again after 2 hours.
5. If glucose has not decreased, do both of the following:
   - Take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.
   - Replace the Pod. Use a new vial of insulin to fill the new Pod. Then contact your healthcare provider for guidance.

   Note: The Omnipod 5 System cannot track insulin that is administered outside of the system. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.
6. If you feel nauseated at any point, check for ketones and contact your healthcare provider immediately.

Diabetic Ketoacidosis (DKA)

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

Pods use rapid-acting insulin, which has a shorter duration than long-acting insulin, so you have no long-acting insulin in your body when using the Omnipod 5 System. If insulin delivery from the Pod is interrupted (a blockage or occlusion), your glucose can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but preventable—emergency that can occur if high glucose is not resolved, in times of illness, or when there is not enough insulin working in your body.

Symptoms of DKA

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your glucose and check for ketones to rule out DKA.

To avoid DKA

The easiest and most reliable way to avoid DKA is by checking your glucose at least 4–6 times a day. Routine checks allow you to identify and treat high glucose before DKA develops.

To treat DKA

- Once you have begun treatment for high glucose, check for ketones. Check for ketones any time your glucose is 250 mg/dL or above.
- If ketones are negative or trace, continue treating for high glucose.
- If ketones are positive and you are feeling nauseated or ill, immediately contact your healthcare provider for guidance.

- If ketones are positive but you are not feeling nauseated or ill, replace the Pod using a new vial of insulin.
- Check your glucose again after 2 hours. If your glucose has not declined or if your ketone levels have risen or remain elevated, immediately contact your healthcare provider for guidance.

15.5 Handling Special Situations

Sick Days

Any physical or emotional stress can cause your glucose to rise, and illness is physical stress. Your healthcare provider can help you make a plan for sick days. The following are only general guidelines.

When you are ill, check your glucose more often to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your glucose to rule out DKA (see "Diabetic Ketoacidosis (DKA)" on page 208).

To handle sick days:

- Treat the underlying illness to promote faster recovery.
- Eat as normally as you can. Your body still needs carbohydrates and insulin for energy.
- Adjust bolus doses, if necessary, to match changes in meals and snacks.
- Always continue your basal insulin, even if you are unable to eat. Contact your healthcare provider for suggested basal rate adjustments during sick days.
- Check your glucose every 2 hours and keep careful records of results.
- Check for ketones when your glucose is 250 mg/dL or higher, and/or when you are feeling ill, as ketones can also be present when glucose is in range during illness.
- Follow your healthcare provider's guidelines for taking additional insulin on sick days.
- Drink plenty of fluids to avoid dehydration.
- Contact your healthcare provider if symptoms persist.

Exercising, Playing Sports, or Working Hard

Check your glucose before, during, and after exercising, playing sports, or doing unusually hard physical labor.

The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products.

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

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

Make sure to check your glucose before removing the Pod and after applying a new one. Pods are designed for one-time use. Do not attempt to reapply a Pod that has been removed.

If you will need to remove the Pod for more than one hour, ask your healthcare provider to recommend appropriate guidelines.

X-rays, MRIs, and CT Scans

Warning: Device components including the Pod, Sensor, and Transmitter 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.

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

Surgery or Hospitalization

For scheduled surgeries or hospitalization, you should tell the physician/surgeon or hospital staff about your Pod. It may be necessary to remove it for certain procedures or treatments. Remember to replace the basal insulin that was missed while the Pod was removed. Your healthcare provider can help you prepare for these situations.

3

SMARTBOLUS CALCULATOR

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SmartBolus Calculator Important Safety Information

SmartBolus Calculator Warnings

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 check your glucose frequently when you use the extended bolus function to avoid hypoglycemia or hyperglycemia.

Warning: AVOID entering a blood glucose reading that is older than 10 minutes. If you use a reading older than 10 minutes, the bolus calculator could calculate and recommend an incorrect dose, which could result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

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 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.

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

SmartBolus Calculator Precautions

Caution: ALWAYS check your glucose prior to delivering a bolus so you are better informed on how much to take. Delivering a bolus without checking your glucose could result in the over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

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.

CHAPTER 16

Delivering a Bolus

Contents

16.1 Delivering a Manual Bolus

In certain situations, you may decide to deliver a manual bolus. A manual bolus is a bolus that you have calculated without the help of the SmartBolus Calculator. You can use manual boluses when the SmartBolus Calculator is temporarily disabled or when you choose not to use the SmartBolus Calculator. Consult your healthcare provider for instructions about how to calculate a bolus.

You can extend some or all of a manual bolus in Manual Mode.

When delivering a manual bolus, the Omnipod 5 System does not adjust the bolus amount based on your glucose value, carbohydrates being consumed, or IOB as it does when the SmartBolus Calculator is used.

Note: Any bolus delivered by you will be considered as IOB and may impact automated insulin delivery in Automated Mode. Current glucose values will continue to be considered in Automated Mode and may impact automated insulin delivery.

A bolus cannot be greater than your Maximum Bolus setting and cannot be delivered while insulin is paused.

Note: The Extended Bolus feature can only be used in Manual Mode. All other therapy settings are used similarly in both Manual and Automated Modes.

To deliver a manual bolus:

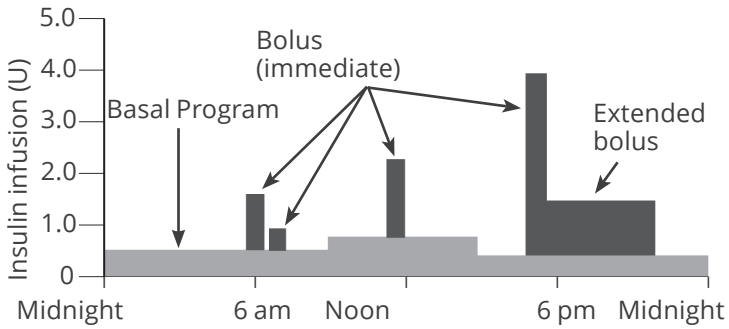
1. On the Home screen, tap the Bolus button.
2. Tap the **Total Bolus** field and enter the bolus amount.
3. Tap **Done**.
4. To deliver the entire bolus immediately, tap **CONFIRM**.
5. Review the bolus details on the Confirm Bolus screen.
6. Tap **START** to begin the bolus.

The bolus amount and bolus details are stored in your history records. The Home screen tracks the delivery of an immediate or extended bolus.

16.2 Delivering Immediate and Extended Boluses

A bolus is an extra dose of insulin that is delivered in addition to the continuous basal rate of insulin delivery. Use boluses to cover the carbohydrates in a meal and/or bring down a high glucose.

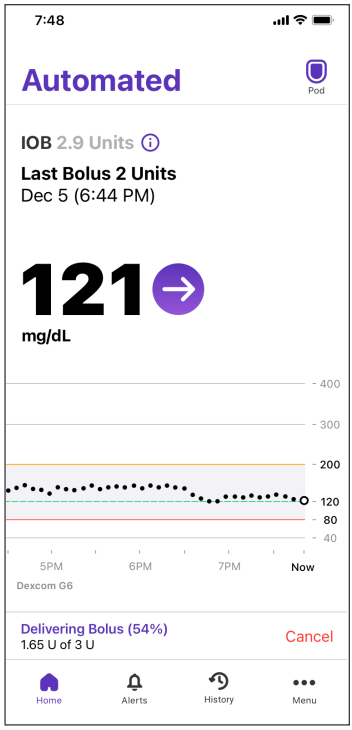
You have the option of delivering the entire bolus at once. This is referred to as an "immediate bolus" or, simply, a "bolus." In Manual Mode, you can also spread out the delivery of all or part of a meal bolus so that it is delivered steadily over a specified period of time. This is referred to as an "extended bolus."



You may want to extend a bolus if your meal contains high-fat or high-protein foods. These foods slow down digestion and therefore slow down the post- meal rise in your glucose.

16.3 Tracking the Progress of a Bolus

During a bolus, the Home screen displays a progress bar at the bottom of the screen.



Immediate bolus progress

During an immediate bolus, the Home screen displays a Delivering Bolus message along with a progress bar and details.

An estimate of the IOB is displayed in the upper left of the screen.

If IOB is unavailable, then the amount of the last completed bolus is displayed in the upper left of the screen.

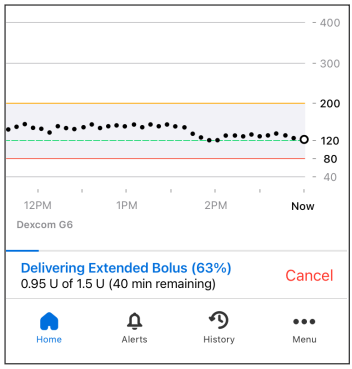
Note: You cannot navigate within the Omnipod 5 App during an immediate bolus.

Note: Look for the progress bar to confirm the bolus delivery has started before navigating away from the Omnipod 5 App.

To cancel a bolus, tap Cancel.

Extended bolus progress

During an extended bolus, the Home screen displays a Delivering Extended Bolus message along with a progress bar and other details.



An estimate of the IOB is displayed in the upper left of the screen.

If IOB is unavailable, then the amount of the last completed bolus is displayed in the upper left of the screen.

Note: You can still navigate within the Omnipod 5 App during an extended bolus, but some functions will be unavailable until the bolus is complete.

Unless you cancel the extended bolus, the Pod will finish delivering the bolus whether or not it is in range of your iPhone running your Omnipod 5 App. To cancel an extended bolus, tap Cancel.

16.4 Canceling a Bolus in Progress

When an immediate bolus is in progress, you must cancel it or allow it to finish before performing any other action.

During an extended bolus, you can use your Omnipod 5 System normally, except that the Bolus button will be inaccessible, preventing you from delivering an additional bolus. You have the options to:

- Cancel the bolus.
- Cancel the bolus in progress and then deliver another bolus.
- If you get a communication error message when canceling a bolus, see "Error when canceling a bolus" on page 358.

Cancel a bolus

To cancel an immediate or extended bolus:

1. At the bottom of the Home screen, tap **CANCEL**.
2. Tap **YES** to confirm canceling the bolus. The Pod beeps to confirm that the bolus is canceled.

Tip: To see how much insulin was delivered from a bolus, tap the History button, and tap **Events**. For more information, see "Immediate and extended boluses" on page 139.

Deliver a new bolus before an extended bolus has ended

To deliver a bolus while an extended bolus is in progress:

1. Cancel the extended bolus as described in the previous procedure, "Cancel a bolus."
2. Find out how much insulin was remaining (not delivered) from the canceled bolus. You can find bolus details at History > Summary.
3. From the Bolus screen, enter the carbs and glucose (or Use Sensor) information.
4. Optional: take into consideration the amount remaining from the canceled bolus and add the amount in the Total Bolus field.
5. Check if the amount entered in the Total Bolus field is correct. Then tap **CONFIRM**.
6. Tap **START**.

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CHAPTER 17

Delivering a Bolus with the SmartBolus Calculator

Contents

17.1 About the SmartBolus Calculator

A bolus is a dose of insulin taken to cover carbohydrates in a meal, drink, or snack (a meal bolus) or to correct elevated glucose (a correction bolus). The SmartBolus Calculator calculates a suggested bolus amount of insulin to bring down high glucose (a correction bolus) and/or to cover carbohydrates in a meal (a meal bolus).

Compatible Devices for Use with the SmartBolus Calculator

Device Type	Device Manufacturer	Brand Name
Blood Glucose Meter	All FDA-cleared blood glucose meters	
iCGM	Dexcom	Dexcom G6 Continuous Glucose Monitor
Alternate Controller Enabled Insulin Pump (Insulin Pump)	Insulet Corporation	Omnipod 5 ACE Pump (Pod)
Interoperable Automated Glycemic Controller software (Automated Insulin Delivery Software)	Insulet Corporation	SmartAdjust technology

About Correction Boluses and Meal Boluses

If you enter a blood glucose reading or sensor glucose value that is above target, but enter no carbs, a correction bolus is calculated. If you enter carbs, but not a blood glucose reading or sensor glucose value, a meal bolus is calculated. If you enter both a blood glucose reading or sensor glucose value and carbs, both factors are used to calculate a suggested bolus.

Value Entered		Type of Bolus Calculated
Blood Glucose Reading or Sensor Value Above Target	Carbohydrates	
		Correction bolus
	√	Meal bolus
√	√	Combined suggested bolus

About Using a Sensor Glucose Value with Trend

Your Sensor trend is based on the recent pattern of glucose changes. If you use your sensor glucose value, your sensor glucose value and trend will be used to calculate a suggested bolus amount. The sensor glucose value and trend will be used along with your Correction Factor to determine the correction portion of your bolus. The SmartBolus Calculator will use the Sensor trend to adjust the correction bolus amount.

When sensor values are...	The SmartBolus Calculator tries to keep glucose within target range and...
Trending up (increasing)	Adds more insulin to the correction bolus.
Trending down (decreasing)	Subtracts insulin from the correction bolus.
Steady	No adjustment to the correction bolus.

Additional information

You may choose to accept or change the final recommendation before the bolus is delivered.

After opening the SmartBolus Calculator, bolus delivery must be initiated within 5 minutes or values will need to be refreshed. If more than 5 minutes pass, you will see a message that values have expired. Tap CONTINUE to refresh the SmartBolus Calculator, then enter or use your current values.

To change your personal settings used by the SmartBolus Calculator, see "SmartBolus Calculator Settings" on page 237.

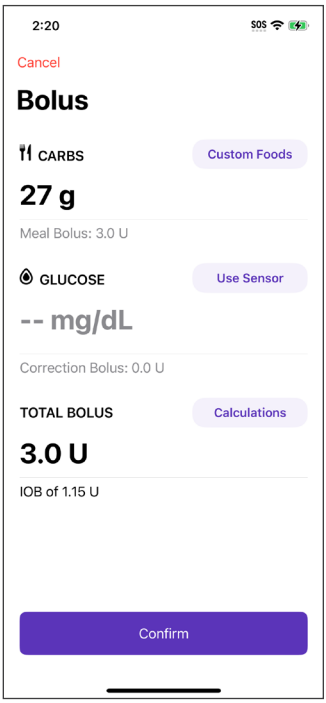
Note: To use the SmartBolus Calculator, the Omnipod 5 App and the Pod must be communicating. If there is no Omnipod 5 App to Pod communication, you will be prompted to re-establish a Pod connection. To find out what to do when your Omnipod 5 App and Pod have a communication issue, see "Frequently Asked Questions and Troubleshooting" on page 342.

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.

Tip: If you already know the number of units for the bolus you want to deliver, tap **Total Bolus**. Enter the bolus amount and tap **Done**. Then go to "17.9. Delivering an Immediate Bolus" on page 231.

17.2 Entering Meal Information

To enter carbohydrates, or "carbs," for your meal:



1. On the Home screen, tap the **Bolus** button.

   Note: The Bolus screen is valid for only 5 minutes. After 5 minutes, if bolus delivery has not started, you must refresh and re-enter new values.

2. Tap the **Carbs** field. Enter the grams of carbs and tap **Done**.

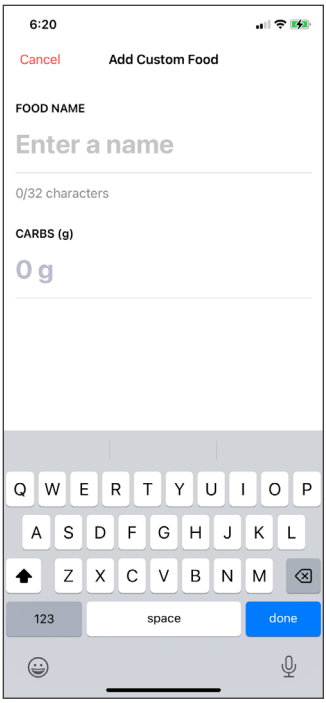
   Note: Consult your healthcare provider about how to calculate the grams of carbs.

   Note: You can also pull the values in from your Custom Foods. See "17.5 Entering Meal Information Using Custom Foods" on page 226.

3. Review the suggested meal bolus, which is shown below the grams of carbs.

4. Optional: tap **Calculations** to see the details.

17.3 Creating a Custom Food

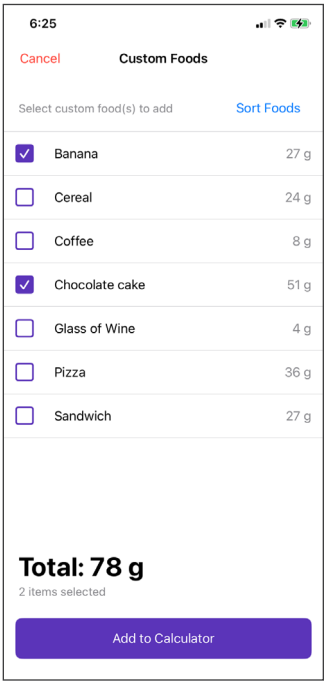


The SmartBolus Calculator allows you to save carb information about certain favorite foods, snacks, or meals (Custom Foods) that you might eat frequently. You can use these carb values in your bolus calculations.

To create a custom food:

1. Tap **Menu** > **Custom Foods**.
2. Tap **Add Custom Food**.
3. Enter a name for your Custom Food. Tap **Done**.
4. Add the total carb count for the entry. Tap **Done**.
5. Tap **Save to Custom Foods**. You will see a green badge that reads NEW next to your new entry.

17.4 Editing Custom Foods



To edit your list, tap Edit in the upper right- hand corner.

- To move an item up or down in your list, tap and hold the icon to the right of the item as you drag the item to your desired location.
- To delete items, tap the (⊖) icon to the left of the item. Tap **Delete**. Tap **Yes** to confirm that you'd like to delete the Custom Food.
- To edit the name or carb count of the Custom Food, tap the item name. Edit the item details. Tap **Save Custom Food**.

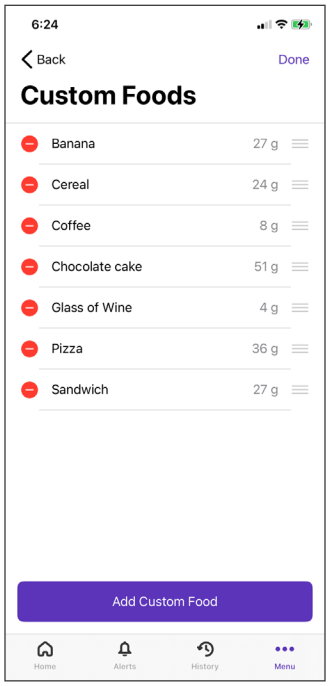
17.5 Entering Meal Information Using Custom Foods

To enter carbs from saved Custom Foods:

1. On the Bolus screen, tap **Custom Foods** in the upper right-hand corner above the Carbs field.
2. You will see a list of your Custom Foods.

Note: Tapping Sort Foods allows you to change how the items are sorted and displayed. You can choose: alphabetically, by recently added, from highest to lowest carbs, or from lowest to highest carbs.

3. Select the button(s) next to the food (or foods) you'd like to select. The total amount of carbs will display at the bottom of the screen.
4. Tap **Add to Calculator**. The SmartBolus Calculator screen appears.



17.6 Entering a Blood Glucose Reading or Using a Sensor Glucose Value

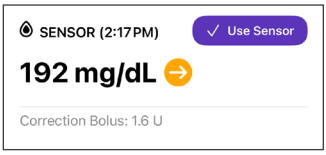
The SmartBolus Calculator uses your glucose information to calculate a correction portion of your bolus. The following sections describe how to give the SmartBolus Calculator your glucose information by either manually entering a blood glucose reading or by obtaining and using the current sensor glucose value.

Note: The SmartBolus Calculator can generate a suggested bolus dose based on the carbohydrates in a meal and the blood glucose reading, or sensor glucose value with trend. Entering a recent blood glucose reading or using a sensor glucose value with trend can help with safety and accuracy.

Manually Enter Your Blood Glucose Reading

Warning: AVOID entering a blood glucose reading that is older than 10 minutes. If you use a reading older than 10 minutes, the bolus calculator could calculate and recommend an incorrect dose, which could result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

To enter a blood glucose reading:



1. Tap the **Glucose** field. If you have manually entered a blood glucose reading from a meter within the past 10 minutes, that value automatically appears in the Glucose field. If you want the SmartBolus Calculator to use that value, skip the next two steps.
2. Enter your current blood glucose reading (taken using a BG meter) in the field. Tap **Done**.
3. Tap **Add to Calculator**. The SmartBolus Calculator screen appears.
4. Review the suggested correction bolus, which is shown below the blood glucose reading. The correction bolus has been adjusted for any insulin on board (IOB) (see "SmartBolus Calculator Rules" on page 254).

Import and Use Sensor Glucose Value

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 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.

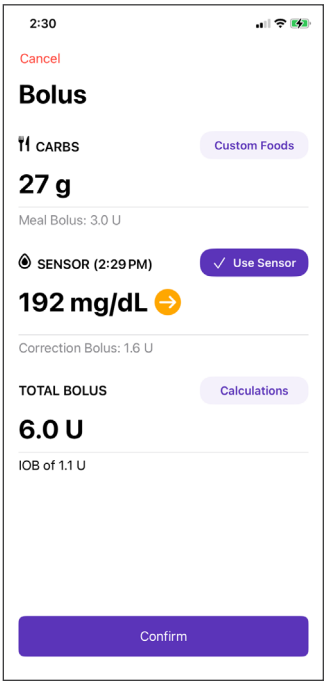
If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *Technical User Guide*, contact your healthcare provider.

If a Sensor is connected, you can use the current sensor glucose value and trend in both Manual and Automated Modes:

➢ Tap **Use Sensor.**

Tip: If the current sensor glucose value is below the defined Minimum Glucose for Calculations setting, you will see a message that the SmartBolus Calculator is disabled. If the sensor glucose value displays "HIGH", the SmartBolus Calculator is also temporarily disabled.

Note: If your Omnipod 5 System does not have a valid sensor glucose value or trend at the time you open the SmartBolus Calculator, the Use Sensor option is disabled.



Tip: If you want to replace the sensor glucose value with a blood glucose reading, tap the Sensor field. See "Manually Enter Your Blood Glucose Reading" on page 227.

17.7 Insulin On Board (IOB)

Insulin on board, also known as IOB or active insulin, is the amount of insulin that is still "active" in the body from a previous bolus or from automated insulin delivery.

The SmartBolus Calculator considers the current IOB when calculating a suggested bolus. Insulin on board may come from:

- Meal IOB - from previous meal boluses.
- Correction IOB - can be from previous correction boluses or from automated insulin deliveries.

For more information, see "SmartBolus Calculator Rules" on page 254 and "SmartBolus Calculator Equations" on page 252.

In certain circumstances you may decide to enter only carbs or the bolus amount into the SmartBolus Calculator. This may be desired if you want to only bolus for carbs using your programmed insulin to carbohydrate ratio, or you want to deliver an amount of insulin based on your own estimate. If entering only carbs or a bolus amount without a glucose value, IOB is not subtracted from your suggested bolus dose as the calculator is not able to adjust the bolus dose if your glucose value is not known. If you want IOB to be considered, enter a glucose value. Here is an example to demonstrate when you may choose to enter only the carb or bolus amount into the SmartBolus Calculator.

Example: You are about to have lunch and you are unsure of how much you will eat. To avoid taking too much insulin, you deliver a meal and correction bolus based on the carbs you know you will eat and your glucose value. After delivering the bolus and eating the first portion, you decide you want to finish the remaining portion. Since you already delivered a correction with the previous bolus, and you know glucose values are on the rise, you decide to deliver a second bolus for only the remaining carbs in your meal and not enter another glucose value.

17.8 Adjustments to Your Calculation

A suggested meal bolus that is calculated using your Insulin to Carb (IC) Ratio may be further adjusted for other values entered into and used by the SmartBolus Calculator, including: blood glucose readings, sensor glucose value and trend, and/or IOB. These adjustments can be for the following:

- Insulin on board—either meal or correction IOB.
- Reverse correction, if this feature is turned on and your glucose is below your Target Glucose.
- Blood glucose reading, if manually entered
- Sensor glucose value and trend (see "19.5. Sensor Trend Arrows" on page 266)

17.9 Delivering an Immediate Bolus

The Total Bolus field shows the proposed bolus. The amount of any IOB adjustment appears below the Total Bolus field.

Note: The Extend Bolus option is available during meal bolus entry when the system is in Manual Mode and the extended bolus setting is on.

To review and deliver the immediate bolus:

1. Review the suggested bolus.
   a. To adjust it, tap the Total Bolus field and enter a revised bolus.
2. To deliver the entire bolus immediately, tap **Confirm**.
3. Review the bolus details on the Confirm Bolus screen.

Grams of carbs

Blood glucose or sensor glucose value

The total bolus includes any IOB adjustments and any adjustments you made to the calculated bolus.

