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REF PDM-H001-G-XX

Serial Number: _____

Controller FCC ID: 2ADINN5004L

Controller FCC ID: 2ADINN5004LR1

Pod FCC ID: RBV-029

Pod FCC ID: RBV-029C

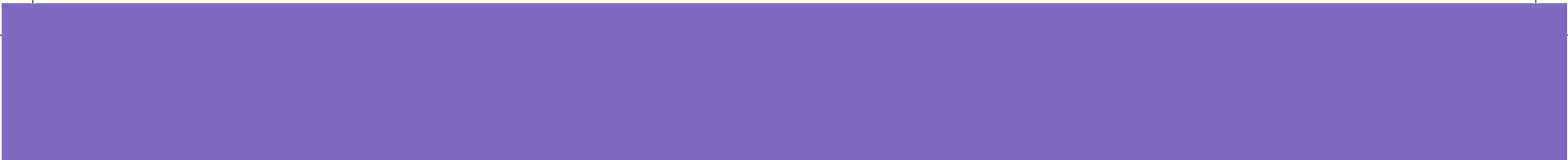
Pod FCC ID: RBV-029D

Pod FCC ID: RBV-029E

Omnipod 5 Automated Insulin Delivery System

Start Date: _____

Healthcare Provider Name Street Address CityStateZip Phone Email	Omnipod Trainer Name Street Address CityStateZip Phone Email
Health Insurance Name Street Address CityStateZip Phone Policy Number	Pharmacy Name Street Address CityStateZip Phone Email



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Patent: www.insulet.com/patents

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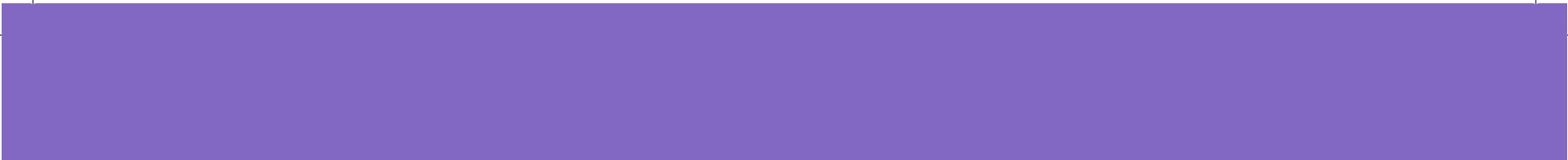
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BEFORE YOU BEGIN

- 1** Introduction





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CHAPTER 1

Introduction

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1 Introduction

1.1 Welcome to Your Omnipod 5 System

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

The follow sensors are compatible with the Omnipod 5 System:

- Dexcom G6 Continuous Glucose Monitoring System
- Dexcom G7 Continuous Glucose Monitoring System
- FreeStyle Libre 2 Plus sensor
- FreeStyle Libre 3 Plus sensor

The Omnipod 5 System Features

- **Pod:** The Pod provides continuous subcutaneous insulin delivery. It may be worn for up to 3 days and can be filled with up to 200 units of U-100 rapid-acting insulin (minimum 85 units).
- **No tubing:** There is no tubing with the Pod allowing you to place the Pod almost anywhere you would give yourself an injection. The Pod is waterproof for depths up to 25 feet (7.6 meters) for up to 60 minutes (IP28).
- **Omnipod 5 App:** The Omnipod 5 App allows you to select a basal profile, target glucose and bolus settings, activate and deactivate the Pod, connect with a compatible glucose sensor, and select insulin delivery mode. The Omnipod 5 App comes installed on an Insulet-provided Controller or can be downloaded to a compatible smartphone. For a list of the latest compatible smartphones, please visit <https://omnipod.com/compatibility>.
- **Compatible glucose sensors:** The Omnipod 5 System is designed to work with either the Dexcom G6 or Dexcom G7 Continuous Glucose Monitoring (CGM) Systems or the Libre 2 Plus or Libre 3 Plus sensors. Sensors must be obtained separately. Sensor glucose values and trends are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode.
 - The Dexcom G6 Transmitter must be connected and active within the Dexcom G6 App to send sensor glucose values to the Pod.

- The Dexcom G7 sensor must be connected and active within the Dexcom G7 App to send sensor glucose values to the Pod. The Dexcom G7 15 Day sensor can communicate with a display device (either a Dexcom receiver or a smartphone using the Dexcom G7 app) while paired with a Pod. Dexcom G6 and Standard Dexcom G7 sensors cannot communicate with a Dexcom receiver while paired with a Pod.
- The Libre 2 Plus sensor must be connected and active within the Omnipod 5 App on the Insulet-provided Controller to send sensor glucose values to the Pod.
- The Libre 3 Plus sensor must be connected and active within the Omnipod 5 App to send sensor glucose values to the Pod.
- **Pod Site tracker:** When activating a new Pod, the System provides the option to track the site on which you have applied a Pod. This allows you to reference past Pod sites when deciding where to place your next Pod.
- **Keeping Track of Sensor Glucose and Insulin:** The Omnipod 5 System records up to 90 days of information, including basal delivery, bolus doses, carbohydrates, alarms, and glucose-related data. In Automated Mode, the system records automated insulin delivery and corresponding sensor glucose values every 5 minutes. The Home screen features a Sensor Graph which allows for reference of your sensor glucose values and displays some information about insulin delivery.

Omnipod 5 SmartBolus Calculator Features

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

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Omnipod 5 Algorithm 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 the Omnipod 5 algorithm 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 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.
- **Compatible glucose sensors:** The Omnipod 5 System is designed to work with either the Dexcom G6 or Dexcom G7 Continuous Glucose Monitoring (CGM) Systems or the Libre 2 Plus or Libre 3 Plus sensors. Sensors must be obtained separately. Sensor glucose values and trends are used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode.
 - The Dexcom G6 Transmitter must be connected and active within the Dexcom G6 App to send sensor glucose values to the Pod.
 - The Dexcom G7 sensor must be connected and active within the Dexcom G7 App to send sensor glucose values to the Pod.
 - The Libre 2 Plus sensor must be connected and active within the Omnipod 5 App on the Insulet-provided Controller to send sensor glucose values to the Pod.
 - The Libre 3 Plus sensor must be connected and active within the Omnipod 5 App to send sensor glucose values to the Pod.
- **Activity feature:** While in Automated Mode, you can enable the Activity feature in times when you need less insulin, for example, when you are getting ready to exercise. When the Activity feature is enabled, the system gives less insulin and aims for a Target Glucose of 150 mg/dL.

- **Keeping track of Automated Insulin:** In Automated Mode, the system records automated insulin delivery and corresponding sensor glucose values every 5 minutes. The Home screen features a Sensor Graph which allows for reference of your sensor glucose values and displays some information about insulin delivery, including automation status.

1.2 About This *Technical User Guide*

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

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

- The Insulet-provided Controller with the Omnipod 5 App.

REF PDM-H001-G-XX

- The Omnipod 5 App on a compatible smartphone. To learn which version of the Insulet-provided Controller you have, turn it over. If you see "PDM-H001-G-XX" on the back of the Controller, this is the correct *Technical User Guide*. If you do not see it, contact Customer Care. Using an incorrect *Technical User Guide* can lead to improper use of the Omnipod 5 System.

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

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

1 Introduction

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.

The Omnipod 5 algorithm 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. The Omnipod 5 algorithm 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. The Omnipod 5 algorithm 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 and using a Dexcom sensor as it could lead to falsely elevated sensor glucose values and result in over-delivery of insulin that can lead to severe hypoglycemia.
- Do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders.

The Pod must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment, and the Controller or 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[®], Admelog[®], and Kirsty[®].

The Omnipod 5 algorithm is compatible with the following U-100 insulins: NovoLog[®], Humalog[®], Admelog[®], and Kirsty[®].

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

1 Introduction

1.5 General Warnings

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

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

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

Warning: DO NOT use the Omnipod 5 System if you are unable or unwilling to use it as instructed by this *Technical User Guide* and your healthcare provider. Failure to use this system as intended could result in over-delivery or under-delivery of insulin which can lead to 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 The Omnipod 5 algorithm in pregnant women, critically ill patients, and those on dialysis. The safety of The Omnipod 5 algorithm has not been evaluated in these populations. Consult with your healthcare provider if any of these conditions apply to you before using The Omnipod 5 algorithm.

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), Admelog (insulin lispro), and Kirsty (insulin aspart) insulin in the Omnipod 5 System as they have been tested and found to be safe for use with this system. NovoLog, Humalog, Admelog, and Kirsty 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 () 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.

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

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

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

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

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

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

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

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

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

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

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

Warning: DO NOT use the Omnipod 5 System with the Libre 2 Plus or Libre 3 Plus sensor if you are taking more than 1000 mg of ascorbic acid (Vitamin C) per day, a substance found in supplements like multivitamins or cold remedies such as Airborne® and Emergen-C®. Taking more than 1000 mg of Vitamin C per day may falsely raise your sensor readings and result in over-delivery of insulin that could result in severe hypoglycemia.

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

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) (see "⚠ Blockage Detected" on page 185).

Warning: The Omnipod 5 algorithm should NOT be used by anyone under the age of 2 years old. The Omnipod 5 algorithm 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.

1 Introduction

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

Warning: DO NOT use the Omnipod 5 System in high atmospheric pressure environments (above 1060 hPA), which can be found in a hyperbaric chamber. Hyperbaric, or high pressure, chambers, are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to high atmospheric pressure environments can damage your Pod and Omnipod 5 Controller which could result in under-delivery of insulin which can lead to hyperglycemia.

1.6 General Precautions

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

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

Caution: ONLY use the Omnipod 5 System with authorized devices (Omnipod 5 App, Controller and Pod, and Libre 2 Plus or Libre 3 Plus sensors or Dexcom G6 or Dexcom G7 CGM). DO NOT attempt to use the Omnipod 5 System with unauthorized devices. Attempting to use the Omnipod 5 System with unauthorized devices could interrupt your insulin delivery and put your health and safety at risk.

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

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

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

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

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

1 Introduction

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: Dexcom G6 and Standard Dexcom G7 sensors cannot communicate with a Dexcom receiver while paired with a Pod. The Dexcom G7 15 Day sensor can communicate with a display device (either a Dexcom receiver or a smartphone using the Dexcom app) while paired with a Pod.

Caution: During the first 12 hours of use of a Libre 2 Plus or Libre 3 Plus sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

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

Potential Benefits

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

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

Potential Risks

- The Omnipod 5 System uses sensor glucose values and trends to calculate insulin delivery. If the sensor glucose values are inaccurate, the System could deliver an inaccurate dose of insulin which can lead to hypoglycemia or hyperglycemia.
- The Omnipod 5 System uses information and settings that you enter to calculate and adjust insulin delivery. If the information you enter is inaccurate, or if you don't give the System information about carbs and glucose, the System could deliver an inaccurate dose of insulin which can lead to hypoglycemia or hyperglycemia.
- Wearing a Pod might cause infection. Be aware of signs of infection, including: bleeding, pain, and skin irritation, including redness. See your healthcare provider if irritation occurs.
- Kinks in the cannula or dislodging of the cannula can interrupt insulin delivery. Glucose that does not decrease after a bolus, or other unexplained high glucose, are signs of a blockage (occlusion) or other interruption in insulin delivery.
- Air bubbles in the Pod or cannula can affect insulin delivery. If there is a large amount of air in the Pod, the System could deliver an inaccurate dose of insulin which can lead to hypoglycemia or hyperglycemia.
- Infusion site complications like scar tissue and infection can make insulin delivery less effective. Glucose that does not decrease after a bolus, or other unexplained high glucose, is a sign of ineffective insulin delivery.
- Hardware defects, software glitches, and Pod failures can cause an interruption in insulin delivery. A Pod failure can lead to hypoglycemia, hyperglycemia, or diabetic ketoacidosis. Keep your Omnipod 5 Controller and/or smartphone on and nearby to ensure you are notified of recent insulin delivery and important alarms and messages.

