



ENG-AW Rev007  
PCO-000267  
22 DEC 2020

# User Guide

**Omnipod® 5** Automated Insulin Delivery System



## Contacts and Important Information

### Customer Care

*1-800-591-3455 — 24 hours/7 days*

*1-978-600-7850 when calling from outside the United States of America*

**Customer Care Fax:** 877-467-8538

**Website:** [omnipod.com](http://omnipod.com)

**Address:** Insulet Corporation  
100 Nagog Park, Acton MA 01720

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

**Controller Model** PDM-USA-H001-MG

**Serial Number** \_\_\_\_\_

**Controller FCC ID:** 2ADINN5004L

**Pod FCC ID:** RBV-029

**Omnipod® 5 Automated Insulin Delivery System**

**Start Date** \_\_\_\_\_

#### Healthcare Provider

Name \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Phone \_\_\_\_\_

Email \_\_\_\_\_

#### Omnipod® Trainer

Name \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Phone \_\_\_\_\_

Email \_\_\_\_\_

#### Health Insurance

Name \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Phone \_\_\_\_\_

Policy Number \_\_\_\_\_

#### Pharmacy

Name \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_

Phone \_\_\_\_\_

Email \_\_\_\_\_

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Patent information at [www.insulet.com/patents](http://www.insulet.com/patents).

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# Chapter 1: Introduction

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## 1.1. Welcome to your Omnipod® 5 System

The Omnipod® 5 System is the first wearable, on-body, tubeless automated insulin delivery system. The Omnipod 5 System consists of a tubeless insulin Pod, the Omnipod® 5 app, and the Dexcom G6® Continuous Glucose Monitoring System. The Omnipod 5 System continuously adapts and automatically delivers insulin to your personal needs.

The Omnipod 5 System has several features to help manage your diabetes including:

- **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 connecting the Pod to the Omnipod 5 app. You can wear the Pod under your clothes and carry the Omnipod 5 app separately. You can swim wearing the Pod and leave the Omnipod 5 app on dry land. The Pod is waterproof to 25 feet (7.6 meters) for up to 60 minutes (IP28). The controller provided is not waterproof.
- **Omnipod® 5 application:** The Omnipod 5 app allows you to select a basal profile, target glucose and bolus settings; activate and deactivate the Pod, connect with a Dexcom G6, and select insulin delivery mode. The Omnipod 5 System allows you to use the Omnipod 5 app with your own compatible smartphone or an Insulet-provided controller. For a list of the latest compatible smartphones, please visit <https://omnipod.com/compatibility>.
- **Dexcom G6 Continuous Glucose Monitoring (CGM) System:** The Omnipod 5 System is designed to work with the Dexcom G6. CGM values and trends can be used for automated insulin delivery in Automated Mode, as well as bolus calculations in both Automated and Manual Mode.
- **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 an algorithm that adjusts insulin every 5 minutes to bring your glucose value to your customized glucose target. The adjustment is based on a prediction of where your blood glucose will be 60 minutes in the future and considers your CGM value and trend, adaptive basal rate and insulin that is still working in your body.
  - **Manual Mode:** The Omnipod 5 System delivers insulin based on user-defined Basal Programs. During Manual Mode, there is no automated adjustment of insulin delivery.
- **HypoProtect™:** While in Automated Mode, you can use HypoProtect™ in times when you need less insulin, for example, when you are getting ready to

exercise. When HypoProtect is activated, the system gives less basal insulin and aims for a Target Blood Glucose of 150 mg/dL.

- **Bolus Calculator:** If your glucose level is high or if you are planning to eat, the Bolus Calculator can suggest a bolus amount of insulin based on your individual settings, entered values, and CGM trend when available. The Bolus Calculator allows for the immediate delivery of the bolus insulin in both Automated and Manual Mode. In Manual Mode, the Bolus Calculator also allows for an extended bolus. The extended bolus can be customized to deliver the bolus dose over a period of time.
- **Food Library:** Within the Bolus Calculator, there is an integrated food library that contains thousands of common foods. You can use the Food Library to BROWSE for individual items or create MY FOODS lists. When you are about to eat, you can use the MY FOODS list or the BROWSE list to transfer the number of carbs in a meal to the Bolus Calculator.
- **Keeping Track of CGM and Insulin** The Omnipod 5 System records up to 90 days of information, including basal rates, bolus doses, carbohydrates, alarms, and glucose-related data. In Automated Mode, the system records automated insulin delivery and corresponding CGM values every 5 minutes. The Home screen features a CGM graph which allows for reference of your CGM values and displays some information about insulin delivery.
- **Pod Site tracker:** When activating a new Pod, the System provides the option to track where you have applied a Pod. This allows you to reference past Pod sites when deciding where to place your next Pod.

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# 1 Introduction

## 1.2. About this User Guide

**Caution:** This *User Guide* is intended for use only with the Insulet-provided controller with the Omnipod 5 app, model PDM-USA-H001-MG, or the Omnipod 5 app on a compatible smartphone. To learn which version of the Insulet-provided controller you have, turn it over. If you see "PDM-USA-H001-MG" on the back of the controller, this is the correct *User Guide*. If you do not see it, call Customer Care.

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

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

## 1.3. Indications for Use

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

### Indications for use

The Omnipod 5 Application and Omnipod 5 Algorithm are intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of insulin based on current and predicted glucose values to achieve the user-selected target glucose.

The Omnipod 5 Application and Omnipod 5 Algorithm are intended for the management of type 1 diabetes mellitus in persons 6 years of age and greater.

The Omnipod 5 Application and Omnipod 5 Algorithm are intended for single-patient use and requires a prescription.

The Omnipod 5 Application and Omnipod 5 Algorithm are indicated for use with NovoLog, Humalog, Admelog, and Apidra U-100 insulin.

The Omnipod 5 Bolus Calculator is a decision-support software intended for the management of diabetes in persons aged 6 and older requiring rapid-acting U-100 insulin. The Omnipod 5 Bolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose reading (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. Use of the Omnipod 5 Bolus Calculator with sensor glucose may reduce the risk of hypoglycemia compared to blood glucose readings alone.

The Omnipod 5 Insulin Delivery Device (the Pod) is intended to be used with a compatible Controller for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The Pod is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands reliably and securely from these devices.

The Pod is intended for single patient, home use and requires a prescription. The Pod is indicated for use with NovoLog, Humalog, Admelog, and Apidra U-100 insulin.

### Contraindications

Insulin pump therapy is NOT recommended for people who are:

- Unable to monitor glucose levels as recommended by their healthcare provider.
- Unable to maintain contact with their healthcare provider.
- Unable to use the Omnipod 5 System according to instructions.

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## 1.4. General Warnings and Safety Information

**Warning:** The Omnipod 5 System is designed to use rapid-acting U-100 insulin. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: NovoLog® (insulin aspart), Humalog® (insulin lispro), Admelog® (insulin lispro), and Apidra® (insulin glulisine). NovoLog, Humalog, and Admelog are compatible with the Omnipod 5 System for use up to 72 hours (3 days). Apidra is compatible with the Omnipod 5 System for use up to 48 hours (2 days). Before using a different insulin with the Omnipod 5 System, check the insulin drug label and consult your healthcare provider. Refer to the insulin labeling and follow your healthcare provider's directions for how often to replace the Pod.

**Warning:** The Omnipod® 5 System relies on accurate, current CGM values to determine your insulin needs. Always make sure you are using the CGM per manufacturer's instructions and do not extend the sensor wear beyond the recommended duration.

**Warning:** If you notice that your CGM value does not match your symptoms, check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary, and contact your healthcare provider.

- Always make sure you are using the CGM per manufacturer's instructions and do not extend the sensor wear beyond the recommended duration.
- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness and death.
- Erroneously low CGM values can cause prolonged insulin suspension leading to hyperglycemia, DKA, and death.

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

**Warning:** Not recommended for individuals with hearing loss. Always verify your ability to hear Pod/Omnipod 5 app alarms and notifications.

**Warning:** If you are unable to use the Omnipod 5 System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the Omnipod 5 System properly.

**Warning:** After use, parts of the device are considered biohazardous and can potentially transmit infectious diseases.

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

**Warning:** The Omnipod 5 System should NOT be used at low atmospheric pressure (below 700 hPA). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 10,000 feet (3,000 meters).

**Warning:** The Omnipod 5 System should NOT be used in oxygen rich environments (greater than 25% oxygen) or at high atmospheric pressure (above 1060 hPA), both of 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.

**Warning:** Do NOT attempt to use the Omnipod 5 System before you receive training. Inadequate training could put your health and safety at risk.

**Caution:** Do not navigate away from the Omnipod 5 app while you are in the process of making changes to your insulin delivery programs. A phone call or other distraction may cause you to miss an important alarm or update, putting you at risk of developing hypoglycemia or hyperglycemia. If you are unsure about the insulin therapy being provided or about messages sent by your Omnipod 5 app, review your alarms, your Home screen and your history records.

## Potential benefits

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

- Adjusting insulin delivery based on CGM value and trend in order to reduce the duration of hypoglycemia and hyperglycemia and increase time spent in normal glycemic range.
- Keeping glucose levels in range on a daily basis aids in preventing both short-term (e.g. hypoglycemia, hyperglycemia) and long term complications.
- Continuous insulin delivery without the need to disconnect prevents elevated glucose levels caused by short-term interruptions.
- Rotation of insulin infusion sites aids in prevention of infusion site complications.

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# 1 Introduction

## Potential risks

- The Omnipod 5 System uses CGM values and trends to calculate insulin delivery. If the CGM values are inaccurate, the System could deliver an inaccurate dose of insulin which could result in hypoglycemia or hyperglycemia.
- Wearing a Pod might cause infection. Be aware of signs of infection including: bleeding, pain, and skin irritation including redness. See your healthcare provider if irritation occurs.
- Kinks or air bubbles in the cannula, or dislodging of the cannula can affect insulin delivery. BGs that do not decrease after a bolus, or other unexpected high BGs are signs of a blockage and an interruption in insulin delivery.
- Hardware defects, software glitches, and Pod failures can cause an interruption in insulin delivery. A pump failure can lead to hypoglycemia, hyperglycemia, or diabetic ketoacidosis. Keep your Omnipod 5 app on and nearby to ensure you are notified of recent insulin delivery and important alarms and messages.

## Emergency kit

**Warning:** Keep an emergency kit with you at all times to quickly respond to any diabetes emergency.

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 "1.4. General Warnings and Safety Information" on page 8 for insulins cleared for use in the Omnipod 5 Pod)
- Syringes or pens for injecting insulin
- Glucose tablets or another fast-acting source of carbohydrate
- Dexcom G6 Continuous Glucose Monitor (CGM) System and supplies
- Blood glucose test strips
- Blood glucose meter
- Ketone test strips
- Lancing device and lancets
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System

- Phone numbers for your healthcare provider and/or physician in case of an emergency
- Glucagon kit and written instructions for administering glucagon dosage if you are unconscious (see "24.4. Avoiding Lows, Highs, and Diabetic Ketoacidosis" on page 276)

**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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# Chapter 2: System Terminology and Navigation

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## 2 System Terminology and Navigation

### 2.1. Terminology

Term	Description
Activation	The process of waking up a Pod and setting up exclusive communication with the Omnipod 5 app that woke it up.
Adaptive basal rate	Insulin delivery, in units per hour, that is calculated by Omnipod 5 to keep your blood glucose within your desired range. This amount changes over time based on your history, CGM value, and trend.
Automated Mode	An insulin delivery method that uses your history, CGM value, and trend to adjust the amount of insulin that you receive.
Automated Mode: Limited	Automated insulin delivery used when CGM values are not available. Insulin delivery is based on your settings and recent history.
Basal insulin	A small amount of insulin that is delivered throughout the day and night to help keep blood glucose levels stable.
Basal Program	Insulin delivery schedule used to deliver insulin in Manual Mode. Also used as a base for Automated Mode calculations.
Basal rate	The number of units of insulin delivered in one hour (U/hr).
BG	Blood Glucose
Bolus insulin	A dose of insulin taken to correct a high glucose level (a correction bolus) or to offset the carbohydrates in a drink, meal, or snack (meal bolus).
Cannula	A small, thin tube inserted under the skin, that the Pod uses to deliver insulin.
Carbs (carbohydrates)	Sugars and starches that the body breaks down into glucose.
CGM (Continuous Glucose Monitor)	System to track blood glucose levels throughout the day and night, supplied by a third-party medical device manufacturer.
CGM sensor	Component of a CGM that is inserted under the skin to measure glucose levels in interstitial fluid.