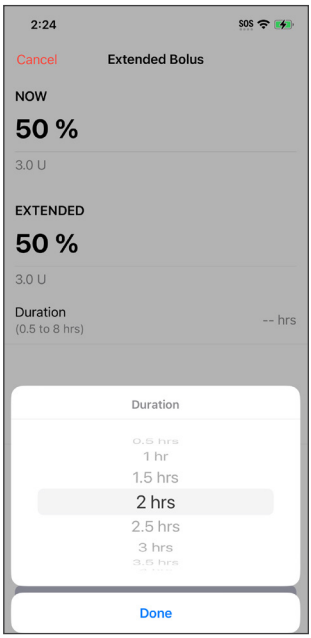
Adjusted for IOB of x U means the SmartBolus Calculator took IOB into account.

4. Tap **START** to begin the bolus.

   The Home screen tracks the delivery of an immediate or extended bolus (see "16.3. Tracking the Progress of a Bolus" on page 218).

17.10 Delivering an Extended Bolus

Warning: ALWAYS check your glucose frequently when you use the extended bolus function to avoid hypoglycemia or hyperglycemia.



Note: You can extend a bolus only while in Manual Mode.

To review, extend and deliver the bolus:

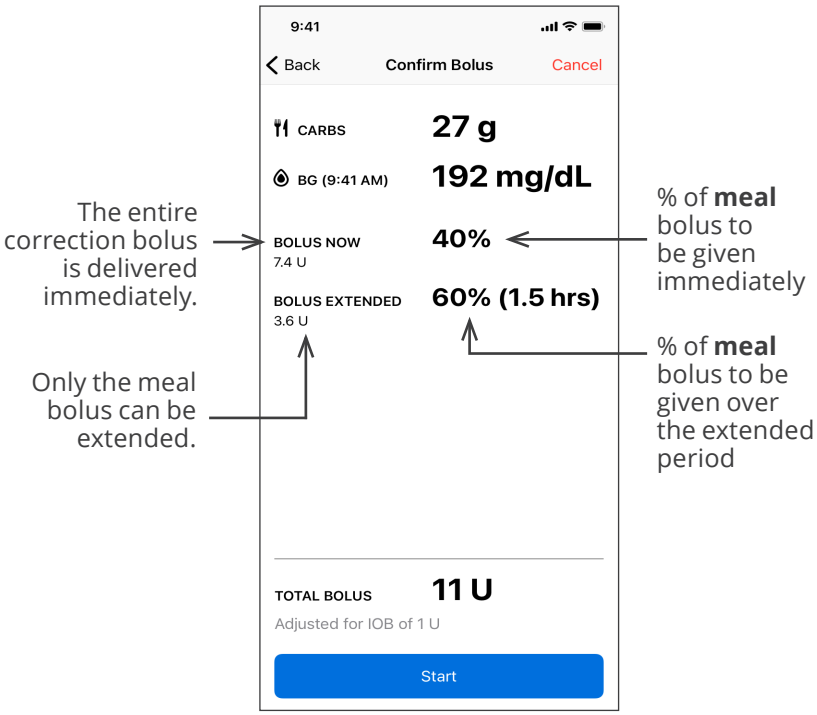
1. Review the suggested bolus.
   a. To adjust it, tap the **Total Bolus** field and enter a revised bolus.
2. Tap **Extend Bolus** at the bottom of the screen.
3. Tap the **Now** field to enter the percentage of the bolus to be delivered immediately or tap the **Extended** field to enter the percentage to be extended. Changing one value will automatically change the other so that they total 100%.

   The number of units to be delivered now and over the extended period appear below the percentage (%).

   Note: You can extend only the meal portion of the bolus. A correction portion of the bolus, if any, is always delivered immediately.
4. Tap the **Duration** field and use the scroll wheel to select the duration for the extended portion of the bolus.
5. Tap **Done**. Tap **Confirm**.

   The extended bolus screen shows how much of the bolus will be delivered immediately and how much will be extended.

6. Review the bolus details on the Confirm Bolus screen.



7. Review the bolus details, then tap **START** to begin the bolus.

17.11 Bolus 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.

These settings allow you to change your Maximum Bolus, extended bolus, and SmartBolus Calculator settings.

Impacts to Suggested Bolus Calculations

The following table describes what each SmartBolus Calculator setting does, how you can adjust them and how they are used to calculate a suggested bolus.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Carbs (grams) 0.1 – 225 g (0.1 g increments)	Enter in SmartBolus Calculator	Increase in carb amount value increases amount of suggested bolus dose. Decrease in carb amount value decreases amount of suggested bolus dose.
Sensor Value (mg/dL) 40 – 400 mg/dL (1 mg/dL increments)	Select Use Sensor within SmartBolus Calculator (Value comes from your connected Sensor)	Increase in Sensor Value increases amount of suggested bolus dose. Decrease in Sensor Value decreases amount of suggested bolus dose.
Blood Glucose Reading (mg/dL) 20 – 600 mg/dL (1 mg/dL increments)	Enter in SmartBolus Calculator (Value comes from your blood glucose meter)	Increase in BG Reading increases amount of suggested bolus dose. Decrease in BG Reading decreases amount of suggested bolus dose.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Maximum Bolus 0.05 – 30 U (0.05 U increments)	Enter in Omnipod 5 App Settings or during First Time Setup	Limits amount of single bolus dose.
Extended Bolus (Manual Mode only) On/Off	Enter in Omnipod 5 App Settings or during First Time Setup	Allows for bolus delivery over a user-selected period of time .
Target Glucose & Correct Above Target Glucose: 110 – 150 mg/dL Correct Above: Target Glucose – 200 mg/dL (10 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Minimum Glucose for Calculations 50 – 70 mg/dL (1 mg/dL increments)	Enter in Omnipod 5 App Settings	Disables SmartBolus Calculator when glucose is at or below setting value.
Insulin to Carb Ratio 1 – 150 g (0.1 g increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Correction Factor 1 – 400 mg/dL (1 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Reverse Correction On/Off	Enter in Omnipod 5 App Settings	If "On," suggested bolus is decreased when glucose is below Target Glucose value.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Duration of Insulin Action 2 – 6 hours (0.5 hour increments)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value may decrease amount of suggested bolus dose for longer periods.

Note: The Extended Bolus feature can only be used in Manual Mode. All other therapy settings are used similarly in both Manual and Automated Modes.

Maximum Bolus

The Maximum Bolus setting defines the upper limit for a bolus. The SmartBolus Calculator prevents you from entering a bolus over this amount. It also prevents you from entering a carb amount that will cause your calculated bolus to exceed this amount. The largest allowed value of the Maximum Bolus is 30 units.

To change your Maximum Bolus:

1. Navigate to: **Menu > Bolus Settings > Maximum Bolus.**
2. Tap the **Max Bolus** field and enter the new Maximum Bolus value. Tap **Done**.
3. Tap **Save**.

Extended Bolus

An extended bolus is delivered over a user specified period of time. Only the meal portion of a bolus can be extended. A correction bolus cannot be extended. To turn off the extended bolus feature or to change your extended bolus configuration:

1. Navigate to: **Menu > Bolus Settings.**
2. Tap the switch next to Extended Bolus to turn on or off the ability to extend a bolus.

SmartBolus Calculator Settings

This section describes how to adjust the settings used by the SmartBolus Calculator to calculate meal and correction boluses.

Tip: Write a list of all of the desired settings and segments to guide you through re-entering the values for each segment.

Target Glucose and Correct Above

In both Automated and Manual Mode, the SmartBolus Calculator aims to bring your glucose to your Target Glucose. However, the SmartBolus Calculator only calculates a correction bolus if your glucose is above your Correct Above setting. In Automated Mode, the Omnipod 5 System will adjust your automated insulin delivery with the goal of bringing you to your Target Glucose.

To edit Target Glucose or Correct Above values:

1. Navigate to:
   Menu > Bolus Settings > Target Glucose & Correct Above.
2. To edit a segment, tap the row containing the segment you want to edit.
   a. Tap the **End Time** field to enter a new end time.
   b. Tap the **Target Glucose** field to enter a new Target Glucose.
   c. Tap the **Correct Above** field to enter a new Correct Above value.
   d. Tap **Next**.
3. Repeat the previous step as needed for the remaining segments.
4. After confirming that all segments are correct, tap **Save**.

Note: You can add and delete segments by editing the existing segments.

Minimum Glucose for Calculations

Your Minimum Glucose for Calculations is used to prevent you from delivering a bolus when your glucose is too low. If your glucose is below your Minimum Glucose for Calculations, the SmartBolus Calculator is disabled and does not calculate a bolus. To edit this value:

1. Navigate to:
   Menu > Bolus Settings > Minimum Glucose for Calculations.
2. Tap the **Minimum Glucose for Calculation**s field and enter the desired value.
3. Tap **Save**.

Insulin to Carb Ratio (IC Ratio)

The Insulin-to-Carbohydrate ratio (IC Ratio) defines how many grams of carbohydrates are covered by one unit of insulin. The SmartBolus Calculator uses your IC Ratio to calculate a meal bolus when you are going to eat.

To edit this value:

1. Navigate to: **Menu** > **Bolus Settings** > **Insulin to Carb Ratio.**
2. To edit a segment, tap the row containing the segment you want to edit.
    a. Tap the **End Time** field to enter a new end time.
    b. Tap the **1 Unit of Insulin Covers** field to enter a new IC Ratio.
    c. Tap **Next**.
3. Repeat the previous step as needed for the remaining segments.
4. After confirming that all segments are correct, tap **Save**.

Note: You can add and delete segments by editing the existing segments.

Correction Factor

The SmartBolus Calculator uses your Correction Factor to calculate a correction bolus when your glucose is above your Correct Above setting. To edit this value:

1. Navigate to: **Menu** > **Bolus Settings** > **Correction Factor.**
2. To edit a segment, tap the row containing the segment you want to edit.
    a. Tap the **End Time** field to enter a new end time.
    b. Tap the **1 U of Insulin Decreases Glucose** by field to enter a new Correction Factor.
    c. Tap **Next**.
3. Repeat the previous step as needed for the remaining segments.
4. After confirming that all segments are correct, tap **Save**.

Note: You can add and delete segments by editing the existing segments.

Reverse Correction

The Reverse Correction setting determines how the SmartBolus Calculator handles meal boluses when your glucose is below your Target Glucose.

See "Reverse Correction bolus calculation" on page 245 for more details. To turn Reverse Correction on or off:

1. Navigate to: **Menu > Bolus Settings.**
2. Tap the switch on the Reverse Correction line to turn it on or off.

Duration of Insulin Action

The SmartBolus Calculator uses your Duration of Insulin Action setting to calculate the amount of insulin on board (IOB) from a previous bolus. To edit this value:

1. Navigate to: **Menu > Bolus Settings > Duration of Insulin Action**
2. Tap the Duration of Insulin Action field. Select a value and tap **Done**.
3. Tap **Save**.

Note: While in Automated Mode, SmartAdjust technology does not use this Duration of Insulin Action setting to calculate automated basal insulin delivery. See "17.7. Insulin On Board (IOB)" on page 229.

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CHAPTER 18

Understanding SmartBolus Calculator Calculations

Contents

18.1 The SmartBolus Calculator

Your Omnipod 5 System's SmartBolus Calculator can do a lot of the work of calculating a bolus for you. The SmartBolus Calculator uses your personal settings and also considers any insulin that remains (referred to as insulin on board or IOB) from automated insulin delivery and from recent boluses.

SmartBolus Calculator Boluses

When calculating a bolus, the SmartBolus Calculator considers a bolus to be made up of the following two components:

- **Correction bolus:** Used to lower glucose when it gets too high.
- **Meal bolus:** Used to cover carbs in a meal.

Extended boluses

When using the SmartBolus Calculator, you can extend some or all of a meal bolus in Manual Mode, but a correction bolus cannot be extended. A correction bolus is always delivered immediately. In the following example, three units of insulin are extended:

Total bolus = 5 units (1 unit correction bolus + 4 units meal bolus)
Deliver now = 2 units (1 unit correction + 1 unit meal bolus)
Extend = 3 units (3 units meal bolus)

Maximum Bolus

The Omnipod 5 System does not allow you to enter a bolus that is above your Maximum Bolus setting. If the SmartBolus Calculator calculates a bolus amount greater than your Maximum Bolus, you will only be able to deliver up to the Maximum Bolus amount. To adjust it, tap the Total Bolus field and enter a revised bolus.

Controlling the bolus amount

The SmartBolus Calculator is a useful tool, but you have the ultimate control over the amount of a bolus to be delivered. After the SmartBolus Calculator suggests a bolus amount, you can confirm the suggested bolus or increase or decrease it. Always check the Calculations to confirm the amount of insulin before it is delivered.

When the SmartBolus Calculator Does Not Work

The SmartBolus Calculator does not work when it is disabled or when there is no Pod communication. Being "disabled" means that the SmartBolus Calculator is temporarily unable to calculate a suggested bolus. Your Omnipod 5 System may disable the SmartBolus Calculator in a few situations.

Conditions that disable the SmartBolus Calculator:	The SmartBolus Calculator is disabled until:	While the SmartBolus Calculator is disabled:
Your glucose is below your Minimum Glucose for Calculations setting.	Ten minutes pass. or A new glucose reading is above your Minimum Glucose for Calculations setting.	IOB is displayed on the Home screen.
Your manually-entered blood glucose reading is greater than 600 mg/dl or "HIGH."	Ten minutes pass. or A new blood glucose reading is lower than "HIGH."	IOB is displayed on the Home screen.
There is an unconfirmed bolus when you discard a Pod.	A complete Duration of Insulin Action period passes. For example, if your duration of insulin action is set at "2 hours", and you receive an unconfirmed bolus at 8 am you will be unable to use the SmartBolus calculator until 10 am (2 hours after the unconfirmed bolus).	IOB is not displayed on the Home screen.

Factors Used in the SmartBolus Calculator Calculations

The SmartBolus Calculator accounts for the following when it calculates a bolus:

- Your current glucose (manually entered or from Sensor), sensor glucose trend (if sensor glucose value is used), Target Glucose, Correct Above threshold, and Correction Factor.
- The carbs you are about to eat or drink and your IC Ratio.
- Your Duration of Insulin Action and insulin on board (IOB).

- Your Minimum Glucose for Calculations.
- Reverse Correction, if it is enabled.

  Note: In both Automated and Manual Mode, if using a sensor glucose values and trend in the Calculator, the SmartBolus Calculator may reduce the suggested insulin dose, even if your reverse correction setting is off.

Sensor glucose trend

The sensor glucose trend is used to suggest up to 30% more correction insulin when your values are rapidly rising, or up to 100% when your values are rapidly falling, compared to the bolus amount suggested with just a blood glucose reading alone.

Target Glucose

When calculating a correction bolus, the SmartBolus Calculator aims to bring your glucose down to your Target Glucose.

Correct Above threshold

The SmartBolus Calculator only suggests a correction bolus if your glucose is above your Correct Above setting. This feature can prevent corrections to glucose that is only slightly higher than your Target Glucose.

Insulin on board

Insulin on board (IOB) is the amount of insulin still active in your body from basal insulin delivery and from earlier boluses. IOB from previous correction boluses is referred to as correction IOB. IOB from previous meal boluses is referred to as meal IOB. Additionally, in Manual or Automated Modes, the Omnipod 5 algorithm constantly calculates IOB from your basal delivery.

When calculating a new bolus, the SmartBolus Calculator may reduce the suggested bolus based on the IOB.

Note: The SmartBolus Calculator only subtracts IOB from a suggested bolus if your current glucose is known. You should always check your glucose prior to delivering a bolus.

Duration of Insulin Action

The SmartBolus Calculator uses your Duration of Insulin Action setting to calculate the insulin on board from prior boluses.

The Duration of Insulin Action setting represents the amount of time that insulin remains "on board" or "active" in your body.

Minimum Glucose for Calculations

The SmartBolus Calculator does not suggest a bolus if your glucose is below your Minimum Glucose for Calculations level. You can adjust this level down to 50 mg/ dL.

Reverse Correction

If the Reverse Correction setting is turned on and your glucose is below your Target Glucose, the SmartBolus Calculator reduces the meal bolus. This allows part of the meal to be used to raise the glucose towards the Target Glucose.

If the Reverse Correction setting is turned off, the SmartBolus Calculator suggests the full meal bolus even if your glucose is below your Target Glucose.

Note: In Automated Mode, if using a sensor glucose value and trend in the Calculator, the SmartBolus Calculator may subtract insulin even if your Reverse Correction setting is off in situations with a decreasing sensor glucose trend.

The below table shows how each value is used in the SmartBolus Calculator to calculate the total bolus volume:

	Accepted Value	How does the SmartBolus Calculator use this value?
Using Omnipod 5 System with an FDA-Cleared Blood Glucose Meter		
Blood Glucose Reading from a BG Meter	20-600 mg/dL	To calculate total bolus volume. You can enter a blood glucose reading directly into the SmartBolus Calculator. If 5 or more minutes have passed since entering the reading, it will expire. Reading saved to the Omnipod 5 System history may be used for up to 10 minutes after entry.
Omnipod 5 Insulin Pump		
Minimum Glucose for Calculations	50-70 mg/dL	Disables bolus delivery when glucose is below this value. You can adjust this value in your Omnipod 5 System settings.
Correction Factor	1-400 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates how much one unit of insulin will lower your blood glucose.

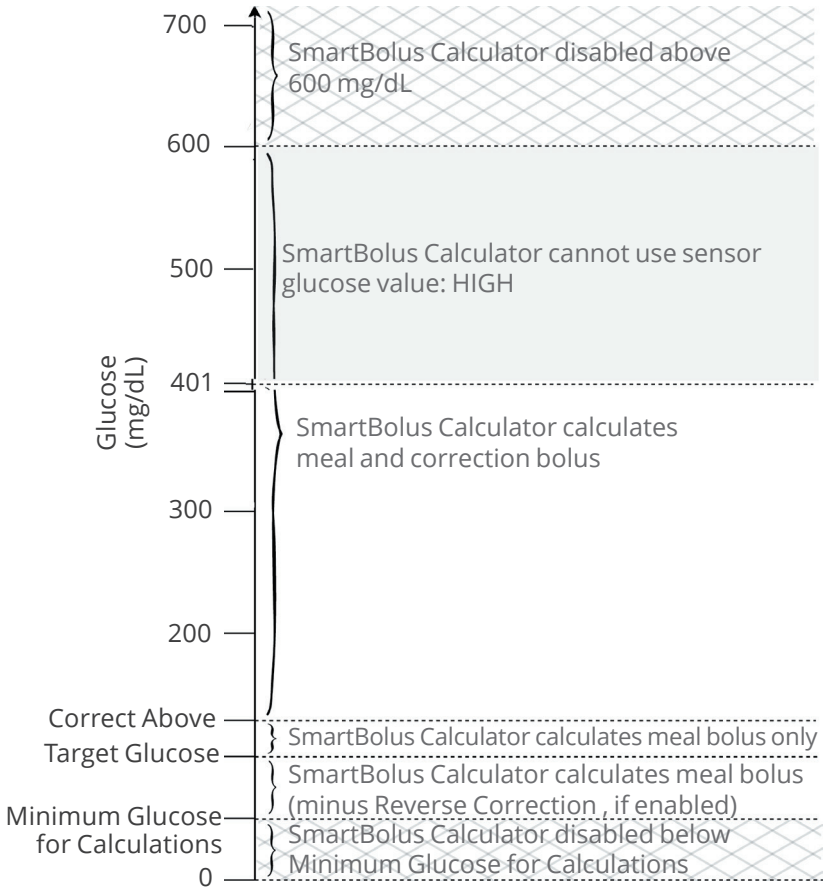
Correct Above	Target Glucose-200 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates the minimum glucose at which a Correction Bolus will be included in the total bolus volume.
Carbohydrates	0.1-225 grams	To calculate total bolus volume. You can enter your Carbohydrates value directly into the calculator to inform the Meal Bolus.
Insulin to Carb Ratio	1-150 grams	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates the grams of carbohydrate covered by one unit of insulin.
Duration of Insulin Action	2-6 hours	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates how long insulin remains in effect after the bolus has delivered.
Meal IOB Portion	0-X Units	To calculate total bolus volume. The value is known by the Omnipod 5 System and used by the Calculator to indicate any previously delivered Meal Boluses that may still be in effect.
Target Glucose	110-150 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. In Automated Mode, basal insulin delivery will be adjusted automatically to bring you towards your Target Glucose. The value informs the Correction Bolus volume.

SmartAdjust™ technology (Automated Mode)		
Target Glucose	110-150 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. In Automated Mode, basal insulin delivery will be adjusted automatically to bring you towards your Target Glucose. The value informs the Correction Bolus volume.
Correction IOB Portion	0-X Units	To calculate total bolus volume. This value is known by the Omnipod 5 System and used by the Bolus Calculator to indicate any previously delivered Correction Boluses that may still be in effect.
Using Omnipod 5 with a compatible iCGM		
Sensor Glucose Value	40-400 mg/dL	To calculate total bolus volume. If you elect to use a Sensor, you can select USE SENSOR directly in the Bolus Calculator. As a safety constraint, the Calculator will only accept sensor glucose values that are on trend with previous sensor glucose values.

Boundaries of the SmartBolus Calculator suggestions

The following figure shows the boundaries between the types of calculations performed by the SmartBolus Calculator depending on your glucose. Some examples of how to read the figure are provided below:

- When your glucose is between your Target Glucose and your Correct Above the SmartBolus Calculator calculates a meal bolus only
- When your sensor glucose value is over 400 mg/dL the value is recorded as "HIGH" and cannot be used for bolusing.
- When your blood glucose reading is above 600 mg/dL the reading is recorded as "HIGH" and the SmartBolus calculator is disabled.



Considerations about SmartBolus Calculator Recommendations

Keep the following in mind when using the SmartBolus Calculator and reviewing its recommendations:

- The SmartBolus Calculator uses your SmartBolus Calculator settings for the time you are requesting a bolus (See "SmartBolus Calculator Settings" on page 237).
- The SmartBolus Calculator refreshes values every 5 minutes. If you do not start your bolus within 5 minutes of entering the SmartBolus Calculator, the Omnipod 5 System will need to clear the screen so that it has the latest IOB and Sensor information.
- When changing time zones, always check your IC Ratio and Correction Factor settings for the new time to ensure it still meets your body's true insulin needs.
- The SmartBolus Calculator will suggest doses depending on the carbs you enter and the glucose at that time. Check the nutritional content of your meals to ensure the carbs entered is as accurate as possible. Only enter BG readings that have been obtained with the last 10 minutes or Use Sensor. These factors will make sure that the SmartBolus Calculator suggests a bolus dose that is suitable for you.

If your sensor glucose value or trend does not match your symptoms or expectations, use a fingerstick blood glucose reading in the SmartBolus Calculator.

When programming and delivering boluses, always confirm that the values you enter and the suggested bolus dose you receive are what you intend and align with what you want at that time. The Omnipod 5 System has features that help with preventing unintended delivery amounts.

Delivery Limitations	Description
Maximum Bolus Setting	The SmartBolus Calculator will not deliver boluses that exceed the Maximum Bolus Setting you entered (0.05 -30 U). For example, if you rarely deliver more than 5 U boluses, and you set the Maximum Bolus Setting at 5 U, the system will prevent you from delivering anything greater than this amount.

Blood Glucose Reading Time Out	The SmartBolus Calculator will not calculate a suggested bolus dose using a blood glucose reading you entered that is older than 10 minutes. You will need to enter a more recent blood glucose reading within the SmartBolus Calculator.
SmartBolus Calculator Time Out	The SmartBolus Calculator considers the values you input for a given bolus calculation valid for up to 5 minutes from initial entry of the value into the SmartBolus Calculator. If 5 minutes or more have elapsed, you will be notified that you must refresh the SmartBolus Calculator and input the values again.
Time Zones	The SmartBolus Calculator relies on accurate, updated insulin delivery history and data logging from your Omnipod 5 System. If a time zone change is detected by the Controller or smartphone, the system will notify you. Update time zones on your Omnipod 5 App according to your healthcare provider's guidance.