1 Introduction

Important User Information

Pay special attention to Warnings and Precautions in this *Technical User Guide*. The words “**Warning**” and “**Caution**” are displayed in red, bolded text.

The Omnipod 5 System is designed to work with either the Dexcom G6, Dexcom G7, Libre 2 Plus, or Libre 3 Plus sensors.

- To use the Dexcom G6 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G6 sensor, Transmitter, and Instructions for Use and download the Dexcom G6 App on your personal smartphone.
- To use the Standard Dexcom G7 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G7 sensor and Instructions for Use, and download the Dexcom G7 App on your personal smartphone.
- To use the Dexcom G7 15 Day CGM with the Omnipod 5 System, you will need to obtain the Dexcom G7 sensor and *Instructions for Use* and either obtain a Dexcom receiver or download the Dexcom G7 app on your personal smartphone.
- To use the Libre 2 Plus sensor with the Omnipod 5 System, you will need to obtain Libre 2 Plus sensors and the Libre 2 Plus sensor Instructions for Use.
- To use the Libre 3 Plus sensor with the Omnipod 5 System, you will need to obtain Libre 3 Plus sensors and the Libre 3 Plus sensor Instructions for Use.

If you are new to using a glucose sensor, continue using your blood glucose meter until you are familiar with sensor usage.

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

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

Emergency Kit

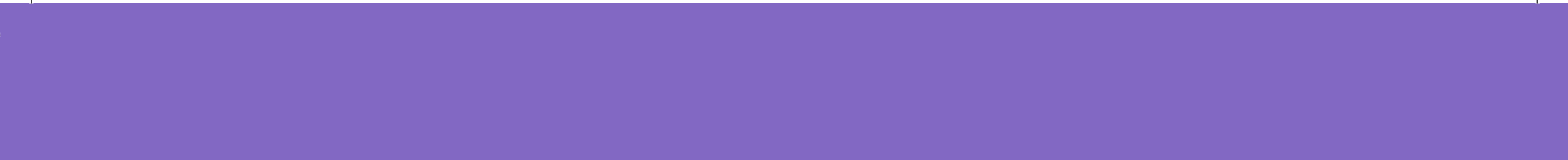
Warning: ALWAYS keep an emergency kit with you to quickly respond to any diabetes emergency or in the case that your Omnipod 5 System stops working. Always carry supplies to perform a Pod change should you need to replace your Pod at any time.

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

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

- Several new, sealed Omnipod 5 Pods
- A vial of rapid-acting U-100 insulin (see "1.5 General Warnings" on page 10 for insulins cleared for use in the Omnipod 5 Pod).
- Syringes or pens for injecting insulin
- Glucose tablets or another fast-acting source of carbohydrate
- Glucose sensor supplies
 - Dexcom G6 or Dexcom G7 Continuous Glucose Monitor (CGM) System and supplies.
 - Libre 2 Plus or Libre 3 Plus sensors
- Blood glucose test strips
- Blood glucose meter
- Ketone test strips
- Lancing device and lancets
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted.
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System.
- Phone numbers for your healthcare provider and/or physician in case of an emergency.
- Glucagon kit and written instructions for administering glucagon dosage if you are unconscious (see "Avoiding Lows, Highs, and Diabetic Ketoacidosis" on page 239).

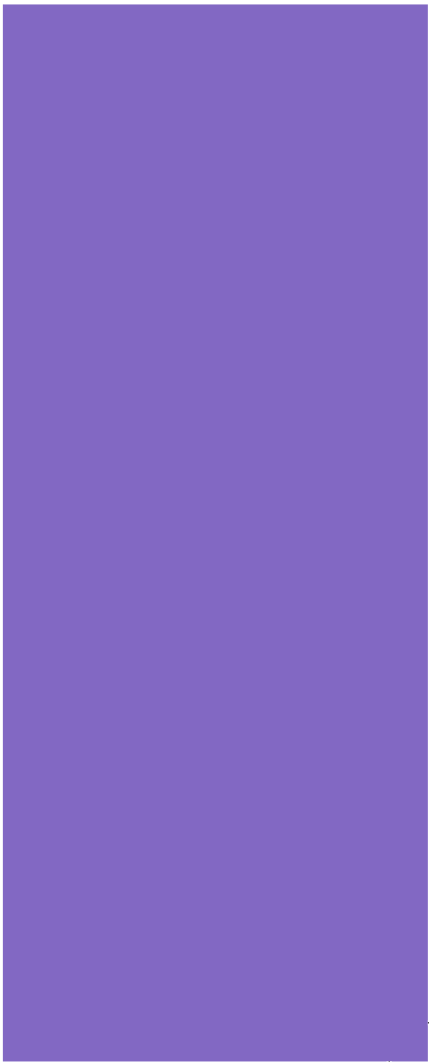
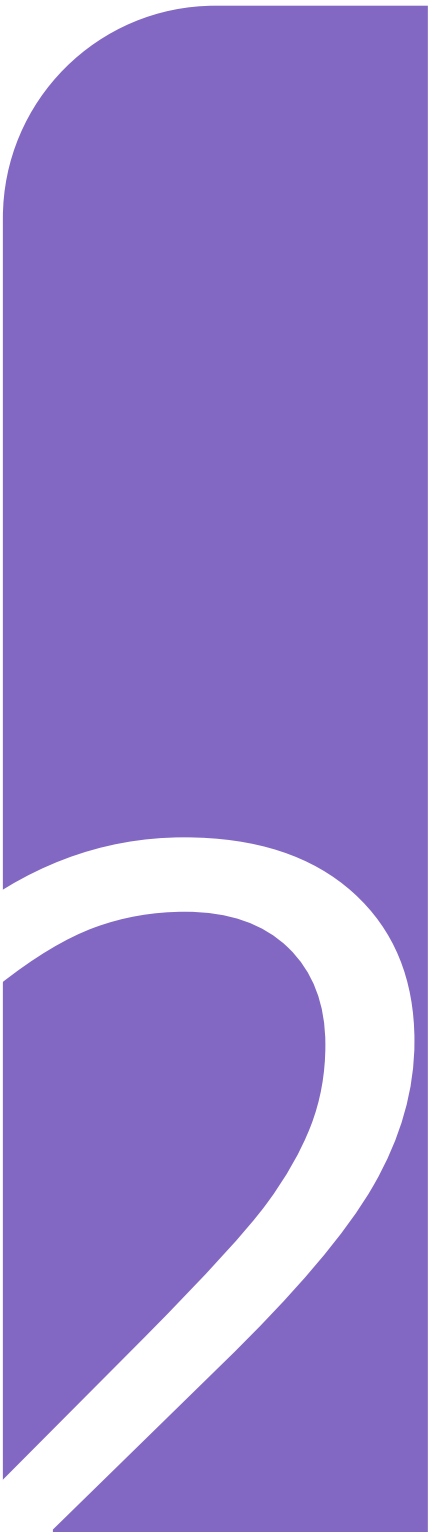
Tip: Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.

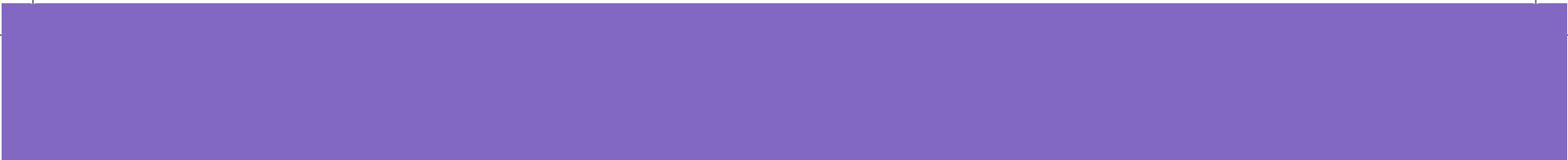


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OMNIPOD 5 PUMP FEATURES

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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), Admelog (insulin lispro), and Kirsty (insulin aspart) insulin in the Omnipod 5 System as they have been tested and found to be safe for use with this system. NovoLog, Humalog, Admelog, and Kirsty are compatible with the Omnipod 5 System for use up to 72 hours (3 days). Follow

your healthcare provider’s directions for how often to replace the Pod.

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

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

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

Important Safety Information

Omnipod 5 System

Warning: ALWAYS remove and dispose of the Pod before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan (or any similar test or procedure). In addition, place the Controller or smartphone outside of the procedure room. Exposure to X-ray, MRI, or CT treatment can damage these components. Check with your healthcare provider for Pod removal guidelines.

If your sensor's instructions for use indicate that the sensor is approved for X-rays, MRIs, or CT scans, and you do not remove the sensor during these procedures, DO NOT use Automated Mode and ALWAYS use a blood glucose reading when bolusing after the procedure. For information about when you can once again use sensor glucose values after the procedure, see your sensor's instructions for use.

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

Pod

Warning: Do NOT use a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin. Applying a Pod under these

circumstances could put your health at risk.

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

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

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

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

Important Safety Information

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

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

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

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

Warning: DO NOT 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 continue using an activated Pod that fails to beep during a diagnostic test. The Pod should be changed immediately. If the Omnipod 5 App fails to beep during a diagnostic test, contact Customer Care immediately. Continuing to use the Omnipod 5 System in these situations may put your health and safety at risk.

Important Safety Information

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

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

Warning: DO NOT use the Omnipod 5 System in high atmospheric pressure environments (above 1060 hPA), which can be found in a hyperbaric chamber. Hyperbaric, or high pressure, chambers, are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness. Exposure to high atmospheric pressure environments can damage your Pod and Omnipod 5 Controller which could result in under-delivery of insulin which can lead to hyperglycemia.

Controller and Smartphone

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

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

Important Safety Information

Warning: ALWAYS contact Customer Care if your Omnipod 5 System Controller is damaged and not working properly. If a Controller replacement is needed, ALWAYS consult with your healthcare provider to get instructions on using other backup insulin delivery methods, like insulin injections. Make sure to check your glucose frequently.

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

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

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

Alarms

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

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

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) "⚠️ Blockage Detected" on page 185.

Glucose Monitoring

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

Important Safety Information

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

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

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

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

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

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

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

Important Safety Information

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

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

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

Pump Precautions

Omnipod 5 System

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

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

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

Caution: If you decide later to switch between the Controller and your smartphone, you will need to start setup again on the new device. New setup requires entry of all your personalized settings. Consult with your healthcare provider if you are unsure about how to set up the new device. If you are wearing a Pod and need to switch devices, you will need to deactivate your Pod and activate a new one, since the Pod cannot communicate with two devices at one time. If possible, wait to switch between devices until a scheduled Pod change.

Important Safety Information

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

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

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

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

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

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

Important Safety Information

Pod

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

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

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

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

- Wash your hands.
- Clean the top of the insulin vial with an alcohol prep swab.

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

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

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

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

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

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

Important Safety Information

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

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

Controller

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

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

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

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

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

Caution: Use ONLY the charging adapter and orange or black charging cable that came with your Controller, as they are designed to limit the power to safely charge the battery. Third-party accessories may allow much higher power, increasing the risk of overheating, spark, or fire, which may lead to minor injuries or serious burns.