CGM transmitter	Component of a CGM that sends CGM values to the Pod.
CGM value	Glucose level measured by a CGM. CGMs send the current glucose value with a "trend arrow" which indicates whether your glucose values are going up, down, or remaining steady.
Connecting	In Omnipod 5, "connecting" refers to setting up wireless communication between system components. Omnipod 5 uses Bluetooth® wireless technology to communicate with your Pod.
Controller	Omnipod 5 device, supplied by Insulet, that you use to control your Pod.
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.
Hyperglycemia	High blood glucose. A higher-than-normal level of glucose in the blood; generally above 250 mg/dL.
Hypoglycemia	Low blood glucose. A lower-than-normal level of glucose in the blood; generally below 70 mg/dL.
Hypoglycemia unawareness	A condition in which a person does not feel or recognize the symptoms of hypoglycemia.
Infusion site	The place on the body where a Pod's cannula is inserted to deliver insulin.
Insulin on board (IOB)	Insulin that is still active (available to lower glucose) in the body.



## 2 System Terminology and Navigation

Ketoacidosis (Diabetic ketoacidosis, or DKA)	Diabetic ketoacidosis (DKA) is a serious condition in which extremely high blood glucose levels 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.
Manual bolus	A bolus amount chosen by you (not calculated by the Bolus 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.
Omnipod 5 application (app)	Software on the controller or smartphone that controls the Omnipod 5 System.
Units	How insulin is measured.

### 2.2. Using the Touchscreen and Entering Information

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

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



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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.  <b>Note:</b> 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 153. The screen dims 6-10 seconds before it times out. If the screen dims, tap the screen to prevent it from timing out.

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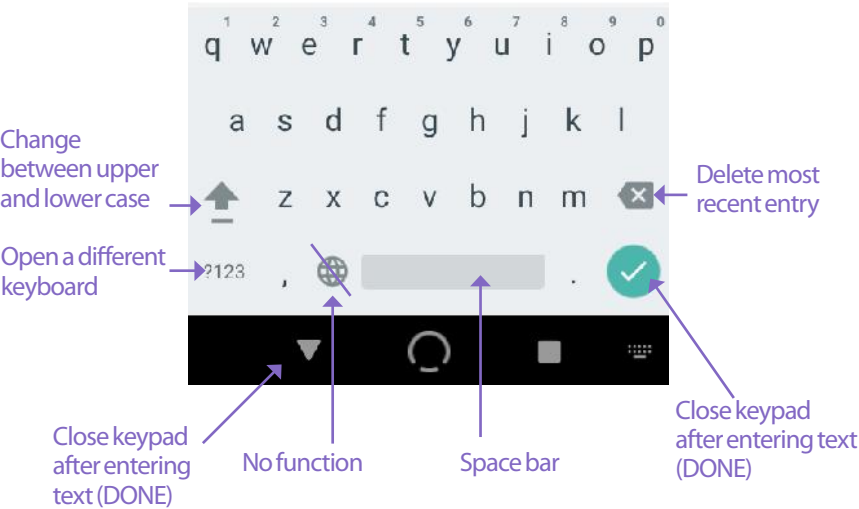
# 2 System Terminology and Navigation

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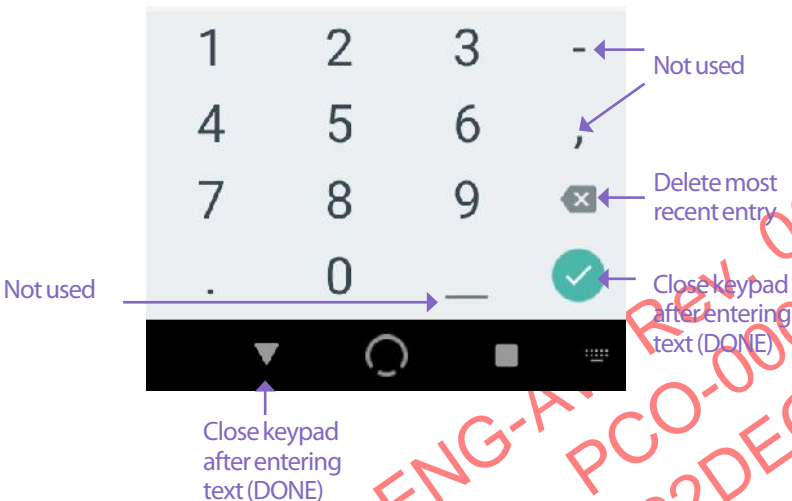
## Entering numbers and text

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

### Using a keypad



### Using a numberpad



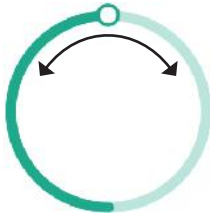
## Using a scroll wheel



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

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

## Using a slider



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

## Selecting, adding, and deleting Items

### Toggles



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

Toggles allow you to turn a feature ON or OFF. The toggle is on the right side and blue 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.

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## 2 System Terminology and Navigation

### Navigation icons and navigation shorthand

#### Options icon



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

#### User Guide navigation shorthand

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

- Menu icon (☰) > Pod > CHANGE POD

tells you to:

1. Tap the Menu icon (☰) 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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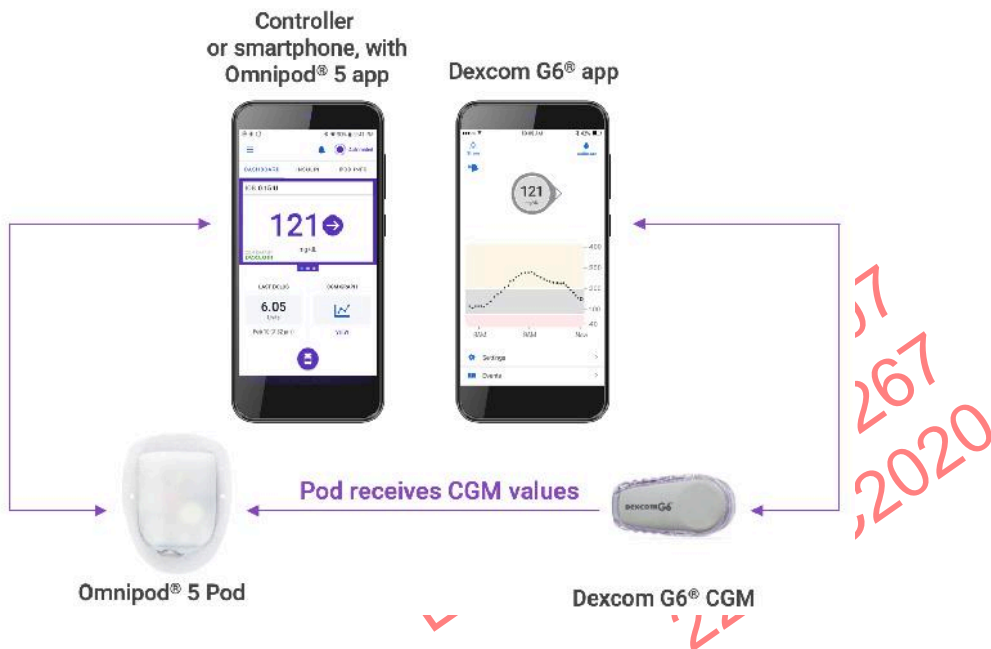
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## 3.1. Omnipod 5 App and Dexcom Communication

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

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

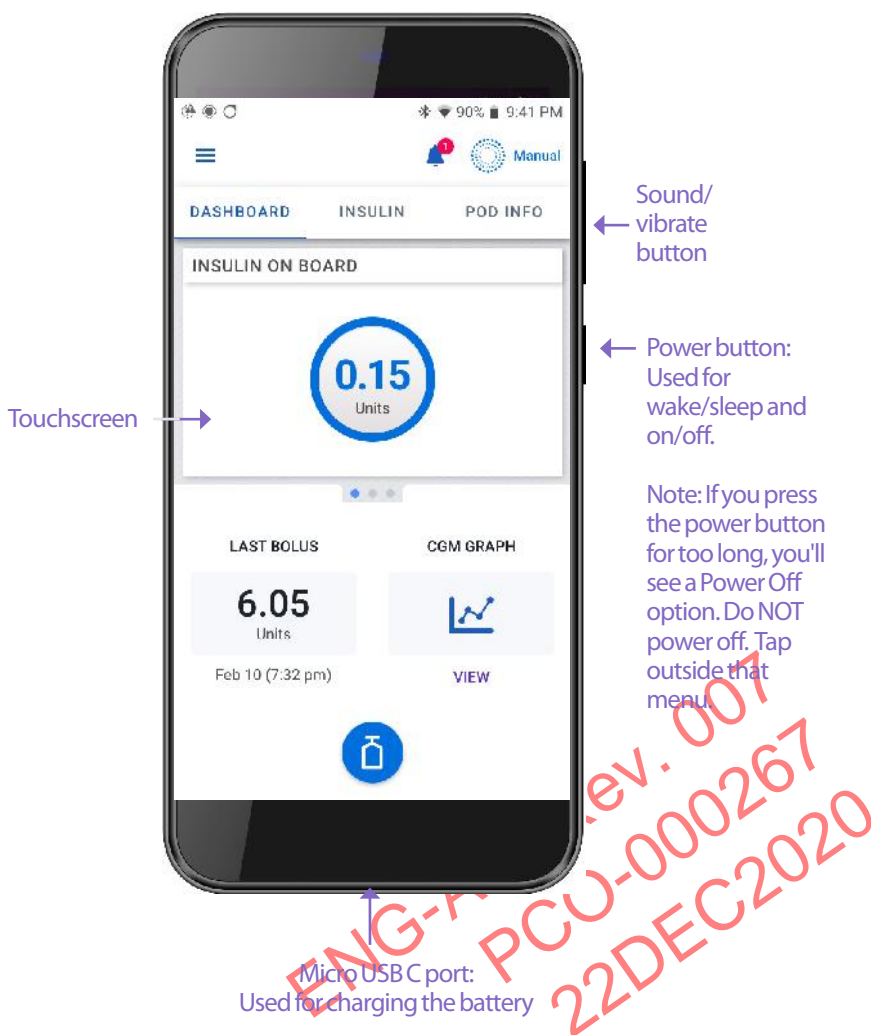


## 3.2. Omnipod 5 App

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:** The Omnipod 5 app does not need to be near the Pod for the system to deliver your basal program in Manual Mode or to deliver automated basal in Automated Mode. It is recommended to keep the Omnipod 5 app nearby as the app provides important information including alerts and alarms.

### The Omnipod 5 controller





## 3 Omnipod 5 System Overview

### 3.3. Status Bar

At the top of the screen is a status bar that shows you the following and other information described in the table (when enabled or applicable):

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

Status bar icon definitions:



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



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



Hazard alarm



Advisory alarm



Action Item Notification



Reminder



Vibrate/Mute



Airplane mode ON



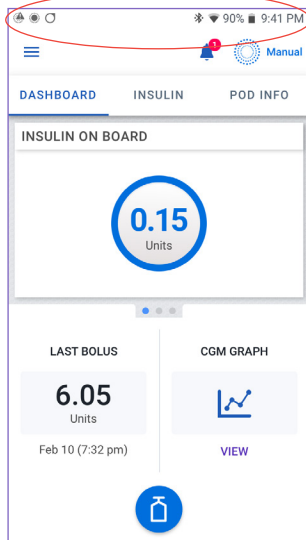
Bluetooth® wireless technology setting ON



Cellular connectivity



Wifi



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

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### 3.4. Controller Lock Screen and Security

After you set up your provided controller, the Lock and PIN screens appear whenever you wake up your controller. The Lock and PIN screens help confirm that you are using the correct 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

**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 safe and within your control to ensure others cannot make changes to your insulin therapy. Do not share your controller PIN or your smartphone screen lock security with anyone.

### Omnipod 5 app security on your controller

#### Unlock your controller

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

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

#### Lock your controller

To lock your controller when you are finished using it:

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

**Note:** Store your controller in a safe, accessible location.

**Caution:** Only press the Power button briefly. If the controller asks if you would like to "Power Off", tap outside the message to cancel the instruction.

## 3 Omnipod 5 System Overview

Once you begin using your controller, do not turn the power off. The controller can sound an alarm only when powered on and with sound enabled. The Pod will alarm regardless of the state of the controller.

### Forgot your PIN?

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

### Omnipod 5 app security on your smartphone

The Omnipod 5 app uses your smartphone's security settings to protect against unintended use of the app. See "Recommended smartphone settings" on page 45 for more information.