Insulin on Board (IOB)

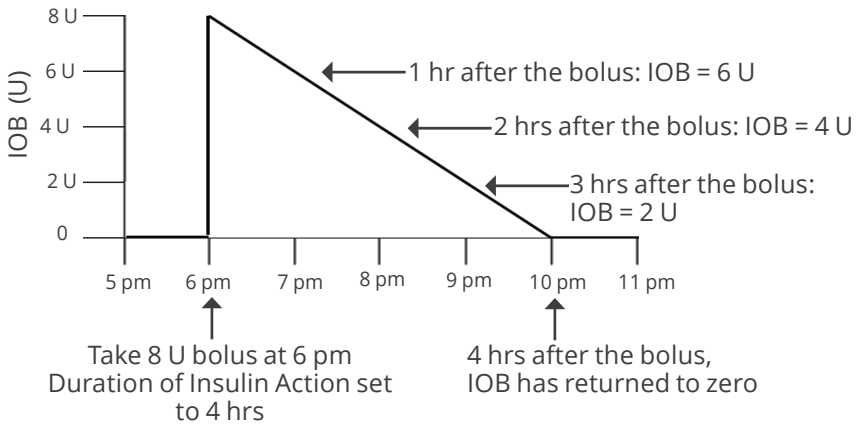
After a bolus is delivered, the amount of insulin that is active in the body decreases over several hours. The IOB from a bolus decreases based on your defined Duration of Insulin Action value within your profile settings.

When using the SmartBolus Calculator, your Omnipod 5 System may, due to IOB, decrease your suggested bolus amount to help prevent giving too much insulin.

Note: You must bring your Controller or smartphone running the Omnipod 5 App near the Pod to get the most recent IOB value on your Omnipod 5 App Home screen.

Bolus IOB depletion

The graph below shows the IOB from an 8 unit bolus depleting over the set Duration of Insulin Action of 4 hours.



In the Omnipod 5 System, the correction IOB can also change depending on the SmartAdjust technology calculations. It can increase or decrease automatically..

Insulin on board (IOB) calculations

$$\frac{\text{Duration of Insulin Action} - \text{time since previous bolus}}{\text{Duration of Insulin Action}} \times \text{previous bolus}$$

IOB from a previous correction bolus is called a “correction IOB.”

IOB from a previous meal bolus is called a “meal IOB.”

Correction IOB example

Duration of Insulin Action: 3 hours
Time since previous correction bolus: 1 hour
Previous correction bolus: 3 U

$$\frac{3 \text{ hours} - 1 \text{ hour}}{3 \text{ hours}} \times 3 \text{ U} = 2 \text{ U correction IOB}$$

Final IOB shown to you:

2U correction IOB + 1U automatic adjustment = 3U overall IOB

In other words, one hour after your previous correction bolus, your body has used up 1 unit from the correction bolus. The remaining 2 units of insulin are still working in your body to lower glucose. Additionally, the system can automatically adjust the correction IOB based on its estimate of your insulin needs. In this example, the automatic adjustment added 1 unit for a total of 3 units working to lower your glucose.

Correction Meal IOB example

Duration of Insulin Action: 3 hours
Time since previous meal bolus: 2 hours
Previous meal bolus: 4.5 U

$$\frac{3 \text{ hours} - 2 \text{ hours}}{3 \text{ hours}} \times 4.5 \text{ U} = 1.5 \text{ U meal IOB}$$

In other words, two hours after your previous meal bolus, your body has used up 3 units from the meal bolus. The remaining 1.5 units of insulin are still in your body, working to cover your meal.

SmartBolus Calculator Equations

The SmartBolus Calculator first calculates a preliminary correction and meal bolus. It adjusts these values for IOB, if necessary. It then suggests a final total bolus that includes the adjusted correction bolus and meal bolus.

Your adjustments from the sensor glucose trend can add or subtract insulin from the correction and/or the meal portion.

$$\text{Preliminary correction bolus} = \frac{\text{Current BG or Sensor - Target Glucose}}{\text{Correction Factor}}$$

Example: Current BG or Sensor: 200 mg/dL,
Target Glucose: 150 mg/dL
Correction Factor (CF): 50

$$\frac{200 \text{ mg/dL} - 150 \text{ mg/dL}}{50} = 1 \text{ U prelim. correction bolus}$$

$$\text{Preliminary meal bolus} = \frac{\text{Carb intake}}{\text{Insulin-to-Carb (IC) ratio}}$$

Example: Carb intake: 45 grams of carb, IC ratio: 15

$$\frac{45}{15} = 3 \text{ U prelim. meal bolus}$$

Correction bolus = (prelim. correction bolus - meal IOB) - correction IOB

The meal IOB is subtracted first. If the preliminary correction bolus is still above zero, then the correction IOB is subtracted.

Meal bolus = prelim. meal bolus - remaining correction IOB

Meal IOB is never subtracted from a meal bolus. Only a remaining correction IOB is subtracted from a meal bolus.

Calculated bolus = correction bolus + meal bolus

Reverse Correction bolus calculation: If the Reverse Correction feature is turned ON and if your current glucose is below your Target Glucose but above your Minimum Glucose for Calculations, the SmartBolus Calculator subtracts a correction amount from the preliminary meal bolus.

Meal bolus with Reverse Correction = Reverse Correction + prelim meal bolus

Example: Current BG or Sensor: 75 mg/dL,
Target Glucose: 150 mg/dL
Correction Factor: 50, Preliminary meal bolus: 2.5 U

$$\frac{75\ \text{mg/dL} - 150\ \text{mg/dL}}{50} = -1.5\ \text{U Reverse Correction}$$

- 1.5 U (Reverse Correction) + 2.5 U (prelim meal bolus) = 1.0 U meal bolus

A Reverse Correction is only applied to the meal bolus. In this example, the meal bolus is reduced by 1.5 units, resulting in a meal bolus of 1.0 U.

SmartBolus Calculator Rules

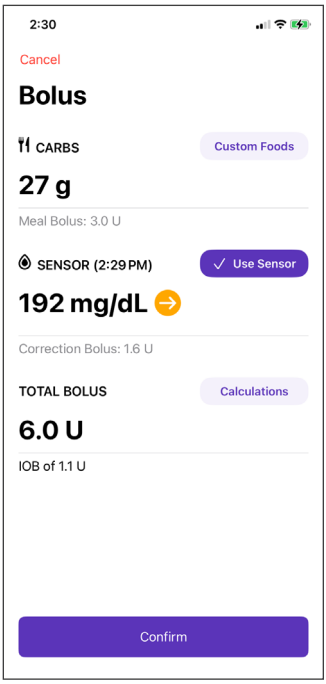
The SmartBolus Calculator applies the following rules to the suggested bolus doses:

Rule	Detail		
Rounding	Boluses will always be rounded *down* to the nearest 0.05 U and will never be below 0 U. IOB will always be rounded *up* to the nearest 0.05 U and will never be below 0 U.		
Factors that influence the size of your bolus	**Factor**	**Increase**	**Decrease**
	Carbs entered	√	
	Sensor or BG value	√	√
	IOB		√
	Sensor trend (if using Sensor)	√	√
	Target Glucose	√	√
	Reverse Correction setting		√
Correction IOB	Correction IOB is subtracted from both meal and correction boluses.		
Meal IOB	Meal IOB is subtracted only from the correction boluses.		

Overview of the Bolus Calculations Screen

You can tap the Calculations button above the Total Bolus field on the SmartBolus Calculator screen if you want to view bolus calculation details.

When a sensor glucose value and trend are used for a bolus, the SmartBolus Calculator will not only consider the value but may also adjust the bolus amount for the trend. You will see these adjustments labeled in the Bolus Calculations Screen.

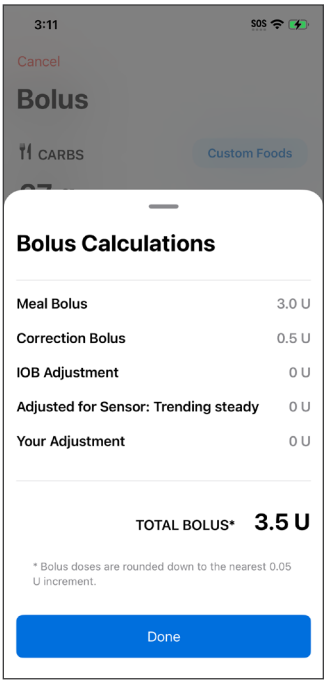


The Bolus Calculations sheet will appear to break the total suggested bolus down by:

- Meal Bolus
- Correction Bolus
- IOB or Sensor Adjustment
- Your Adjustment

When a sensor glucose value and trend are used for a bolus, the SmartBolus Calculator will not only consider the value but may also adjust the bolus amount for the trend.

You will see these adjustments labeled in the Bolus Calculations Screen.



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4

USING A SENSOR WITH OMNIPOD 5

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Sensor Important Safety Information

Sensor Warnings

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 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.

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 can lead to hypoglycemia or hyperglycemia.

Warning: ALWAYS confirm the Dexcom G6 Transmitter serial number (SN) you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses the Dexcom G6, mis-matching Transmitter serial numbers (SN) could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia and hyperglycemia.

Warning: Device components including the Pod, Transmitter, and 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 use the Omnipod 5 System with Dexcom G6 if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom G6 sensor glucose values may be falsely elevated and result in over-delivery of insulin that can result in severe hypoglycemia.

Sensor Precautions

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

CHAPTER 19

About the Dexcom G6

Contents

19.1 Sensor Overview

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 value do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor 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.

The Omnipod 5 System is designed to connect with the Dexcom G6 CGM System. When connected to the Dexcom G6, the Pod receives glucose values and trends from the Dexcom G6 Transmitter. In Automated Mode, the Pod uses sensor glucose values to make automated insulin dosing decisions every 5 minutes. In both Manual Mode and Automated Mode, a sensor glucose value and trend can be used in the SmartBolus Calculator to calculate a suggested bolus.

Read and follow all Dexcom G6 product instructions, including Safety Statements, in the Dexcom G6 CGM System Instructions for Use.

Note: All Sensor and Transmitter-specific actions and alerts are controlled through your Dexcom G6 app. See your Dexcom G6 CGM System Instructions for Use for additional information.

Note: The Dexcom G6 app and Omnipod 5 App do not directly communicate with each other. They have their own separate communication channels to acquire sensor glucose values. As a result, you may notice that, at times, the sensor glucose values may slightly differ in each app.

When connecting and using a Transmitter, be aware of the following:

- Always check the Dexcom G6 expiration dates for the Sensor and Transmitter. Only use a Sensor and Transmitter that are within their use-by date.
- Adhere to Dexcom's approved site placements for Dexcom G6 wear.
- All Dexcom G6 alerts are configured and driven by your Dexcom G6 app. Set your Low and High alerts, as well as any other alerts in your Dexcom G6 app before using the Omnipod 5 System.

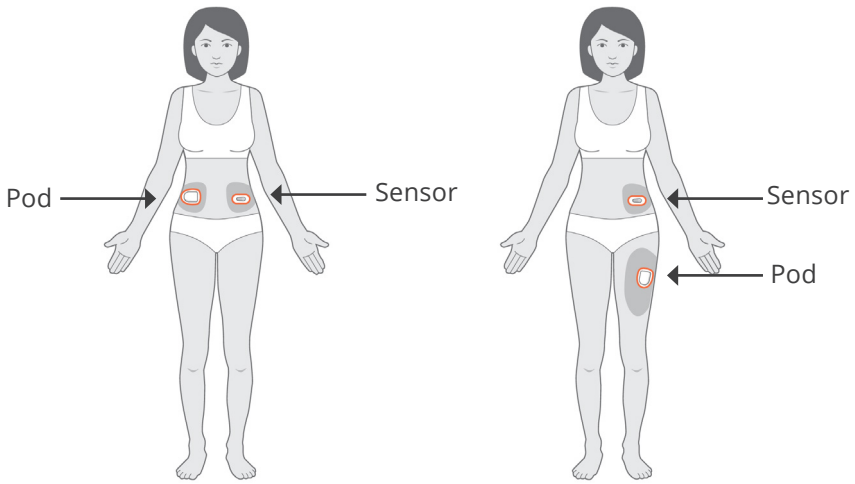
  Note: The Omnipod 5 System also alerts you when your sensor glucose values are at or below 55 mg/dL.
- Always ensure the Transmitter serial number (SN) entered in the Dexcom G6 and Omnipod 5 Apps match the Transmitter on your body.

19.2 Sensor Placement

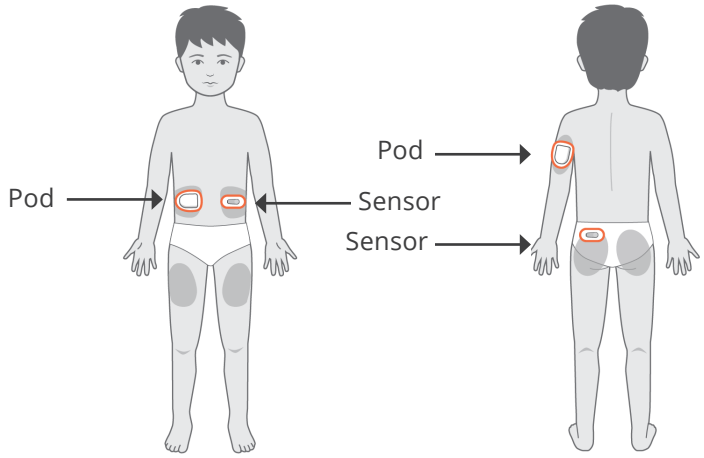
The Bluetooth connection between the Sensor and the Pod is optimal when the signal does not pass through the body. Keeping both devices at least 3 inches (8 cm) apart and within line of sight allows for consistent Sensor communication with the Pod.

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.

Adult placement examples



Pediatric placement examples



Note: Consult the *Dexcom G6 CGM System Instructions for Use* for more information on approved Sensor placement locations.

19.3 Using the Dexcom G6 with Omnipod 5

When using Omnipod 5 System with the Dexcom G6 CGM System, you need to use the Dexcom G6 app to control your Sensor.

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

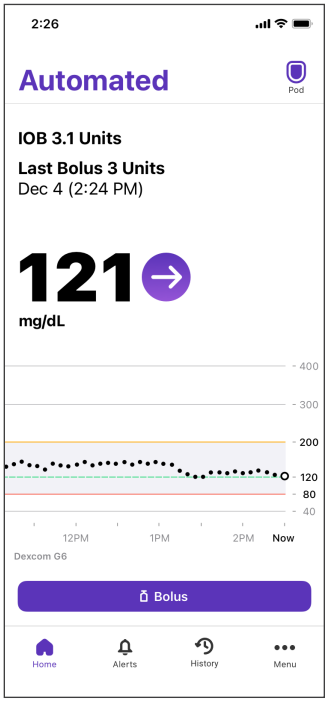
19.4 Sensor Values

Sensor glucose values are displayed in the center of your Home screen along with a trend arrow to indicate whether sensor glucose values are trending up, down, or holding steady.

In Automated Mode, the system takes your Sensor trend into account every 5 minutes when making automated insulin delivery decisions.

In Manual Mode and Automated Mode, the sensor glucose value and trend can be used in the SmartBolus Calculator. The SmartBolus Calculator can increase or decrease your bolus as needed based on your sensor glucose value and trend.

Note: Both value and trend must be available to tap Use Sensor with the SmartBolus Calculator.



High and Low Sensor Values

The Omnipod 5 app indicates high and low sensor glucose values as follows.

Sensor Glucose Value	Screen display
Above 400 mg/dL	HIGH
Below 40 mg/dL	LOW

Note: Sensor glucose values are automatically recorded on the Omnipod 5 System and do not need to be entered on the Enter BG screen.

Urgent Low Glucose

Warning: ALWAYS promptly treat low glucose. 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.

When your sensor glucose value is at or below 55 mg/dL, your Dexcom G6 will send the value to your Pod. The Pod will sound an Advisory alarm to let you know that your glucose is very low. You can acknowledge the alarm from your Controller or smartphone. See "13.7. Advisory Alarm List" on page 167.

Note: This Alarm will occur again if another sensor glucose value of 55 mg/dL or lower is received after the initial Advisory Alarm was acknowledged.

Note: This Advisory Alarm will only stop repeating after a glucose value of 56 mg/dL or greater is received. You may silence this Advisory Alarm for 30 minutes by acknowledging the on-screen message.

Note: Use a BG meter to confirm your glucose. Treat low glucose as needed.

Note: The Urgent Low Glucose Advisory Alarm has to do directly with your body’s current glucose, while other alarms have to do with the Pod or Omnipod 5 App state.

19.5 Sensor Glucose Trend Arrows

Trend arrows display per Dexcom specifications. The arrow color matches the sensor glucose value color. For more information, refer to the *Dexcom G6 CGM System Instructions for Use*.

The color of the sensor glucose value and/or trend arrow can vary as follows:

Sensor Glucose Value Color	Description
Purple	Sensor glucose value is within Glucose Goal Range (Automated Mode)
Blue	Sensor glucose value is within Glucose Goal Range (Manual Mode)
Red	Sensor glucose value is below Glucose Goal Range
Yellow	Sensor glucose value is above Glucose Goal Range

The following table describes the sensor glucose trend arrows. The trend arrows are shown in blue for example purposes only.

Sensor Trend Arrows	Description
	Steady; decreasing/increasing less than 1 mg/dL per minute
	Slowly falling/rising; glucose could decrease/increase 30-60 mg/dL in 30 minutes
	Falling/rising; glucose could decrease/increase 60-90 mg/dL in 30 minutes
	Rapidly falling/rising; glucose could decrease/increase more than 90 mg/dL in 30 minutes

19.6 Dexcom G6 Communication Messages

Communication Message	Description
Connecting Transmitter...	Occurs after you have entered a Transmitter serial number (SN) and the Pod is attempting to connect with the Transmitter.
Dexcom issue detected	When sensor glucose values are not available due to a Sensor error (including Sensor expiration). See the Dexcom G6 app for details. No action is required within the Omnipod 5 App.
Searching for Pod...	When Pod communication was not established within the most recent 5- minute update interval. Tap More Information for potential causes and recommended actions.
Searching for Sensor...	When the Sensor is active and connected to the Omnipod 5 Pod but the most recent sensor glucose value was not acquired within the 5-minute window. There may be no valid sensor glucose value available due to a Pod/ Sensor communication issue or a temporary Sensor issue (recoverable without any user action). Tap More Information for recommended action. Review Pod and Sensor placement. Pod and Sensor should be at least 3 inches (8 cm) apart and within line of sight.
Transmitter error	When the Transmitter connected with the Omnipod 5 System has expired or experienced a non-recoverable error. Tap Need help? for potential causes and recommended actions. To set up a new Transmitter, see "20.3 Connecting the Dexcom G6 Transmitter" on page 271.
Transmitter not found	When the Transmitter is connected but sensor glucose values are unavailable because the Dexcom G6 is in Sensor warm-up or requires calibration. See the Dexcom G6 app for details. No action is required within the Omnipod 5 App.
Waiting for Dexcom Setup...	When the Transmitter is connected but sensor glucose values are unavailable because the Dexcom G6 is in Sensor warm-up or requires calibration. See the Dexcom G6 app for details. No action is required within the Omnipod 5 App.

Note: For all Sensor-related issues, refer to your Dexcom G6 CGM System Instructions for Use.

CHAPTER 20

Connecting Dexcom G6 to the Pod

Contents

20.1 About Connecting Dexcom G6 to the Pod

The Omnipod 5 System is designed to work with the Dexcom G6 Sensor. To use the Dexcom G6 Sensor with the Omnipod 5 System, you will need to obtain the Dexcom G6 Sensor and Transmitter, Dexcom G6 Instructions for Use, and download the Dexcom G6 app on your iPhone.

Before you can view and use sensor glucose values in the in the Omnipod 5 System, you must first set up the Omnipod 5 System to allow the Pod to communicate with the Sensor. Once connected, you will be able to use the system in Automated Mode, view sensor glucose values in the Omnipod 5 App, and use sensor glucose values in the bolus calculator in both Manual and Automated Modes.

Note: The Dexcom G6 Sensor must be started in the Dexcom G6 app to use sensor glucose values and trends in the Omnipod 5 System.

Before you begin, do the following:

➢ The Omnipod 5 System will not connect with the Transmitter if you are using the Dexcom G6 receiver. If you have an existing Transmitter that is connected to your receiver, turn off your receiver. You will need to use the Dexcom G6 app on your smartphone. For instructions about using the Dexcom G6 CGM System, see the Dexcom G6 CGM System Instructions for Use.

20.2 Connecting the Dexcom G6 during Initial Pod Setup

To connect the Transmitter during initial Pod setup:

1. After activating your Pod during initial setup, tap Connect Sensor.

   Note: If you tap Not Now after activating your Pod during initial setup, you can connect the Sensor at a later time. See "Connecting the Dexcom G6 Transmitter" below.

2. Go to step 3 of "Connecting the Dexcom G6 Transmitter" below.

20.3 Connecting the Dexcom G6 Transmitter

Warning: ALWAYS confirm the Dexcom G6 Transmitter serial number (SN) you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses the Dexcom G6 Sensor, mis-matching Transmitter serial numbers could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia and hyperglycemia.

If you had previously connected a Transmitter and your Transmitter has expired, or you have deleted the Transmitter serial number (SN) and wish to reconnect, you must enter a new SN. You must be in Manual Mode to manage your Transmitter SN.

To connect the Dexcom G6 Transmitter:

1. Tap **Menu** > **Manage Sensor**. The Transmitter screen displays the saved SN.

Note: If the Transmitter SN was previously deleted, the SN field is empty. (See "20.4. Disconnecting the Sensor from the Pod" on page 272).

2. Tap **Enter New**.
3. Tap the SN field to display the alphanumeric keypad.
4. Enter the SN printed on the back of your Transmitter or on the Transmitter box, then tap **Done**.
5. Tap **Save**.

Note: If you tap Cancel, the SN is not saved. Tap Confirm to start connecting your Transmitter to your Pod. The connection process can take up to 20 minutes.

6. Tap **Confirm** to start connecting your Transmitter to your Pod. The connection process can take up to 20 minutes. When Pod communication is successful, the screen displays "Connecting Transmitter."

If the Pod is unable to connect with the Transmitter within 20 minutes, the message "Transmitter Not Found" displays. Tap Need Help for more information. See "26.3. Sensor FAQs" on page 349 for additional information.

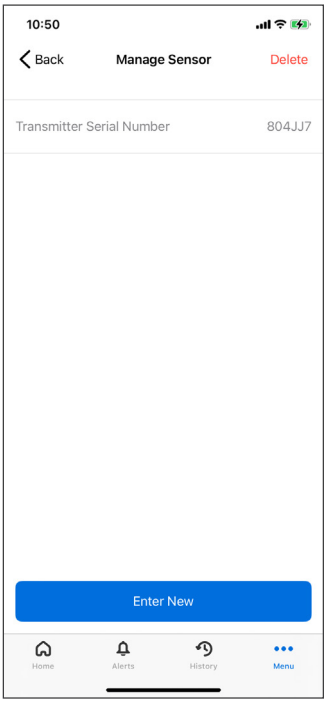
If you do not have an active Pod or you are changing your Pod, the Transmitter serial number (SN) will be saved and sent to the next Pod that is activated.

20.4 Disconnecting the Transmitter from the Pod

To stop the Pod from communicating with the Transmitter, delete the SN. If you delete the SN, you will no longer be able to enter Automated Mode until a new Transmitter SN is added.

To delete the serial number (SN):

1. From the Home screen, tap **Menu** > **Manage Sensor**. The Transmitter screen displays the saved SN.
2. Tap **Delete**.
3. Tap **OK**, **Delete** to confirm.



AUTOMATED MODE

5

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Automated Mode Important Safety Information

Automated Mode Warnings

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

Warning: 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 can 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 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 Guid*e, contact your healthcare provider.

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: ALWAYS monitor for symptoms of hypoglycemia while the Activity feature is enabled. Hypoglycemia can still occur when using the Activity feature. Follow your healthcare provider's advice on hypoglycemia avoidance and treatment. If untreated, hypoglycemia can lead to seizure, loss of consciousness or death.

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

CHAPTER 21

About Automated Mode

Contents

21.1 About Automated Mode

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: 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 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 for iPhone*, contact your healthcare provider.

Caution: ALWAYS check your glucose prior to delivering a bolus so you are better informed on how much to take. Delivering a bolus without checking your glucose could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

Automated Mode is the defining feature of the Omnipod 5 System. In Automated Mode, SmartAdjust™ technology (the Omnipod 5 algorithm) predicts where your glucose will be 60 minutes into the future. SmartAdjust technology uses this information, along with your current sensor glucose value and trend, to automatically adjust insulin delivery every 5 minutes. The System's goal is to help you bring your glucose to your defined Target Glucose.

SmartAdjust technology is on the Pod itself. You will stay in Automated Mode even if the Controller or smartphone running your Omnipod 5 App is out of range of the Pod. When the Pod and Controller or smartphone are in range, the Pod sends its information back to the Omnipod 5 App, updating its Home screen to show your current IOB along with recent sensor glucose value and trend.

Note: ALWAYS bolus for meals as directed by your healthcare provider. In Automated Mode, bolus doses for meals still require your programming and delivery. Failure to deliver a bolus for meals could lead to hyperglycemia.