Important Safety Information

Caution: ALWAYS follow safe guidelines for charging your Controller. Before each charge, check the Controller, cable, and adapter, and do not use them if they are damaged. Do not force or bend the end of the charging cable into the Controller charging port. Monitor the Controller while it's charging. Always charge your Controller on a hard, flat surface away from flammable items (like bedding or paper), and never cover your Controller while charging. Unplug your Controller immediately if it feels too hot, and make a habit of unplugging it when it reaches 100% charge.

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

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

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

Smartphone

Caution: DO NOT navigate away from the Omnipod 5 App while you are in the process of making changes to your insulin delivery settings. If you leave the

app before saving the setting change and before the app puts the setting change into effect, the system will continue to use your last saved settings. As a result, you may continue with therapy settings that you did not intend. If you are unsure about whether your changes were saved, review your settings. DO NOT stop the Omnipod 5 App in a way that stops it from running in the background (called force stopping) on your smartphone. The Omnipod 5 App must be open or be running in the background in order to display and sound alarms on the smartphone. If the app is not running, you could miss important alarms and notifications on the smartphone. If you do not hear alarms and notifications from your smartphone, you might not make the changes you need to make to your therapy in a timely manner. Your Pod will continue to operate and sound alarms. In addition, if you stop the Omnipod 5 App while sending commands to the Pod, the command can be interrupted and may not be completed.

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

Important Safety Information

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

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

Communication

Caution: When there is no communication between the Pod and the Controller or smartphone, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode. Restoring communication is needed to see your system status, notifications, and to send new instructions to the Pod. To restore communication try bringing the Controller or smartphone within 5 feet (1.5 m) of the Pod. See "28.5 Pod Communication Issues – "Try Again"" on page 460.

Caution: DO NOT use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 12 inches (30 cm) to any part of the Omnipod 5 System, as it may impact the communication between your smartphone or Controller and your Pod.

Alarms and Sound

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

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

Caution: ALWAYS check the alarm function when you change the Pod if you suspect any issue with the Pod's sounds to ensure you don't miss important alarms during use (see "Check alarms" on page 184).

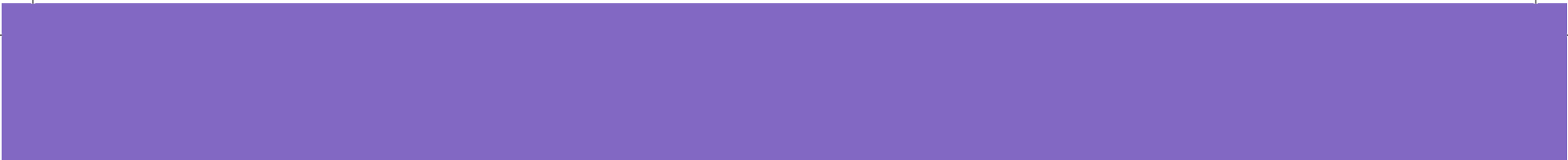
Caution: ALWAYS make sure you can hear alarms and notifications when paired to alternative audio devices (e.g. Bluetooth speaker, headphones).

Important Safety Information

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App. Avoid the use of tools that limit sounds and notifications, including but not limited to:

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

If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able to see the Alarm or Notification displayed on the Omnipod 5 App.



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CHAPTER 2

System Terminology and Navigation

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2 System Terminology and Navigation

2.1 Terminology

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

Carbs (carbohydrates)	Sugars and starches that are consumed and the body breaks down into glucose.
Connecting	In Omnipod 5 , "connecting" refers to setting up wireless communication between system components. Omnipod 5 uses Bluetooth® wireless technology to communicate with your Pod and from the sensor to the Pod.
Controller	Omnipod 5 device, supplied by Insulet, that contains the Omnipod 5 App for use to control the Omnipod 5 System. A compatible personal smartphone may be used with the Omnipod 5 App installed instead of a Controller. Throughout the <i>Technical User Guide</i> , the term Controller refers to the handheld Insulet-provided device.
Deactivate	Preferred method for shutting down the Pod. Deactivation turns off insulin delivery in the Pod and allows the Omnipod 5 App to activate a new Pod.
Device	In Omnipod 5 , “device” refers to the smartphone or Omnipod 5 Controller used to control the Omnipod 5 App.
Discard Pod	When a communication problem prevents you from deactivating a Pod, the DISCARD option allows Omnipod 5 to activate a new Pod without shutting down the active Pod. Always remove a "discarded" Pod from your body, as it may still be delivering insulin.
Hazard Alarm	An alarm that alerts you to a problem with the Omnipod 5 System that needs your immediate attention, such as a disruption to your insulin delivery.
Hyperglycemia	High glucose. A higher-than-normal level of glucose in the blood; generally above 250 mg/dL.
Hypoglycemia	Low glucose. A lower-than-normal level of glucose in the blood; generally below 70 mg/dL.

2 System Terminology and Navigation

Hypoglycemia unawareness	A condition in which a person does not feel or recognize the symptoms of hypoglycemia.
Infusion site	The place on the body where a Pod's cannula is inserted to deliver insulin.
Insulin on board (IOB)	Insulin that is still active (available to lower glucose) in the body.
Ketoacidosis (Diabetic ketoacidosis, or DKA)	Diabetic ketoacidosis (DKA) is a serious condition in which extremely high glucose and a severe lack of insulin cause the body to break down fat for energy. The breakdown of fat releases ketones into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.
Ketones	Acidic by-products that result from the breakdown of fat for energy. The presence of ketones indicates that the body is using stored fat (instead of glucose) for energy.
Line of sight	How to wear the Pod and sensor on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.
Manual bolus	A bolus amount chosen by you (not calculated by the SmartBolus Calculator).
Manual Mode	Insulin delivery method that delivers insulin amounts according to the basal rates in your Basal Program.
Microbolus	A small amount of insulin calculated by the Omnipod 5 algorithm delivered automatically by the Pod every 5 minutes during Automated Mode.

Omnipod 5 algorithm	Pod software used to calculate automated insulin delivery to bring your glucose to your customized glucose target, or Target Glucose. Every 5 minutes, the System makes a decision about your insulin. It pauses or decreases insulin to protect against hypoglycemia or corrects for hyperglycemia.
Omnipod 5 Application (App)	Software on the Controller or smartphone that is the primary user interface of the Omnipod 5 System.
Sensor Glucose Monitoring System	System to track glucose throughout the day and night, supplied by a third-party medical device manufacturer. Also known as Continuous Glucose Monitor (CGM).
Sensor	Component of a sensor glucose monitoring system that is inserted under the skin to measure glucose in interstitial fluid.
Transmitter	Component of a sensor glucose monitoring system that sends sensor glucose values to the Pod (Dexcom G6 only).
Sensor Glucose Value	Glucose measured by a sensor. Sensor glucose values include trend, which indicates whether your glucose is going up, down, or remaining steady.
Target Glucose	The user-customizable glucose target used by both the Omnipod 5 algorithm and the Omnipod 5 SmartBolus Calculator to calculate how much insulin you need based on both your manually entered blood glucose readings and the glucose values from your sensor. Target Glucose can be set from 100–150 mg/dL in 10 mg/dL increments. Note: The 100 mg/dL Target Glucose setting is available only when using a Pod with a software version of 12.0 or greater.
Units	How insulin is measured.

2 System Terminology and Navigation

2.2 Using the Touchscreen and Entering Information

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

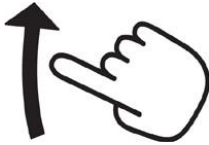
Note: If you are using your smartphone with the Omnipod 5 App, images in this section may differ from your smartphone.

Touchscreen Basics

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

Tapping and swiping

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

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

Note: A screen protector may decrease the touchscreen sensitivity.

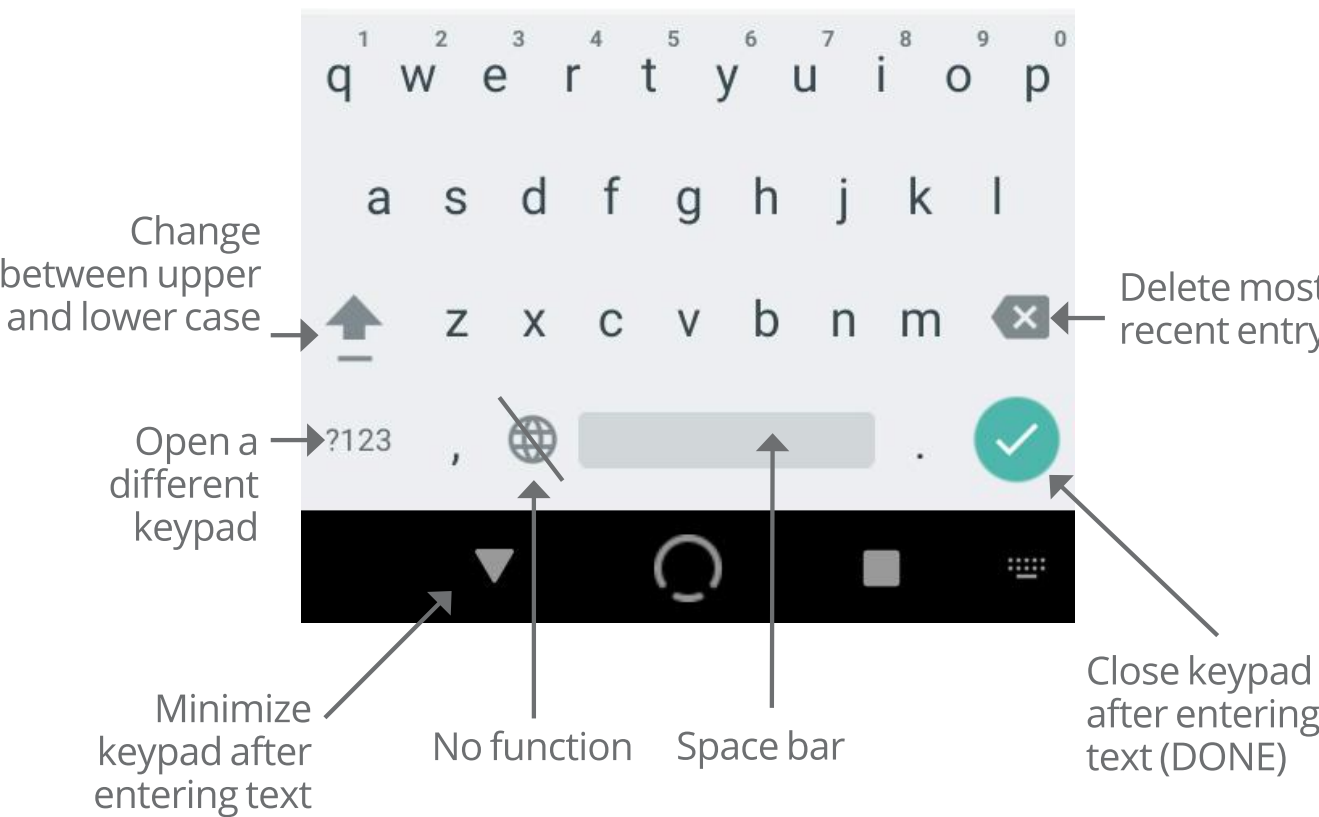
Screen time-out and brightness

The screen on the Controller turns black, called "timing-out", after a period of inactivity. To control the screen time-out and brightness settings, see "Screen Display" on page 145. The screen dims 6-10 seconds before it times out. If the screen dims, tap the screen to prevent it from timing out.