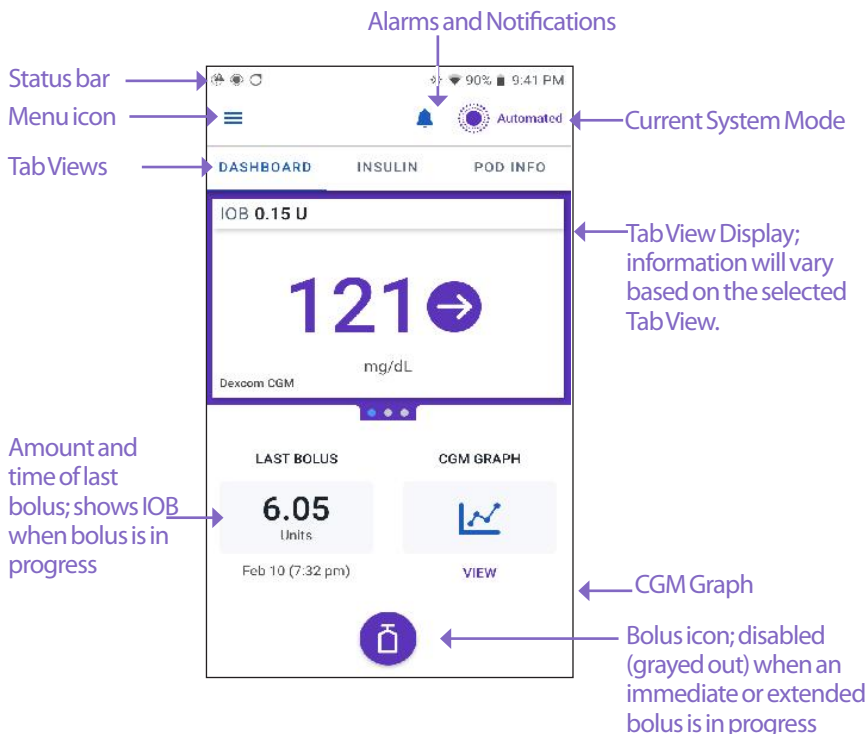
**Warning:** Always identify the Omnipod 5 app as yours before using it. Using a security PIN can prevent accidental insulin delivery.

**Caution:** Do not turn off the Omnipod 5 security setting within the Omnipod 5 app. If Omnipod 5 security is off, someone could potentially use your Omnipod 5 app to change your insulin therapy without your permission.

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## 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 which information is 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 running, a bolus progress bar and a button to cancel the bolus is shown on the Home screen. The three tabs are not visible if an immediate bolus is running. (See "8.6. Delivering an Immediate Bolus" on page 94).

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## 3 Omnipod 5 System Overview

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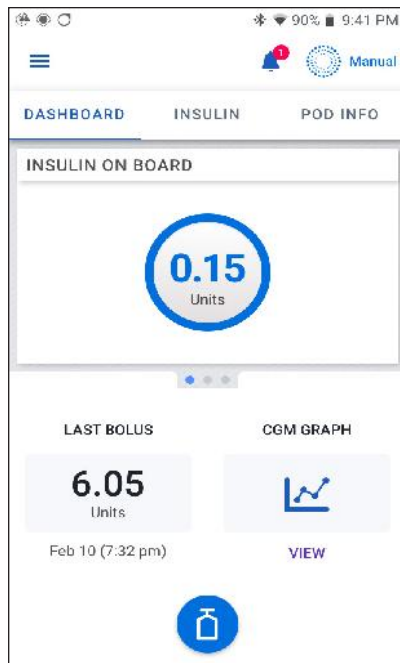
### DASHBOARD tab

The DASHBOARD tab displays the following information.

**Note:** The DASHBOARD tab shows different content if a CGM transmitter is paired to the Omnipod 5 app.

#### Without paired CGM 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.



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## With paired CGM transmitter

- **INSULIN ON BOARD (IOB)**
- **CGM value (with trend arrow):** when a CGM value is available. See "13.5. CGM Trend Arrows" on page 131.
- **CGM value (without arrow):** when transmitter supplies a CGM value but is unable to report CGM trend.
- **HIGH:** when CGM value received from your CGM transmitter is greater than 400. See "13.4. CGM Values" on page 130.
- **LOW:** when CGM value received from your CGM transmitter is less than 40. See "13.4. CGM Values" on page 130.

The DASHBOARD tab also displays information related to potential CGM communication issues. See page 132 for more information.



A progress bar appears when a bolus is in progress (see "8.8. Tracking the Progress of a Bolus" on page 98).

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## 3 Omnipod 5 System Overview

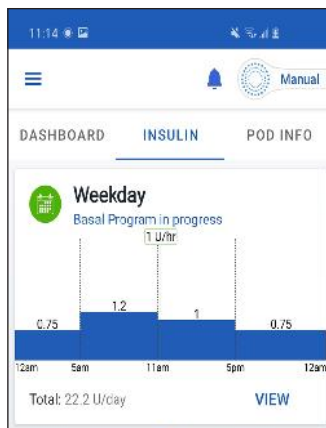
### INSULIN tab

The INSULIN tab label changes to PROTECT when HypoProtect™ is running 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 "History information overview" on page 171.

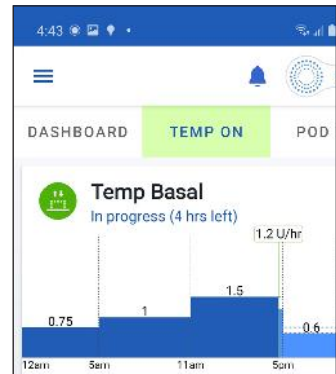
Tap VIEW to see details about other Basal Programs.

For more information on using Manual Mode, see "Section 3: Manual Mode" on page 75.

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## Temp basal

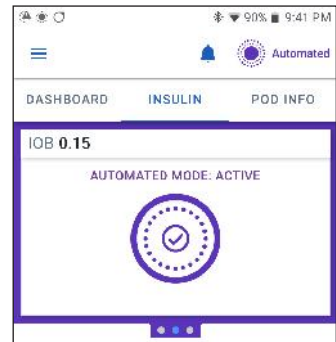
If a temp basal is running, the INSULIN tab label changes to TEMP ON and is highlighted in green. It displays the temp basal graph and allows you to cancel the temp basal. See "7.1. About Temporary Basal Rates" on page 82.



Before You Begin

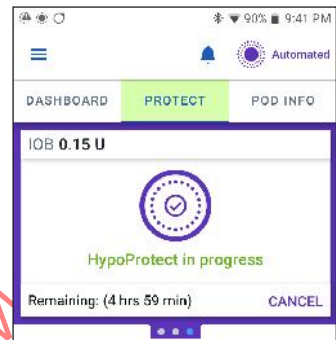
## Automated Mode

In Automated Mode, the INSULIN tab shows AUTOMATED MODE: ACTIVE and displays LAST BOLUS and CGM INFO. For more information on using Automated Mode, see "Section 5: Automated Mode" on page 133.



## HypoProtect™

In Automated Mode, if HypoProtect™ is active, the INSULIN tab label changes to PROTECT, highlighted in green, and shows HypoProtect™ is Active. See "16.1. About HypoProtect™" on page 146 for more information.



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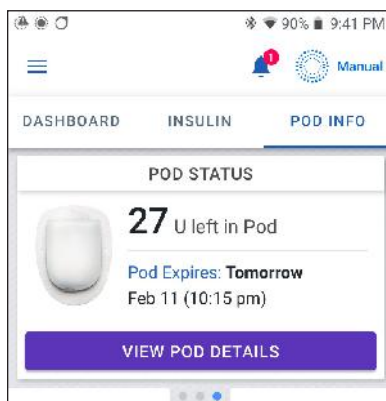
### POD INFO tab

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 says "No Pod Communication." Tap MORE INFORMATION for details.

**Note:** When there is no communication, the Pod continues delivering insulin according to the instructions it was given.

**Tip:** Bringing the Omnipod 5 app and the active Pod within 5 feet of one another may quickly restore their communication.



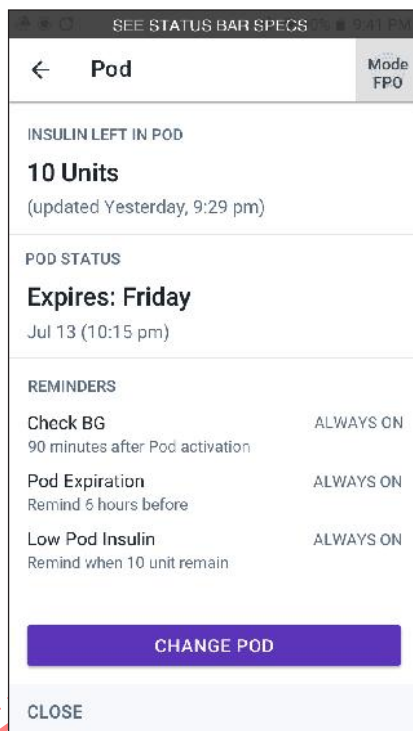
If there is no active Pod, the POD INFO tab says "No Active Pod." To set up a new Pod, see "Chapter 5: Activating and Changing Your Pod" on page 59.

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.
- Any active reminders.
- A CHANGE POD button.


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

CHANGE POD SOON




27 U left in Pod

Pod Expires: **Today**  
Feb 10 (10:15 pm)

VIEW POD DETAILS

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

CHANGE POD




15 U left in Pod


Pod Expires: **Today**  
Feb 10 (10:15 pm)

VIEW POD DETAILS

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.

 LOW POD INSULIN



Less than 5 U

Pod Expires: **Tomorrow**  
Feb 10 (10:15 pm)

VIEW POD DETAILS

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## 3 Omnipod 5 System Overview

### Bolus information and button

The lower left section of the Home screen displays bolus information. The Bolus icon 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 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 177).

#### Bolus icon


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



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## 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 icon (  ) 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 functions available to you vary according to the current mode: Manual or Automated. Functions in gray are disabled based on current mode or settings.

Function	Manual Mode	Automated Mode
<b>Frequent Tasks</b>		
Switch Mode	✓	✓
Set Temp Basal	✓	
HypoProtect™		✓
Pod	✓	✓
Enter BG	✓	✓
Pause Insulin	✓	
<b>Manage Programs &amp; Presets</b>		
Basal Programs	✓	
Temp Basal Presets	✓	
<b>History</b>		
History Detail	✓	✓
Notifications	✓	✓
<b>Settings</b>		
PDM Device	✓	✓
CGM Transmitter	✓	✓
Pod Sites	✓	✓
Reminders	✓	✓
CGM/BG Goal Range	✓	✓
Basal & Temp Basal	✓	✓
Bolus	✓	✓

## 3 Omnipod 5 System Overview

### About screen

The About screen displays details about your Omnipod 5 System, such as the Omnipod 5 application version number, the Customer Care phone number, the controller serial number, 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

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 most recent first. Hazard alarms are most important, followed by Advisory alarms, Action Item Notifications, and lastly, Reminders.


**Warning:** Do not turn off or prevent Omnipod 5 notifications from appearing on your phone. Without notifications enabled, you may miss alarms and important updates.


**Warning:** Do not shut down the Omnipod 5 app in a way that stops it from running in the background (called force stopping). The Omnipod 5 app must be open or be running in the background in order to display or sound an alarm.

**Warning:** Do not set your phone to Do Not Disturb, Silent, or Vibrate. If you do, you may not hear alarms and notifications from the Omnipod 5 app.

### Alarms

Alarms require your immediate attention (see page 187). 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 () are accompanied by a continuous vibration or tone and 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 needs your attention in the near future. For example, if the level of insulin in your Pod is getting low, the Omnipod 5 app issues an advisory alarm.

## Action Item notifications

Action item notifications (see page 205) are tasks that should be responded to as soon as possible. Action item notifications are related to changes you may have made to your Omnipod 5 app that could affect safe use of the system. For example, a Turn on Bluetooth action item means your Bluetooth has been shut off and your app is no longer communicating with your Pod.

## Reminder notifications

Reminder notifications () remind you about actions you may want to perform (see "20.12. Reminder Notifications List" on page 219). For example, Check BG after Bolus.

## 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 "Chapter 21: Troubleshooting" on page 223).

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### 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.


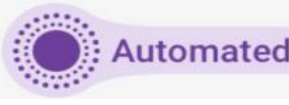


**Note:** A ✓ in the field indicates the task can be performed in the specified mode. A blank field indicates the task cannot be performed in the specified mode.

Task	Manual Mode	Automated Mode
Omnipod 5 app setup	✓	
Add/Delete CGM Serial Number	✓	
Change Pod	✓	✓
Enter BG readings	✓	✓
Activate HypoProtect™		✓
Pause/start insulin	✓	
Modify Basal Programs	✓	
Activate a Basal Program	✓	
Change settings	✓	✓
Review history	✓	✓
Review alarms and notifications	✓	✓
Activate a temp basal	✓	
Cancel a temp basal	✓	
Activate a temp basal preset	✓	
Enter BG or use CGM (before bolus)	✓	✓
Deliver or cancel an immediate Bolus	✓	✓
Deliver or cancel an extended Bolus	✓	
Using the Food Library	✓	✓

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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.
	Displays when the Omnipod 5 System is in Automated Mode and the Pod is providing automated insulin delivery.
	Displays when the Omnipod 5 System is in Automated Mode: Limited state. The most common reason is that the Pod is not receiving CGM values. In response, the system is delivering basal insulin based on a calculation of user-entered settings and past insulin delivery. Check your CGM to make sure it is functioning. The position of the Pod and CGM may also be contributing to loss of connectivity between the devices.
	Displays when the Omnipod 5 System is in Manual Mode and delivering the active Basal Program.