How insulin is calculated and delivered during Automated Mode

The Omnipod 5 System uses your total daily insulin history over the last few Pods to determine how much insulin your body needs. The calculated amount per hour is known as the Adaptive Basal Rate, which provides a baseline for automated insulin delivery.

With each Pod change, the Omnipod 5 System will learn your recent daily insulin needs and update information about your total daily insulin, resulting in your adaptive basal rate changing with each new Pod to better match your true insulin needs.

Using this Adaptive Basal Rate as a starting point, the System can automatically increase, decrease, or pause insulin delivery every 5 minutes to help you reach your Target Glucose.

Increasing Insulin Delivery

The System can increase insulin delivery by delivering a series of insulin microboluses (small amounts of insulin delivered every 5 minutes) to respond to elevated glucose or if it predicts your glucose to be above your Target Glucose in the next 60 minutes.

Decreasing and Pausing Insulin Delivery

The System can decrease or pause automated insulin delivery at any time if you are predicted to be below your Target Glucose or to protect against hypoglycemia.

It will always pause insulin when the last sensor glucose value recorded was below 60 mg/dL.

Viewing Automated Insulin Delivery

The Sensor Graph on the Home screen shows when the Omnipod 5 System paused insulin delivery or has reached the maximum delivery. See page 134.

The automated insulin delivery amount given every 5 minutes while in Automated Mode can be seen in the Auto Events tab of the History Detail screen. See "11.4 Events" on page 138.

The Auto Events tab shows the total amount of automated insulin delivered every 5 minutes. This tab shows all automated insulin, both your baseline adaptive basal rate and any adjustment up or down due to your sensor glucose value, trend, and 60-minute prediction. The values will always be small. (Remember that a basal rate of 0.60 U/hr would be like getting 0.05 U every 5 minutes.)

Note: Your sensor glucose value informs how much insulin the System will deliver in the next 5-minute time period. For example, if your sensor glucose value at 11:00 dropped to 58 mg/dL, SmartAdjust technology will not deliver a microbolus at 11:05. Your Auto Events tab will display 0 U at 11:05, as shown in the table below.

	Sensor (mg/dL)	Insulin Amount (U)
11:05	62	0
11:00	58	0.05

Adjusting settings for Automated Insulin Delivery

While you are using Automated Mode, the main adjustable setting affecting automated insulin delivery is Target Glucose. Target Glucose is customizable from 110-150 mg/dL (10 mg/dL increments), and you can create up to 8 different time segments per day. As you increase the Target Glucose setting value, SmartAdjust technology will deliver less automated insulin. Changing your Target Glucose can be useful if:

- There are times of the day when you are more or less sensitive to insulin (For example you and your healthcare provider identify a time in your day when you are more at risk of hypoglycemia which may require a higher Target Glucose). Your provider can help you select different Target Glucose values for different times of day.
- You would like to gradually bring your Sensor glucose values down to a lower Target Glucose (For example starting the system for the first time).

Consult with your healthcare provider before making any changes in your Target Glucose. See "Omnipod 5 Clinical Studies" on page 301 for clinical study information at each Target Glucose.

SmartBolus Calculator settings can also be adjusted to impact your total daily insulin delivered and impact post-meal glucose. These settings include Insulin-to-Carbohydrate ratio,

Correction Factor, Correct Above, Reverse Correction and Duration of Insulin Action. These all affect the bolus amounts you deliver during both Manual Mode and Automated Mode.

Note: It is important to understand that changing your Basal Programs, Max Basal, Correction Factor, or Duration of Insulin Action setting will not impact SmartAdjust technology (the Omnipod 5 algorithm).

21.2 About the Dexcom G6 in Automated Mode

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 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.

While in Automated Mode, the Omnipod 5 System relies on your current and predicted sensor glucose values to calculate automated insulin delivery. Sensor glucose values and trends may also be used by the SmartBolus Calculator in both Automated and Manual Modes.

It is important that your Dexcom G6 is functioning properly, delivering accurate values, and connecting to your Pod.

To ensure Sensor accuracy, be aware of your sensor glucose values. If you are experiencing symptoms that do not match your sensor glucose values, use a separate BG meter.

When your Pod and Sensor lose communication in Automated Mode, the System will enter Automated: Limited state. For more about Automated: Limited, see "21.5 About Automated Mode: Limited" on page 284.

If you experience frequent connectivity loss between the Pod and Sensor, see "26.3 Sensor FAQs for iPhone" on page 349.

Connectivity issues can often be resolved by the following:

- Wear the Pod and Sensor in line of sight in such a way that the two devices can “see” one another.
- Check that your current, active Transmitter is paired to the Pod by checking that the Transmitter serial number (SN) stored in both the Omnipod 5 App and in the Dexcom G6 mobile app are the same.
- Check that your active Transmitter is not paired with a Dexcom G6 receiver or another medical device. When using Omnipod 5, the Pod is the only medical device the Transmitter can pair with. You must use the Dexcom G6 mobile app on a smartphone to manage Sensor alarms and to start and stop Sensors and Transmitters.

21.3 Bolus Settings and Importance of a Bolus

In Automated Mode, the Omnipod 5 System automatically delivers insulin every 5 minutes. However, you still need to deliver a bolus dose for meals. For information on how to deliver a bolus, see "SmartBolus Calculator" on page 211.

When delivering a bolus, it is recommended to:

- Tap **USE SENSOR** to use your Sensor glucose value in the SmartBolus Calculator. This will ensure that your sensor trend is included in the calculations and necessary adjustments are made to account for the trend.
- Review the SmartBolus Calculator calculations for accuracy. If the calculations show an amount you are not expecting, cancel the bolus and begin again.
- Always look for the progress bar to confirm that delivery has begun before exiting the Omnipod 5 App.

Note: If you leave the Omnipod 5 App for more than 5 minutes while making changes to your bolus delivery, you will lose the information you have entered into the SmartBolus Calculator.

21.4 Pod Adaptivity

In Automated Mode, automated insulin delivery adapts to your changing needs as you wear the System. As you use the Omnipod 5 System and gather insulin delivery history, SmartAdjust technology will automatically update your next Pod with information from your last few Pods about your recent total daily insulin (TDI).

Your baseline Adaptive Basal Rate is based on how much total daily insulin you have needed over the past few weeks. With each Pod change, SmartAdjust technology uses this updated TDI to set a new Adaptive Basal Rate for you.

When sensor glucose values and trend are available, SmartAdjust technology will also adjust this rate up or down every 5 minutes in response to your current and predicted glucose.

The First Pod

During your first Pod wear (or if you've gone 30 days or longer between Pods), since no recent history is available, the Omnipod 5 System estimates your total daily insulin by looking at your active Basal Program (from Manual Mode). SmartAdjust technology sets a starting baseline Adaptive Basal Rate from that estimated TDI. That is the starting rate that will be adjusted up or down based on your current and predicted glucose and trend.

The System also sets a limit on how much insulin the first Pod's 5-minute adjustments can deliver for your safety.

At your next Pod change, if at least 48 hours of history was collected, SmartAdjust technology will start using your insulin delivery history instead of its original estimate to update the Adaptive Basal Rate.

Ongoing Use

With each Pod change, for as long as you wear the System, updated insulin delivery information is sent and saved in the Omnipod 5 App so that the next Pod that is started is updated with the new Adaptive Basal Rate.

Note: Your total daily insulin (TDI) includes all of the insulin delivered in either Automated or Manual Mode. You can view your TDI for each day by navigating to **Menu** > **History Detail** and looking at the Total Insulin value.

21.5 About Automated Mode: Limited

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 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.

At times, your Pod and Sensor may lose communication while you are in Automated Mode. There are several reasons this could happen, including:

- The Pod and Sensor not being within line of sight on your body
- Temporary loss of communication due to environmental interference
- Sensor warm-up or required calibration
- Your Transmitter is still paired with a Dexcom G6 receiver or other medical device.

When this occurs, SmartAdjust technology can no longer adjust your automated insulin delivery based on glucose because the Pod is not receiving updated glucose information from the Sensor.

After 20 minutes of the Pod not receiving sensor glucose values, you move into a state of Automated Mode called Automated: Limited. The Omnipod 5 App will display 'Limited' on the Home screen. Your System will remain in Automated: Limited until Sensor communication is restored or the Sensor warm-up period ends.

When the System enters Automated: Limited state, SmartAdjust technology bases its insulin delivery on the following:

- It looks at your basal rate in Manual Mode at this time of day and your adaptive basal rate for this Pod and chooses the lower of the two values every 5 minutes. In this way, SmartAdjust technology never gives more than the Basal Program that would be active during Manual Mode.
- If SmartAdjust technology had paused your insulin before the Pod lost connection with your Sensor, it will continue to pause insulin up to 40 minutes for a total of 1 hour paused. After 1 hour of no sensor glucose information, it will resume your insulin at your adaptive or manual basal rates, whichever is lower.
- Without sensor glucose information, the rate delivered in Automated: Limited will not adjust up or down for current or predicted glucose.

After an hour of missed sensor glucose values, the Missing Sensor Glucose Values advisory alarm is presented. This alarm will repeat every 15 minutes until acknowledged and every 60 minutes until Sensor communication is restored. For more information on this alarm, see "Missing Sensor Glucose Values" on page 300.

The System also enters Limited state after receiving the Automated Delivery Restriction Advisory alarm. For more information about Automated Delivery Restriction, see "21.6 Automated Delivery Restriction" on page 286.

You may also choose to switch to Manual Mode to start your Basal Program. See "22.2 Switching from Automated Mode to Manual Mode" on page 292

Check your Dexcom G6 app to see if there are any Sensor actions you need to take to re-establish communication. See your Dexcom G6 CGM System Instructions for Use.

Automated: Limited state can occur due to a loss of communication between the Sensor and Pod. It is possible that your Dexcom G6 app is still receiving sensor glucose values. Open your Dexcom G6 app to check.

21.6 Automated Delivery Restriction

There may be times when the System has been working to bring your glucose into range but has not seen your glucose change the way it expected. In this case, it will switch to Automated: Limited state.

During these times, you'll see an orange bar on your Sensor Graph for "Insulin max reached" or a red bar for "Insulin paused." The System will show an Advisory Alarm that says "Automated Delivery Restriction."

For more information about this alarm, see "Automated Delivery Restriction" on page 298.

Low Glucose

If your glucose has been trending low, SmartAdjust technology may have paused insulin.

If there has been little to no impact to your sensor glucose value from pausing, the System assumes there may be a problem you need to troubleshoot. Pausing insulin for too long could put you at risk of hyperglycemia.

The Automated Delivery Restriction can let you know that you need to step in and check the following:

- Is your Sensor reporting your glucose accurately? Check your BG with a BG meter to confirm.
- Has your glucose been low despite treatment? Consider eating additional fast-acting carbs.

High Glucose

If your glucose has been trending high, SmartAdjust technology may have delivered the maximum amount of insulin microboluses allowed by the System.

Note: This maximum amount is different than your Max Basal setting in Manual Mode. Adjusting your Max Basal setting in Manual Mode will not impact the amount that SmartAdjust technology can deliver in Automated Mode. This insulin max value is unique to each person and based on your recent total daily insulin use. It may change over time as your System continually adapts with each Pod change. You cannot directly impact this setting.

If there has been little to no impact to your sensor glucose value from delivering at the insulin max, the System assumes there may be a problem you need to troubleshoot. Delivering too much insulin for too long could put you at risk of hypoglycemia.

The Automated Delivery Restriction can let you know that you need to step in and check the following:

- Is your Sensor reporting your glucose accurately? Check your BG with a BG meter to confirm. You may need to replace your Sensor.
- Could there be a problem with your Pod or cannula? Check that your Pod is securely applied, and that there are no signs of wetness or leaking around the adhesive. Check for ketones. You may need to replace your Pod.
- Do you need more insulin? Tap the bolus button, tap Use Sensor on the Bolus screen, and see if additional insulin is recommended. You may need a correction bolus.

Switch to Manual Mode

When the Automated Delivery Restriction alarm appears, the System will ask you to switch to Manual Mode for 5 minutes or longer. This step allows the System to know that you are aware of the situation and considering action. While in Manual Mode, you can check BG, review the Sensor Graph and troubleshoot your Sensor and Pod. You can then return to Automated Mode by tapping **Menu** > **Switch Mode**.

Note: If you get this alarm often, your Target Glucose or bolus settings may need to be adjusted. Consult your healthcare provider for help adjusting these settings on Omnipod 5.

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CHAPTER 22

Switching Between Manual Mode and Automated Mode

Contents

22.1 Switching from Manual Mode to Automated Mode

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 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.

Before you begin

First, make sure you have an active Pod and connected Sensor. See "Activating and Changing Your Pod" on page 84 and "Connecting Dexcom G6 to the Pod" on page 270.

Do the following, if necessary:

- Cancel your temp basal or extended bolus, if either is running. See "7.3. Canceling a Temp Basal" on page 111 or "16.4. Canceling a Bolus in Progress" on page 219.
- Start insulin, if it is paused. See "9.3. Starting Insulin Delivery" on page 124.

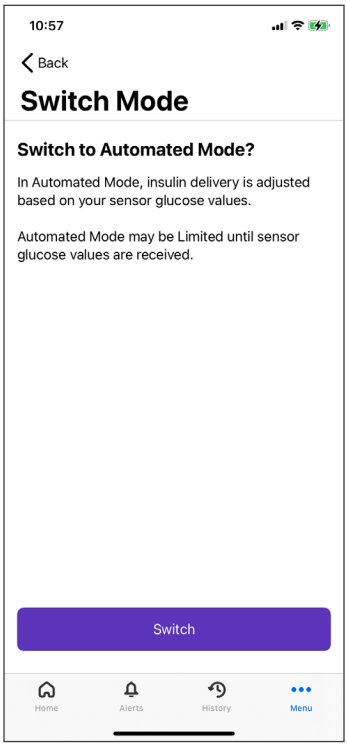
To switch to Automated Mode

To switch from Manual Mode to Automated Mode:

1. From the Home screen, tap **Menu** > **Switch Mode**.

   Note: If Switch is disabled (grayed out), take the corrective action described on the screen before you try again.

2. Tap **Switch** .



22.2 Switching from Automated Mode to Manual Mode

When you switch from using Automated Mode to using Manual Mode, basal insulin will be delivered based on the Basal Program scheduled for the current time. If the Sensor System is connected, you will still be able to view these values and use them in the SmartBolus Calculator while in Manual Mode.

Before you begin, do the following:

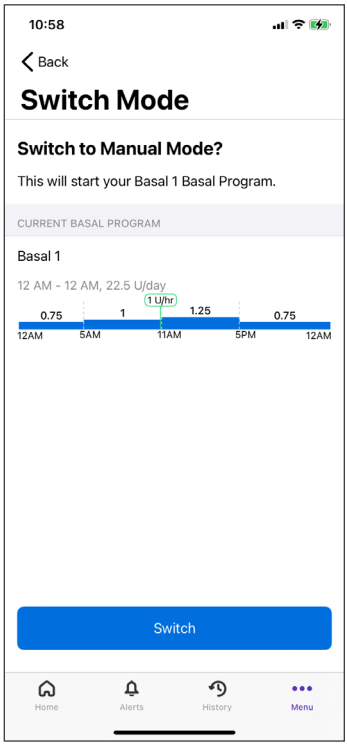
➢ Cancel the Activity feature if it is enabled. See "23.3. Canceling the Activity Feature" on page 296.

To switch to Manual Mode

1. From the Home screen, tap **Menu** > **Switch Mode**.

   Note: If Switch is disabled (grayed out), take the corrective action described on the screen before you try again.

2. Tap **Switch**.



CHAPTER 23

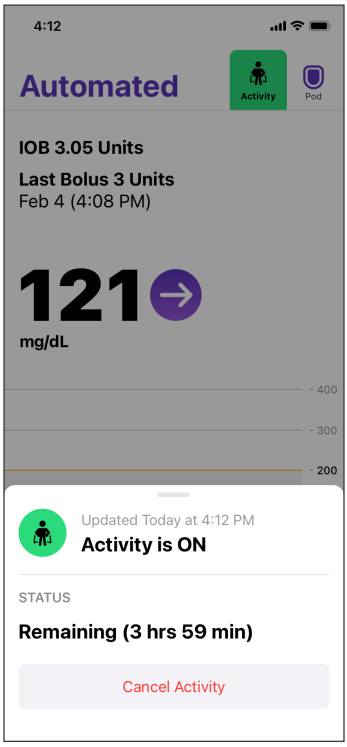
Activity Feature

Contents

23.1 About the Activity Feature

Warning: ALWAYS monitor for symptoms of hypoglycemia while the Activity feature is enabled. Hypoglycemia can still occur when using the Activity feature. Follow your healthcare provider's advice on hypoglycemia avoidance and treatment. If untreated, hypoglycemia can lead to seizure, loss of consciousness or death.

While in Automated Mode, you cannot start a temp basal or manually pause insulin delivery. The Omnipod 5 System provides an option for modified automated insulin delivery through the Activity feature. The Activity feature can be useful in times when you need less insulin, for example, when you are exercising.



While Activity is enabled, the Omnipod 5 System does the following:

- Reduces automated insulin delivery
- Sets your Target Glucose to 150 mg/dL, regardless of your target settings.

With Activity enabled, you can still deliver a bolus as you normally would.

Activity can be set for a duration of 1-24 hours, in increments of 1 hour. You can cancel Activity at any time. Upon cancellation or expiration of the defined time period, full automated insulin delivery starts on its own and SmartAdjust technology returns to using the Target Glucose defined in your settings.

The Activity feature ends if the Pod is deactivated. You need to re-enter Automated Mode and then enable Activity with your new Pod.

Talk to your healthcare provider about the timing of starting the Activity feature to address your anticipated period of decreased insulin needs.

Note: In the event of a loss of Pod and Sensor communication and the Omnipod 5 System enters Limited state, Activity remains enabled.

Note: You may see an increase in your displayed IOB when the Activity feature starts and a decrease in your IOB when the Activity feature time period ends because of the way insulin is calculated.

23.2 Starting the Activity Feature

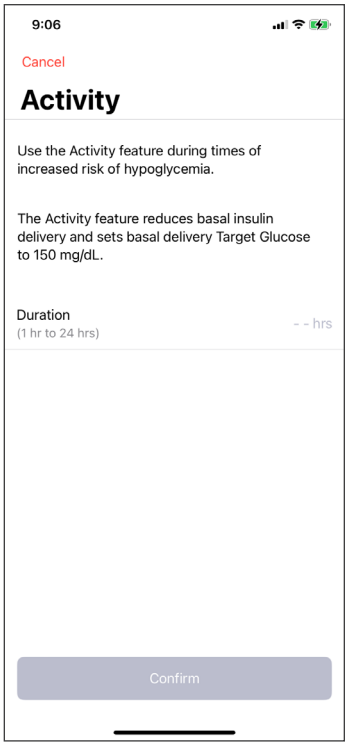
Before you begin, do the following:

➢ Switch to Automated Mode if currently using Manual Mode. See "22.1. Switching from Manual Mode to Automated Mode" on page 290.

To enable Activity:

1. Navigate to: **Menu > Activity**
2. Tap the Duration field and select the Activity feature duration.
3. Tap **CONFIRM**.
4. From the Confirmation screen, tap **START**.

The green ACTIVITY tab will appear as a status icon on the Home screen when the Activity feature is enabled.



23.3 Canceling the Activity Feature

The Activity feature automatically stops at the end of the selected duration; Automated Mode continues, using the Target Glucose defined in your user settings. The Pod beeps when the Activity feature time period completes or when you cancel it.

To cancel Activity before the end of its time period:

1. Navigate to the Home screen and tap the ACTIVITY status icon.
2. Tap **Cancel Activity**.
3. Tap **YES** to confirm cancellation. The Omnipod 5 App cancels Activity and full automated insulin delivery starts.

Note: You may see a decrease in insulin on board (IOB) when canceling the Activity feature.

CHAPTER 24

Automated Mode Alarms for iPhone

Contents

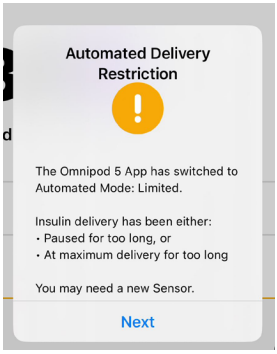
24.1 Advisory Alarm List

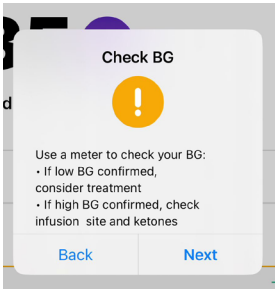
Advisory alarms inform you of a situation that needs your attention in the near future.

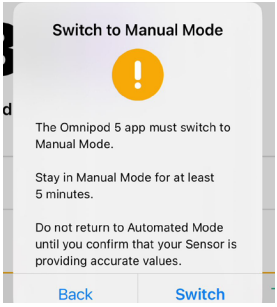
Automated Delivery Restriction

Only occurs in Automated Mode.

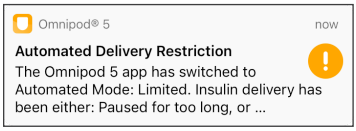
Omnipod 5 App Screens:







Lock Screen:



Cause	Insulin was either paused for too long or at maximum delivery for too long while the Omnipod 5 System was in Automated Mode.
Tone (Pod)	• 6 beep tone, repeats once every minute for 3 minutes. • Pattern repeats every 15 minutes.
Vibration/Tone (Controller or smartphone)	• 3 second tone • Standard iPhone vibration • Vibration and tone repeat every 15 minutes until acknowledged.

What to do	1. Tap **NEXT** to see the next screen. 2. Use a BG meter to confirm your blood glucose. - If low confirmed, consider treatment. - If high confirmed, check infusion (Pod) site and ketones. - If your sensor glucose value is not what you expected, you may need to calibrate or replace your Dexcom G6 Sensor. 3. Tap **Next** after you confirm your blood glucose. 4. Tap **Switch**, then stay in Manual Mode for at least five minutes.

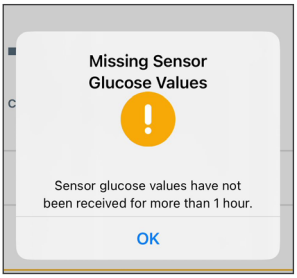
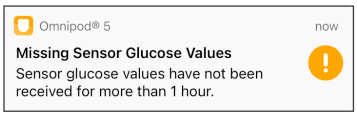
While in Manual Mode, you can check your Sensor Graph to find out whether your insulin has been paused or has been at a maximum for a long time.

After at least 5 minutes of Manual Mode, you can return to Automated Mode after you have confirmed your Sensor readings are accurate.

For more information about the Automated Delivery Restriction, see "21.6. Automated Delivery Restriction" on page 286.

Missing Sensor Glucose Values

Only occurs in Automated Mode.

<table>
<tr><th>Screen Alert</th><th>Description</th></tr>
<tr><td rowspan="2">Omnipod 5 App:
 
</td><td>Why it occurs: The Pod has not received sensor glucose values for more than one hour. The system will continue to operate in Automated Mode: Limited state until sensor glucose values are received or until you switch to Manual Mode.</td></tr>
<tr><td>Pod sound:
• 3 beep tone
• Repeats every 60 minutes</td></tr>
<tr><td rowspan="2">Lock Screen:
 
</td><td>iPhone sound and vibration:
• 3 second tone
• Standard iPhone vibration
• Vibration or tone repeat every 15 minutes until acknowledged.
• If sensor glucose values have still not been received after 60 minutes, a new notification will be generated.</td></tr>
<tr><td>What to do:
➢ Tap OK to acknowledge the alert.</td></tr>
</table>

For more information about Automated Mode: Limited state, see page 284.

Check your Dexcom G6 app to see if there are sensor glucose values present or if the cause of the loss of communication is related to the Sensor. Examples to look for within the Dexcom G6 app include Sensor error/expiration, Transmitter error/expiration, Sensor warm-up, or signal loss alert.

If the Dexcom G6 app is receiving sensor glucose values, there may be a temporary communication issue between your Pod and the Dexcom G6. You may decide to switch to Manual Mode or wait for a sensor glucose value to be received while in Automated Mode: Limited state. If this is frequently occurring, check to see if the Pod and Sensor are located on your body at least 3 inches (8 cm) apart and within line of sight. If not, when you remove one, position the new one so that your Pod and Sensor are within line of sight to one another.

For information about your Dexcom G6 app, refer to your *Dexcom G6 CGM System Instructions for Use*.