Entering Numbers and Text

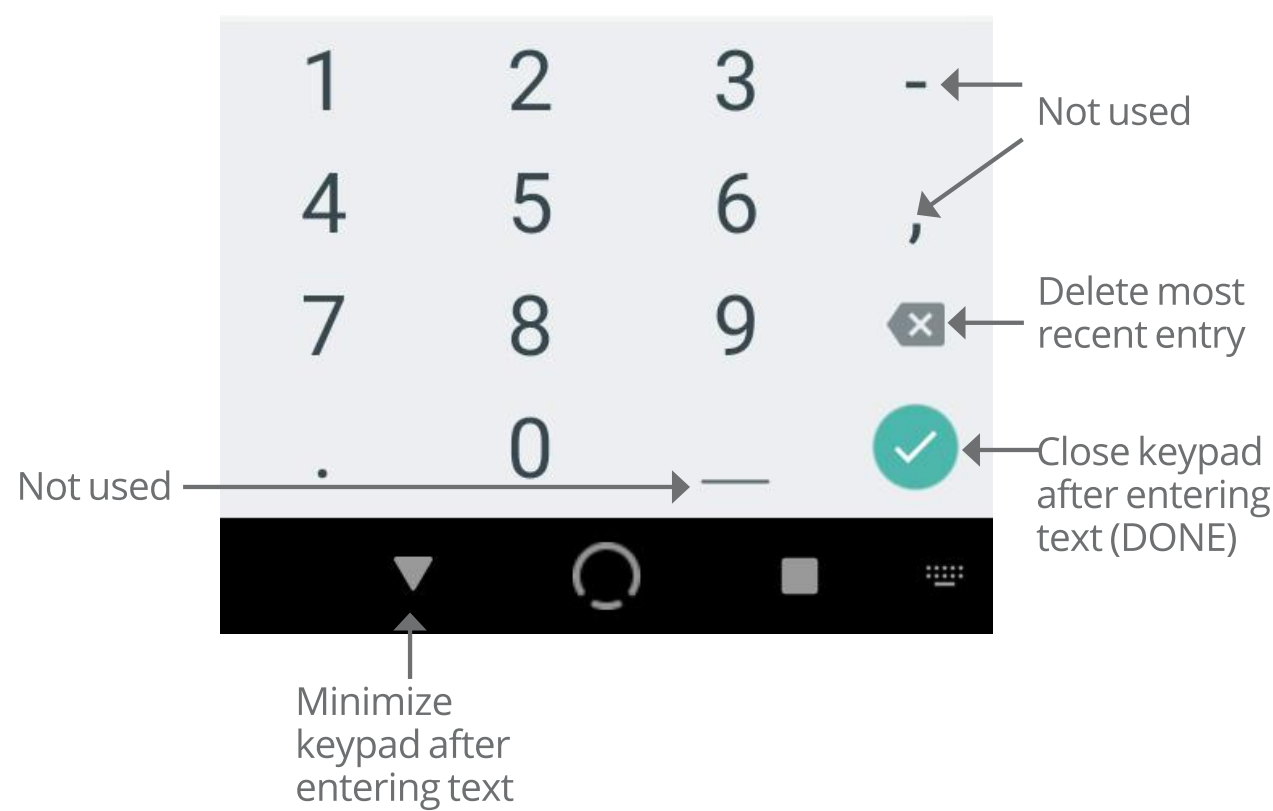
Tapping in an editable field can bring up a keypad or number pad.

Using a keypad



2 System Terminology and Navigation

Using a number pad



Using a scroll wheel

Basal Rate	
☐	0.60 U/hr
☐	0.65 U/hr
☐	0.70 U/hr
☒	0.75 U/hr
☐	0.80 U/hr
CANCEL DONE	

Tapping an editable field can bring up a scroll wheel. Place your finger on the scroll wheel. Swipe up or down to select your desired value.

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

Selecting, Adding, and Deleting Items

Toggles

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

Add and delete buttons

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

Navigation Buttons and Navigation Shorthand



Options button

The Options button () appears on the right side of certain lists. Tapping the Options button brings up a list of options relevant to the item on that row.

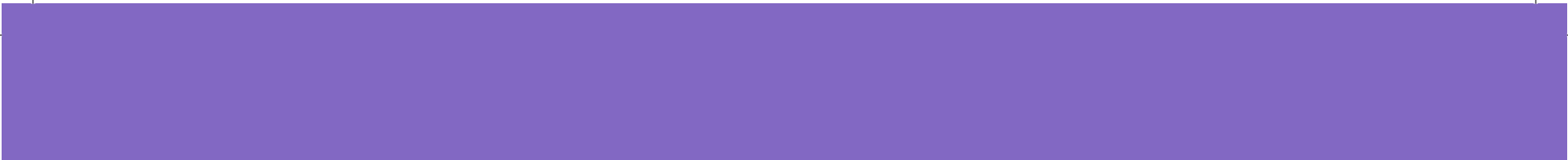
Technical User Guide navigation shorthand

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

- **Menu button** () > **Pod** > **CHANGE POD**

tells you to:

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



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CHAPTER 3

Omnipod 5 System Overview

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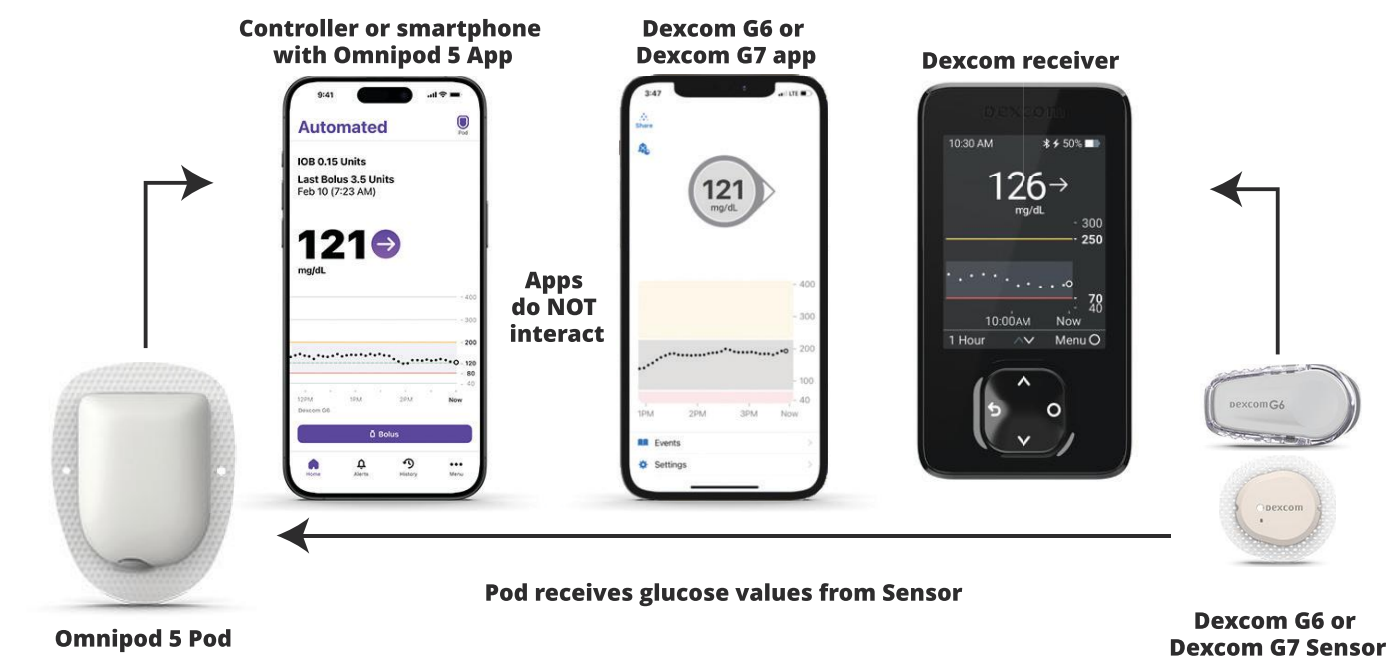
3.1 Omnipod 5 App and Sensor Communication

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

Omnipod 5 App and Dexcom Communication

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

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

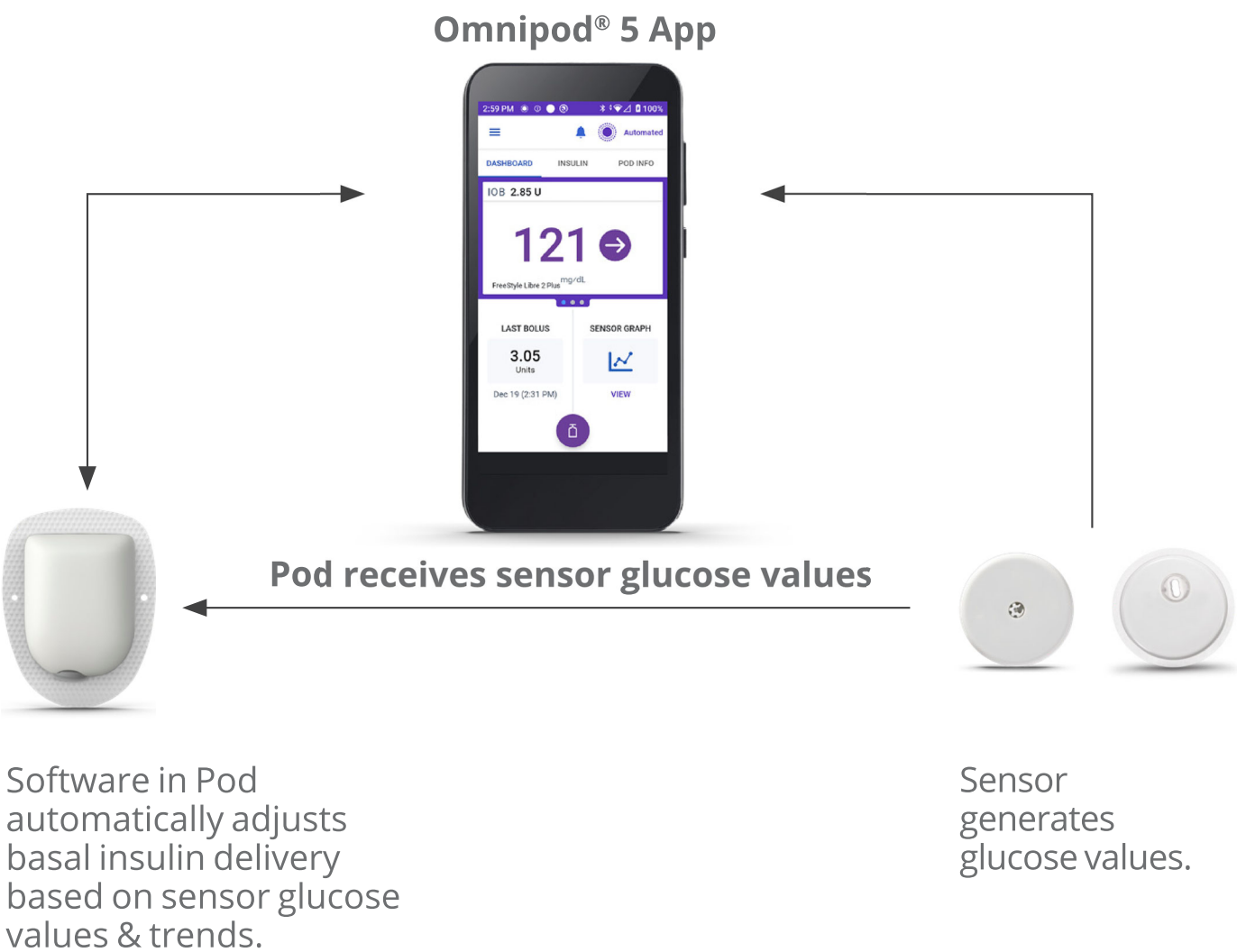


Omnipod 5 App and Libre Plus Sensor Communication

The Omnipod 5 System communicates with Libre Plus sensors.