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Begin

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## STARTING OMNIPOD 5

- 4 Setting Up Your Omnipod 5 Application
- 5 Activating and Changing Your Pod

## 22 Taking Care of Your Controller and Pod

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

**Warning:** Store all Omnipod 5 System products and supplies, including unopened Pods, in a cool, dry place. Products or supplies that have been exposed to extreme temperatures may not function properly.

### 22.1. Pod and Insulin Storage and Care

This section describes proper care of your Pod.

#### Pod and insulin storage

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

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

#### Pods and the environment

##### Avoid extreme temperatures

The Pod's operating temperature is between 73°F and 98.6°F (between 23°C and 37°C). Under normal circumstances, your body temperature keeps the Pod well within this range.

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

**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.

If you remove your Pod to avoid exposing it to extreme temperatures, remember to check your blood glucose levels frequently. Check with your healthcare provider for guidelines if you will not use a Pod for extended periods.

## Water and your Pod

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

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

## Cleaning your Pod

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

**Caution:** Hold the Pod securely and take care while cleaning it, so the cannula does not kink and the Pod does not detach from your skin.

---

## 22.2. Controller Storage and Care

When you are not using your controller, store it in a convenient, nearby location that is cool and dry.

**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.

### Long term storage of your controller

If you are not going to use your controller for an extended period of time, allow your battery to reach approximately 50% to 60% charge. Then press and hold the Power button to turn the controller OFF.

**Caution:** Do not turn your controller off for more than six months at a time.

## Your controller and the environment

### Avoid extreme temperatures

Extreme operating temperatures can affect the controller battery and interfere with Omnipod 5 System operation. Avoid using the controller in temperatures below 32°F (0°C) or above 131°F (55°C).

**Caution:** Do not store or leave the controller where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the controller to malfunction.

# 22 Taking Care of Your Controller and Pod

## Water and your controller

The controller is not waterproof. Do not place it in water or leave it near water where it can accidentally fall in. If it gets wet:

1. Dry the outside of the controller with a clean, lint-free cloth.  
**Caution:** Never use a blow dryer or hot air to dry the controller. Extreme heat can damage the electronics.
2. After the controller has thoroughly air-dried, turn ON the controller to see if it is working.
3. If the controller is not working, call Customer Care.

**Caution:** The controller is not waterproof. Do NOT place it in or near water.

## Electrical interference

The controller is designed to withstand normal radio interference and electromagnetic fields, including airport security and cellular phones. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. In most cases, interruptions are easy to resolve by moving to a new location (for more information, see "21.10. "Try Again" - Pod Communication Issues" on page 234).

## USB cable

**Caution:** Only connect a USB cable to your controller when charging the battery. Never connect a USB cable to the controller for any other reason.

**Note:** You can use the controller while it is charging.

**Caution:** When you connect a USB cable to the controller, only use a cable that is less than or equal to 4 feet (1.2 meters) in length.

## Cleaning your controller

Always keep your controller USB port free of debris and liquids. Dirt, dust, and liquids can impair the functionality of your controller or damage it.

**Caution:** Do not use solvents to clean your controller. Do not immerse your controller in water.

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To clean your controller:

1. Press the Power button briefly to put your controller to sleep.
2. Wipe the outer surface of the controller with a damp, lint-free cloth. If necessary, use a solution of a mild detergent mixed in warm water.
3. Dry the outer surface with a dry, lint-free cloth.

**Caution:** While cleaning, do NOT allow debris or liquid to get into the USB port, speaker, earphone jack socket, Sound/vibrate button, or Power button.

Every time you clean your controller, examine the entire controller for discoloration, cracks, or separations. Also check for deteriorating performance, such as illegible messages, button malfunction, or repeated communication failures. If you notice any signs of deterioration, stop using the controller. Call Customer Care if you have questions.

## If you drop the controller

Shock or a severe impact can damage your controller. If you drop the controller or if it is otherwise subjected to severe impact:

1. Inspect the outside of the controller for visible signs of damage.
2. Press and hold the Power button to see whether the controller turns on and the Lock screen appears.

**Caution:** Do not use the controller if it appears damaged or is not working as it should. Do not use the controller if its screen is broken.

---

## 22.3. Controller Battery Care

The provided controller uses a rechargeable lithium ion battery. If there is a problem with your battery or charger, contact Customer Care.

### Safe use of the controller battery

**Warning:** Do not expose your battery to high heat. 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.

**Warning:** Do not incinerate a battery. Dispose of an old battery in accordance with local waste disposal regulations.

## 22 Taking Care of Your Controller and Pod

To safely use the rechargeable battery:

- To prolong battery life, store and charge it in a cool, dry place out of direct sunlight. Avoid leaving the battery in a car where temperature extremes can permanently damage the battery.
- Your controller may become warm after prolonged use or when exposed to high temperatures. If your controller or battery become hot to the touch, unplug the USB cable if it is plugged in, and avoid touching or holding the controller. Place it in a cool location and allow it to cool down to room temperature.
- Do not connect the battery poles with pieces of metal, such as keys or jewelry. Doing so may short-circuit the battery and cause injuries or burns.
- Do not expose the battery or its charger to liquids, including water, rain, or snow, as this can cause malfunction. If the battery or charger is exposed to liquid, allow it to dry.
- Do not allow anyone, including children and pets, to put the battery in their mouth. Doing so may result in damage or explosion.
- Do not place the controller or battery on or in heating devices, such as microwave ovens, stoves, or radiators. The battery may explode if overheated.
- Do not drop the battery.
- Only use an Insulet approved battery, charger, and cable to charge your controller. Using unapproved batteries, chargers, or cables can cause the battery to explode or damage the controller, and may void the warranty.
- If the battery is damaged so that fluid leaks from the battery, do not allow the leaked fluid to make direct contact with your skin or eyes. If this happens, immediately flush your skin or eyes with clean water and consult a doctor.
- If the battery deforms, changes color, or overheats while charging, during use, or in storage, immediately remove the battery. Continued use may lead to battery leakage, fire, or explosion.
- Inspect your controller battery charger before each use. If the adapter for the charger falls in water or is cracked, do not use it.

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## Charging the controller battery

Under normal use, the battery should hold its charge for more than one day.

An Omnipod 5 app message alerts you when the battery charge is low. The battery icon in the status bar tracks the remaining charge in the battery (see "3.3. Status Bar" on page 24). To charge the battery, see "Charge the battery" on page 46.

You can charge your battery many times, but all batteries have a limited lifespan. If you notice a significant deterioration in the duration of the controller's battery charge, contact Customer Care.

**Note:** Charging times can vary depending on the surrounding temperature and the remaining battery level.

**Tip:** *Develop a routine to charge the controller battery at the same time every day. Do not wait for the low battery message.*

**Warning:** If the battery state of charge becomes critically low, the controller turns itself OFF. At this point, you cannot use the controller until you have plugged in the charger to recharge the battery.

**Note:** If the controller battery is critically low and the controller has turned OFF, your Pod continues to deliver Automated Mode insulin or Manual Mode basal insulin according to the Basal Program in progress or temp basal. If you do not charge your controller battery, this insulin delivery continues until the Pod expires.

**Note:** The history records stay in memory for 1 year even if the battery power is critically low.

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# Chapter 23: Understanding Insulin Delivery and Calculations

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23.1. Basal Insulin Delivery

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

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

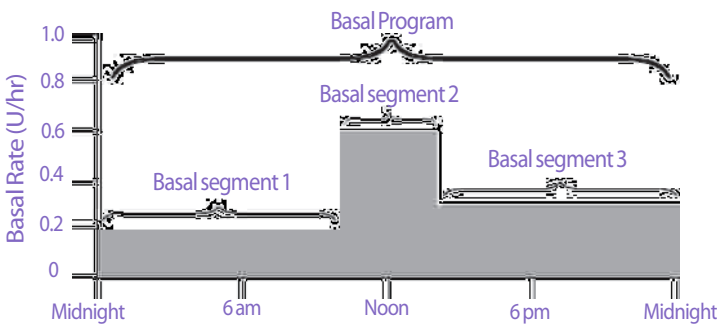
In the Omnipod 5 System, basal delivery occurs differently depending on which of the two modes you are operating in: Manual or Automated.

Manual Mode Basal Programs

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

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

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



Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver more or less insulin at certain times of day. For example, you could deliver a lower rate of insulin during the night and a higher rate during the day. This figure shows a Basal Program with three basal segments that deliver 7.4 U total in a 24 hour period.

To create the Basal Program shown in the preceding figure, the following basal segments are programmed into the Omnipod 5 app:

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

You may have different routines on different days of the week; for example, your weekend routine may differ from your weekday routine. To handle these predictable changes in your routine, you can create up to 12 different Basal Programs (see "6.2. Creating New Basal Programs" on page 78).

Temporary basal rates

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

For example, if you are going cross-country skiing for several hours, you could set a temp basal to lower your basal rate during and after your exercise (see "Chapter 7: Temporary Basal Rates and Presets" on page 81).

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

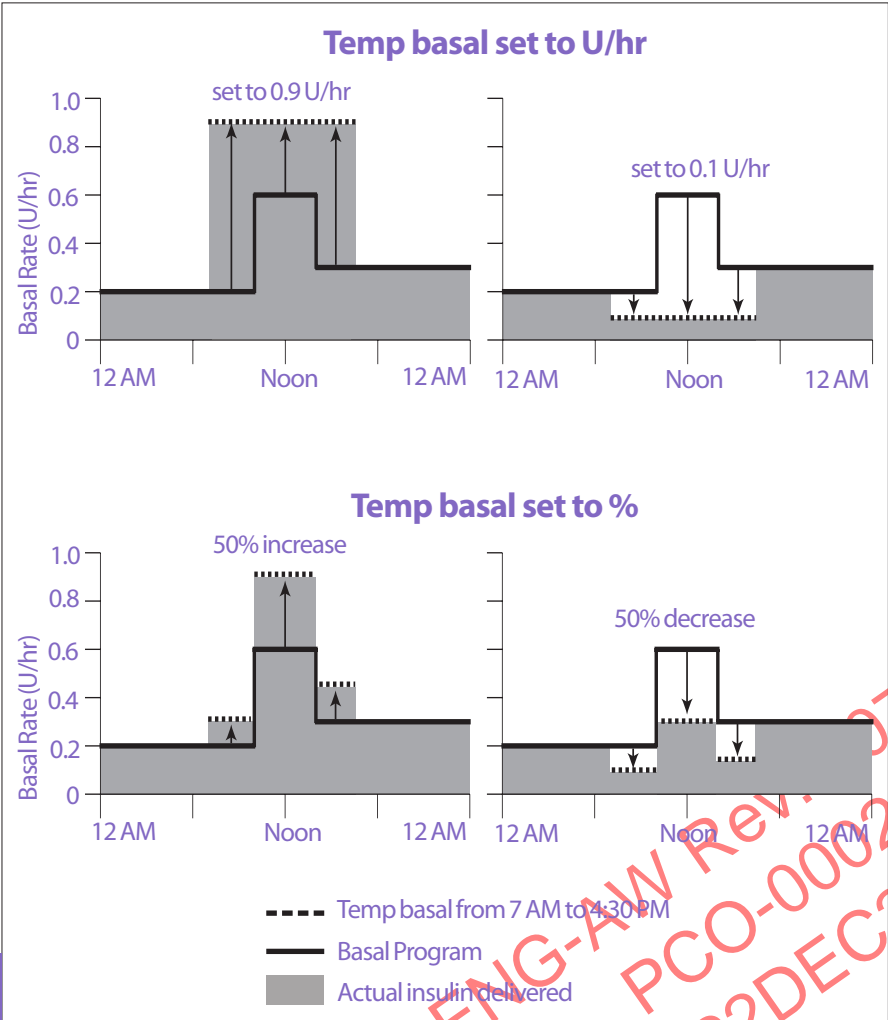
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Temp basal settings: Units per hour (U/hr) or percent (%)

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

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

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



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

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

\* Segments are defined by the currently scheduled Basal Program.

## Temp basal limitations

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

### Maximum temp basal:

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

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

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

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

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

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

**Tip:** Using a temp basal to turn off basal insulin delivery is useful if you want your Basal Program to automatically start when the temp basal ends (see "Chapter 7: Temporary Basal Rates and Presets" on page 81).

Temp basal presets

Some temporary changes in your daily routine are easy to predict, and you may know from experience how they affect your insulin needs. For example, you might join a summer soccer league or attend an exercise class. For women, your monthly hormonal change can affect blood glucose in a predictable manner.

To handle predictable, short-term changes, you can define temp basal presets (see "Chapter 7: Temporary Basal Rates and Presets" on page 81). Once stored, a temp basal preset can be started quickly at a later time.

Methods to temporarily pause insulin delivery in Manual Mode

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

- Pause insulin delivery:  
Menu icon (≡) > Pause Insulin.
- Set a temp basal to turn off insulin delivery:  
Menu icon (≡) > Set Temp Basal. Then select 100% decrease or 0 U/hr.