CHAPTER 25

Omnipod 5 Clinical Studies

Contents

25.1 Studies in Children, Adolescents, and Adults with Type 1 Diabetes

Omnipod 5 Pivotal Study in Children, Adolescents, and Adults (6–70 years)

The goal of the US-based pivotal study of the Omnipod 5 System was to assess the safety and effectiveness of the system. This single-arm, multicenter, prospective study enrolled 112 children (6 to 13.9 years) and 128 adolescents and adults (14 to 70 years). A 2-week standard therapy phase (usual insulin regimen) was followed by 3 months of the Omnipod 5 System use in Automated Mode. The primary analysis consisted of A1C and sensor glucose time in range (70–180 mg/dL) results. The primary safety endpoints included an assessment of severe hypoglycemia and diabetic ketoacidosis (DKA) events. An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary, secondary, and safety results are presented in the tables below.

Of the 240 participants enrolled, 98% completed the trial (111 children and 124 adolescents and adults). The study population consisted of people with type 1 diabetes for at least 6 months. All participants were required to have a A1C < 10.0% at screening. Participants < 18 years had to be living with a parent or legal guardian. No participants with the following conditions were enrolled:

- History of severe hypoglycemia or DKA in the past 6 months.
- Sickle cell disease, adrenal insufficiency , eating disorder, abnormal kidney function (eGFR < 45), hemophilia or any other bleeding disorders, untreated thyroid disease.
- History of cardiovascular disease including coronary artery disease, heart attack, and cardiac intervention procedure or coronary bypass surgery in past year.
- Abnormal ECG in participants > 50 years or diagnosed with diabetes > 20 years .
- Plans to receive blood transfusion during study.
- Taking oral or injectable steroids or diabetes medications other than metformin and insulin.
- Pregnant or lactating women.

The safety and effectiveness of the Omnipod 5 System in users with the conditions above is unknown. Please note that the study exclusion list above is condensed and does not include every exclusion criterion. The trial was registered at clinicaltrials.gov, a national database of clinical trials in the United States, with ID number NCT04196140. Full details of the study criteria can be found there.

Demographics

Baseline characteristics including demographics of the participants at the start of the 3-month Omnipod 5 treatment phase are provided in the table below.

Baseline Characteristics at Omnipod 5 Treatment Phase Start (n = 240)

Characteristic	Children (6 to 13.9 years)	Adolescents & Adults (14 to 70 years)
n	112	128
Age (years) ± SD	10.3 ± 2.2	36.9 ± 13.9
Duration of diabetes (years)	4.7 ± 2.6	17.9 ± 11.6
A1C§	7.67% ± 0.95%	7.16% ± 0.86%
Daily insulin dose (U/kg)¥	0.85 ± 0.24	0.61 ± 0.22
Body mass index (BMI)	18.6 ± 3.2	26.6 ± 4.7
Female sex	60 (53.6%)	78 (60.9%)
Previous¶ or current continuous glucose monitor (CGM) use	108 (96.4%)	126 (98.4%)
Previous¶ or current pump use	100 (89.3%)	115 (89.8%)
Race / Ethnicity‡		
White	110 (98.2%)	118 (92.2%)
Hispanic or Latino	8 (7.1%)	10 (7.8%)
Black or African American	5 (4.5%)	5 (3.9%)
Asian	3 (2.7%)	2 (1.6%)
Native Hawaiian or other Pacific Islander	1 (0.9%)	0 (0.0%)
American Indian or Alaska Native	0 (0.0%)	4 (3.1%)

Plus-minus values are average ± standard deviation; results reported with number in brackets afterwards represent number of participants (% of participants).
§ Glycated hemoglobin determined from laboratory assessment.
¥ Baseline total daily insulin dose was determined from data collected during the standard therapy phase.
¶ Previous use is defined as having used the device for any duration in the past.
‡ Race and ethnicity were reported by the participants. Groups are not mutually exclusive .

Glycemic Results

The tables below include information on the primary and secondary glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (70–180 mg/dL). Adolescents, adults, and children experienced improvements in overall A1C and time in range after 3 months of Omnipod 5 System use. This was achieved with a reduction of time > 180 mg/dL in adolescents, adults, and children as well as a reduction in median time < 70 mg/dL in adolescents and adults.

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycemic improvement; 2) standard therapy phase was shorter than the Omnipod 5 System phase; 3) minimal use of the 140 and 150 mg/dL Target Glucose settings in adults and adolescents limited the assessment of glycemic results at those settings and, for that reason, results at these Target settings were not included in this *Technical User Guide*.

Glycemic Results Overall (24 hours)

Characteristic	Children (6 to 13.9 years) (n = 112)			Adolescents & Adults (14 to 70 years) (n = 128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	7.67% (0.95%)	6.99% (0.63%)	-0.71%*	7.16% (0.86%)	6.78% (0.68%)	-0.38%*
Avg % time 70–180 mg/dL (std dev)	52.5% (15.6%)	68.0% (8.1%)	15.6%*	64.7% (16.6%)	73.9% (11.0%)	9.3%*
Avg sensor glucose, mg/dL (std dev)	183 (32)	160 (15)	-23*	161 (28)	154 (17)	-8*
Avg standard deviation of sensor glucose, mg/dL (std dev)	68 (13)	60 (10)	-9*	57 (14)	49 (11)	-8*
Avg coefficient of variation of sensor glucose, % (std dev)	37.5% (5.1%)	37.0% (3.9%)	-0.4%	35.2% (5.7%)	31.7% (4.7%)	-3.5%*
% Time in Glucose Range						
Median % < 54 mg/dL (Q1, Q3)	0.10% (0.00, 0.41)	0.23% (0.08, 0.42)	0.04%	0.22% (0.00, 0.77)	0.17% (0.06, 0.28)	-0.08%*
Median % < 70 mg/dL (Q1, Q3)	1.38% (0.42, 2.67)	1.48% (0.65, 2.23)	0.06%	2.00% (0.63, 4.06)	1.09% (0.46, 1.75)	-0.89%*
Avg % > 180 mg/dL (std dev)	45.3% (16.7%)	30.2% (8.7%)	-15.1%*	32.4% (17.3%)	24.7% (11.2%)	-7.7%*
Avg % ≥ 250 mg/dL (std dev)	19.1% (13.1%)	9.6% (5.4%)	-9.4%*	10.1% (10.5%)	5.8% (5.5%)	-4.3%*
Avg % ≥ 300 mg/dL (std dev)	8.5% (8.9%)	3.5% (2.9%)	-5.1%*	3.7% (5.5%)	1.7% (2.5%)	-2.0%*

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range < 70 mg/dL and ß< 54 mg/dL is reported as medians with interquartile ranges in brackets(Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic Results Overnight (12:00AM to 6:00AM)

Characteristic	Children (6 to 13.9 years) (n = 112)			Adolescents & Adults (14 to 70 years) (n = 128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg % time 70-180 mg/dL (std dev)	55.3% (19.0%)	78.1% (10.8%)	22.9%*	64.3% (19.5%)	78.1% (13.9%)	13.8%*
Avg sensor glucose, mg/dL (std dev)	177 (35)	149 (17)	-29*	160 (34)	149 (21)	-11*
Avg standard deviation of sensor glucose, mg/dL (std dev)	61 (15)	48 (12)	-13*	56 (17)	44 (13)	-12*
Avg coefficient of variation of sensor glucose, % (std dev)	34.6% (7.1%)	31.9% (5.6%)	-2.8%*	35.0% (7.9%)	28.9% (5.8%)	-6.2%*
Percentage time in glucose range, %						
Median % < 54 mg/dL (Q1,Q3)	0.00% (0.00, 0.30)	0.09% (0.02, 0.32)	0.02%	0.00% (0.00, 1.06)	0.09% (0.02, 0.30)	0.00%*
Median % < 70 mg/dL (Q1,Q3)	0.78% (0.00, 2.84)	0.78% (0.37, 1.49)	0.01%*	2.07% (0.50, 5.54)	0.82% (0.31, 1.62)	-0.86%*
Avg % > 180 mg/dL (std dev)	42.2% (20.0%)	20.7% (10.8%)	-21.5%*	32.1% (20.2%)	20.7% (14.1%)	-11.3%*
Avg % ≥ 250 mg/dL (std dev)	16.3% (15.0%)	5.4% (5.1%)	-10.9%*	10.6% (12.7%)	4.8% (7.0%)	-5.7%*
Avg % ≥ 300 mg/dL (std dev)	6.7% (9.1%)	1.8 (2.5%)	-4.8%*	4.2% (8.0%)	1.5% (3.1%)	-2.7%*

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C% from baseline to the end of the 3-month Omnipod 5 System treatment phase analyzed by baseline A1C% in children (6 to 13.9 years) and adolescents and adults (14 to 70 years). Adolescents, adults, and children experienced a reduction in A1C after 3 months of Omnipod 5 System use regardless of baseline A1C < 8% or ≥ 8% category.

Subgroup Analysis of Change in Average A1C(%) by Baseline A1C(%)

Adolescents & Adults	Baseline A1C < 8% (n = 105)			Baseline A1C ≥ 8% (n = 23)		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)‡	6.86% (0.59%)	6.60% (0.53%)	-0.27%*	8.55% (0.42%)	7.63% (0.67%)	-0.91%*
Children	**Baseline A1C < 8% (n = 73)**			**Baseline A1C ≥ 8% (n = 39)**		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)	7.11% (0.50%)	6.69% (0.44%)	-0.45%*	8.73% (0.63%)	7.56% (0.54%)	-1.18%*

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡Average A1C values are reported with standard deviation values in brackets.

Glycemic Results by Baseline Treatment

The table below provides information on the average glycemic results at baseline (or during standard therapy phase) and the 3-month Omnipod 5 System treatment phase analyzed by baseline treatment (standard therapy). Standard therapy consisted of multiple daily insulin injections (MDI) or insulin pump use. Time in range (70–180 mg/dL) and A1C were improved after 3 months of Omnipod 5 System use regardless of baseline treatment type. After 3 months of Omnipod 5 System use, time < 70 mg/dL improved in adolescents and adults regardless of baseline therapy, but remained unchanged in children.

Subgroup Analysis of Average Glycemic Results by Baseline Treatment in Children (6 to 13.9 years)

Characteristic	MDI (n = 13)		Insulin Pump (n = 99)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70–180 mg/dL	52%	69%*	53%	68%*
% Time < 70 mg/dL‡	1.54%	1.41%	1.38%	1.49%
A1C%	7.7%	6.7%*	7.7%	7.0%*

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡ Values presented for % Time < 70 mg/dL are medians, the remaining values in the table are averages.

Subgroup Analysis of Average Glycemic Results by BaselineTreatment in Adolescents and Adults (14 to 70 years)

Characteristic	MDI (n = 20)		Insulin Pump (n = 105)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70–180 mg/dL	60%	72%*	66%	74%*
% Time < 70 mg/dL‡	2.38%	0.79%*	1.93%	1.16%*
A1C%	7.6%	7.0%*	7.1%	6.7%*

**Change between baseline/standard therapy and the Omnipod 5 System phase was statistically significant.*

‡ Values presented for % Time below 70mg/dL are medians, the remaining values in the table are averages.

An analysis by baseline demographic characteristics, including those mentioned in the subgroup analyses above, demonstrated similar glycemic improvement as the overall study population. Please note that the study was not designed to determine differences in benefit or risk from each subgroup.

Insulin Requirements

The table below provides information on the average insulin requirements during the standard therapy phase and the 3-month Omnipod 5 System phase. Total daily insulin requirements increased in children and decreased slightly in adolescents and adults.

Characteristic	Children (6 to 13.9 years) (n = 112)			Adolescents & Adults (14 to 70 years) (n = 128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg total daily insulin (U) (std dev)	34.4 (17.5)	37.2 (19.6)	2.9*	48.2 (21.0)	46.4 (18.1) -	-1.8*
Avg total daily insulin, U/kg (std dev)	0.85 (0.24)	0.92 (0.25)	0.07*	0.61 (0.22)	0.59 (0.21)	-0.02*
Avg total daily basal insulin, U/kg (std dev)	0.36 (0.13)	0.47 (0.15)	0.10*	0.31 (0.11)	0.30 (0.11)	-0.01
Avg total daily bolus insulin, U/kg (std dev)	0.48 (0.18)	0.45 (0.13)	-0.03*	0.31 (0.16)	0.29 (0.12)	-0.01

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Body Mass Index Results

The table below provides information on the average body mass index (BMI), which is a measure of weight adjusted for height, and BMI z-score, which is a measure of weight adjusted for height, sex, and age, during the standard therapy phase and the 3-month Omnipod 5 System phase in children. Although BMI increased in children, the BMI z-score remained unchanged.

Characteristic	Children (6 to 13.9 years) (n = 112)		
	Standard Therapy	Omnipod 5	Change
BMI, kg/m^2 (std dev)	18.6 (3.2)	19.2 (3.6)	0.54*
BMI z-score (std dev)	0.4 (0.8)	0.4 (0.8)	0.03

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Omnipod 5 System Use

The table below provides information on the average % of time study participants used the Omnipod 5 System in Automated Mode.

Percent Time Spent in Automated Mode

	Children (6 to 13.9 years) (n = 112)	Adolescents & Adults (14 to 70 years) (n = 128)
% Time in Automated Mode (std dev)	95.2% (4.0%)	94.8% (6.0%)

Adverse Events

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase. There were 3 severe hypoglycemia events not attributable to the Omnipod 5 System automated insulin delivery or system malfunction and 1 DKA event from a suspected infusion site failure. Other related, but non-glycemic adverse events included infection or irritation at infusion site (2 children, 2 adolescents/adults).

Adverse Events during the Omnipod 5 System Phase

Adverse Event Type	Children (6 to 13.9 years) (n = 112)	Adolescents & Adults (14 to 70 years) (n = 128)	Total (6 to 70 years) (n = 240)
Hypoglycemia ‡	1	0	1
Severe Hypoglycemia §	1	2	3
DKA	1	2	1
Hyperglycemia ‖	1	2	3
Prolonged Hyperglycemia **	13	5	18
Other	8	8	16

Results reported as number of events.

‡ Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia.

§ Required the assistance of another person.

‖ Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event.

*** Meter blood glucose measuring ≥ 300 mg/dL and ketones > 1.0 mmol/L*

Glycemic Results at Target Glucose Settings in Pivotal Study

The tables below provide information on the glycemic results at various self-selected Target Glucose settings during the 3-month Omnipod 5 System phase of the pivotal study. Of the customizable Glucose targets, the most selected was 110 mg/dL.

Overall (24 hours) Glycemic Results at Target Glucose Settings in Children (6 to 13.9 years) from Pivotal Study

Characteristic	110mg/dL Target Glucose (n = 98)	120mg/dL Target Glucose (n = 74)	130mg/dL Target Glucose (n = 47)	140mg/dL Target Glucose (n = 12)	150mg/dL Target Glucose* (n = 9)
Avg % time 70–180 mg/dL (std dev)	68.4% (9.1%)	67.5% (9.7%)	64.2% (14.3%)	59.2% (16.9%)	53.3% (18.2%)
Avg sensor glucose, mg/dL (std dev)	159 (17)	163 (16)	169 (24)	178 (24)	183.6 (23.9)
% Time in glucose range					
Median % < 54 mg/dL (Q1, Q3)	0.22% (0.06, 0.49)	0.18% (0.05, 0.33)	0.09% (0.00, 0.21)	0.04% (0.00, 0.34)	0.00% (0.00, 0.00)
Median % < 70 mg/dL (Q1, Q3)	1.51% (0.76, 2.38)	1.16% (0.58, 1.94)	0.71% (0.26, 1.63)	0.59% (0.05, 1.52)	0.12% (0.00, 0.21)
Avg % > 180 mg/dL (std dev)	29.7% (9.6%)	31.1% (10.0%)	34.5% (14.8%)	39.9% (16.6%)	46.4% (18%)
Avg % ≥ 250 mg/dL (std dev)	9.7% (5.8%)	10.0% (6.3%)	11.8% (9.0%)	14.6% (11.1%)	13.3% (11.9%)
Cumulative number of person-days	6,289	2,716	941	99	73

Overall (24 hours) Glycemic Results at Target Glucose Settings in Adolescents and Adults (14 to 70 years) from Pivotal Study

Characteristic	110 mg/dL Target Glucose (n = 121)	120 mg/dL Target Glucose (n = 54)	130 mg/dL Target Glucose* (n = 9)
Avg % time 70–180 mg/dL (std dev)	75.6% (9.9%)	73.4% (12.1%)	63.6% (25.9%)
Avg sensor glucose, mg/dL (std dev)	151 (15)	156 (18)	172 (33)
% Time in glucose range			
Median % < 54 mg/dL (Q1, Q3)	0.16% (0.05, 0.26)	0.11% (0.00, 0.33)	0.00% (0.00, 0.00)
Median % < 70 mg/dL (Q1, Q3)	0.99% (0.47, 1.67)	0.91% (0.31, 1.68)	0.26% (0.05, 0.63)
Avg % > 180 mg/dL (std dev)	23.1% (10.2%)	25.4 % (12.3%)	35.9% (26.1%)
Avg % ≥ 250 mg/dL (std dev)	5.1% (4.6%)	5.8% (6.4%)	9.6% (12.3%)
Cumulative number of person-days	9,278	1,827	178

**Results for the 140 mg/dL and 150 mg/dL (with the Activity feature OFF) Target Glucose settings in adults are not shown due to too few participants selecting them (n ≤ 2).*

Omnipod 5 System Pre-Pivotal Glycemic Results at Target Glucose Settings

Glycemic Results at Target Glucose Settings in Pre-Pivotal Study

The goal of the pre-pivotal study of the Omnipod 5 System was to assess the safety and efficacy of the system. This single-arm, multicenter, prospective study enrolled 18 children (6 to 13.9 years) and 18 adults (14 to 70 years) with type 1 diabetes. A 2-week standard therapy phase (usual insulin regimen) was followed by 2 weeks of Omnipod 5 System use in Automated Mode. The 2-week Omnipod 5 phase included 3 days of required use at each of the Target Glucose settings of 130 mg/dL, 140 mg/dL, and 150 mg/dL for a total of 9 days, followed by 5 days of free choice of Target Glucose ranging from 110–150 mg/dL.

Overall (24 hours) Glycemic Results at Target Glucose Settings in Children (6 to 13.9 years) from Pre-Pivotal Study

Characteristic	110 mg/dL Target Glucose (n = 11)	120 mg/dL Target Glucose (n = 3)	130 mg/dL Target Glucose (n = 18)a	14 mg/dL Target Glucose (n = 18)	150 mg/dL Target Glucose (n = 18)b
Avg % time 70–180 mg/dL (std dev)	71.2% (10.2%)	66.8% (12.9%)	61.5% (7.7%)	64.8% (11.6%)	53.5% (11.0%)
Avg sensor glucose, mg/dL (std dev)	155.2 (18.2)	170 (16)	174.1 (11.4)	172.7 (17.2)	182.9 (15.3)
% Time in glucose range					
Median % < 54 mg/dL (Q1, Q3)	0.1% (0.0, 0.4)	0.2% (0.0, 0.3)	0.0% (0.0, 0.3)	0.0% (0.0, 0.0)	0.0% (0.0, 0.1)
Median % < 70 mg/dL (Q1, Q3)	0.9% (0.4, 2.8)	0.3% (0.2. 2.2)	0.5% (0.1, 0.8)	0.1% (0.0, 0.5)	0.5% (0.0, 0.8)
Avg % > 180 mg/dL (std dev)	27.1% (11.4%)	32.3% (11.9%)	37.7% (7.9)	34.6% (12.1%)	45.9% (11.0%)
Avg % ≥ 250 mg/dL (std dev)	6.8% (6.3%)	14.4% (6.2%)	13.2% (5.8%)	10.6% (7.3%)	12.8% (8.1%)

Cumulative number of person-days	47.7	8.7	73.3	56.3	61.5

[a]All participants initiated the system at the 130 mg/dL Target Glucose for 3 days.
[b]The glycemic results at the 150 mg/dL Target Glucose setting include times with the Activity feature ON and OFF, meaning the results recorded during this time may include those when participants felt their insulin needs were reduced.

Overall (24 hours) Glycemic Results at Target Glucose Settings in Adolescents and Adults (14 to 70 years) from Pre-Pivotal Study

Characteristic	110 mg/dL Target Glucose (n = 12)	120 mg/dL Target Glucose (n = 7)	130 mg/dL Target Glucose (n = 18)a	140 mg/dL Target Glucose (n = 18)	150 mg/dL Target Glucose (n = 18) b
Avg % time 70–180 mg/dL (std dev)	72.5% (9.4%)	70.9% (11.3%)	75.1% (11.6%)	67.6% (9.2%)	63.7% (7.8%)
Avg sensor glucose, mg/dL (std dev)	153.8 (14.8)	159.7 (11)	153.8 (14.9)	165.4 (11.5)	169.8 (9.4)
% Time in glucose range					
Median % < 54 mg/dL (Q1, Q3)	0.0% (0.0, 0.0)	0.0% (0.0, 0.0)	0.0% (0.0, 0.2)	0.0% (0.0, 0.1)	0.0% (0.0, 0.2)
Median % < 70 mg/dL (Q1, Q3)	0.5% (0.0, 1.4)	0.4% (0.0, 0.6)	0.9% (0.4, 1.2)	0.1% (0.0, 0.6)	0.2% (0.0, 0.9)
Avg % > 180 mg/dL (std dev)	26.4% (10.0%)	28.7% (11.2%)	23.4% (11.4%)	31.7% (9.2%)	35.7% (7.9%)
Avg % ≥ 250 mg/dL (std dev)	4.1% (3.4%)	5.2% (5.5%)	5.0% (4.6%)	5.1% (4.5%)	6.0% (4.8%)
Cumulative number of person-days	41.1	28	58.8	58.4	60.3

[a]All participants initiated the system at the 130 mg/dL Target Glucose for 3 days.
[b]The glycemic results at the 150 mg/dL Target Glucose setting include times with the Activity feature ON and OFF, meaning the results recorded during this time may include those when participants felt their insulin needs were reduced.

CGM-Informed SmartBolus Calculator Clinical Study in Children, Adolescents, and Adults

A study was conducted on 25 participants with type 1 diabetes aged 6–70 years to assess the Omnipod 5 Sensor-informed SmartBolus Calculator. During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected Sensor (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected Sensor (CGM-informed SmartBolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/or either a manually entered glucose value (standard SmartBolus Calculator) or an imported current sensor glucose value and trend (CGM-informed SmartBolus Calculator). Both versions of the SmartBolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the sensor glucose trend. The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by Sensor between the two study phases. The results indicate that the use of the Sensor-informed SmartBolus Calculator was associated with less time in hypoglycemia within 4 hours of bolusing.

Comparison of Glycemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (n = 25)

Percent time in glucose range as measured by Sensor	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70–180 mg/dL	65.1% (15.4)	63.8% (15.7)	-1.3%
< 70 mg/dL	2.8% (2.7)	2.1% (2.0)	-0.6%*
< 54 mg/dL	0.5% (1.0)	0.3% (0.7)	-0.2%
> 180 mg/dL	32.1% (15.7)	34.0% (16.0)	1.9%
≥ 250 mg/dL	8.2% (6.9)	9.7% (10.3)	1.4%
≥ 300 mg/dL	2.0% (2.6)	2.6% (3.7)	0.6%

Data is presented as average (standard deviation). Significant differences ($p < 0.05$) are highlighted with an asterisk.

25.2 Studies in Very Young Children with Type 1 Diabetes

Omnipod 5 Clinical Study in Very Young Children

The goal of this study was to assess the safety and effectiveness of the Omnipod 5 System in children with type 1 diabetes aged 2 to 5.9 years. This single-arm, multicenter, prospective study enrolled 80 children.

A 2-week standard therapy phase (usual insulin regimen) was followed by 3 months of the Omnipod 5 System use in Automated Mode. The primary analysis consisted of A1C and sensor glucose time in range (70–180 mg/dL) results.

The primary safety endpoints included the incidence of severe hypoglycemia and diabetic ketoacidosis (DKA). An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary, secondary, and safety results are presented in the tables below.

Of the 80 participants enrolled, 100% completed the trial. The study population consisted of children diagnosed with type 1 diabetes based on the investigator's clinical judgement. All participants were required to have an A1C < 10.0% at screening. Participants had to be living with a parent or legal guardian. No participants with the following conditions were enrolled:

History of severe hypoglycemia or DKA in the past 6 months

- Sickle cell disease, adrenal insufficiency, abnormal kidney function (eGFR < 45), hemophilia or any other bleeding disorders, untreated thyroid disease
- Plans to receive blood transfusion during study
- Taking oral or injectable steroids or diabetes medications other than metformin and insulin

The safety and effectiveness of the Omnipod 5 System in users with the conditions above is unknown. Please note that the study exclusion list above is condensed and does not include every exclusion criterion. The trial was registered at clinicaltrials.gov, a national database of clinical trials in the United States, with ID number NCT04476472. Full details of the study criteria can be found there.

Demographics

Baseline characteristics, including demographics of the participants at the start of the 3-month Omnipod 5 treatment phase, are provided in the table below.