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

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



3 Omnipod 5 System Overview

3.2 Omnipod 5 App

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

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

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

The Omnipod 5 Controller



3.3 Lock Screen and Security

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

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

Omnipod 5 App Security on Your Controller

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

The Lock screen displays:

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

Unlock your Controller

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

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

Note: If you enter the number incorrectly 5 times, there will be a delay before you can try again

4. Tap **OK**. The Home screen or your most recent screen appears.

3 Omnipod 5 System Overview

Lock your Controller

To lock your Controller when you are finished using it:

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

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

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

Forgot your PIN?

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

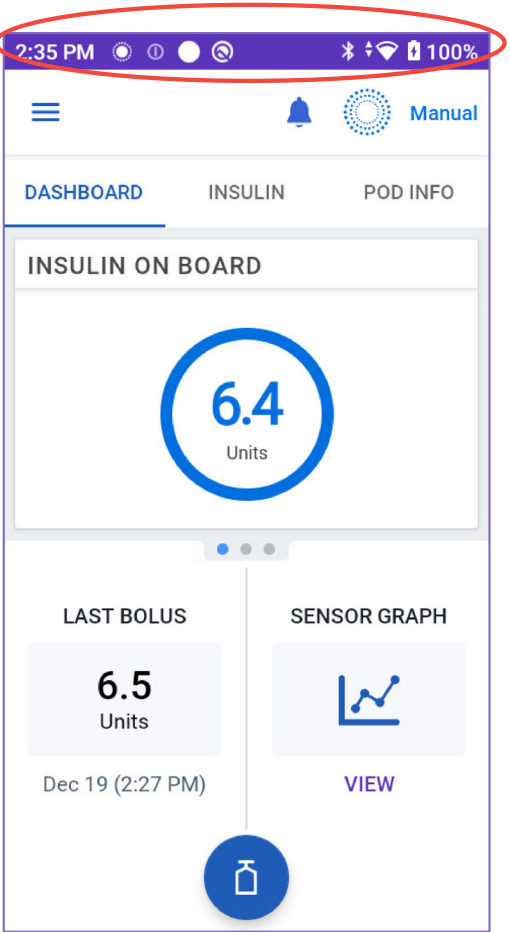
3.4 Status Bar

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

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

Status bar icon definitions:

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



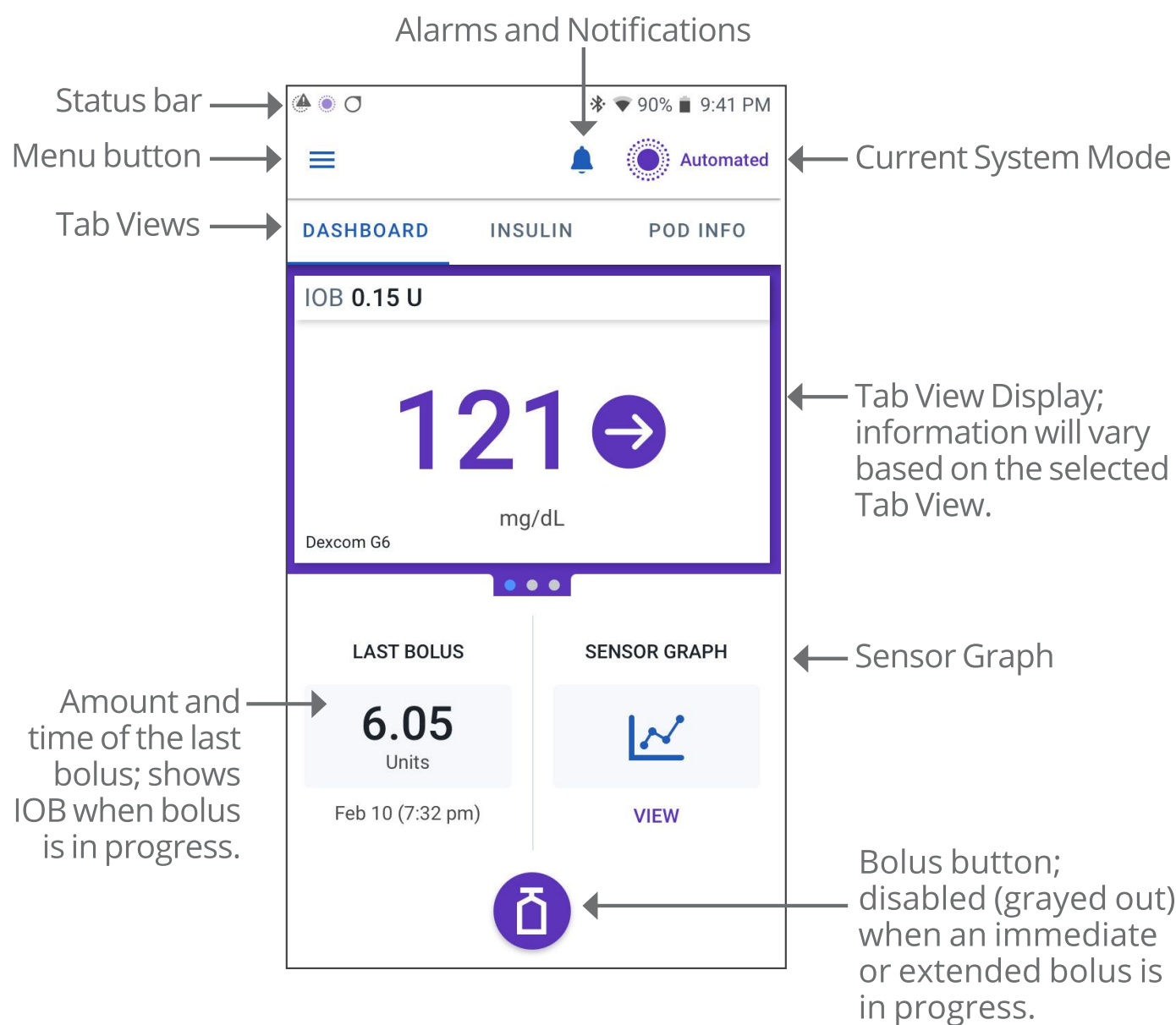
Note: Swipe down from the status bar for more details on what's currently displayed on the status bar. Then, swipe up to close.

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

3 Omnipod 5 System Overview

3.5 Home Screen

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



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

- Tap **DASHBOARD, INSULIN, or POD INFO.**
- Swipe right or left in the middle portion of the screen (directly below the Home screen tabs) to move between tab views.
- If an immediate bolus is in progress, a bolus progress bar and a button to cancel the bolus are shown on the Home screen. The three tabs are not visible if an immediate bolus is running. (See "17.9 Delivering an Immediate Bolus" on page 271).

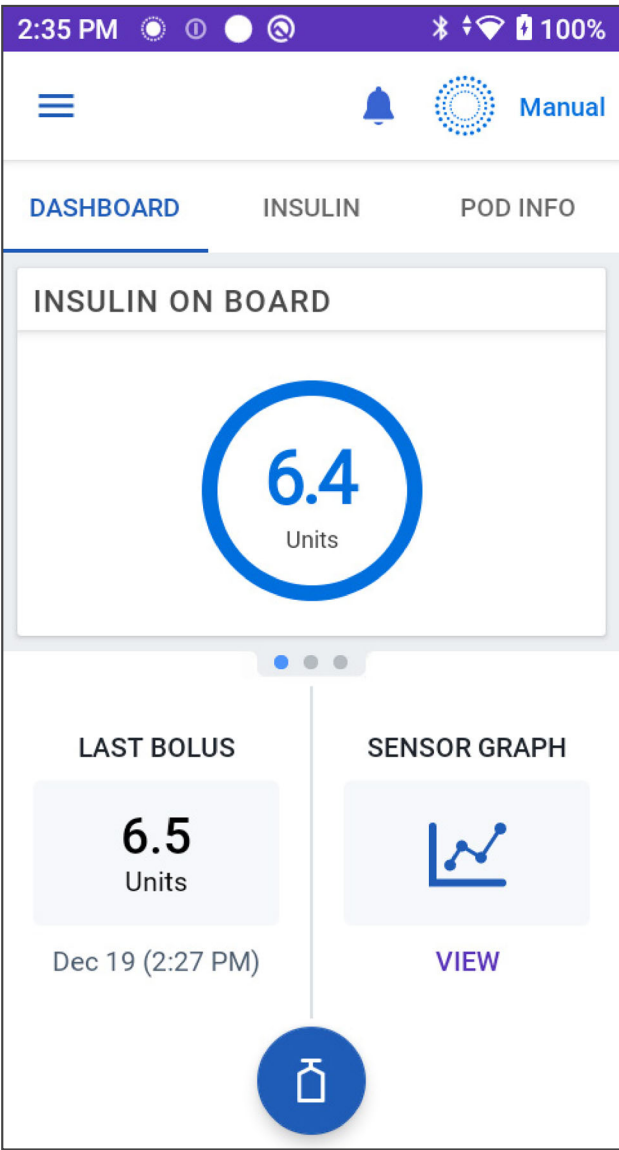
DASHBOARD Tab

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

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

Without paired sensor or Transmitter

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



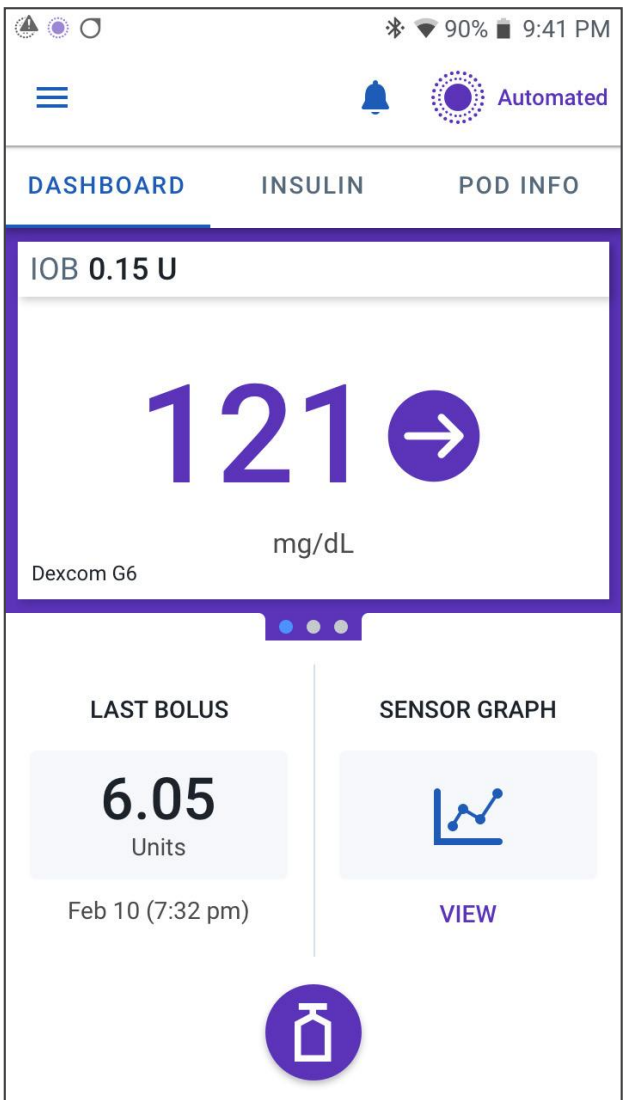
3 Omnipod 5 System Overview

With paired sensor or Transmitter

- **INSULIN ON BOARD (IOB)**
- **Sensor glucose value** (with trend arrow): when a sensor glucose value is available. See "19.5 Sensor Glucose Trend Arrows" on page 311.
- **Sensor glucose value** (without arrow): when sensor supplies a sensor glucose value but is unable to report sensor glucose trend.
- **HIGH:** when sensor glucose value received from your sensor is greater than 400 mg/dL.
- **LOW:** when sensor glucose value received from your sensor is less than 40 mg/dL.