The following table compares these options for pausing insulin delivery.

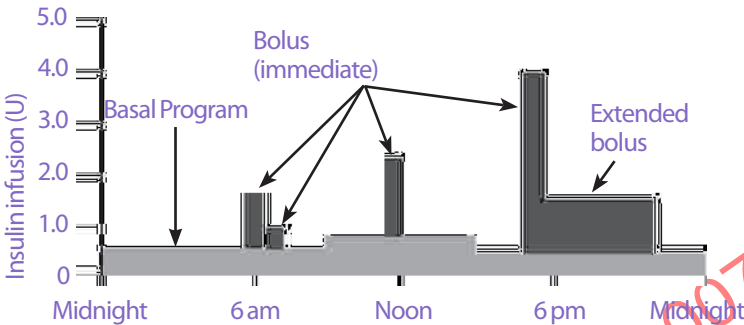
	Pause insulin	Temp basal of 0 U/hr
Effect on basal and bolus insulin delivery	No basal delivery No bolus delivery	No basal delivery Boluses allowed
Minimum duration for pausing insulin	30 min	30 min
Maximum duration for pausing insulin	2 hrs	12 hrs
Insulin delivery starts automatically	No	Yes
Screen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

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

23.2. Immediate and Extended Boluses

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

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



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



## 23.3. About Manual Boluses

A manual bolus is a bolus that you have calculated without the help of the Bolus Calculator. You can use manual boluses when the Bolus Calculator is temporarily disabled or when you choose not to use the Bolus Calculator. Consult your healthcare provider for instructions about how to calculate a bolus.

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

## 23.4. The Bolus Calculator

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

### Bolus Calculator boluses

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

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

### Extended boluses

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

Total bolus = 5 units (1 unit correction bolus + 4 units meal bolus)

- Deliver now = 2 units (1 unit correction + 1 unit meal bolus)
- Extend = 3 units (3 units meal bolus)

### Maximum Bolus

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

### Controlling the bolus amount

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

## When the Bolus Calculator does not work

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

Conditions that disable the Bolus Calculator:	The Bolus Calculator is disabled until:	While the Bolus Calculator is disabled:
Your glucose reading is below your Minimum BG for Calcs setting.	Ten minutes pass. or A new glucose reading is above your Min BG for Calcs setting.	IOB is displayed on the Home screen.
Your manually entered blood glucose reading is greater than 600 mg/dl or “HI.”	Ten minutes pass. or A new blood glucose reading is lower than “HI.”	IOB is displayed on the Home screen.
There is an unconfirmed bolus when you discard a Pod.	A complete Duration of Insulin Action period passes.	IOB is not displayed on the Home screen.

## Factors used in the Bolus Calculator's calculations

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

- Your current glucose level (manually entered or from CGM), CGM trend (if CGM value is used), Target BG, Correct Above threshold, and Correction Factor
- The carbs you are about to eat or drink and your IC Ratio
- Your Duration of Insulin Action and insulin on board (IOB)
- Your Minimum BG for Calcs
- Reverse Correction, if it is enabled

**Note:** In both Automated and Manual Mode, if using a CGM and trend in the Calculator, the Bolus Calculator may reduce suggested insulin dose, even if your reverse correction setting is OFF.

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# 23 Understanding Insulin Delivery and Calculations

## CGM trend

The CGM trend is used to suggest up to 30% more correction insulin when your values are rapidly rising, or suggest a subtraction if your values are rapidly falling, compared to just a BG value alone.

## Target BG

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

## Correct Above threshold

The Bolus Calculator only suggests a correction bolus if your blood glucose reading is above your Correct Above setting. This feature can prevent corrections to blood glucose values that are only slightly higher than your Target BG.

## Insulin on board

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

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

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

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

## Duration of insulin action

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

## Minimum BG for Calcs

The Bolus Calculator does not suggest a bolus if your blood glucose reading is below your Minimum BG for Calcs level. You can adjust this level down to 50 mg/dL.

## Reverse Correction

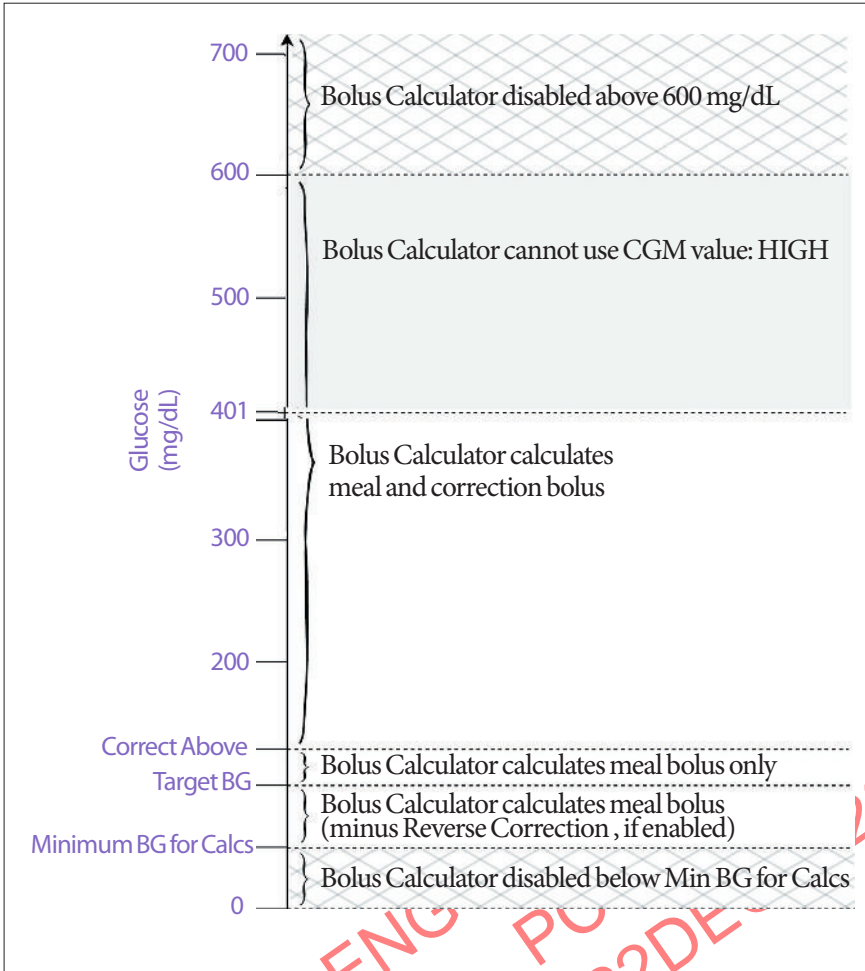
If the Reverse Correction setting is turned ON and your glucose level is below your Target BG, the Bolus Calculator reduces the meal bolus. This allows part of the meal to be used to raise the blood glucose level towards the Target BG.

If the Reverse Correction setting is turned OFF, the Bolus Calculator suggests the full meal bolus even if your blood glucose level is below your Target BG.

**Note:** In Automated Mode, if using a CGM and trend in the Calculator, the Bolus Calculator may subtract insulin even if your reverse correction setting is OFF, in situations with a decreasing CGM trend.

**Boundaries of the Bolus Calculator suggestions**

The following figure shows the boundaries between the types of calculations performed by the Bolus Calculator. For example, the Bolus Calculator suggests a meal bolus, but not a correction bolus, if your glucose reading is between your Target BG and your Correct Above settings. If your manually entered blood glucose is above 600 mg/dL, the reading is recorded as "HI" and the Bolus Calculator cannot calculate a bolus. If your CGM value is over 400 mg/dL, it is recorded as "HIGH" and cannot be used for bolusing.



### Considerations about Bolus Calculator recommendations

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

- The Bolus Calculator uses your Bolus Calculator settings for the time you are requesting a bolus (See "Bolus Calculator settings" on page 164).
- The Bolus Calculator refreshes values every 5 minutes. If you do not start your bolus within 5 minutes, the Omnipod 5 app will need to clear the screen so that it has the latest IOB and CGM information.
- When changing time zones, always check your IC Ratio and Correction Factor settings for the new time to ensure it still meets your body's true insulin needs.
- The Bolus Calculator will suggest doses depending on the carbs you enter and the CGM value at the time. Check the nutritional content of your meals to ensure this is as accurate as possible. Only enter BG values that have been obtained with the last 10 minutes or use CGM. These factors will ensure that the Bolus Calculator suggests a bolus dose that is suitable for you.

If your CGM value or trend do not match your symptoms or expectations, use a fingerstick blood glucose value in the Bolus Calculator.

### Insulin on board (IOB)

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

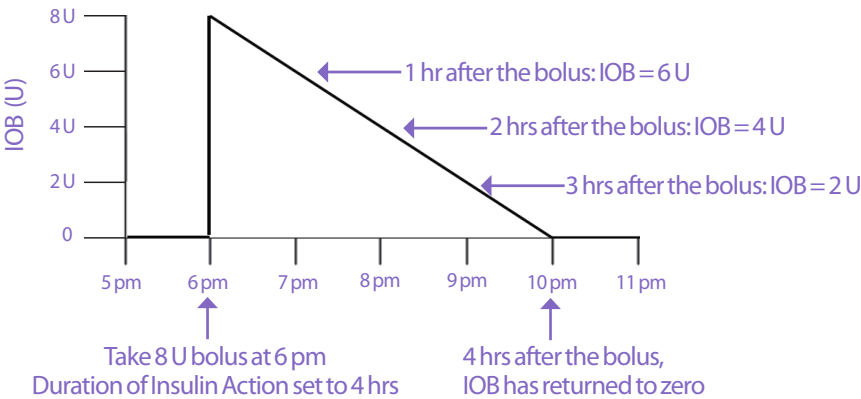
When using the Bolus Calculator, your Omnipod 5 app may, due to IOB, decrease your suggested bolus amount to help prevent giving too much insulin.

**Note:** You must bring your Omnipod 5 app near the Pod to get the most current IOB value on your Omnipod 5 app Home screen.

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**Bolus IOB depletion**

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



In the Omnipod 5 app, the correction IOB can also change depending on the algorithm's calculations. It can increase or decrease automatically.

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# 23 Understanding Insulin Delivery and Calculations

## Insulin on board (IOB) calculations

$$\frac{\text{Duration of insulin action} - \text{time since previous bolus}}{\text{Duration of insulin action}} \times \text{previous bolus}$$

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

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

### Correction IOB example

Duration of insulin action: 3 hours

Time since previous correction bolus: 1 hour

Previous correction bolus: 3 U

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

Final IOB shown to you:

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

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

### Meal IOB example

Duration of insulin action: 3 hours

Time since previous meal bolus: 2 hours

Previous meal bolus: 4.5 U

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

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

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## Bolus Calculator equations

The Bolus Calculator first calculates a preliminary (prelim.) correction and meal bolus. It then adjusts these preliminary values for IOB, if applicable. The final suggested bolus is equal to the sum of the resulting correction bolus and meal bolus.

**Note:** Your adjustments from CGM trend can add or subtract insulin from the correction and/or the meal portion.

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

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

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

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

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

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

$$\text{Final correction bolus} = (\text{prelim. correction bolus} - \text{meal IOB}) - \text{correction IOB}$$

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

**Note:** A correction bolus is never reduced below 0 U.

$$\text{Final meal bolus} = \text{prelim. meal bolus} - \text{remaining correction IOB}$$

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

**Note:** A meal bolus is never reduced below 0 U.

$$\text{Calculated bolus} = \text{final correction bolus} + \text{final meal bolus}$$

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

$$\text{Meal bolus with Reverse Correction} = \text{Reverse Correction} + \text{prelim meal bolus}$$

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

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

$$-1.5 \text{ U (Reverse Correction)} + 2.5 \text{ U (prelim meal bolus)} = 1.0 \text{ U meal bolus}$$



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

## Bolus Calculator rules

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

Rule	Detail		
<b>Rounding</b>	Boluses will always be rounded <i>down</i> to the nearest 0.05 U.  IOB will always be rounded <i>up</i> to the nearest 0.05 U.  Bolus and IOB will never be below 0 U.		
<b>Factors that influence the size of your bolus</b>	<b>Factor</b>	<b>Increase</b>	<b>Decrease</b>
	Carb entered	✓	
	CGM or BG value	✓	✓
	IOB		✓
	CGM trend (if using CGM)	✓	✓
	Target BG	✓	✓
<b>Correction IOB</b>	Reverse Correction setting		✓
	Correction IOB is subtracted from both meal and correction boluses.		
<b>Meal IOB</b>	Meal IOB is only subtracted from the correction boluses.		

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Overview of the Bolus Calculator CALCULATIONS screen

You can tap VIEW BOLUS CALCULATIONS from the Insulin & BG history screen or tap CALCULATIONS from the Bolus Calculator screen if you want to view bolus calculation details.