Baseline Characteristics at Omnipod 5 Treatment Phase Start

Characteristic	
n	80
Age (years) ± std dev	4.7 ± 1.0
Duration of diabetes (years)	2.3 ± 1.1
A1C§	7.4% ± 1.0%
Daily insulin dose (U/kg) ¥	0.69 ± 0.18
Body mass index (BMI) (kg/m2)	16.7 ± 1.5
Female sex	34 (42.5%)
Previous¶ or current continuous glucose monitor (CGM) use	78 (97.5%)
Previous¶ or current pump use	68 (85.0%)
Using multiple daily injection as standard therapy method	12 (15.0%)
Race/ Ethnicity‡	
White	67 (83.8%)
Hispanic or Latino	5 (6.3%)
Black or African American	4 (5.0%)
Black or African American, White	3 (3.8%)
Asian	3 (3.8%)
Asian, White	2 (2.5%)
Hispanic or Latino	1 (1.3%)
Not Hispanic or Latino	1 (1.3%)
Other (Dominican)	1 (1.3%)
Hispanic or Latino	1 (1.3%)

Plus-minus values are average ±standard deviation; results reported with number in brackets afterwards represent number of participants (% of participants). § A1C determined from laboratory assessment.

¥ Baseline total daily insulin dose was determined from data collected during the standard therapy phase.

¶ Previous use is defined as having used the device for any duration in the past.

‡ Race and ethnicity were reported by the participants. Groups are not mutually exclusive.

Glycemic Results

The tables below include information on the primary and secondary glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (70–180 mg/dL). Participants experienced improvements in A1C and overall time in range after 3 months of Omnipod 5 System use. This result was achieved with a reduction of time > 180 mg/dL as well as a reduction in median time < 70 mg/dL.

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycemic improvement; 2) standard therapy phase was shorter than the Omnipod 5 System phase.

Glycemic Results Overall (24 hours)

Characteristic	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	7.4% (1.0%)	6.9% (0.7%)	-0.55%*
Avg % time 70–180 mg/dL (std dev)	57.2% (15.3%)	68.1% (9.0%)	10.9%*
Avg sensor glucose, mg/ dL, (std dev)	171.1 (30.5)	157.4 (16.8)	-13.7*
Avg standard deviation of sensor glucose, mg/dL (std dev)	64.9 (13.4)	59.6 (10.3)	-5.3*
Avg coefficient of varia- tion of sensor glucose, % (std dev)	38.1% (5.5%)	37.7% (4.0%)	-0.4%
% Time in Glucose Range			
Median % < 54 mg/dL (Q1, Q3)	0.24% (0.05, 0.84)	0.26% (0.16, 0.60)	0.06%
Median % < 70 mg/dL (Q1, Q3)	2.19 (0.89, 4.68)	1.94 (1.18, 3.43)	-0.27%*
Avg % > 180 mg/dL (std dev)	39.4% (16.7%)	29.5% (9.8%)	-9.9%*
Avg % ≥ 250 mg/dL (std dev)	14.8% (12.1%)	9.2% (5.6%)	-5.6%*
Avg % ≥ 300 mg/dL (std dev)	6.0% (7.3%)	3.2% (2.8%)	-2.7%*

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range < 70 mg/dL and < 54 mg/dL is reported as medians with interquartile ranges in brackets(Q1, Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.
**Change between standard therayp phase and Omnipod 5 System phase was statistically significant.*

Glycemic Results Overnight (12:00AM to 6:00AM)

Characteristic	Standard Therapy	Omnipod 5	Change
Avg % time 70–180 mg/dL (std dev)	58.2% (18.7%)	81.0% (10.0%)	22.8%*
Avg sensor glucose, mg/ dL, (std dev)	168.1 (33.3)	140.7 (16.4)	-27.4*
Avg standard deviation of sensor glucose, mg/dL (std dev)	58.0 (14.0)	45.5 (10.8)	-12.5*
Avg coefficient of varia- tion of sensor glucose, % (std dev)	34.7% (6.6%)	32.1% (5.2%)	-2.6%*
% Time in Glucose Range			
Median % < 54 mg/dL (Q1, Q3)	0.00% (0.00, 0.97)	0.18% (0.06, 0.53)	0.00%
Median % < 70 mg/dL (Q1, Q3)	1.66% (0.40, 4.21)	1.58% (0.65, 2.89)	-0.44%*
Avg % > 180 mg/dL (std dev)	38.4% (20.1%)	16.9% (10.3%)	-21.5%*
Avg % ≥ 250 mg/dL (std dev)	13.0% (13.2%)	3.9% (3.9%)	-9.1%*
Avg % ≥ 300 mg/dL (std dev)	4.3% (6.7%)	1.2% (1.6%)	-3.1%*

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C% from baseline to the end of the 3-month Omnipod 5 System treatment phase analyzed by baseline A1C%. Participants experienced a reduction in A1C after 3 months of Omnipod 5 System use regardless of baseline A1C < 8% or ≥ 8% category.

Subgroup Analysis of Change in Average A1C(%) by Baseline A1C(%)

	Baseline A1C < 8% (n = 55)			Baseline A1C ≥ 8% (n = 25)		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)‡	6.9% (0.6%)	6.6% (0.6%)	-0.31%*	8.5% (0.5%)	7.5 (0.4%)	-1.06%*

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡Average A1C values are reported with standard deviation values in brackets.

Glycemic Results by Baseline Treatment

The table below provides information on the average glycemic results at baseline (or during standard therapy phase) and the 3-month Omnipod 5 System treatment phase analyzed by baseline treatment (standard therapy). Standard therapy consisted of multiple daily insulin injections (MDI) or insulin pump use. Time in range (70–180 mg/dL) and A1C were improved after 3 months of Omnipod 5 System use regardless of baseline treatment type. Time < 70 mg/dL improved in participants on an insulin pump at baseline and remained low in those on MDI at baseline.

Subgroup Analysis of Average Glycemic Results by Baseline Treatment

Characteristic	MDI (n = 12)		Insulin Pump (n = 68)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70–180 mg/dL	48%	62%*	59%	69%*
% Time < 70 mg/dL‡	1.45%	1.48%	2.44%	2.00%*
A1C%	8.4%	7.5%*	7.3%	6.8%*

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡ Values presented for % Time < 70 mg/dL are medians, the remaining values in the table are averages.

Insulin Requirements

The table below provides information on the average insulin requirements during the standard therapy phase and the 3-month Omnipod 5 System phase. Total daily insulin requirements remained unchanged except for an increase in total daily basal insulin.

Characteristic	Standard Therapy	Omnipod 5	Change
Avg total daily insulin (U) (std dev)	13.7 (4.4)	14.1 (4.0)	0.4
Avg total daily insulin, U/kg (std dev)	0.69 (0.18)	0.71 (0.15)	0.02
Avg total daily basal insulin, U/kg, (std dev)	0.28 (0.12)	0.32 (0.10)	0.04*
Avg total daily bolus insulin, U/kg, (std dev)	0.41 (0.15)	0.39 (0.10)	-0.02 (0.10)

**Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Body Mass Index Results

The table below provides information on the average body mass index (BMI) and BMI z-score during the standard therapy phase and the 3-month Omnipod 5 System phase. BMI and BMI z-score did not change between the two phases.

Characteristic	Standard Therapy	Omnipod 5	Change
BMI, kg/m2 (std dev)	16.7 (1.5)	16.7 (1.4)	0.1
BMI z-score (std dev)	0.74 (0.95)	0.76 (0.89)	0.05

Omnipod 5 System Use

The median (Q1, Q3) % of time study participants used the Omnipod 5 System in Automated Mode was 97.8% (95.8, 98.5).

Adverse Events

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase. Other related, but non-glycemic adverse events included skin irritation (n = 2), cellulitis (n = 1), and ketosis not meeting the DKA definition (n = 2).

Adverse Events during the Omnipod 5 System Phase

Adverse Event Type	Omnipod 5
Hypoglycemia ‡	0
Severe Hypoglycemia §	0
DKA	0
Hyperglycemia‖	4
Prolonged Hyperglycemia **	20
Other	5

Results reported as number of events.

‡ Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia.

§ Required the assistance of another person.

‖ Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event.

*** Meter blood glucose measuring ≥ 300 mg/dL and ketones > 1.0 mmol/L*

Glycemic Results at Target Glucose Settings

The tables below provide information on the glycemic results at various self- selected Target Glucose settings during the 3-month Omnipod 5 System phase of the pivotal study. The most commonly selected target glucose values were 110 mg/dL and 120 mg/dL, which were used 33% and 42% of the time, respectively.

Overall (24 hours) Glycemic Results at Target Glucose Settings

Characteristic	110 mg/dL Target Glucose (n = 47)	120 mg/dL Target Glucose (n = 61)	130 mg/dL Target Glucose (n = 47)	140 mg/dL Target Glucose (n = 20)	150 mg/dL Target Glucose* (n = 16)
Avg % time 70–180 mg/dL, (std dev)	69.3% (9.5%)	68.3% (11.3%)	67.3% (14.6%)	63.0% (11.9%)	65.0% (15.0%)
Avg sensor glucose, mg/dL, (std dev)	153 (18)	157 (21)	161 (25)	169 (18)	169 (20)
% Time in glucose range					
Median % < 54 mg/dL, (Q1, Q3)	0.3% (0.2, 0.7)	0.2% (0.1, 0.5)	0.2% (0.05, 0.7)	0.2% (0.03, 0.5)	0.06% (0.0, 0.2)
Median % < 70 mg/ dL, (Q1, Q3)	2.4% (1.5, 3.9)	1.6% (1.1, 2.7)	1.4% (0.6, 2.9)	1.4% (0.4, 2.7)	0.8% (0.1, 2.0)
Avg % > 180 mg/dL (std dev)	27.6% (10.5%)	29.3% (12.1%)	30.4% (15.4%)	35.4% (12.2%)	33.9% (15.0%)
Avg % ≥ 250 mg/dL (std dev)	7.7% (5.9%)	8.9% (6.2%)	10.6% (9.4%)	12.6% (6.2%)	11.4% (7.2%)
Cumulative number of person-days	2438.4	3083.5	1066.6	404.0	237.0

**Glycemic measures reported at the 150 mg/dL Target Glucose setting only included those with the Activity feature turned OFF.*

CGM-Informed SmartBolus Calculator Clinical Study in Very Young Children

A study was conducted on 5 participants with type 1 diabetes aged 2–5.9 years to assess the Omnipod 5 CGM-informed SmartBolus Calculator in Manual Mode. During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected Sensor (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected Sensor (CGM-informed SmartBolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/ or either a manually entered glucose value (standard SmartBolus Calculator) or an imported current sensor glucose value and trend (CGM-informed SmartBolus Calculator). Both versions of the SmartBolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the sensor glucose trend. The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by Sensor between the two study phases. The results showed that the CGM-informed SmartBolus Calculator provided similar glycemic results as the standard SmartBolus calculator when used in Manual Mode.

Comparison of Glycemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (n = 5)

Percent time in glucose range as measured by Sensor	Standard Smart- Bolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70–180 mg/dL	59.6% (7.1%)	62.8% (15.5%)	3.15%
< 70 mg/dL	5.16% (4.99%)	4.03% (3.28%)	-1.13%
< 54 mg/dL	1.47% (1.88%)	0.81% (0.91%)	-0.66%
> 180 mg/dL	35.2% (10.3%)	33.2% (18.5%)	-2.03%
≥ 250 mg/dL	9.4% (5.7%)	7.9% (6.4%)	-1.55%
≥ 300 mg/dL	2.33% (2.69%)	1.99% (2.05%)	-0.34%

Data is presented as average (standard deviation).

25.3 Studies in Adults with Type 2 Diabetes

Omnipod 5 Pivotal Study in Adults with Type 2 Diabetes (18–75 years)

The goal of this U.S.-based pivotal study was to assess the safety and efficacy of the Omnipod 5 System in adults with type 2 diabetes aged 18 to 75 years. This study enrolled 343 participants.

A 2-week standard therapy phase where participants used their usual insulin delivery method was followed by 3 months of participants using the Omnipod 5 System. The system was used in Automated Mode with a Dexcom G6 continuous glucose monitor (CGM). The primary safety outcome is that Omnipod 5 does not worsen A1C compared to baseline/standard therapy. The primary effectiveness outcome is that Omnipod 5 lowers A1C compared to baseline/standard therapy.

The study also tested other outcomes for safety and benefit. The results for the primary, secondary, and safety results and other study data are presented in the tables below.

Of the 343 participants enrolled, 305 started Omnipod 5 and 289 completed the study. The study population consisted of adults diagnosed with type 2 diabetes on insulin (basal-bolus, basal only, or pre-mix insulin). All participants were required to have an A1C < 12.0% at screening. Those on basal insulin only also had to have an A1C ≥ 7%. No participants with the following conditions were enrolled:

- Use of insulin pump in automated mode in the past 3 months.
- History of severe hypoglycemia (very low blood glucose event) or DKA in the past 6 months.
- History of heart or blood vessel disease, heart attack, or heart surgery in the past 12 months.
- Plans to receive blood transfusion during study.
- Taking steroids in past 8 weeks or plans to take steroids during the study.
- Pregnant or lactating, planning to become pregnant during study, or woman of childbearing potential not using birth control methods.

The safety and effectiveness of the Omnipod 5 System in users with the conditions above is unknown. Please note that the study exclusion list above is a summary and does not include all criteria. The trial was registered at clinicaltrials.gov, a national database of clinical trials in the United States, with ID number NCT05815342. Full details of the study criteria can be found there.

Demographics

Baseline characteristics, including demographics, at the start of the 3-month Omnipod 5 treatment phase are provided in the table below.

Characteristic	Adults
Number of Participants (n)	305
Age (years)	57 ± 11
Female sex	175 (57%)
Duration of diabetes (years)	17 (11, 24)
A1C at screening (%)	8.2% ± 1.4%
Insulin delivery type	
Insulin pump	17 (6%)
Injections	288 (94%)
Insulin therapy	
Basal & bolus	240 (79%)
Basal only	63 (21%)
Pre-mix	2 (<1%)
Daily insulin dose	
Units/kg/day	0.80 ± 0.46
Units/day	79.9 ± 50.0
Non-insulin diabetes medications	
GLP-1 agonists	168 (55%)
SGLT1 or SGLT2 inhibitors	135 (44%)
DPP4 inhibitors	8 (3%)
Continuous Glucose Monitor (CGM) Use	
Never	75 (25%)
In past, but not current	42 (14%)
Current	188 (62%)
Body mass index (BMI) (kg/m^2)[†]	35 ± 8
Race	
White	198 (65%)
Black/African American	72 (24%)
American Indian/Alaskan Native	5 (2%)
Asian	5 (2%)

Characteristic	Adults
More than one race	3 (<1%)
Native Hawaiian/Other Pacific Islander	2 (<1%)
Unknown/not reported	20 (7%)
Ethnicity	
Hispanic	66 (22%)
Non-Hispanic	237 (78%)
Unknown/not reported	2 (<1%)
Health Insurance	
Private	161 (53%)
Medicaid	27 (9%)
Medicare	52 (17%)
Other government	27 (9%)
No coverage	18 (6%)
No answer	20 (7%)

Plus-minus values are average ± standard deviation; results reported with one number in brackets afterwards represent number of participants (% of participants); remaining values are medians with interquartile ranges in brackets (Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

[†] *Body-mass index is the weight in kilograms divided by the square of the height in meters.*

Glycemic Results

The tables below include information on the glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System phase in adults with type 2 diabetes. The primary result of the study is average change in A1C. Participants experienced an improvement in A1C and % time in range (70–180 mg/dL) after 3 months of Omnipod 5 System use. This was achieved with no increase in hypoglycemia (low blood sugar).

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycemic improvement, and 2) standard therapy phase was shorter than the Omnipod 5 System phase.

Outcome	Standard Therapy†	Omnipod 5†	Change
Avg A1C% (std dev)	8.2% (1.3%)	7.4% (0.9%)	-0.8%*
Avg sensor glucose, mg/dL (std dev)	11.2, 202 (2.8, 50)	9.4, 170 (1.3, 24)	-1.8, -32*
Avg coefficient of variation of sensor glucose, % (std dev)	27.8% (6.3%)	27.1% (5.1%)	-0.7%
% Time glucose range			
Avg % 70–180 mg/dL (std dev)	45% (25%)	66% (17%)	20%*
Avg % 70–140 mg/dL (std dev)	21% (18%)	33% (17%)	12%*
Avg. % < 54 mg/dL (std dev)	0.01% (0.02%)	0.04% (0.05%)	0.01%§
Avg % < 70 mg/dL (std dev)	0.2% (0.3%)	0.2% (0.2%)	0.0%§
Avg % > 180 mg/dL (std dev)	54% (25%)	34% (17%)	-20%*
Avg % > 250 mg/dL (std dev)	20% (22%)	7% (8%)	-12%*
Avg % > 300 mg/dL (std dev)	7.7% (10.3%)	1.8% (2.4%)	-5.2%*

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) was 299 for all outcomes above except A1C which was 296.*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

§ *The difference in the results is non-inferior (not worse) than standard therapy.*

Glycemic Results Daytime vs Overnight

The tables below include information on the glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System phase in adults with type 2 diabetes during the day and overnight.

Outcome	Daytime (6:00AM to < 12:00AM)†			Overnight (12:00AM to <6:00AM)†		
	Standard Therapy (n = 303)	Omnipod 5 (n = 300)	Change*	Standard Therapy (n = 300)	Omnipod 5 (n = 300)	Change*
Avg Sensor glucose, mg/dL (std dev)	11.3, 204 (2.8, 50)	9.6, 172 (1.3, 24)	-1.8, -32	10.9, 196 (2.9, 53)	9.2, 165 (1.5, 27)	-1.7, -31
Avg coefficient of variation of sensor glucose, % (std dev)	27.6% (6.3%)	27.3% (5.0%)	-0.3%	25.8% (7.5%)	24.6% (5.8%)	-1.1%
% Time glucose range						
Avg % 70–180 mg/dL (std dev)	44% (25%)	64% (17%)	20%	49% (29%)	70% (20%)	20%
Avg % 70-140 mg/dL (std dev)	21% (18%)	32% (16%)	11%	24% (22%)	36% (22%)	12%
Avg % < 54 mg/dL (std dev)	0.00% (0.00%)	0.03% (0.05%)	0.01%	0.00% (0.00%)	0.03% (0.05%)	0.01%
Avg % < 70 mg/dL (std dev)	0.16% (0.24%)	0.17% (0.21%)	0.00%	0.10% (0.14%)	0.22% (0.31%)	0.04%
Avg % > > 180 mg/dL (std dev)	55% (25%)	36% (17%)	-20%	50% (29%)	30% (20%)	-20%
Avg % > 250 mg/dL (std dev)	21.3% (22.6%)	7.9% (8.2%)	-12.7%	17.7% (22.9%)	4.8% (6.2%)	-10.9%
Avg % > 300 mg/dL (std dev)	8.2% (11.1%)	2.0% (2.7%)	-5.4%	5.8% (8.6%)	1.0% (1.4%)	-3.4%

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) was 303 for day299 for all outcomes above except A1C which was 303.*

* *Statistical testing not done to assess significance of change between standard therapy phase and Omnipod 5 System phase*

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C from baseline to the end of the 3 months of Omnipod 5 use grouped by what the baseline A1C was prior to starting Omnipod 5. Those with a higher baseline A1C had a greater decrease in A1C.

Subgroup Analysis of Change in Average A1C (%) by Baseline A1C

Baseline A1C	Avg A1C% Baseline (std dev)	Avg A1C% Omnipod 5 (std dev)	Change*
<7.0% (n = 42)	6.5% (0.4%)	6.5% (0.6%)	0.0%
7.0-7.9% (n = 104)	7.5% (0.3%)	7.1% (0.6%)	-0.4%
8.0-8.9% (n = 82)	8.5% (0.3%)	7.6% (0.8%)	-0.8%
≥ 9.0% (n = 68)	10.1% (0.9%)	8.1% (0.9%)	-2.1%

Averages (avg) with standard deviation (std dev) values in brackets.

* *Statistical testing not done to assess significance of change between standard therapy phase and Omnipod 5 System phase.*

Subgroup Analysis of Average Glycemic Results by Baseline Insulin Therapy

The table below provides information on the average glycemic results during the standard therapy phase and the 3-month Omnipod 5 System phase analyzed by baseline insulin therapy in adults with type 2 diabetes. Standard therapy consisted of multiple daily injections or basal-only insulin. There were improvements in A1C and % time in range outcomes for those using multiple daily injections and for those using basal-only insulin at baseline.

Outcome	Multiple Daily Injections (n = 219)			Basal-Only Insulin (n = 62)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	8.2% (1.4%)	7.4% (0.9%)	-0.8%*	8.6% (1.2%)	7.5% (0.8%)	-1.2%*
Avg % Time in range 70–180 mg/dL (std dev)	45% (25%)	66% (17%)	20%*	40% (25%)	64% (17%)	23%*
Avg % Time < 70 mg/dL (std dev)	0.28% (0.41%)	0.21% (0.25%)	-0.04%	0.07% (0.10%)	0.13% (0.15%)	0.05% (0.11%)

Averages (avg) with standard deviation (std dev) values in brackets.

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic outcomes were analyzed by other baseline demographics, and it was found that the improvements in glycemic outcomes for all groups were similar to those of the full study population, with the exception of race/ethnicity. Those who are Latino/Hispanic or listed as "other" experienced a greater decrease in A1C with Omnipod 5 than other race/ethnicity groups, although all race/ethnicity groups saw benefit. Note that the study was not designed to determine differences in benefit or risk from each subgroup.

Percent of Participants Meeting Recommended Glucose Targets

The table below provides information on the % of participants who met recommended glucose targets for A1C and % time in range (70–180 mg/dL). A high % of participants achieved an A1C < 8%.

Glucose Target	Standard Therapy[†]	Omnipod 5
% achieving A1C < 7%	15%	37%
% achieving A1C< 8%	50%	76%
% achieving time in range, 70–180 mg/dL, > 70%	19%	42%

Statistical testing not done to assess change between standard therapy phase and Omnipod 5 System phase.

[†] *Number of participants (n) for A1C outcomes was 305 for Standard Therapy phase and 296 for Omnipod 5 phase. Number of participants (n) for % time in range outcomes was 299 for both phases.*

Quality of Life

The table below provides information on the results of surveys assessing diabetes distress, sleep, and hypoglycemia confidence during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes. Participants on Omnipod 5 reported experiencing less diabetes distress.

Outcome[†]	Standard Therapy[†]	Omnipod 5	Change
Avg Type 2 Diabetes Distress Assessment System (T2-DDAS) survey score	2.5 (1.0)	2.2 (0.9)	-0.3*
% of participants with high diabetes distress (T2-DDAS ≥ 2.0%)	66%	55%*	
Avg Pittsburgh Sleep Quality Index (PSQI) survey score (std dev)	7.3 (4.0)	7.0 (4.1)	-0.4[§]
% of participants with poor sleep (PSQI > 5.0)	63%	59%[§]	

Outcome†	Standard Therapy†	Omnipod 5	Change
Avg Hypoglycemia Confidence Scale (HCS) survey score (std dev)	3.2 (0.6)	3.3 (0.6)	0.1
% of participants with low hypoglycemia confidence (HCS < 3.0)	32%	25%	

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) for T2-DDAS outcomes was 305 for Standard Therapy phase and 301 for Omnipod 5 phase. Number of participants (n) for PSQI outcomes was 304 for Standard Therapy phase and 294 for Omnipod 5 phase. Number of participants (n) for HCS outcomes was 305 for Standard Therapy phase and 300 for Omnipod 5 phase.*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant and clinically meaningful.*

§ *Change in total score between standard therapy phase and Omnipod 5 phase was statistically significant, but the change was not clinically meaningful. As a result, participants on Omnipod 5 did not experience improved sleep.*

Insulin Requirements

The table below provides information on the average insulin requirements during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes.

	Standard Therapy†	Omnipod 5†	Change
Avg total daily insulin, U/kg/day (std dev)	0.80 (0.46)	0.57 (0.29)	-0.23*
Avg total daily insulin, U/day (std dev)	79.9 (50.0)	57.3 (33.0)	-22.7

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) for U/kg/day outcomes was 305 for Standard Therapy phase and 300 for Omnipod 5 phase. Number of participants (n) for U/day outcomes was 305 for Standard Therapy phase and 304 for Omnipod 5 phase.*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Body Mass Index

The table below provides information on body mass index (BMI), which is a measure of weight adjusted for height, during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes.

	Standard Therapy (n = 305)	Omnipod 5 (n = 300)	Change
Avg BMI	34.9 (7.5)	35.1 (7.6)	0.3*

Averages (avg) with standard deviation (std dev) values in brackets.