The **DASHBOARD** tab also displays information related to potential sensor communication issues. See Dexcom G6 Communication Messages on page 312 for more information.

A progress bar appears when a bolus is in progress (see "16.3 Tracking the Progress of a Bolus" on page 258).



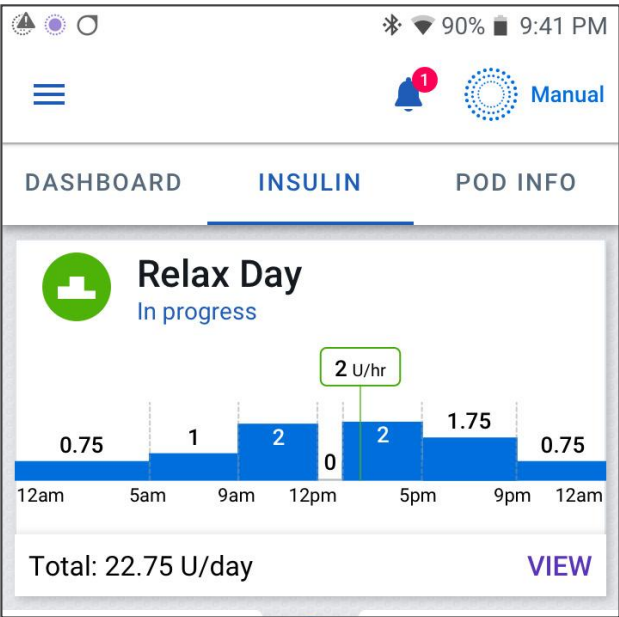
INSULIN Tab

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

Manual Mode

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

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



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

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

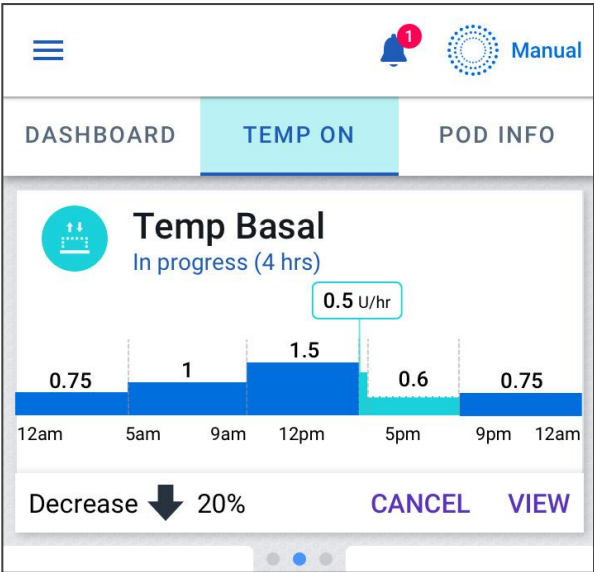
To see the total amount of insulin that your Pod has actually delivered, including temp basals and boluses, see "Browsing Your History and Records" on page 153.

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

3 Omnipod 5 System Overview

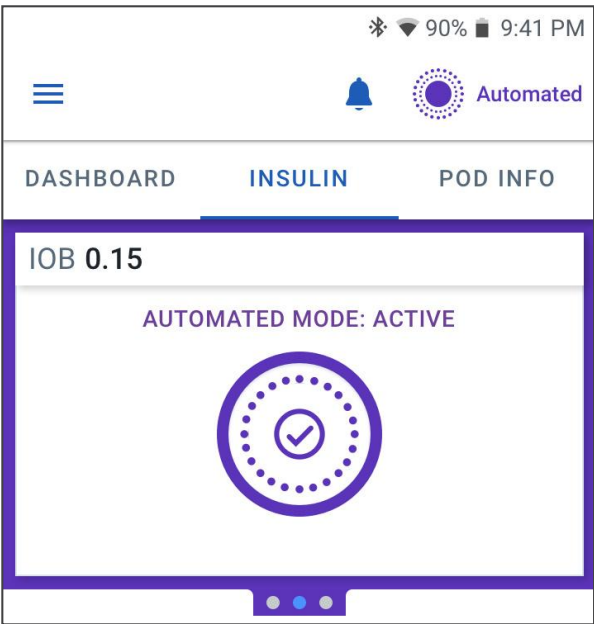
Temp basal

When a temp basal is running, the **INSULIN** tab label changes to **TEMP ON** and is highlighted in light blue. It displays the temp basal graph and allows you to cancel the temp basal. See "7.1 About Temporary Basal Rates" on page 124.



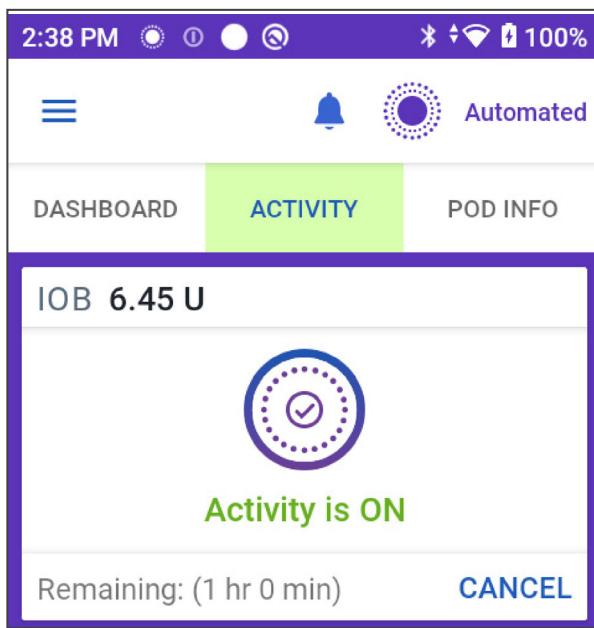
Automated Mode

In Automated Mode, the **INSULIN** tab shows **AUTOMATED MODE: ACTIVE** and displays **LAST BOLUS** and **SENSOR INFO**. For more information on using Automated Mode, see "23.1 About Automated Mode" on page 370.



Activity feature

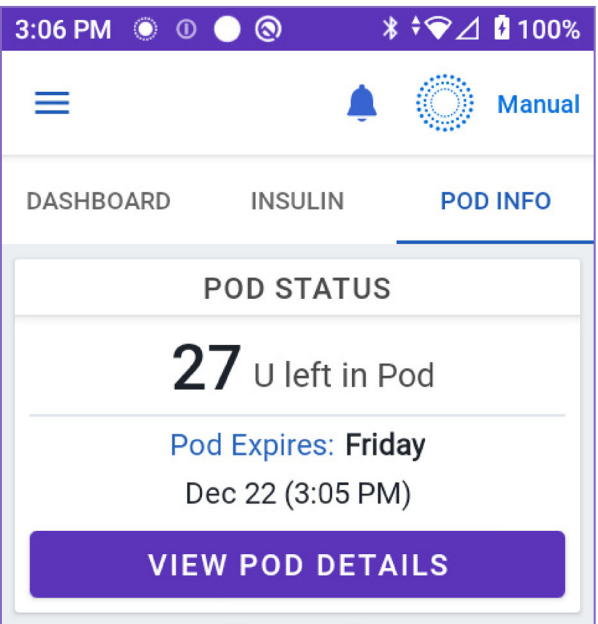
In Automated Mode, when the Activity feature is enabled, the **INSULIN** tab label changes to **ACTIVITY**, highlighted in green, and shows **Activity is ON**. See "25.1 About the Activity Feature" on page 386 for more information.



POD INFO Tab

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

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



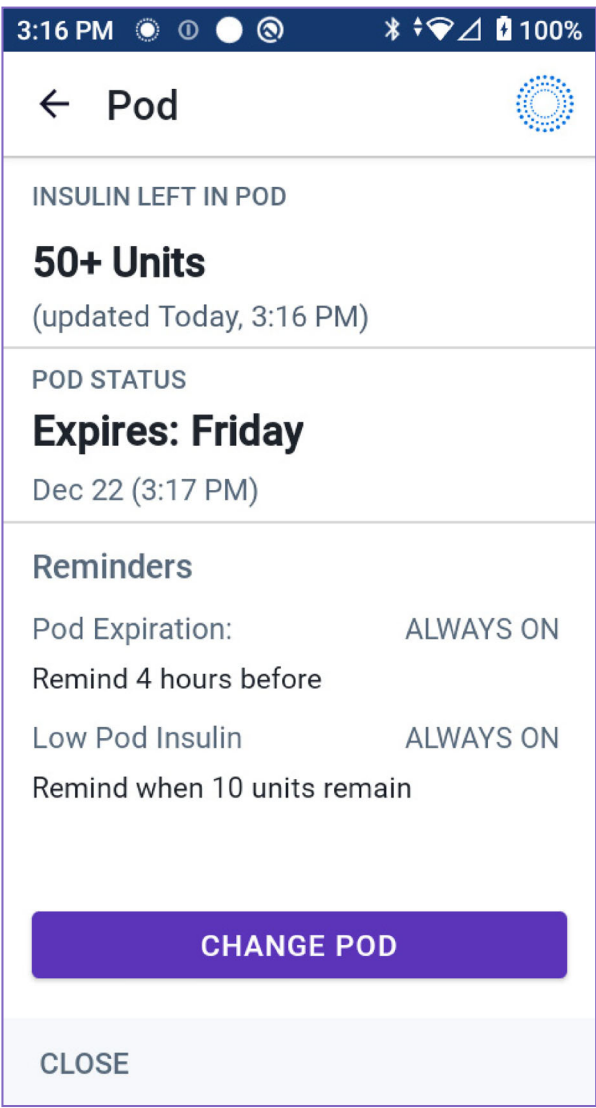
Caution: When there is no communication between the Pod and the Controller or smartphone, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode. Restoring communication is needed to see your system status, notifications, and to send new instructions to the Pod. To restore communication, try bringing the Controller or smartphone within 5 feet (1.5 m) of the Pod. See "28.5 Pod Communication Issues – "Try Again"" on page 460.

If there is no active Pod, the **POD INFO** tab shows "**No Active Pod.**" To set up a new Pod, see "Activating and Changing Your Pod" on page 97.

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

The **VIEW POD DETAILS** screen shows:

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

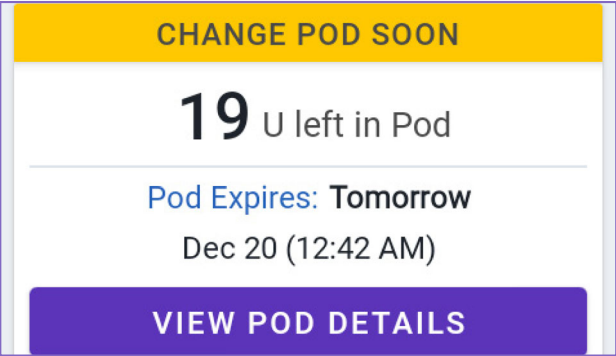


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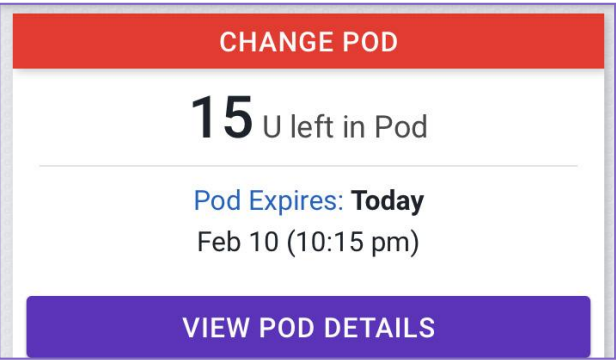
Tip: You can also access this screen by tapping **Menu button** () > **Pod**.