Bolus Calculator CALCULATIONS screen (using CGM value)

When your CGM value and trend are available, the Bolus Calculator internally calculates your suggested bolus . It is normal if, for some bolus calculations, the adjustments are shown as a calculated correction with CGM trend and, for other bolus calculations, the adjustments are split into Adjusted correction and Adjusted meal bolus (each with CGM trend).

Current CGM Value

←

Bolus Calculations

Correction Bolus:

0 u

CGM = 99, Target BG = 110

Correction Factor = 50

Calculated correction ≈ 0 U

Adjusted for CGM: Rapidly rising

Meal IOB adjustment

Meal IOB = 0 U

N/A: Correction bolus is ≤ 0 U

Correction IOB adjustment

Correction IOB = 0.45 U

N/A: Correction bolus is ≤ 0 U

Meal Bolus:

7.05 u

Carbs = 75 g, IC Ratio = 10 g/U

75 / 10 ≈ 7.5 U

Correction IOB adjustment

Remaining correction IOB = 0.45 U

7.5 U - 0.45 U ≈ 7.05 U

Calculated Bolus

7.05 u

Total Bolus

=

7.05 u

Correct Above: 110 mg/dL

CLOSE

Calculated correction and Adjusted for CGM trend

265

Additional Information

Effective Date: 22DEC2020, PCO-000267

23.5. Bolus Calculator Examples

Example 1

Eating 50 g carbs, and 0.6 U meal IOB and 0.5 U correction IOB from previous meal and correction boluses. CGM is not available and BG not entered.

<b>Correction Bolus</b>	-- U	
BG = N/A, Target BG = N/A		
Correction Factor = N/A		
<b>Meal IOB adjustment</b>		
Meal IOB = 0.6 U		← The Bolus Calculator does not adjust your correction bolus by the meal IOB since there is no BG reading.
N/A: No BG reading		
<b>Correction IOB adjustment</b>		
Correction IOB = 0.5 U		← The Bolus Calculator also does not adjust your correction bolus by the correction IOB since there is no BG reading.
N/A: No BG reading		
<b>Meal Bolus</b>	5 U	
Carbs = 50 g, IC Ratio = 10 g/U		← You are eating 50 g carbs. With your IC ratio at 10, you will need a 5 U meal bolus.
50 / 10 = 5 U		
<b>Correction IOB adjustment</b>		
IOB is subtracted from a bolus only when BG is known.		← Your meal bolus is not adjusted by your IOB when there is no BG or CGM value.
<b>Calculated Bolus</b>	5 U	← The calculated bolus is just the meal bolus, since there is no correction bolus.
<b>Your Adjustment</b>	2 U	← You can make manual adjustments to your bolus by tapping on the Total Bolus field at the bottom of the Bolus Calculator screen.
Meal bolus + 2U		

<b>Total Bolus</b>	<b>= 7 U</b>	← The Total Bolus is the sum of the calculated bolus and any adjustments you made.
--------------------	--------------	--

Example 2

Eating 30 g carbs, no meal or correction IOB. Used CGM value of 180 mg/dL, with rising trend.

<b>Correction Bolus</b>	<b>1.2 U</b>	← Your glucose value is 180 mg/dL which is 50 mg/dL over your target. Because your correction factor is 50, the initial correction bolus is 1 U.
CGM = 170, Target BG = 130		
Correction Factor = 50		
$(180 - 130) / 50 = 1 \text{ U}$		
<b>Meal IOB adjustment</b>		← The Bolus Calculator does not adjust your correction bolus by the meal IOB since there is no meal IOB.
Meal IOB = 0 U		
$1 \text{ U} - 0 \text{ U} = 1 \text{ U}$		
<b>Correction IOB adjustment</b>		← The Bolus Calculator also does not adjust your correction bolus by the correction IOB since there is no correction IOB.
Correction IOB = 0 U		
$1 \text{ U} - 0 \text{ U} = 1 \text{ U}$		
Adjusted correction bolus = 1.2 U		
<b>Adjusted for CGM: Rising</b>		← The correction bolus is increased to account for your rising CGM trend.
<b>Meal Bolus</b>	<b>3.6 U</b>	← You are eating 30 g carbs. With your IC ratio at 10, you will need a 3 U meal bolus.
Carbs = 30 g, IC Ratio = 10 g/U		
$30 / 10 = 3 \text{ U}$		
		← The Bolus Calculator does not adjust your meal bolus by the correction IOB since there is no correction IOB.

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<b>Correction IOB adjustment</b> Remaining correction IOB = 0 U $3\text{ U} - 0\text{ U} = 3\text{ U}$		← The Bolus Calculator does not adjust your meal bolus by the correction IOB since there is no correction IOB.
Adjusted meal bolus = 3.6 U <b>Adjusted for CGM: Rising</b>		← The meal bolus is increased to account for your rising CGM trend.
<b>Calculated Bolus</b>	<b>4.8 U</b>	← The calculated bolus is the sum of your correction bolus and meal bolus that has been adjusted for rising CGM value.
<b>Total Bolus</b>	<b>4.8 U</b>	← The total bolus is the sum of the calculated bolus and any adjustment you made.

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## Example 3

No carbs entered, used CGM of 180 mg/dL with decreasing trend. There is 0.8 U meal IOB and 0.5 U correction IOB from previous meal and correction boluses.

### Correction Bolus

CGM = 180, Target BG = 130  
Correction Factor = 50  
 $(180 - 130) / 50 = 1 \text{ U}$

0 U

Your glucose is 180 mg/dL, which is 50 mg/dL over target. Because your correction factor is 50, the initial correction bolus is 1 U.

### Meal IOB adjustment

Meal IOB = 0.8 U  
 $1 \text{ U} - 0.8 \text{ U} = 0.2 \text{ U}$

Since you have 0.8 U of meal IOB remaining from a previous meal bolus, this is subtracted from the initial correction bolus of 1 U, and you have 0.2 U of correction bolus remaining.

### Correction IOB adjustment

Correction IOB = 0.5 U  
 $0.2 \text{ U} - 0.5 \text{ U} \leq 0 \text{ U}$

You also have 0.5 U of correction IOB from previous insulin action. This is subtracted from the remaining correction bolus of 0.2 U, driving the final calculated correction bolus to 0 U. Note that 0.3 U of correction IOB still remains after driving correction bolus to 0 U, and this is used in the meal bolus calculations.

### Meal Bolus

Carbs = 0 g, IC Ratio = 10 g/U  
 $0 / 10 = 0 \text{ U}$

0 U

You did not enter any carbs, so you do not receive any calculated meal bolus dose.

### Correction IOB adjustment

Remaining correction IOB = 0.3 U  
 $0 \text{ U} - 0.3 \text{ U} \leq 0 \text{ U}$

Although there is remaining correction IOB of 0.3 U, your initial meal bolus is already at 0 U, so it is not adjusted further, and your meal bolus remains at 0 U.

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Calculated Bolus	0 U	Even though your glucose is above target, you have enough IOB. As a result, the Bolus Calculator recommends that you do not deliver any additional insulin.
Total Bolus	0 U	

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# Chapter 24: Living with Diabetes

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## 24.1. Infusion Site Checks

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

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

### Warning:

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 blood glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected elevated blood glucose levels, change your Pod.

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

## 24.2. Being Aware of Your Blood Glucose Levels

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

Check your glucose level:

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

When using a CGM, if your CGM values are different than what you expect based on how you feel, then check your blood glucose using a BG meter to verify your CGM value's accuracy. For example, if you feel shaky and sweaty, which

usually means your glucose is very low, but your CGM value shows as in your acceptable range, you should confirm by testing with your BG meter.

If your BGs are verified too low or too high, consider treatment.

A sensor calibration may also be needed; consult your compatible CGM *User Guide* for more information.

**Warning:** If you notice that your CGM value does not match your symptoms, check your blood glucose using a BG meter and consider treatment and/or CGM sensor calibration if necessary.

- Always make sure you are using the CGM per manufacturer's instructions and do not extend the sensor wear beyond the recommended duration.
- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness and death.
- Erroneously low CGM values can cause prolonged insulin suspension leading to hyperglycemia, DKA and death.

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## 24.3. Traveling and Vacations

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

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

### Keep supplies accessible

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

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

**Note:** Generic medications may be easier to find than brand names outside your country.

- Snacks and hypoglycemia treatment, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of your physician and of a physician at your final destination

**Note:** For information about the recommended CGM supplies to carry, see your compatible CGM *User Guide*.

**Note:** Keep your emergency kit with you during trips or vacations (see "Emergency kit" on page 10). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

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

## Plan for changing time zones

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

## Airports and flying

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

### Airport security

Prepare for your travel:

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

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

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

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

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

**Note:** For information about passing CGM equipment through airport X-ray machines, see your compatible CGM *User Guide*.

### Flying and airplane mode

**Warning:** The atmospheric pressure in an airplane cabin can change during flight, which may affect the Pod's insulin delivery. Check your blood glucose frequently while flying. If needed, follow your healthcare provider's treatment instructions.

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

If use of a Personal Medical Electronic Device using Bluetooth® technology is allowed, set your Omnipod 5 app to airplane mode while on the airplane (see "Airplane mode" on page 153). The Bluetooth® setting remains enabled in the controller's airplane mode so you can communicate with your Pod.

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

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### 24.4. Avoiding Lows, Highs, and Diabetic Ketoacidosis

You can avoid most risks related to using the Omnipod 5 System by practicing proper techniques and by acting promptly at the first sign of hypoglycemia, hyperglycemia, or diabetic ketoacidosis (DKA). The easiest and most reliable way to avoid these conditions is to check your glucose level often.

#### General precautions

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

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## Hypoglycemia (low blood glucose)

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

### Symptoms of hypoglycemia (low glucose)

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

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

**Tip:** Hypoglycemia unawareness is a condition in which you do not realize when your glucose level is low. If you are prone to hypoglycemia unawareness, you may want to use the Omnipod 5 app's blood glucose reminder and check your glucose level more frequently (see "Check BG after bolus" on page 158).

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

**Tip:** Even if you cannot check your glucose level, do NOT wait to treat symptoms of hypoglycemia, especially if you are alone. Waiting to treat symptoms could lead to severe hypoglycemia, which can quickly lead to shock, coma, or death.

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

### To avoid hypoglycemia (low glucose)

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

- Keep a glucagon kit with your emergency supplies. Teach friends and family members how to administer a glucagon dosage in case you have severe hypoglycemia and become unconscious.

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

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

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

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

Possible causes of hypoglycemia	Suggested action
Incorrect Basal Program (Manual Mode)	Confirm that the correct Basal Program is active. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too large	Take bolus with food. Check blood glucose before giving a meal bolus. If necessary, adjust the bolus. Check the bolus size and timing. Do not overcorrect for post-meal glucose levels. Check carb intake. Consult your healthcare provider for guidance.
Incorrect Target BG level or incorrect Correction Factor or incorrect IC Ratio	Consult your healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia or hypoglycemia unawareness	Consult your healthcare provider about hypoglycemia unawareness and about raising Target BG levels.
Unplanned physical activity	Consult your healthcare provider about using a temp basal (temporary basal rate) or HypoProtect™ to avoid hypoglycemia.

Possible causes of hypoglycemia	Suggested action
Prolonged or intense exercise	<p>Adjust insulin delivery as instructed by your healthcare provider.</p> <p>Check blood glucose before, during, and after activity and treat as necessary.</p> <p><b>Note:</b> Effects of exercise can last several hours—even a full day—after activity ends.</p> <p>Consult your healthcare provider about adjusting your Basal Programs or using a temp basal (Manual Mode) or HypoProtect™ (Automated Mode) to avoid hypoglycemia.</p>
Low carbohydrate intake prior to activity	<p>Check blood glucose before activity.</p> <p>Consult your healthcare provider for guidance.</p>
Alcohol consumption	<p>Check blood glucose frequently, especially before going to bed.</p> <p>Consult your healthcare provider for guidance.</p>

**To treat hypoglycemia (low glucose)**

Any time your glucose is low, treat it immediately according to your healthcare provider’s instructions. Check your glucose every 15 minutes while you are treating, to make sure you don’t overtreat the condition and cause glucose levels to rise too high. Contact your healthcare provider as needed for guidance.

**Hyperglycemia (high glucose)**

Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If a blockage (interruption of insulin delivery from the Pod) occurs, your glucose level can rise rapidly.

**Warning:** A blockage may result from blocked tubing, Pod malfunction, or from using old or inactive insulin (see Blockage Detected on page 195). If insulin delivery is interrupted by a blockage, check your glucose levels and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.

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



Symptoms of hyperglycemia (high glucose)

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

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

To avoid hyperglycemia (high glucose)

Check your glucose levels:

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

Possible causes of hyperglycemia	Suggested action
Expired insulin or insulin exposed to extreme temperatures	Deactivate and remove the used Pod. Apply a new Pod filled from a new vial of insulin.
Infusion site in or near a scar or mole	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Infected infusion site	Deactivate and remove the used Pod. Apply a new Pod in a different location and consult your healthcare provider.
Dislodged cannula	Deactivate and remove the used Pod. Apply a new Pod in a different location. <b>Note:</b> Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.