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Omnipod 5 System Use

The table below provides information on the median % of time study participants used the Omnipod 5 System in Automated Mode.

	Omnipod 5 (n = 305)
% Time in Automated Mode	93% (87%, 97%)

Value is median with interquartile ranges in brackets (Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

Adverse Events

The table below provides a list of the glycemic adverse events per participant that occurred during the 3-month Omnipod 5 System treatment phase. Severe hypoglycemia was the only severe adverse event that occurred that was related to glycemia. Thirteen non-glycemic serious adverse events were reported during the Omnipod 5 phase. All 13 of those events were not related to Omnipod 5 and resulted in a full recovery except one event of stomach pain due to ascites.

Glycemic Adverse Events during the Omnipod 5 System Phase

Adverse Event Per Participant	Omnipod 5 (n = 305)
Severe hypoglycemia	1
DKA	0
Hyperosmolar hyperglycemic syndrome (HHS)	0

ADDITIONAL INFORMATION

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CHAPTER 26

Frequently Asked Questions and Troubleshooting

Contents

26.1 Omnipod 5 Pump FAQs

The following topics have been frequently asked during the use of Omnipod 5 when used with the Omnipod 5 App for iPhone, and the main causes and recommended actions are listed below.

Pod Issues

Issue	Possible Cause	What you can do
During Pod activation, did not hear the 2 beep confirmation after filling the Pod with insulin	Pod not filled with at least 85 units of insulin.	Make sure the Pod is filled with at least 85 units of insulin. If you have filled the Pod with at least 85 units and you still do not hear 2 beeps, you will need to discard the Pod and start a new one.
The adhesive around the Pod keeps lifting from the skin	It is important that the Pod stays on the body to ensure that the cannula stays under the skin to deliver insulin. If the area where you apply the Pod is not cleaned and dry, the adhesive may not stick well.	Make sure that the skin is cleaned and dry before applying the Pod. Avoid the use of moisturizers, oils, conditioners, sunscreen, or insect repellent around the site. If there is a lot of body hair, you may need to clip or shave the area 24 hours prior to Pod change. Be sure to remove old adhesive residue from the skin. Insulet has produced a special tape called PodPals™ that can help keep the Pod on for longer.

Issue	Possible Cause	What you can do
Pod alarm sounding	Because the delivery of insulin is so critical to your health, it is important to know if the Pod stops working. The Pod may stop working for many reasons, for example, a blockage (occlusion) is detected, electrostatic discharge affects the circuit, or some interference is detected.	This continuous loud noise is intended to alert you to remove the Pod and replace it with a new one. You can try to deactivate the Pod with your Omnipod 5 App. Occasionally, the App will not be able to communicate with the Pod and you will have to discard the Pod. In this case, you will need to remove the Pod and disable the alarm switch. See page 188 for guidance.

Finding Out How Much Insulin Was Delivered Using the App

Issue	What you can do
Where to see how much insulin is delivered while in Automated Mode on iPhone	The Sensor graph will show you the latest sensor glucose value received by the Pod. To see insulin delivery modes, tap the Sensor graph, and rotate the iPhone to see the graph in landscape view. If the view does not change, check that your Portrait Orientation Lock is turned off: 1. Swipe down from the top-right corner of your screen to open Control Center. 2. Tap the Portrait Orientation Lock button to make sure that it's off. The graph will also show when your last boluses were delivered. You can tap items on the graph for more information. Insulin suspension is shown as the red bar, and maximum delivery during Automated Mode is shown as the orange bar. To know the exact amount of insulin delivered in Automated Mode, from the toolbar, tap **History**. Select the Events tab and tap **Auto Events**. This will show you the time, sensor glucose value, and corresponding amount of insulin delivered at each 5-minute interval.
Where to find history of insulin deliveries on iPhone	The Omnipod 5 App maintains the history for previous insulin deliveries. From the toolbar, tap **History**. Select the Summary tab. Scroll down and look for previous insulin deliveries. If you tap the entry, you will see how the calculations for the bolus were made if the SmartBolus Calculator was used.

Controller Issues

See the full *Omnipod 5 Technical User Guide* for the full list of recommendations related to troubleshooting the Controller. Issues shown in this guide are for iPhone-specific System questions only. The *Omnipod 5 Technical User Guide* is available at *https://www.omnipod.com/guides*.

Omnipod 5 App Issues for iPhone

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: DO NOT reset the Omnipod 5 App 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 make sure you have a current record of your settings and a new Pod with supplies to use when restarting the app.

Caution: DO NOT delete the Omnipod 5 App while you have an active Pod. 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.

Issue	Possible Cause	What you can do
Omnipod 5 App does not work on the iPhone	Using an iPhone that is not compatible.	If you are not using a compatible iPhone, you will not be able to use the Omnipod 5 App. To find out if your iPhone is compatible, go to: https://www.omnipod.com/compatibility.
	iPhone operating system is not compatible.	If your operating system is not compatible, you will not be able to use the Omnipod 5 App until your operating system is updated. Update your operating system when an update becomes available.
	Omnipod 5 App is not compatible.	If your Omnipod 5 App is not compatible, you will not be able to use the Omnipod 5 App until it is updated. Update your Omnipod 5 App when an update becomes available.

Issue	Possible Cause	What you can do
Received a "New Device Detected" message when signing into Omnipod 5 App on iPhone	You are currently signed into another device, either the Controller or another smartphone, with your Omnipod ID.	**Note:** If you are wearing an active Pod when signing into a new device, your current Pod will still be delivering insulin, but you will not be able to manage it on the new device. 1. Remove the current Pod in order to stop receiving insulin. 2. After removing the current Pod, you will need to go through the setup process again, including pairing a new Pod and re-entering your Transmitter serial number.
Received an “Omnipod 5 failed to start” message when opening the Omnipod 5 App	Your Omnipod 5 App encountered into a problem starting up.	1. Close the Omnipod 5 App and reopen the App 2. If the problem continues contact Customer Care

Issue	Possible Cause	What you can do
Not receiving important updates about insulin therapy from the iPhone App	You force stopped the Omnipod 5 App by swiping it up to close it. Force stopping is not the same as locking your screen or putting your App to sleep. It means stopping the App from running in the background. The App must be running in order to notify you of important updates regarding your insulin therapy.	Open the App so you can receive important updates. **Note:** Even if you did force stop the Omnipod 5 App, your Pod is still delivering insulin according to the last instruction it received.

26.2 SmartBolus Calculator FAQs for iPhone

Issue	Possible Cause	What you can do
With carbs entered and CGM value available, the SmartBolus Calculator recommends no bolus or 0 insulin.	You have already received a lot of insulin (your IOB is high), and your sensor glucose trend is falling.	You can remove the sensor glucose value so that the calculator only suggests a bolus amount for the carbs entered. Alternatively, you can decide on a different amount and enter this directly into the Total Bolus field at the bottom of the screen. Check your Calculations screen before you deliver a bolus to see how the calculator determines the suggested bolus. Always confirm the bolus amount before you deliver it to make sure the system delivers what you want.

Issue	What you can do
I'm having a second serving of an item at a meal. How should I handle delivering a bolus?	After meals, it is common for glucose to rise. If you have already bolused for carbohydrates and entered a CGM value or blood glucose reading at the start of a meal, you can just enter carbohydrates for the second serving. The SmartBolus Calculator will suggest a bolus amount for the carbohydrates only.
I typically deliver the bolus following the meal as it is difficult to predict how many carbs my child will eat. What is the best way to use the SmartBolus Calculator in this case?	It is difficult, especially for young children, to predict how much will be eaten at each meal. In this case, you may choose to use the SmartBolus Calculator to deliver the correction bolus by tapping USE CGM or entering the blood glucose reading to deliver some insulin prior to the meal. After you are comfortable, you can separately enter the carbohydrates into the SmartBolus Calculator to deliver the full meal bolus.

26.3 Sensor FAQs for iPhone

Issue	Possible Cause	What you can do
Activated a Pod and cannot see sensor glucose values in the Omnipod 5 App on the iPhone	Problem with the Sensor or Transmitter.	Check your Dexcom G6 app and if you do not see sensor glucose values, then follow instructions there.
	Transmitter serial number is not entered into the Omnipod 5 app.	1. Go to: **Menu** > **Manage Sensor**. 2. Make sure the serial number is entered and entered correctly. If you have just connected, it can take up to 20 minutes for values to appear in the Omnipod 5 App.
	You are using the Dexcom G6 receiver.	1. Use the Dexcom G6 app on your smartphone. The Omnipod 5 System is not compatible with the Dexcom G6 receiver. 2. Then, turn off the Dexcom G6 receiver

Issue	Possible Cause	What you can do
Sensor glucose values no longer show up in the Omnipod 5 App on iPhone. Instead, there are dashed lines. The Dexcom G6 app does not show a problem.	The most likely reason for this to happen is an interruption in communication between the Sensor and the Pod.	To minimize the risk of interruption, make sure your Sensor and Pod are worn on the same side of the body. Wireless communications do not travel well through the body. For example, if your Sensor is worn on the abdomen and the Pod is on the back of the arm, the signal may be interrupted. Try to keep the Pod and Sensor on the same side of the body to maximize your time in Automated Mode. You can also try deleting the Transmitter serial number and re-entering it. ➢ Go to: **Menu** > **Manage Sensor**. This resets the communication between the Sensor and the Pod.
Sensor glucose values on the Dexcom G6 app look different from those on the Omnipod 5 App for iPhone.	The Dexcom G6 app receives sensor glucose values directly from the Transmitter. The Omnipod 5 App receives sensor glucose values from the Pod. Occasionally, there is a slight delay before the value is updated on the Omnipod 5 App.	The difference should be minor. To bring the value up to date, bring the iPhone close to the Pod.

High Glucose Issues

Issue	Possible Cause	What you can do
After using the system for a couple of weeks, sensor glucose values are running high after breakfast. The Insulin-to-Carb ratio is the same.	One of the benefits of automated insulin delivery is the greater ability to stay closer to your Target Glucose overnight. What this often means is that prior to breakfast, there is less insulin in your body compared to Manual Mode.	It is common to need changes to your Insulin-to-Carb ratio, generally a lowering of the ratio to receive more insulin before meals (for example, lowering the carbohydrate value covered by 1U of insulin). Another setting that you can change is Reverse Correction. When the toggle for this is on, it means the calculator will recommend less insulin when your sensor glucose value or blood glucose reading is below your Target Glucose. Discuss with your healthcare provider what settings are best for you. Your SmartBolus Calculator settings are available under: **Menu** > **Bolus Settings**.

Issue	Possible Cause	What you can do
After using the system in Automated Mode for a few weeks, sensor glucose values have been running high.	Your Target Glucose may need to be adjusted. In Automated Mode, Target Glucose is the main setting that you can control to adjust automated insulin delivery.	Check your Target Glucose here: **Menu** > **Bolus Settings** The Target Glucose can be set between 110–150 mg/dL. If you're running high, you can try reducing the Target Glucose around the period that you're running higher than desired.
	Other SmartBolus Calculator settings may need to be adjusted.	Think about your SmartBolus Calculator settings: In particular, your Insulin-to-Carb ratio, Correction Factor and Target Glucose might need to be adjusted. For example, if these high periods are after lunch, you might need more insulin around lunchtime to reduce the likelihood of running high in the afternoon. Changing your Basal Programs or Max Basal setting will not make a difference for the Automated Mode function. This only works for Manual Mode. Discuss with your healthcare provider what settings are best for you.

Issue	Possible Cause	What you can do
Sensor glucose values have been running high over several days.	Although the system is able to automate insulin delivery, your body's insulin needs can change daily. This means that every day with diabetes is different.	Think about diet, exercise, Pod insertion site, and change in your body's needs and how they are affecting your glucose. The system will adapt with every new Pod to give you just the right amount of insulin to get you to the Target Glucose. As the system detects higher insulin needs, it will adapt to adjust insulin dosing accordingly.

Low Glucose Issues

Issue	Possible Cause	What you can do
Sensor glucose values have been running low in the late evening; needing hypoglycemia treatment before going to bed.	Your Target Glucose may need to be adjusted for the period to avoid the low.	Check your Target Glucose here: **Menu** > **Bolus**
	If lows are happening soon after the dinner bolus, you might need adjustment of your SmartBolus Calculator settings to receive less insulin for the dinner bolus. Another option is to check how long it has been since the last bolus.	Discuss with your healthcare provider what settings are best for you. Your SmartBolus Calculator settings are available here: **Menu** > **Bolus**

Issue	Possible Cause	What you can do
Following afternoon exercise, sensor glucose values are going low.	During exercise, your body is often prone to low glucose.	To reduce the risk of this low, you can use the Activity feature. With this feature, the system delivers less insulin and also drives insulin delivery to a target of 150 mg/ dL. It is recommended that you turn this setting on at least 30–60 minutes before exercise. Exercise with diabetes requires trial and error. Keep a record of activity, carbohydrates consumed, and insulin delivery to work out the best method for you. Your healthcare provider can help provide different ways to confidently manage your diabetes with exercise.

26.4 Automated Mode FAQs for iPhone

Issue	Possible Cause	What you can do
Activated a Pod and unable to switch to Automated Mode on iPhone	Your Transmitter serial number is not entered into the Omnipod 5 App.	Go to: Menu > Manage Sensor. Tip: Always check that the serial number entered into the App is the same as the number on the Transmitter you are wearing.
Screen on iPhone shows Automated Mode: Limited	Interruption in communication between the Sensor and the Pod.	To minimize the risk of interruption, make sure your Pod and Sensor are worn on the same side of the body. Wireless communications do not travel well through the body. For example, if your Sensor is worn on the abdomen and the Pod is on the back of the arm, the signal may be interrupted.
	Problem with the Sensor or Transmitter	Check your Dexcom G6 app and if you don't see sensor glucose values, then follow instructions there.
	Automated Mode may have reached the limits of insulin delivery, either the maximum or the minimum.	Follow the instructions on the screen to check your glucose. After 5 minutes in Manual Mode and you are confident that your Pod and Sensor are working well, you can switch back to Automated Mode. See page 290.

26.5 Pod Communication Issues – "Try Again"

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.

No Pod Communication

There may be times while wearing an active Pod when the Pod and the Omnipod 5 App are unable to communicate.

If a Pod communication issue occurs, you will see a "No Pod communication" message. Follow the on-screen instructions to resolve the issue. Your iPhone will deliver a notification every 15 minutes when there is an unacknowledged communication issue due to an instruction being unable to be sent to the Pod.

What should you do?

- Bring your Controller or compatible smartphone within five feet of your active Pod to try to restore connection.
- Ensure that no other Pods that have been previously discarded are within 20 feet (6 meters) of your Controller or compatible smartphone.
- If there is an error displayed in your App, tap **Try Again** (or **Check Status**) and follow the on-screen instructions to resolve the issue.
- Toggle Bluetooth ON and OFF, if using a compatible smartphone, and remove other devices that may be connected to Bluetooth.

If the above steps do not resolve the communication issue, attempt the options listed in "Additional Troubleshooting Options" on page 357.

Additional Troubleshooting Options

Discard Pod and Activate a New Pod

This option should only be used when the above troubleshooting steps have not resolved the communication issue in your Omnipod 5 App.

- Select **Discard Pod.**
    - Discarding the Pod will end communication between the Pod and your Omnipod 5 App. The Pod is not deactivated and can still deliver insulin.
- Remove the Pod and ensure it is outside of the communication range of the App (approximately 20 feet or 6 meters).
    - If you previously connected your discarded Pod to your Sensor, you will need to move it out of range of the Sensor (approximately 30 feet or 9 meters) to allow the new Pod and Sensor to establish communication.
- Activate and apply your new Pod.
- When there is a communication issue, the Omnipod 5 app offers you options to help you resolve it. It is in your best interest to leave any options to Discard or Deactivate as the last choice after trying the other option(s).

Tip: When there is a communication issue, the Omnipod 5 App offers you options to help you resolve it. It is in your best interest to leave any options to Discard or Deactivate Pod as the last choice after trying the other option(s).

Error when sending insulin instructions to the Pod

A communication error may occur when the Omnipod 5 App attempts to send insulin delivery instructions to the Pod. If a communication error occurs when the Omnipod 5 App attempts to send an insulin delivery instruction, the Omnipod 5 App offers you different options.

If the Omnipod 5 App has sent the Pod the instruction and hasn't received confirmation that it was carried out, the Omnipod 5 App offers these options:

- Check Status: Move to a new location, then select this option to recheck for confirmation that the instruction was carried out.
- Deactivate Pod: This should not be your first choice. When you select this option, you can follow the instructions for replacing your Pod.

If the Omnipod 5 App has not sent the Pod the instruction, the Omnipod 5 App offers these options:

- Cancel: Select this option to cancel sending the instruction. In this case, the Pod continues with its prior insulin delivery mode. You can try to send the instruction later.
- Try Again: Move to a new location, then select this option to tell the Omnipod 5 App to reattempt to send the instruction to the Pod.

Error when canceling a bolus

If you are trying to cancel a bolus when a communication error occurs, the following options become available:

- Cancel: Select this option to stop attempting to cancel the bolus. The Pod continues to deliver the bolus.
- Try Again: Move to a new location, then select this option to tell the Omnipod 5 App to continue attempting to communicate with the Pod.

If the 'cancel bolus' instruction has already been sent from the Omnipod 5 App when a communication error occurs, the Omnipod 5 App offers these options:

- Check Status: Select this option to attempt to re-establish communication with the Pod and obtain the current status of the 'cancel bolus' command.
- Deactivate Pod: This should not be your first choice. Select this option to deactivate the Pod when Check Status is unsuccessful.

Error when activating a Pod

If a communication error occurs during Pod activation, the following options become available:

- Discard Pod: This should not be your first choice. Select this option to stop attempting to use this Pod.
- Try Again: Select this option to attempt to re-establish communication.

Error when deactivating a Pod

If a communication error occurs during Pod deactivation, the following options become available:

- Discard Pod: Select this option if the Try Again option has not resolved the problem. This will tell your Omnipod 5 System to unpair from that Pod. The Omnipod 5 App instructs you to remove your Pod and tap Continue.
- Try Again: Select this option to attempt to re-establish communication.

Note: After selecting the discard option, you can prevent future alarms from the discarded Pod by following the instructions in "13.9. Silencing Unresolved Alarms" on page 188.

Note: If there is an unconfirmed bolus when you discard a Pod, the Omnipod 5 System does not know how much of the bolus was delivered. Therefore, the Omnipod 5 System temporarily disables the SmartBolus Calculator for a period equal to your Duration of Insulin Action setting. If you tap the Bolus button while the SmartBolus Calculator is disabled, the Omnipod 5 App displays a message that says "SmartBolus Calculator temporarily disabled." You can deliver a manual bolus when the SmartBolus Calculator is disabled.

26.6 About Keeping Your iPhone Nearby

You will use your iPhone to activate a new Pod every 2–3 days. After you activate a Pod, you will start receiving insulin based on your active Basal Program in Manual Mode, whether or not your Controller or smartphone is nearby. You will need to access the App, however, to resolve any alerts or alarms that may originate from your Pod, to deliver a bolus, or check the status of your System and glucose.

After you enter the Transmitter serial number into the Omnipod 5 App and use the Dexcom G6 app on your smartphone to activate your Sensor, you can switch from Manual Mode to Automated Mode. In Automated Mode, the Pod will directly receive sensor glucose values wirelessly and automate insulin delivery depending on your needs.

The system is designed to continue delivering insulin in the absence of your Controller or smartphone, so you will not be alerted that the Pod and display device are out of range of one another if you choose to leave your Controller and/ or smartphone behind.

Although your Omnipod 5 System does not require the iPhone to be nearby to continue your insulin delivery in Manual Mode or Automated Mode, the Omnipod 5 App provide(s) you with important information about recent insulin delivery, alerts, and alarms that come from your Pod, and allows you to deliver a bolus.

Caution: AVOID leaving your iPhone 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 iPhone.

26.7 Deleting the Omnipod 5 App

If you delete the Omnipod 5 App from your iPhone, all your settings and insulin history will be removed. If you choose to download the Omnipod 5 App later, you will have to go through the setup process again, entering all your insulin therapy settings.

> **Caution:** DO NOT delete the Omnipod 5 App while you have an active Pod. 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

- Write down all of your settings in case you need them later. You may wish to take screenshots of your Omnipod 5 App settings and save them on your iPhone to keep for future reference.
- If you wish to stop receiving insulin, remove your Pod.

To delete the Omnipod 5 App:

1. From the iPhone Home screen, touch and hold the App icon.
2. Tap **Remove App**.
3. Tap **Delete App**, then tap **Delete to confirm**.

26.8 Device Complaints

If you have a problem with your System, contact Customer Care at 1-800-591-3455. You may be asked to share device data.

To share device data:

1. Ensure a working Wi-Fi connection.
2. Go to: **Menu** > **About**
3. Tap **Send Log Files**.
4. Enter the code provided by Customer Care

If you see an exclamation mark (!) icon in your Menu, alert your Customer Care representative.

If this occurs: Data upload is pending.

If this occurs: Data upload is full.

Appendix

Summary of Settings and Options

The options for the various Omnipod 5 Automated Insulin Delivery System settings are:

Time format	Mirrors iPhone settings
Time zone	GMT-11:00 to GMT+13.00.
Daylight Savings Time	App will notify when DST time change detected.
Date format	MM/DD/YYYY
Screen time-out	Mirrors iPhone settings
PIN	Mirrors iPhone settings, Biometric can be used.
Dexcom G6 Transmitter serial number	6 characters.
Maximum Basal Rate	Select one value between 0.05-30 U/hr in 0.05 U/hr increments. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
Activity feature	Range: 1 to 24 hrs In increments of 1 hour
Temp basal	%, units/hr, or Off. Default is off. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Glucose Goal Range (for blood glucose history)	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments .
Target Glucose value	Maximum of 8 segments; 110 to 150 mg/dL in 10 mg/dL increments.

Correct Above threshold	Maximum of 8 segments; Target Glucose to 200 mg/dL in 1 mg/dL increments.
Minimum Glucose for Calculations	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.
Reverse Correction	On or Off. Default is On
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Bolus size	Range: 0.05-30 U in 0.05 U increments.
Extended bolus	%, Units, or Off. Default is off. 30 minutes to 8 hours in 30-minute increments.
Pause insulin	30 minutes to 2 hours.
Low Pod Insulin advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Pod Shut-Off timer	Off, or 1 to 24 hours in 1-hour increments. Default is Off.
History screen display	Rolling 90-day period.
Language	English.

Pod Specifications

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

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

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

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

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

Warm-up time (0°C to 20°C): 7 minutes

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

Reservoir volume (deliverable): 200 units

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

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

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

Insulin concentration: U-100

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

Sterilizing agent: sterilized using ethylene oxide

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

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

Operating atmospheric pressure: 700 hPa to 1060 hPa

Storage atmospheric pressure: 700 hPa to 1060 hPa

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.05 U

Flow Capability:

Prime rate: 0.05 unit per second.

Basal: Programmable by the user in 0.05 U increments up to 30.0 U per hour

Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

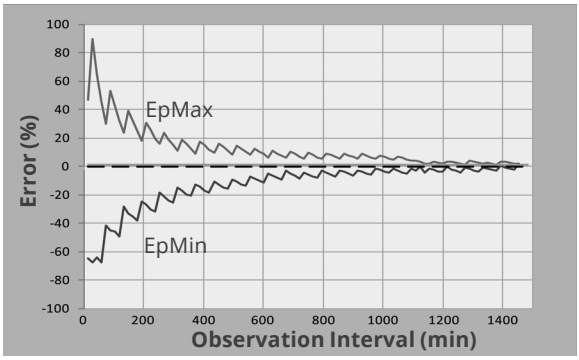
Delivery accuracy (tested per IEC 60601-2-24):

Basal: ± 5% at rates ≥ 0.05 U/hr

Bolus: ± 5% for amounts ≥ 1.0 unit
± 0.05 units for amounts < 1.0 unit

Note: You should consider bolus dose accuracy when setting a bolus dose. When using the lowest bolus dose allowable (0.05 units), the actual bolus delivered may be as low as 0.00 units or as high as 0.10 units.

Accuracy test results: The following graph shows the flow accuracy of the Pod against given time periods. The measurements were made using a Pod with a basal rate of 0.5 µl/h (which delivers 0.05 U/h of U-100 insulin) at a high operating temperature. The overall mean percentage flow error was 1.40%.