POD INFO banners

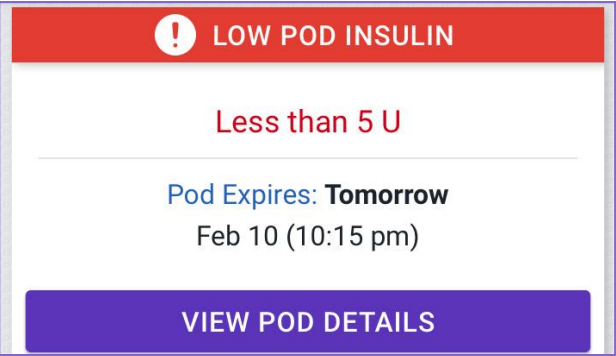
When your Pod will expire soon, a yellow **CHANGE POD SOON** banner appears on the **POD INFO** tab. The yellow banner appears 12 hours before Pod expiration or at the time of your Pod expiration reminder, whichever is earlier.



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



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



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

Bolus Information and Button

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

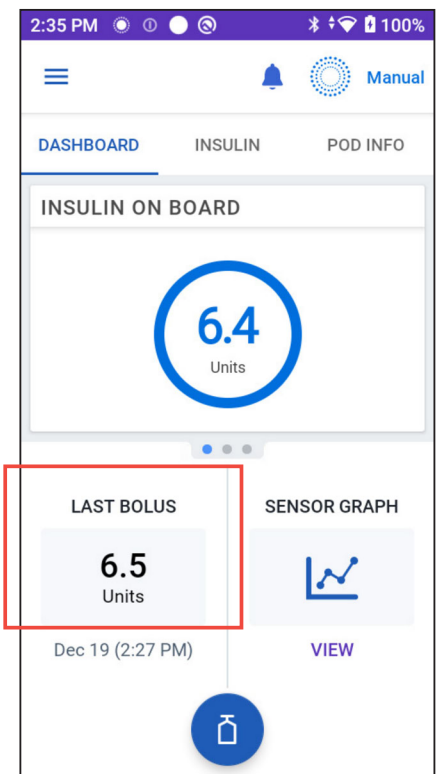
Between boluses

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

During a bolus

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

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



Bolus information if there is no Pod communication

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

Estimated and unconfirmed bolus amounts

The Omnipod 5 App estimates bolus amounts during an ongoing bolus and when the Pod is out of range. A gray icon (ⓘ) marks estimated bolus amounts. A yellow icon (⚠) marks unconfirmed bolus amounts (see "When the Pod has not confirmed a bolus delivery" on page 164).

Bolus button

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



3 Omnipod 5 System Overview

3.6 Home Screen Main Menu

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

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

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

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

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

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

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

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

About screen

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

3.7 Notifications and Messages

Caution: DO NOT stop the Omnipod 5 App in a way that stops it from running in the background (called force stopping) on your smartphone. The Omnipod 5 App must be open or be running in the background in order to display and sound alarms on the smartphone. If the app is not running, you could miss important alarms and notifications 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 prevents you from hearing alarms and notifications from your Omnipod 5 App. Avoid the use of tools that limit sounds and notifications, including but not limited to:

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

If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able see the Alarm or Notification displayed on the Omnipod 5 App.

3 Omnipod 5 System Overview

Note: The Omnipod 5 App on your smartphone requires Do Not Disturb permission and Notifications to be turned ON to ensure you always receive important safety alarms. You cannot use the app until Do Not Disturb permission is provided and Notifications is turned ON.

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

Omnipod 5 Notifications

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

Alarms

Alarms require your immediate attention (see Responding to Alarms on page 182). 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 Action Item Notification List on page 198) are for technical System tasks that should be responded to as soon as possible. Action item notifications are related to changes you may have made to your Omnipod 5 app that could affect safe use of the system. For example, a **Turn on Bluetooth** action item means Bluetooth wireless technology has been shut off and your App is no longer communicating with your Pod.

Reminder notifications

Reminder notifications (🕒) remind you about diabetes management actions you may want to perform (see "13.10 Reminder Notifications List" on page 221).

Status

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

Confirmation Messages

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

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

If an instruction is not successful, the Omnipod 5 app displays a communication error message (see "Frequently Asked Questions and Troubleshooting" on page 441).

3.8 Manual and Automated Mode Overview

Available tasks in each mode

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

	Manual Mode	Automated Mode
How it works		
Basal Insulin Delivery	Insulin is delivered according to the Active Basal Program.	Insulin is delivered and adjusted automatically based on sensor glucose values and prediction.
Bolus Insulin Delivery	Insulin is delivered using the SmartBolus Calculator or entered manually.	Insulin is delivered using the SmartBolus Calculator or entered manually.

3 Omnipod 5 System Overview

	Manual Mode	Automated Mode
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 Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number Switch between sensor brands and models (between Pod changes) Start or delete a Libre 2 Plus or Libre 3 Plus sensor, view wear duration, and configure alarm settings.	View Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number. View Libre 2 Plus or Libre 3 Plus sensor wear duration and configure alarms.
Pause and Start Insulin	Manually pause insulin for a specified duration of up to 2 hours. Manually Start insulin.	System automatically pauses automated insulin delivery based on sensor glucose value/prediction. Switch to Manual Mode to manually pause insulin delivery.
History Details	Review History Details	Review History Details
BG Entry	Enter blood glucose readings to save in History Details.	Enter blood glucose readings to save in History Details.
How you will be notified	See "Alarms, Action and Reminder Notifications" on page 173 for a detailed list of alarms and notifications.	

3 Omnipod 5 System Overview

Identifying System modes

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

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

CHAPTER 4

Setting Up Your Omnipod 5 Application

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

4.1 Setting Up Your Account

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

If you need to create an Omnipod ID:

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

4.2 Preparing for Your Training

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

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

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

4 Setting Up Your Omnipod 5 Application

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

Omnipod 5 Intro Kit contents

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

The Insulet-provided Omnipod 5 Intro Kit contains:

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

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

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

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

Items needed for your training

- Your Controller or smartphone with Omnipod 5 App and charging cable and adapter.
- Your glucose sensor supplies:
 - For Dexcom G6, your Dexcom G6 sensor, Transmitter, and Dexcom G6 App
 - For Standard Dexcom G7, your Dexcom G7 sensor and Dexcom G7 App on your smartphone
 - For Dexcom G7 15 Day, your Dexcom G7 sensor and Dexcom G7 App on your display device (either your smartphone or a Dexcom receiver)
 - For Libre 2 Plus, your Libre 2 Plus sensor
 - For Libre 3 Plus, your Libre 3 Plus sensor
- Two Pods
- The *Technical User Guide* and/or *User Guide*
- BG meter
- Test strips and a lancing device (available from many pharmacies).

- Vial of rapid-acting U-100 insulin (See page 9 for information about the approved types of insulin to use with the Pod).
- Alcohol prep swabs
- Instructions from your healthcare provider with Omnipod 5 app settings tailored to your needs. These settings include Basal Program, Insulin to Carb Ratio, Correction Factor, Target Glucose, and Duration of Insulin Action.

Note: Ensure that your Controller is charged before training begins. To charge your Controller, see "Charging the Battery" on page 230.

4.3 Choosing a Controller or Smartphone

Caution: If you decide later to switch between the Controller and a smartphone, you will need to start setup again on the new device. New setup requires entry of all your personalized settings. Consult with your healthcare provider if you are unsure about how to set up the new device. If you are wearing a Pod and need to switch devices, you will need to deactivate your Pod and activate a new one, since the Pod cannot communicate with two devices at one time. If possible, wait to switch between devices until a scheduled Pod change.

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

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

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

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

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

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4.4 General Settings on Insulet-provided Controller

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

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

Turning On and Signing in to Your Controller

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

1. Press and hold the Power button on the right side until the device manufacturer logo appears.
2. Select your language.
3. The Controller runs through a series of checks. If prompted, allow permissions and connect to Wi-Fi. See page 201 for more details.

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

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

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

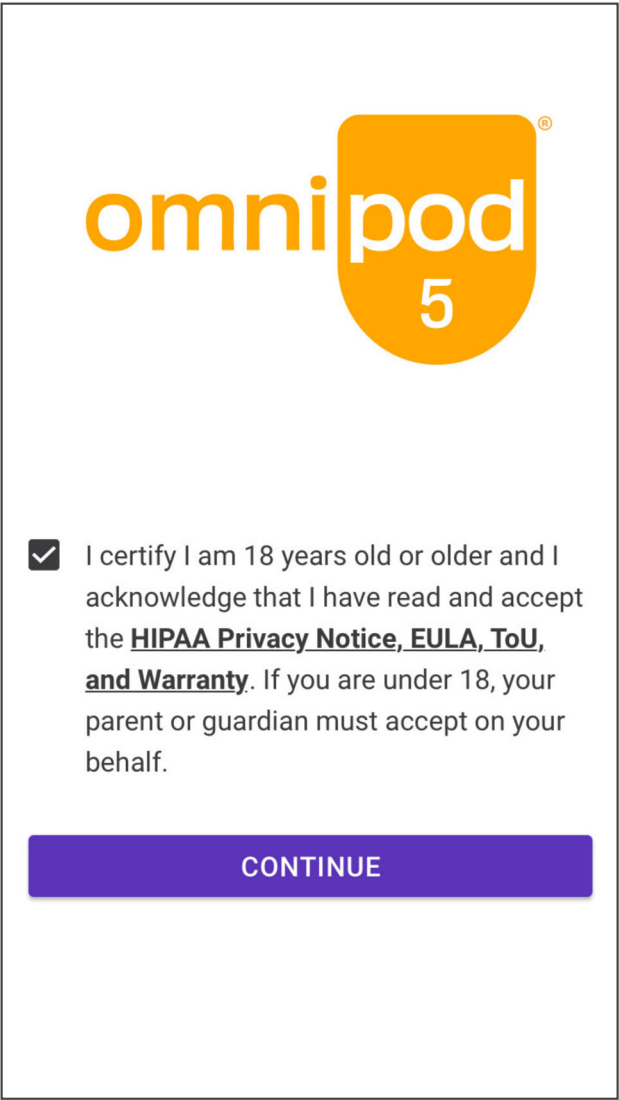
A checkmark is added to the checkbox to indicate agreement.

- b. Tap **CONTINUE**.

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

5. Sign in with your Omnipod ID:
- a. Enter your username.
 - b. Enter your password.
 - c. Tap **SIGN IN**.

Note: The username and password are case-sensitive.



4 Setting Up Your Omnipod 5 Application

Setting Up Training

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

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

After tapping the training option:

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

After signing into your Controller, you may continue setting up your Omnipod 5 System on your Controller, or sign into the Omnipod 5 App on your smartphone. If you intend to use your smartphone for the Omnipod 5 App, continue to "4.5 General Settings on Your Smartphone" on page 78. You do not need to continue with any further Controller setup at this time.



DO NOT PROCEED

You must complete training before you can use this product!

Have you been trained to:

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

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

Please select one of the following:

I will schedule training

I am in training

I completed training

I decline training

Setting Up Your Controller

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

Personalize your Controller

Follow the steps below to personalize your Controller.

- 1. Enter a personalized screen message (at least two characters), tap **Done**, then tap **CONTINUE**.
A screen appears showing several background images.
- 2. Swipe right or left to see more images. Tap on your preferred image, then tap **CONTINUE**.