Possible causes of hyperglycemia	Suggested action
Empty Pod	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Incorrect Basal Program (Manual Mode)	Confirm that the correct Basal Program is active. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too small	Check carb intake. Take bolus with food. Check blood glucose before giving meal bolus. If necessary, adjust bolus. Consult your healthcare provider for guidance.
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type. Consult your healthcare provider about using the extended bolus option.
Less activity than normal	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal (Manual Mode) .
Blood glucose value greater than 250 mg/dL (with ketones present) before exercise	Do not exercise when ketones are present. <b>Note:</b> Glucose increases with exercise when ketones are present. Consult your healthcare provider for guidance.
Infection or illness or medication change	See "Sick days" on page 283. Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain or menstrual cycle or pregnancy	Consult your healthcare provider for guidance.

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## To treat hyperglycemia (high glucose)

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

1. Check your glucose levels. The result will help you to find out how much insulin is needed to return your glucose level to your glucose goal.
2. If your glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check your glucose level again after 2 hours.
5. If glucose levels have not decreased, do both of the following:
  - Take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.
  - Replace the Pod. Use a new vial of insulin to fill the new Pod. Then contact your healthcare provider for guidance.
6. If you feel nauseated at any point, check for ketones and contact your healthcare provider immediately (see "To treat hyperglycemia (high glucose)" on page 282).

**Warning:** If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

## Diabetic ketoacidosis (DKA)

Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If insulin delivery from the Pod is interrupted (a blockage), your glucose level can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but preventable—emergency that can occur if you ignore high glucose levels.

**Warning:** If left untreated, DKA can cause breathing difficulties, shock, coma, and eventually death.

### Symptoms of DKA

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

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

### To avoid DKA

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

### To treat DKA

- Once you have begun treatment for high glucose, check for ketones. Check for ketones any time your glucose is 250 mg/dL or above.
- If ketones are negative or trace, continue treating for high glucose.
- If ketones are positive and you are feeling nauseated or ill, immediately contact your healthcare provider for guidance.
- If ketones are positive but you are not feeling nauseated or ill, replace the Pod, using a new vial of insulin.
- Check your glucose again after 2 hours. If your glucose level has not declined, immediately contact your healthcare provider for guidance.

## 24.5. Handling Special Situations

### Sick days

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

When you are ill, check your glucose levels more often to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the

flu, check your glucose level to rule out DKA (see "To treat hyperglycemia (high glucose)" on page 282).

To handle sick days:

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

### Exercising, playing sports, or working hard

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

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

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

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

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

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

## X-rays, MRIs, and CT scans

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

**Warning:** The Pod and controller may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove and dispose of your Pod and place your controller outside the treatment area. Check with your healthcare provider on Pod removal guidelines.

## Surgery or hospitalization

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

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# Appendix

## Summary of Settings and Options

The options for the various Omnipod 5 Automated Insulin Delivery System settings are:

Time format	12-hour
Time zone	GMT-11:00 to GMT+13.00.
Daylight Savings Time	ON or OFF. Default based on date and time zone.
Date format	MM/DD/YYYY
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9.
CGM G6 transmitter serial number	6 characters.
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
HypoProtect™	Range: 1 - 72 hrs
Temp basal	%, units/hr, or OFF. Default is OFF. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Temp basal presets	Maximum of 12.
BG/CGM Goal Range (for blood glucose history)	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments.
BG reminder	ON or OFF. Default is OFF. Maximum of 4 active at one time. Reminder can occur between 30 min and 4 hrs after bolus is started. Set in 30-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, OFF.
Target BG value	Maximum of 8 segments; 110 to 150 mg/dL in 10 mg/dL increments.



Correct Above threshold	Maximum of 8 segments; Target BG to 200 mg/dL in 1 mg/dL increments.
Minimum BG for Calcs	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.
Reverse Correction	ON or OFF. Default is ON.
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Bolus size	Range: 0.05-30 U in 0.05 U increments.
Extended bolus	%, Units, or OFF. Default is OFF. 30 minutes to 8 hours in 30-minute increments.
MY FOODS list	Maximum of 50 items.
Custom foods	Range: 0-225 g carbohydrates.
Pause insulin	30 minutes to 2 hours.
Low Pod Insulin advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Pod Shut-Off timer	OFF, or 1 to 24 hours in 1-hour increments. Default is OFF.
History screen display	Rolling 90-day period.
Language	English.

## Pod Specifications

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

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

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

**Note:** The Pod temperature equilibrates from 73°F to 98.6°F (23°C to 37°C) when worn on the body.

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

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

**Reservoir volume (deliverable):** 200 units

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

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

**Waterproof rating:** IP28 (25 feet (7.6 meters) for up to 60 minutes)

**Insulin concentration:** U-100

**Alarm type:** Audible. Output:  $\geq 45$  db(A) at 1 meter

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

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

**Operating atmospheric pressure:** 700 hPA to 1060 hPA

**Storage atmospheric pressure:** 700 hPA to 1060 hPA

**Non-pyrogenic:** Fluid pathway only

**Type BF applied part:** Protection from electrical shock

**Maximum infusion pressure:** 35 psi

**Maximum volume infused under single fault conditions:** 0.0 U

#### Flow Capability:

Basal: Programmable by the user in 0.05 U increments up to 30.0 U per hour

Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

#### Delivery accuracy (tested per IEC 60601-2-24):

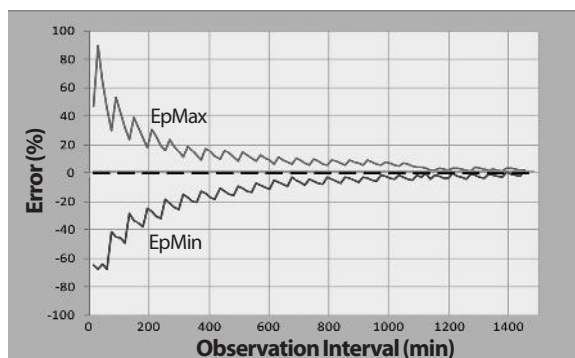
Basal:  $\pm 5\%$  at rates  $\geq 0.05$  U/hr

Bolus:  $\pm 5\%$  for amounts  $\geq 1.0$  unit

$\pm 0.05$  units for amounts  $< 1.0$  unit

**Note:** The user should consider bolus dose accuracy when setting a bolus dose. When using the lowest bolus dose allowable (0.05 units), the actual bolus delivered may be as low as 0.00 units or as high as 0.10 units.

**Accuracy test results:** The following graph shows the flow accuracy of the Pod against given time periods. The measurements were made using a Pod with a basal rate of 0.5  $\mu\text{l/h}$  (which delivers 0.05 U/h of U-100 insulin) at a high operating temperature. The overall mean percentage flow error was 1.40%.



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## Controller Specifications

**Size:** 5.67" high x 2.66" wide x 0.49" deep (143.92 mm x 67.57 mm x 12.33 mm)

**Weight:** 5.82 oz (165 grams)

**Screen active area:** 2.21" wide x 4.75" high (56.16 mm x 120.58 mm)

**Communication distance:** The controller and Pod should be

- At startup: Adjacent and touching, either in or out of tray, to ensure proper communication during priming.
- During normal operation: Within 5 feet (1.5 m) of each other. Depending on the location, the communication distance may handle separations up to 50 feet (15 meters) away.

**Alarm type:** \*\*TBD\*\* Audible. Output:  $\geq 45$  db(A) at 1 meter

**Notification type:** Audible and vibratory

**Battery:** Rechargeable Li-ion battery, 3.8V, 2800 mAh

**Battery life:** Full charge covers approximately 2 days of typical use after 2 years of typical use.

**Battery charger operating line voltage:** 100 to 240 VAC, 50/60 Hz

Only use the Noetic approved power adapter (Insulet PN PT-000428) with the controller.

## Dexcom Specifications

For information about Dexcom operating specifications, see the *Dexcom G6 CGM System User Guide*.

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## Protection from Over-infusion or Under-infusion

The Pod software monitors the infusion rate. If an error that would result in over- or under-infusion is detected and cannot be corrected, insulin delivery stops, and an alarm sounds.

### Blockage detection

A blockage is an interruption in insulin delivery from the Pod. If the Omnipod 5 System detects a blockage, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

A blockage hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts blockage detection for three different situations when using U-100 insulin. For example, if the Pod's cannula becomes blocked when delivering a 5 U bolus, 35 minutes may pass before the Pod sounds a hazard alarm.

	Time between blockage and Pod alarm	
	Typical time	Maximum time
<b>5.00 U bolus</b>	33 minutes	35 minutes
<b>1.00 U/hr basal</b>	3.5 hr	7.0 hr
<b>0.05 U/hr basal</b>	51 hr	80 hr (Pod expiration)

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

If a blockage is detected during an immediate bolus, the Pod sounds a hazard alarm at the conclusion of the immediate bolus.

**Warning:** At very low basal flow rates, checking your blood glucose frequently may give you an early indication of a blockage. Blockages can result in hyperglycemia.

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Performance Characteristics

The Omnipod 5 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Insulet.

Delivery performance characterization

Basal Delivery: To assess basal delivery accuracy, 12 Pods were tested by delivering at low, medium, and high basal rates (0.05, 1.00, and 30.0 U/hr). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.05 U/hr)			
Basal Duration (Number of units requested)	1 hour (0.05 U)	6 hours (0.30 U)	12 hours (0.60 U)
Amount Delivered	0.049 U	0.30 U	0.59 U
[min, max]	[0.00, 0.12]	[0.13, 0.57]	[0.34, 0.99]

Medium Basal Rate Delivery Performance (1.00 U/hr)			
Basal Duration (Number of units requested)	1 hour (1.00 U)	6 hours (6.00 U)	12 hours (12.00 U)
Amount Delivered	0.99 U	5.97 U	11.88 U
[min, max]	[0.65, 1.55]	[5.06, 6.87]	[10.53, 13.26]

High Basal Rate Delivery Performance (30.00 U/hr)		
Basal Duration (Number of units requested)	1 hour (30.00 U)	6 hours (180.00 U)
Amount Delivered	29.82 U	179.33 U
[min, max]	[28.85, 31.39]	[177.49, 181.15]

**Note:** A measurement at the 12-hour period with 30.0 U/hr basal rate is not applicable to the Omnipod 5 System as the reservoir will empty at approximately 6 2/3 hours at this rate.

**Bolus Delivery:** To assess bolus delivery accuracy, 12 Pods were tested by delivering a minimum, intermediate, and maximum bolus amount (0.05, 5.00, and 30.0 Units). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid delivered was used to assess pumping accuracy.

The following table summarizes the typical bolus performance observed for the requested minimum, intermediate, and maximum size bolus for all pumps tested. For each individual target bolus size, the number of boluses observed is shown along with the average (mean), minimum, and maximum units delivered as measured by a scale.

<b>Individual Bolus Accuracy Performance</b>	<b>Target Bolus Size (Units)</b>	<b>Mean Bolus Size (Units)</b>	<b>Min Bolus Size (Units)</b>	<b>Max Bolus Size (Units)</b>
<b>Min Bolus Delivery Performance</b> (n= 5987 boluses)	0.05 U	0.050 U	0.00 U	0.119 U
<b>Intermediate Bolus Delivery Performance</b> (n= 300 boluses)	5.00 U	5.01 U	4.49 U	5.37 U
<b>Max Bolus Delivery Performance</b> (n= 72 boluses)	30.00 U	30.05 U	29.56 U	30.62 U

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The tables below show for each requested bolus size the range of amount of insulin that was observed delivered compared to the requested amount. Each table provides the number and percent of delivered bolus sizes observed within the specified range.