Insulet-provided Controller Specifications

Size: 5.67" high x 2.66" wide x 0.49" deep (143.92 mm x 67.57 mm x 12.33 mm)

Weight: 5.82 oz (165 grams)

Screen active area: 2.21" wide x 4.75" high (56.16 mm x 120.58 mm)

Operating temperature range: 41°F to 104°F (5°C to 40°C)

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

Operating relative humidity range: 20% to 90%, non-condensing

Storage relative humidity range: 20% to 90%, non-condensing

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The Controller and Pod should be:

- At startup: Adjacent and touching, with the Pod either in or out of tray, to ensure proper communication during priming.
- During normal operation: Within 5 feet (1.5 m) of each other. Depending on the location, the communication distance may handle separations up to 50 feet (15 meters) away.

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

IP (Ingress Protection) rating for moisture and dust: IP22 (protected from touch by fingers and objects 12.5 millimeters or larger; not well-protected from water - avoid liquid)

Notification type: Audible and vibratory

Battery: Rechargeable Li-ion battery, 3.8V, 2800 mAh

Battery life: Full charge covers approximately 36 hours of typical use.

Controller Service Life: Approximately 2 years (based on 300-500 charge cycles) with typical use

Shelf Life (Starter Kit): 18 months

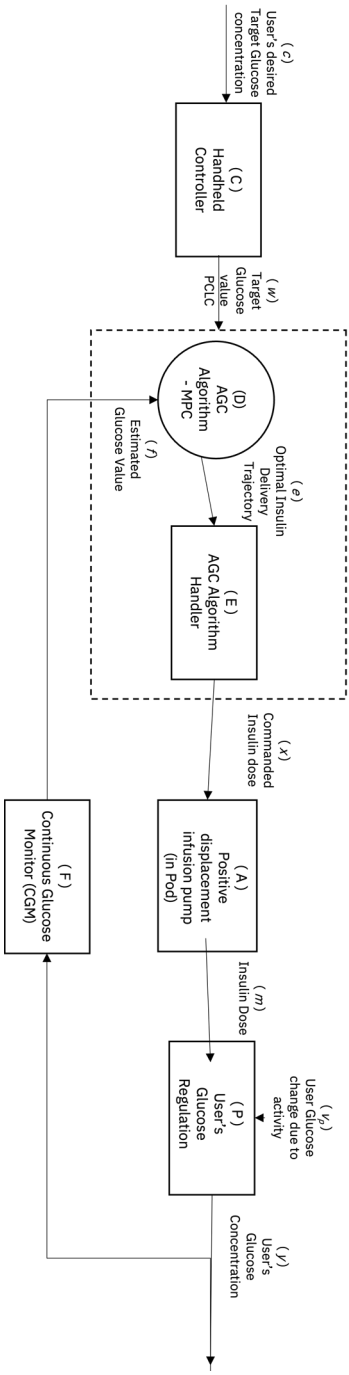
Battery charger operating line voltage: 100 to 240 VAC, 50/60 Hz

> Only use the Noetic approved power adapter (Insulet PN PT-000428) with the Controller.

Dexcom Specifications

For information about Dexcom operating specifications, see the *Dexcom G6 CGM System Instructions for Use.*

Theory of Operation for Physiologic Closed Loop Control System



Protection from Over-Infusion or Under-Infusion

The Pod software monitors the infusion rate. If an error that would result in over- infusion or under-infusion is detected and cannot be corrected, insulin delivery stops, and an alarm sounds.

Blockage detection

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 158).

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.

A blockage (occlusion) is an interruption in insulin delivery from the Pod. If the Omnipod 5 System detects a blockage, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

A blockage hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts blockage detection for three different situations when using U-100 insulin. For example, if the Pod's cannula becomes blocked when delivering a 5 U bolus, 35 minutes may pass before the Pod sounds a hazard alarm.

	Time between blockage and Pod alarm	
	Typical time	Maximum time
5.00 U bolus	33 minutes	35 minutes
1.00 U/hr basal	3.0 hr	5.5hr
0.05 U/hr basal	51 hr	80 hr (Pod expiration)

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

If your Omnipod 5 System detects a potential blockage to your insulin delivery, it will set a blockage alarm to sound. If a blockage alarm is set to alarm while an immediate bolus is in progress, the alarm is delayed until completion of the bolus.

Performance Characteristics

The Omnipod 5 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Insulet..

Delivery performance characterization

- Basal Delivery: In order to assess basal delivery accuracy, 12 Pods were tested by delivering at low, medium, and high basal rates (0.05, 1.00, and 30.0 U/hr). Water was used as a substitute for insulin. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.05 U/hr)			
Basal Duration (Number of units requested)	**1 hour (0.05 U)**	**6 hours (0.30 U)**	**12 hours (0.60 U)**
Amount Delivered	0.049 U	0.30 U	0.59 U
[min, max]	[0.00, 0.12]	[0.13, 0.57]	[0.34, 0.99]

Medium Basal Rate Delivery Performance (1.00 U/hr)			
Basal Duration (Number of units requested)	**1 hour (1.00 U)**	**6 hours (6.00 U)**	**12 hours (12.00 U)**
Amount Delivered	0.99 U	5.97 U	11.88 U
[min, max]	[0.65, 1.55]	[5.06, 6.87]	[10.53, 13.26]

High Basal Rate Delivery Performance (30.00 U/hr)		
Basal Duration (Number of units requested)	**1 hour (30.00 U)**	**6 hours (180.00 U)**
Amount Delivered	29.82 U	179.33 U
[min, max]	[28.85, 31.39]	[177.49, 181.15]

Note: A measurement at the 12-hour period with a 30.0 U/hr basal rate is not applicable to the Omnipod 5 System as the reservoir will empty at approximately 6 ⅔ hours at this rate

Bolus Delivery: In order to assess bolus delivery accuracy, 12 Pods were tested by delivering a minimum, intermediate, and maximum bolus amount (0.05, 5.00, and 30.0 Units). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid delivered was used to assess pumping accuracy.

The following table summarizes the typical bolus performance observed for the requested minimum, intermediate, and maximum size bolus for all pumps tested. For each individual target bolus size, the number of boluses observed is shown along with the average (mean), minimum, and maximum units delivered as measured by a scale.

Individual Bolus Accuracy Performance	Target Bolus Size (Units)	Mean Bolus Size (Units)	Min Bolus Size (Units)	Max Bolus Size (Units)
Min Bolus Delivery Performance (n = 5987 boluses)	0.05 U	0.050 U	0.00 U	0.119 U
Intermediate Bolus Delivery Performance (n = 300 boluses)	5.00 U	5.01 U	4.49 U	5.37 U
Max Bolus Delivery Performance (n = 72 boluses)	30.00 U	30.05 U	29.56 U	30.62 U

The tables below show for each requested bolus size, the range of amount of insulin that was observed delivered compared to the requested amount. Each table provides the number and percent of delivered bolus sizes observed within the specified range.

Amount of Insulin Delivery for a Minimum (0.05 U) Bolus Request

Amount (Units) **(% of settings)**	<0.0125 (<25%)	0.0125–0.0375 (25–75%)	0.0375–0.045 (75–90%)	0.045–0.0475 (90–95%)	0.0475–0.0525 (95–105%)
Number and percent of boluses within range	61/5987 (1%)	639/5987 (10.7%)	1284/5987 (21.4%)	504/5987 (8.4%)	1100/5987 (18.4%)
Amount (Units) **(% of settings)**	0.0525–0.055 (105–110%)	0.055–0.0625 (110–125%)	0.0625–0.0875 (125–175%)	0.0875–0.125 (175–250%)	>0.125 (>250%)
Number and percent of boluses within range	504/5987 (8.4%)	1192/5987 (19.9%)	582/5987 (9.7%)	121/5987 (2%)	0/5987 (0%)

Amount of Insulin Delivery for an Intermediate (5.00 U) Bolus Request

Amount (Units) (% of settings)	<1.25 (<25%)	1.25–3.75 (25–75%)	3.75–4.50 (75–90%)	4.50–4.75 (90–95%)	4.75–5.25 (95–105%)
Number and percent of boluses within range	0/300 (0%)	0/300 (0%)	1/300 (0.3%)	4/300 (1.3%)	287/300 (95.7%)
Amount (Units) (% of settings)	5.25–5.50 (105–110%)	5.50–6.25 (110–125%)	6.25–8.75 (125–175%)	8.75–12.50 (175–250%)	>12.50 (>250%)
Number and percent of boluses within range	8/300 (2.7%)	0/300 (0%)	0/300 (0%)	0/300 (0%)	0/300 (0%)

Amount of Insulin Delivery for a Maximum (30.0 U) Bolus Request

Amount (Units) (% of settings)	<7.5 (<25%)	7.5–22.5 (25-75%)	22.5–27.0 (75–90%)	27.0–28.5 (90–95%)	28.5–31.5 (95–105%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)
Amount (Units) (% of settings)	31.5-33.0 (105–110%)	33.0–37.5 (110–125%)	37.5–52.5 (125–175%)	52.5–75.0 (175–250%)	>75.0 (>250%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)

Omnipod 5 System Label Symbols

The following symbols appear on the Omnipod 5 System or its packaging:

Symbol	Meaning	Symbol	Meaning
	Do not re-use		MR unsafe
	Refer to instruction manual / booklet		Do not use if package is damaged and consult instructions for use
	Sterilized using ethylene oxide		Type BF applied part
	Date of manufacture		Manufacturer
	Country of Manufacture – United States of America		Country of Manufacture – Malaysia
	Country of Manufacture – China		Compatible with
	Batch code		Keep dry
	Use-by date		Temperature limit
	Catalogue number		Humidity limitation
	Serial number		Atmospheric pressure limitation
	UK Conformity Assessed		Australian Regulatory Compliance Mark
	Marking of conformity		Importer
IP28	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; Submersible: Waterproof to 7.6 meters (25 feet) for up to 60 minutes	IP22	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; avoid liquid

Symbol	Meaning	Symbol	Meaning
	Non-pyrogenic fluid path		Medical device
	Do not dispose with household waste	RoHS	RoHS compliant
	Single sterile barrier system		Single patient multiple use
	Compatible with U-100 Insulin Only		Consult instructions for use or consult electronic instructions for use
	Non-pyrogenic fluid path		Medical device
	Do not dispose with household waste	RoHS	RoHS compliant
	Single sterile barrier system		Single patient multiple use
	Compatible with U-100 Insulin Only		Consult instructions for use or consult electronic instructions for use
FCC ID:	Federal Communication Commission Identifier with number	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
IC:	Complies with ISED Canada Radio Standards Specifications	HVIN:	Hardware version identification number
	Switzerland Authorized Representative		Authorized representative in the European Community/ European Union
	UK Conformity Assessed		Intertek Authorized Product Certification Mark
	(France) The Triman indicates that the product must be sorted or returned to a collection point.		Intertek Authorized Product Certification Mark

Symbol	Meaning	Symbol	Meaning
	(France) This product must be separated from conventional perforating DASTRI for recycling.		(France) This pictogram means that the product contains a piercing object.
	(France) Electronic perforating waste must be stored in the secure DASTRI purple box. These purple boxes are distributed free of charge in pharmacies.		(France) All pharmacies distribute and collect DASTRI needle boxes free of charge from self-treatment patients.
	(France) Packaging intended for recycling		(France) The puncture waste must be placed in a DASTRI needle box. These needle boxes are distributed by pharmacies.
	Charging cable		Charging adapter
	Fill Syringe and Needle Assembly		Pod
	Controller skin		Omnipod 5 Controller

Omnipod 5 System Notice Concerning Interference

Caution: DO NOT make changes or modifications to any component of the Omnipod 5 System that has not been authorized by Insulet Corporation. Unauthorized tampering with the System can revoke your right to operate it.

The Omnipod 5 Automated Insulin Delivery System is designed to comply with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with the instructions may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

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

- Move or relocate the Omnipod 5 System.
- Increase the separation between the Omnipod 5 System and the other device that is emitting or receiving interference.
- Consult the dealer or an experienced radio/TV technician for help.

Quality of Service

The Omnipod 5 System includes two wireless transmission pathways. Insulet defines the quality of service of the Omnipod 5 System for each of the two pathways:

Omnipod 5 App to Pod wireless communication definition

Successful transfer of commands, data, and alarms between the Controller or smartphone running the Omnipod 5 App and Pod when in communication range (within 5 ft during normal operation). The Omnipod 5 App informs the user when transfer of commands,

data, and alarms is unsuccessful. For Insulin Delivery commands, the system performance requirements state that communication between the Pod and the Controller or smartphone running the Omnipod 5 App occurs within 8 seconds at a reliability rate of 95%. The Omnipod 5 App will inform the user when there are communication errors between the Pod and the Controller or smartphone. When such an error occurs, the Omnipod 5 App will issue an immediate notification to the user followed by a follow-up every 15 minutes, and the communication failure will continue to be indicated with in the Omnipod 5 App until the communication error is resolved.

Pod to Sensor wireless communication definition

The percentage of sensor glucose values successfully received by the Pod when the Transmitter or Sensor and Pod attempt to communicate every 5 minutes. The System performance requirements state that at least 80% of sensor glucose values will be successfully received by the Pod when the Transmitter or Sensor are worn within line of sight of the Pod. The System informs the user of missing sensor glucose values in real time by the dashes on the home screen or by missed dots on the Sensor Graph.

For additional information on communication errors in the Omnipod 5 System, see Chapter 21. To maintain quality of service when other devices operating in the GHz band are around, the Omnipod 5 System uses the coexistence features provided by Bluetooth® wireless technology.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod 5 System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

The Omnipod 5 System has been tested and found to have acceptable immunity to emissions from RFID and EAS systems.

The Omnipod 5 System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod 5 System fails due to electromagnetic disturbances, you may need to replace it.

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

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

Care should be taken if the Omnipod 5 System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod 5 System should be observed to verify normal operation in this setting.

The Omnipod 5 System communicates by low-level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod 5 System communicates with the following characteristics:

Frequency: 2.400–2.480 GHz, digitally modulated, with an effective Isotropic radiated power of 1.14mW

The Omnipod 5 System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

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.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should ensure that is used in such an environment.		
Emissions	**Compliance according to**	**Electromagnetic environment**
RF Emissions (CISPR11)	Group 1	The Pod, Controller, and Sensor emit low-level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments, including domestic establishments.
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations/ Flicker Emissions (IEC 61000-3-3)	Pst ≤ 1.0 Plt ≤ 0.65 dc ≤ 3% dmax ≤ 4% d(t) ≥ 200 ms during a voltage change should be ≤ 3%	

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this device)**	**Electromagnetic environment**
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Electrical Fast Transient/ burst (IEC 61000-4-4)	± 2 kV power supply lines ± 2 kV Input DC Power Port ± 1 kV input/ output lines	± 2 kV power supply lines ± 2 kV Input DC Power Port ± 1 kV input/ output lines	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Conducted Disturbances induced by RF fields (IEC 61000-4-6)	3V 150 KHz-80 MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MHz	3V 150 KHz-80 MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MH	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

Electromagnetic Immunity			
Voltage Dips, Short Interruptions, Voltage Variations on Power Supply input lines (IEC 61000-4-11)	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user requires continued operation during power mains interruptional, it may be necessary to use an uninterruptible power supply or a battery.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

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

Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380–390	TETRA 400	Pulse modulation b)18Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulatio n b) 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800. ODEM 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	G GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2450–2570	Bluetooth WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	0.2	0.3	9
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5500						
5785						

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

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

Test Frequency	Modulation	Immunity Test Level (A/m)
30kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1 kHz	65 c)
13.56 MHz	Pulse modulation b)	7.5 c)
a) This test is applicable only to ME equipment and ME systems intended in a HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) RMS before modulation is applied		

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

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

Interference from Magsafe Charging

Under certain conditions, magnets and electromagnetic fields can interfere with medical devices when in close contact. The Omnipod 5 System has been tested and found to have acceptable immunity to magnetic field interference from iPhones and phone wireless MagSafe charging when in operation. If you see any communication errors while pairing your your Pod to the Omnipod 5 App while your phone is on a MagSafe charger, remove your iPhone from the MagSafe charger.

The Omnipod 5 System is designed to coexist in the presence of other RF wireless in-band and near-band devices (ex. MagSafe-enabled Apple Products) in proximity while in use. If you experience any type of communication errors between the Omnipod 5 Pod and the iPhone, check the distance between your Pod and iPhone. If the phone is too close, move the iPhone further from the Pod and retry the command.

The test mirrored the test methods specified in ANSI C63.27 for assessing the RF wireless Coexistence of equipment that incorporates RF communications. This table lists the immunity level complied for the proximity magnetic field.

Interference Signal	Magnetic field source description	Distance (mm)	Immunity Test Level (max)
DC Magnetic Field	iPhone 12 Pro	0	138 Gauss
	Ring Magnet	0	2,208 Gauss
	Accessory MagBak case	0	6.4 Gauss
NFC Radiated (Magnetic Field, 1 KHz to 2 MHz)	Near Field Charger	0	-9.123 dBm

Customer's Bill of Rights

Mission Statement

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

Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod 5 Automated Insulin Delivery System.

The Omnipod 5 System consists of the Pod and the handheld, wireless Controller or compatible smartphone running the Omnipod 5 App, which programs the Pod with insulin delivery instructions.

Compliance

The Omnipod 5 Automated Insulin Delivery System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

Inquiries

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

CHAP Accredited

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

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.
2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.

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

You have the responsibility to:

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

Limited Express Warranty, Disclaimer, and Limitation of Remedies for the Controller and Pods

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE Omnipod 5 AUTOMATED INSULIN DELIVERY SYSTEM HANDHELD CONTROLLER AND PODS (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Handheld Controller

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Insulet Corporation ("Insulet") warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System ("Omnipod 5 System"), that, if Insulet determines, during the period of four (4) years from the date of purchase, that the Omnipod 5 System handheld hardware Controller ("Controller") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will either repair or replace, at its sole option, the Controller. This four-year (4) warranty period applies only to new Controllers and, in the event the Controller is repaired or replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Controller under this Limited Express Warranty, the warranty coverage for the replacement Controller shall expire four (4) years from the date of purchase of the original Controller.

Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Pods

Subject to this Limited Express Warranty, Insulet warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System, that, if Insulet determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod 5 Automated Insulin Delivery System Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e., occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet of the claim).

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

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Insulet of the claimed defect with the Controller or the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). For a claim involving the Controller, you must provide the Controller serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the Controller and/or the Pod, the manufacture date of the Pod and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet elects to repair the Controller (which may include, but is not limited to, a repair kit or replacement part(s) Insulet provides) or refers you to a third party, you must obtain a prior authorization and return the Controller or the Pod to Insulet. The Controller or Pod must be properly packaged and returned to Insulet according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a

prior authorization, Insulet will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the Controller or Pod to Insulet under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet, except those performed or provided by third parties to which you were explicitly referred by Insulet.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable

warranty periods, Insulet may require that you provide a valid proof of purchase, manufacture, or activation. Your failure to provide a valid proof of purchase, manufacture, or activation,

as determined by Insulet, may result in the denial of coverage under this Limited Express Warranty.

Exclusions

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

This Limited Express Warranty will apply only if the Controller or the Pod at issue has been used in accordance with the Omnipod 5 Automated Insulin Delivery System Technical User Guide and/ or other written instructions provided by Insulet. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE Controller OR THE POD HAVE BEEN:

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

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

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

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

DISCLAIMER OF IMPLIEDWARRANTIES AND LIMITATION OF REMEDIES

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

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

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

Important Additional Provisions

Insulet Corporation does not warrant the suitability of the Controller or the Pod or the Omnipod 5 Automated Insulin Delivery System for any specific person as health care and treatment are complex subjects requiring the services of qualified health care providers.

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

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. Insulet Corporation's liability in such jurisdictions shall be limited to

the maximum extent permitted by law. Such limitations shall include but are not limited to the following: any implied warranties that cannot be disclaimed under the law of a particular jurisdiction are limited, to the extent allowed by law, to the time period covered by the above limited express warranty, or to the applicable time period provided by law, whichever period is shorter.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System. No employee, agent, or other representative of Insulet or any other party is authorized to make any product warranty or agreement applicable to a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod 5 Automated Insulin Delivery System, please return any Omnipod 5 Automated Insulin Delivery System products (including any Controller and Pods) to Insulet in exchange for a full refund. Failure to return such Omnipod 5 Automated Insulin Delivery System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Rev: January 2021

HIPAA Privacy Notice

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

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

Uses and Disclosures of Medical Information

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

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

- **Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided by Us**
- **Treatment, Payment and Health Care Operations:** We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.
    - Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

  - Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.
  - Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.
- **Appointment Reminder and Other Communications:** We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.
- **Family, Friends and Emergencies:** If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.
- **Marketing:** We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

- **Required by Law:** We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.
- **Public Health:** We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.
- **Communicable Diseases:** We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.
- **Health Oversight:** We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs and civil rights laws.
- **Food and Drug Administration:** We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated

products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

- **Legal Proceedings:** We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.
- **Law Enforcement:** We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.
- **Research:** We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.
- **Criminal Activity:** Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.
- **Military Activity and National Security:** When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities; , or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.
- **Workers' Compensation:** We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.
- **Inmates:** We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and good order of the correctional institution.

- **Required Uses and Disclosures:** Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.
- **Non-identifiable Information:** We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

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

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please submit a request here. We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a request to review your Medical Information, please submit a request here. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

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

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

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

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

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

Our Duties

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

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical

Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our Website at www.omnipod.com. If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request here.

What to Do If You Have a Problem or Question

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

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

Insulet Corporation

Attn: Privacy Officer

Email: privacy@insulet.com

(866) 941-0155

Our mailing address is:

100 Nagog Park

Acton, MA 01720

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling 877-696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

Revision Date: April 1, 2009, September 20, 2013, April 22, 2014, September 2, 2014, June 1, 2019, and September 15, 2022.

Index

H

I

K

L

M

N

O

P

R

S

T

U

V

W

X

My Settings

Use these pages to keep track of your important settings. Remember to update your information if you change or add settings.

Basal Program 1

Name_____ Basal rate

midnight	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*

Basal Program 2

Name_____ Basal rate

midnight	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*

Basal Program 3

Name_____ Basal rate

midnight	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*

Basal Program 4

Name_____ Basal rate

midnight	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*
_____	to	_____	_____	*U/hr*

Target Glucose

Time segment			**Target Glucose:** Bolus Calculator aims for this value	**Correct Above:** Suggest correction if glucose is above
midnight	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*	_____ *mg/dL*

Correction Factor

Correction Factor for each time segment			1 unit of insulin lowers glucose by
midnight	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*
_____	to	_____	_____ *mg/dL*

Insulin-to-Carbohydrate Ratio (IC Ratio)

IC Ratio for each time segment			1 unit of insulin lowers glucose by
midnight	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*
_____	to	_____	_____ *g carb*

Duration of Insulin Action

Time that insulin remains "active" in the body after a bolus _____ hrs

Favorite Foods

Name	Grams of carbohydrates
_____	_____ *g carb*
_____	_____ *g carb*
_____	_____ *g carb*
_____	_____ *g carb*
_____	_____ *g carb*
_____	_____ *g carb*
_____	_____ *g carb*

Max Basal Rate

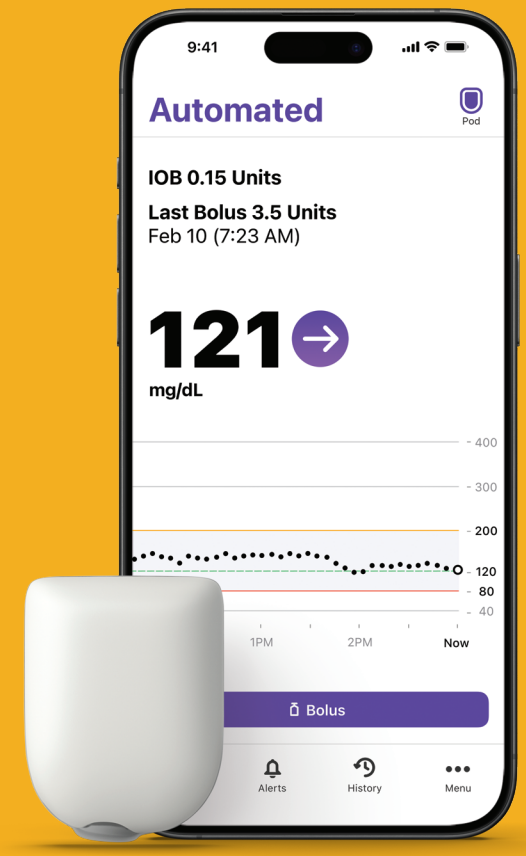
Upper limit for basal rates in a Basal Program or temp basal _____U/hr

Max Bolus

Maximum amount of insulin that you can request in a single bolus ____U/hr

My Notes

omnipod 5



Insulet Corporation
100 Nagog Park
Acton, MA 01720
1-800-591-3455 | 1-978-600-7850
omnipod.com

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

PT-000941

Reference #: PDM-H001-G-MG PT-000941-AW Rev. 06 09/24