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

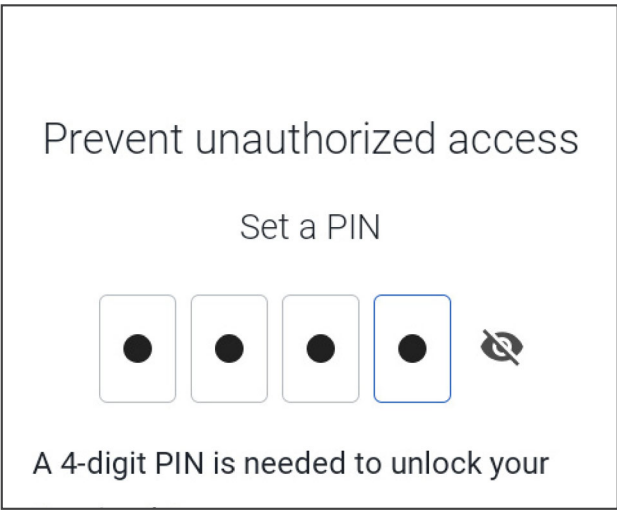
Setting the PIN on your Controller

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

To set a PIN:

- 1. Choose 4 numbers to be your PIN. You will use this PIN every time you wake up your Controller. You may want to record the PIN in a safe place.
Tip: To keep the PIN visible, tap the eye icon located to the right of the PIN entry fields. To hide the number, tap the eye icon again.
- 2. Tap a field to display the number pad. Enter your 4-digit PIN. Tap **Done**.
- 3. Enter the same 4 numbers again to confirm your PIN. Tap **Done**.

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

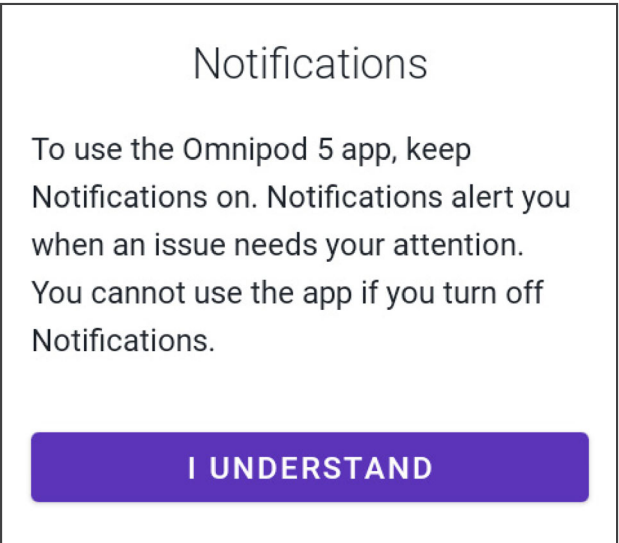


4 Setting Up Your Omnipod 5 Application

Enabling Notifications and Sound on Your Controller

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

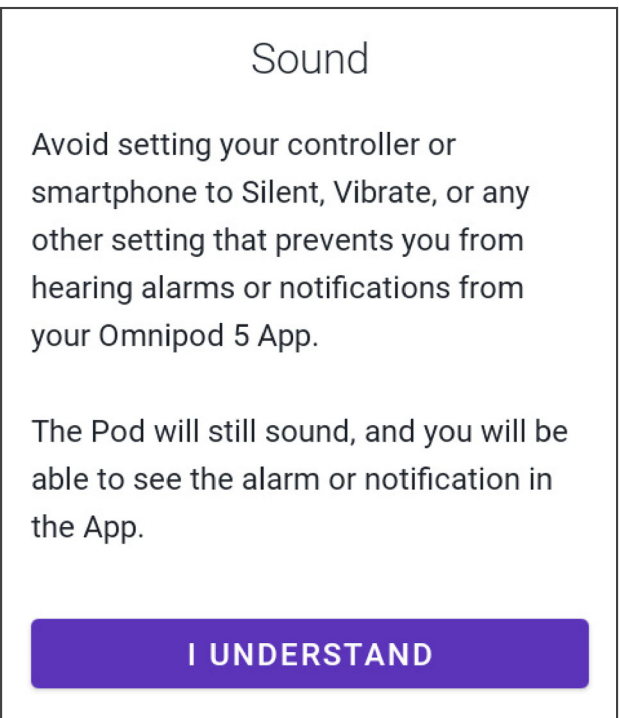
➤ Tap **I UNDERSTAND**.



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

➤ Tap **I UNDERSTAND**.

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



4.5 General Settings on Your Smartphone

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

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

Using the Omnipod 5 App on Your Smartphone

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

Caution: DO NOT install apps on your smartphone from untrusted sources. These apps may contain malware that may impact use of the Omnipod 5 App. Install apps only from trusted sources (i.e. Google Play). If you do not know what an App is, do not install it, regardless of the source.

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

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

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

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

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

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

4 Setting Up Your Omnipod 5 Application

Required smartphone settings

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

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

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

Recommended smartphone settings

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

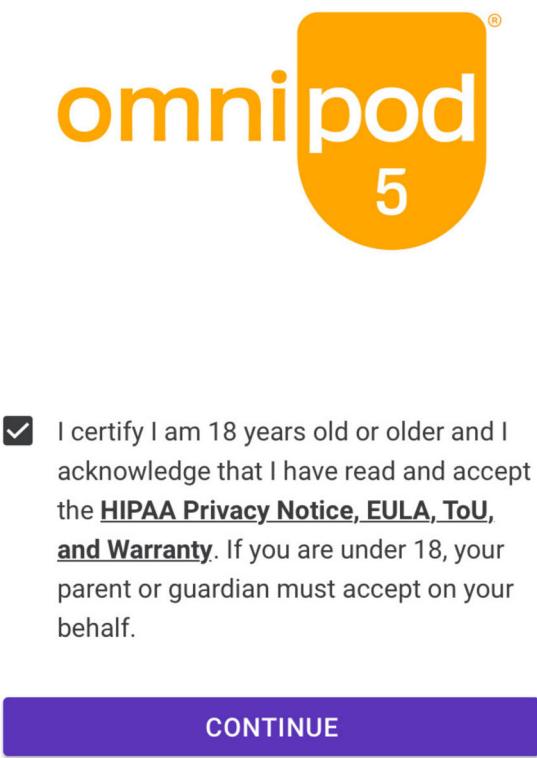
Recommended Setting	Android Settings menu location	ON or OFF
Location	“Location”	ON (recommended for daily use)
Network connectivity (Wi-Fi or cellular)	“Connections” or “Network & internet”	ON

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

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

Signing in to the Omnipod 5 App on Your Smartphone

- 1. Select your language.
- 2. The Omnipod 5 App runs through a series of checks. If prompted, allow permissions and connect to Wi-Fi. See "Connect to a Wireless Network" on page 201 for more details.
- 3. 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.

- 4. 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.

4 Setting Up Your Omnipod 5 Application

Setting Up Training

After signing into the App, 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**.



DO NOT PROCEED

You must complete training before you can use this product!

Have you been trained to:

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

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

Please select one of the following:

[I will schedule training](#)

After signing into the App, you may continue setting up your Omnipod 5 System on your smartphone, or sign into the Controller. If you intend to use your Controller for the Omnipod 5 App, continue to "Setting Up Your Controller" on page 77. You do not need to continue with any further App setup at this time.

Setting Your Omnipod 5 App Security (on Your Smartphone)

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

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

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

Omnipod 5 Security cannot be turned off.

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

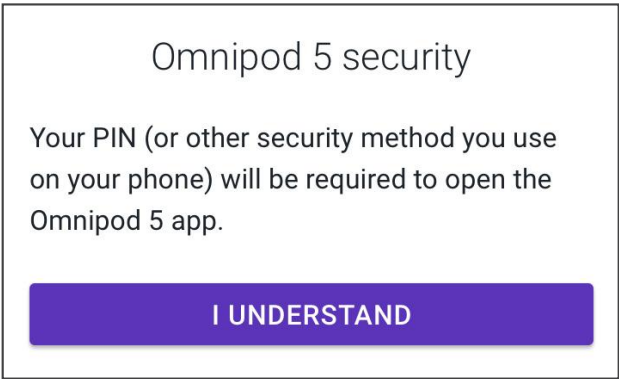
- 1. Read the **Lock Screen Security** screen.

- Tap **I UNDERSTAND**.

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

- 1. Tap **SET UP SECURITY** to continue.
- 2. You will be taken to your smartphone's screen lock settings screen. Select your desired security method and complete security setup.
- 3. After you successfully set your security method, you will see the **Omnipod 5 Security** screen on the Omnipod 5 app.

- Tap **I UNDERSTAND**.



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 Setting Up Your Omnipod 5 Application

4.6 Basal Settings

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

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

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

Set Maximum Basal Rate

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

1. Tap the **Max Basal Rate** field.
2. Scroll to your desired Maximum Basal Rate. When the correct number is in the center of the scroll wheel, tap the number to select it.
Tip: Alternatively, tapping outside of the scroll wheel selects the value in the center of the scroll wheel.
3. Tap **NEXT**.

Note: You can adjust your Maximum Basal Rate later, if your needs change. See "Maximum Basal Rate" on page 152.

← Setup: Basal

Set Maximum Basal Rate

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

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

Max Basal Rate

(0.05 to 30 U/hr)

U/hr

Create a Basal Program

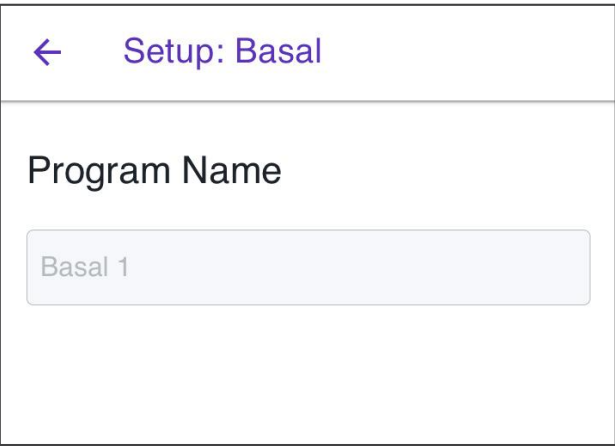
The next step is to create a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Basal Programs" on page 117.

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

Name the Basal Program

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

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



4 Setting Up Your Omnipod 5 Application

Define the segments

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

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

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

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

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

← Setup: Basal

Weekday: Segment 1 Graph: U/hr



Start

12:00 AM

Night

End

-- --

Basal Rate

(up to 30 U/hr)

-- -- U/hr

CANCEL

NEXT

Review the Basal Program

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

- 1. Tap CONTINUE to review your Basal Program.
- 2. Check that the graph and the individual segment values are correct.

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

- 3. To change an end time or basal rate for a segment:
 - a. Tap the row containing the segment you would like to change.
 - b. Tap the **End Time** field and enter the new end time for the segment.
 - c. Tap the **Basal Rate** field and enter the desired basal rate.
 - d. Tap **NEXT**.
 - e. Set the end time and basal rate for any following segments, as needed.
- 4. When the Basal Program is correct, tap **SAVE**.
- 5. To add a new segment:
 - a. Tap the row containing the start time of the new segment.
 - b. Tap the **End Time** field and enter the start time of the new segment as the end time of this segment.
 - c. Change the basal rate, if necessary.
 - d. Tap **NEXT**.
 - e. Set the end time and basal rate for any following segments, as needed.
- 6. To delete a segment:
 - a. Note the end time of the segment you want to delete.
 - b. Tap the segment before the segment you want to delete.