Amount of Insulin Delivery for a Minimum (0.05 U) Bolus Request

Amount (Units)	<0.0125	0.0125- 0.0375	0.0375-0.045	0.045-0.0475	0.0475- 0.0525
(% of set- tings)	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
Number and percent of boluses within range	61/5987 (1%)	639/5987 (10.7%)	1284/5987 (21.4%)	504/5987 (8.4%)	1100/5987 (18.4%)
Amount (Units)	0.0525-0.055	0.055-0.0625	0.0625- 0.0875	0.0875-0.125	>0.125
(% of set- tings)	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
Number and percent of boluses within range	504/5987 (8.4%)	1192/5987 (19.9%)	582/5987 (9.7%)	121/5987 (2%)	0/5987 (0%)

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**Amount of Insulin Delivery for an Intermediate (5.00 U) Bolus Request**

<b>Amount (Units)</b>	<125	1.25-3.75	3.75-4.50	4.50-4.75	4.75-5.25
<b>(% of settings)</b>	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
<b>Number and percent of boluses within range</b>	0/300 (0%)	0/300 (0%)	1/300 (0.3%)	4/300 (1.3%)	287/300 (95.7%)
<b>Amount (Units)</b>	5.25-5.50	5.50-6.25	6.25-8.75	8.75-12.50	>12.50
<b>(% of settings)</b>	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
<b>Number and percent of boluses within range</b>	8/300 (2.7%)	0/300 (0%)	0/300 (0%)	0/300 (0%)	0/300 (0%)

**Amount of Insulin Delivery for a Maximum (30.0 U) Bolus Request**

<b>Amount (Units)</b>	<7.5	7.5-22.5	22.5-27.0	27.0-28.5	28.5-31.5
<b>(% of settings)</b>	(<25%)	(25-75%)	(75-90%)	(90-95%)	(95-105%)
<b>Number and percent of boluses within range</b>	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)
<b>Amount (Units)</b>	31.5-33.0	33.0-37.5	37.5-52.5	52.5-75.0	>75.0
<b>(% of settings)</b>	(105-110%)	(110-125%)	(125-175%)	(175-250%)	(>250%)
<b>Number and percent of boluses within range</b>	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)



CGM-Informed Bolus Calculator Clinical Study

A study was conducted in 25 participants with type 1 diabetes aged 6-70 years to assess the Omnipod 5 CGM-informed Bolus Calculator. During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected CGM (standard Bolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected CGM (CGM-informed Bolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/or either a manually entered glucose value (standard Bolus Calculator) or an imported current CGM value and trend (CGM-informed Bolus Calculator). Both versions of the Bolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the CGM trend. The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by CGM between the two study phases. The results indicate that the use of the CGM-informed Bolus Calculator was associated with less time in hypoglycemia within 4 hours of bolusing.

Comparison of Glycemic Outcomes from Phase 1 (Standard Bolus Calculator) and Phase 2 (CGM-Informed Bolus Calculator) for the 4 hours After any Bolus (N=25)

Percent time in glucose range as measured by CGM	Standard Bolus Calculator	CGM-Informed Bolus Calculator	Difference
70-180 mg/dL	65.1% (15.4)	63.8% (15.7)	-1.3%
< 70 mg/dL	2.8% (2.7)	2.1% (2.0)	-0.6%*
< 54 mg/dL	0.5% (1.0)	0.3% (0.7)	-0.2%
> 180 mg/dL	32.1% (15.7)	34.0% (16.0)	1.9%
≥ 250 mg/dL	8.2% (6.9)	9.7% (10.3)	1.4%
≥ 300 mg/dL	2.0% (2.6)	2.6% (3.7)	0.6%

Data is presented as average (standard deviation). Significant differences ( $p<0.05$ ) are highlighted with an asterisk.

## Omnipod 5 System Label Symbols

The following symbols appear on the Omnipod 5 System or its packaging:

Symbol	Meaning	Symbol	Meaning
	Single use only		MR unsafe
	Consult accompanying documents		Do not use if package is damaged
	Sterilized using ethylene oxide		Type BF applied part
	Date of manufacture		Manufacturer
	Batch code		Keep dry
	Use by date		Storage temperature, Operational temperature
	Reference number		Storage relative humidity, Operational relative humidity
	Serial number		Storage atmospheric pressure, Operational atmospheric pressure
	Submersible: Waterproof to 25 feet (7.6 meters) for up to 60 minutes		Non-pyrogenic fluid path
	Avoid liquid		Prescription only
	Do not dispose with household waste		RoHS compliant
	Marking of conformity		Representative in the European Community
	Pod		Charging cable

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## Omnipod 5 System Notice Concerning Interference

The Omnipod 5 Automated Insulin Delivery System is designed to comply with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

**Caution:** Changes or modifications not expressly approved by Insulet Corporation could void the user's authority to operate the equipment.

Both the Pod and the controller generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications of other devices. There are no guarantees that interference will not occur in a particular installation. If the Omnipod 5 System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

- Move or relocate the Omnipod 5 app
- Increase the distance between the Omnipod 5 app and the other device that is emitting or receiving interference.

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## Quality of Service

Insulet defines the quality of service of the Omnipod 5 System as the successful transfer of commands, data, and alarms between the Controller and Pod when in communication range (within 5 ft during normal operation) and successful transfer of CGM readings and errors between the CGM and the pod while in communication range (line of sight on body). The controller will provide notification when communication errors between the Pod and controller or the Pod and CGM are experienced. For additional information on communication errors in the Omnipod 5 System, see Chapter 21. To maintain quality of service when other devices operating in 2.4 GHz band are around, the Omnipod 5 System uses the coexistence features provided by Bluetooth® wireless technology.

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## Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod 5 System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical

electrical equipment; older equipment may be particularly susceptible to interference.

### General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod 5 System fails due to electromagnetic disturbances, you may need to replace it.

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

**Caution:** Cables and accessories not specified within the instructions for use are not authorized. Using other cables or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the Omnipod 5 System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod 5 System should be observed to verify normal operation in this setting.

The Omnipod 5 System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod 5 System communicates with the following characteristics:

Frequency: 2.400-2.480 GHz, digitally modulated, with an effective radiated power of 1.14mW

The Omnipod 5 System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

**Caution:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the Omnipod 5 System. Otherwise, degradation of the performance of this equipment could result.

### Electromagnetic Emissions

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

Emissions	Compliance according to	Electromagnetic environment
RF Emissions (CISPR 11)	Group 2	The Pod, controller, and CGM emit low level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.

Electromagnetic Emissions		
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

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

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

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## Customer's Bill of Rights

### Mission Statement

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

### Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod 5 Automated Insulin Delivery System.

The Omnipod 5 System consists of the Pod and the handheld, wireless controller with the Omnipod 5 app, which programs the Pod with insulin delivery instructions.

### Compliance

The Omnipod 5 Automated Insulin Delivery System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

### Inquiries

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

### CHAP Accredited

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

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## Customer's Bill of Rights and Responsibilities

### You have the right to:

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

### You have the responsibility to:

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

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## Limited Express Warranty, Disclaimer, and Limitation of Remedies for the Controller and Pods

### **LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE Omnipod 5 AUTOMATED INSULIN DELIVERY SYSTEM HANDHELD CONTROLLER AND PODS (United States of America)**

#### **LIMITED EXPRESS WARRANTY COVERAGE**

##### Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Handheld Controller

Subject to the terms and conditions stated herein (“Limited Express Warranty”), Insulet Corporation (“Insulet”) warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System (“Omnipod 5 System”), that, if Insulet determines, during the period of four (4) years from the date of purchase, that the Omnipod 5 System handheld hardware controller (“Controller”) included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will either repair or replace, at its sole option, the Controller. This four-year (4) warranty period applies only to new Controllers and, in the event the Controller is repaired or replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Controller under this Limited Express Warranty, the warranty coverage for the replacement Controller shall expire four (4) years from the date of purchase of the original Controller.

##### Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Pods

Subject to this Limited Express Warranty, Insulet warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System, that, if Insulet determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod 5 Automated Insulin Delivery System Pod (“Pod”) included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e. occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet of the claim).

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

#### **LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS**

##### Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Insulet of the claimed defect with the Controller or the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). For a claim involving the Controller, you must provide the Controller serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the Controller and/or the Pod, the manufacture date of the Pod and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet elects to repair the Controller (which may include, but is



not limited to, a repair kit or replacement part(s) Insulet provides) or refers you to a third party, you must obtain a prior authorization and return the Controller or the Pod to Insulet. The Controller or Pod must be properly packaged and returned to Insulet according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a prior authorization, Insulet will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the Controller or Pod to Insulet under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet, except those performed or provided by third parties to which you were explicitly referred by Insulet.

## Proof of Purchase

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

## Exclusions

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

This Limited Express Warranty will apply only if the Controller or the Pod at issue has been used in accordance with the Omnipod 5 Automated Insulin Delivery System User Guide and/or other written instructions provided by Insulet. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE CONTROLLER OR THE POD HAVE BEEN:

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

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

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

## **DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES**

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

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

IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL,

INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN THE CONTROLLER OR A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

#### Important Additional Provisions

INSULET CORPORATION DOES NOT WARRANT THE SUITABILITY OF THE CONTROLLER OR THE POD OR THE OMNIPOD 5 AUTOMATED INSULIN DELIVERY SYSTEM FOR ANY SPECIFIC PERSON AS HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS.

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

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

#### No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System. No employee, agent or other representative of Insulet or any other party is authorized to make any product warranty or agreement applicable to a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System in addition to those made in the foregoing..

#### Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod 5 Automated Insulin Delivery System, please return any Omnipod 5 Automated Insulin Delivery System products (including any Controller and Pods) to Insulet in exchange for a full refund. Failure to return such Omnipod 5 Automated Insulin Delivery System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

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## HIPAA Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

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

### Uses and Disclosures of Medical Information

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

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

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

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

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

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

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

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

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

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

### **Additional Categories of Uses and Disclosures**

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

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

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

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

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

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

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

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

**Criminal Activity:** Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

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

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

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

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

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

## **Your Rights**

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

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

[https://www.omnipod.com/images/upload/HIPAA\\_Privacy\\_Notice\\_Request\\_Form.pdf](https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf)

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

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

[https://www.omnipod.com/images/upload/HIPAA\\_Privacy\\_Notice\\_Request\\_Form.pdf](https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf)

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

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

[https://www.omnipod.com/images/upload/HIPAA\\_Privacy\\_Notice\\_Request\\_Form.pdf](https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf)

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

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

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

[https://www.omnipod.com/images/upload/HIPAA\\_Privacy\\_Notice\\_Request\\_Form.pdf](https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf)

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

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

[https://www.omnipod.com/images/upload/HIPAA\\_Privacy\\_Notice\\_Request\\_Form.pdf](https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf)

and follow the directions included on that form.



## Our Duties

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

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the “Revised HIPAA Privacy Notice”). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our website at <https://www.omnipod.com>. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at

[https://www.omnipod.com/images/upload/HIPAA\\_Privacy\\_Notice\\_Request\\_Form.pdf](https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf)

and follow the directions included on that form.

## What To Do If You Have a Problem or Question

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

Insulet Corporation  
Attn: Privacy Officer  
100 Nagog Park  
Acton, MA 01720  
866-941-0155

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling (877) 696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

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

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# My Settings

Use these pages to keep track of your important settings. Remember to update your information if you change or add settings.

Basal Program 1		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Basal Program 2		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Basal Program 3		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Basal Program 4		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Target BG			
Time segment		Target BG: Bolus Calculator aims for this value	Correct Above: Suggest correction if BG is above
midnight	to	mg/dL	mg/dL
	to	mg/dL	mg/dL
	to	mg/dL	mg/dL
	to	mg/dL	mg/dL
	to	mg/dL	mg/dL
	to	mg/dL	mg/dL
	to	mg/dL	mg/dL
	to	mg/dL	mg/dL

Correction Factor		Insulin-to-Carbohydrate Ratio (IC Ratio)	
Correction Factor for each time segment	<b>1 unit of insulin decreases BG by</b>	IC Ratio for each time segment	<b>1 unit of insulin covers</b>
midnight to _____	_____ mg/dL	midnight to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb
_____ to _____	_____ mg/dL	_____ to _____	_____ g carb

Duration of Insulin Action	
Time that insulin remains “active” in the body after a bolus	_____ hrs

Temp Basal Presets	
Name	Rate (circle measurement)
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %
_____	_____ U/hr or %

Favorite Foods	
Name	Grams of carbohydrates
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

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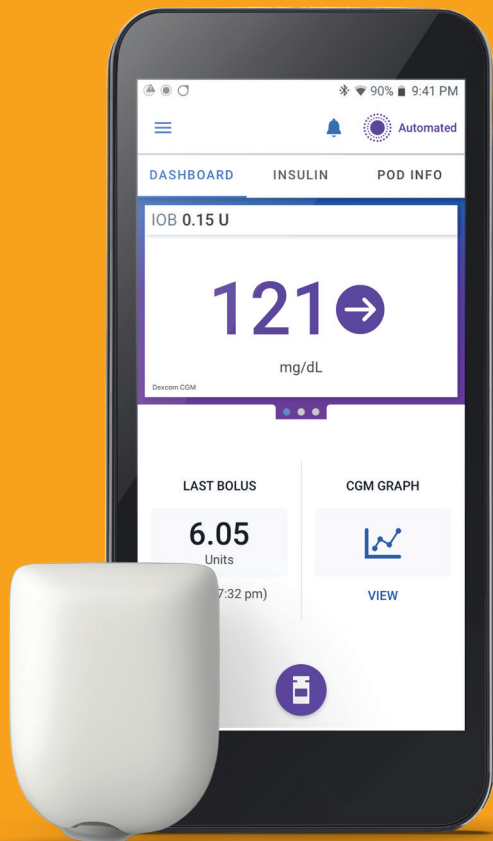
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Pod shown without the necessary adhesive.



# TBD

FCC ID: #TBD  
Controller

FCC ID: #TBD  
Pod

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