



User Guide

Omnipod® 5 Automated Insulin Delivery System



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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.

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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.

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.

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.

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.

Touchscreen basics

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

Tapping and swiping

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

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

Note: A screen protector may decrease the touchscreen sensitivity.

Screen time-out and brightness

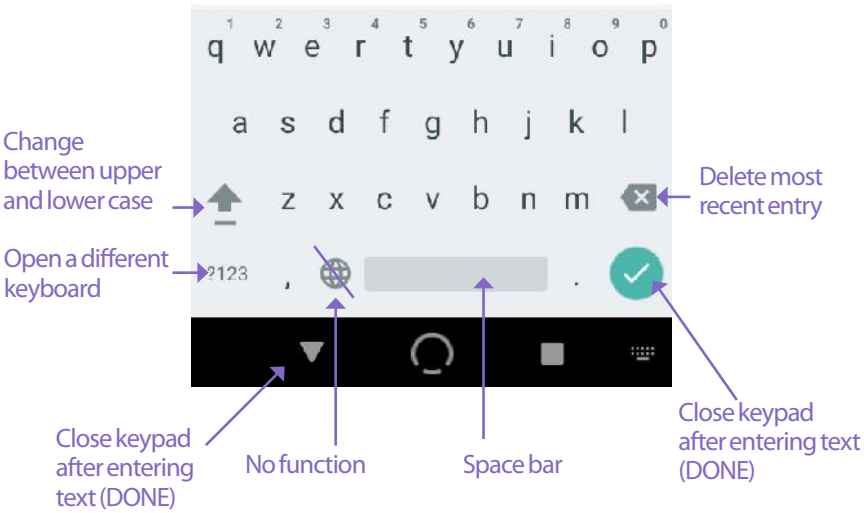
The screen on the controller turns black, called "timing-out", after a period of inactivity. To control the screen time-out and brightness settings, see "Screen display" on page 153. The screen dims 6-10 seconds before it times out. If the screen dims, tap the screen to prevent it from timing out.

2 System Terminology and Navigation

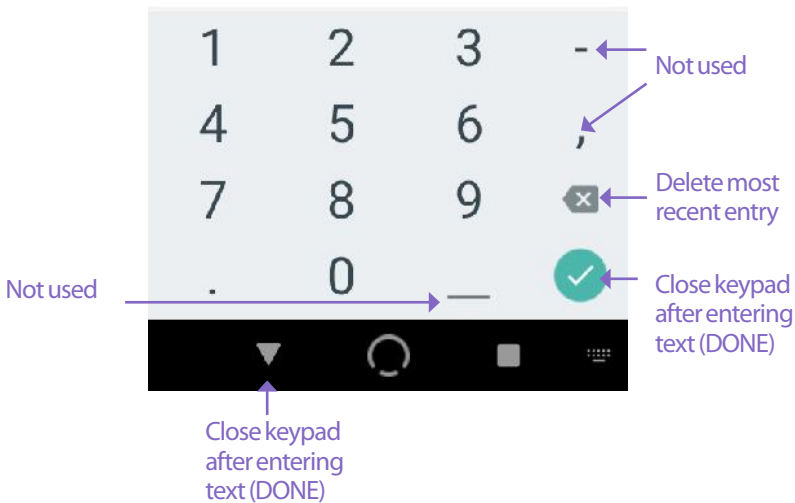
Entering numbers and text

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

Using a keypad



Using a numberpad



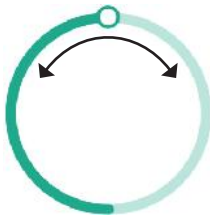
Using a scroll wheel



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.

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.

Chapter 3: Omnipod 5 System Overview

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3.1. Omnipod 5 App and Dexcom Communication

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

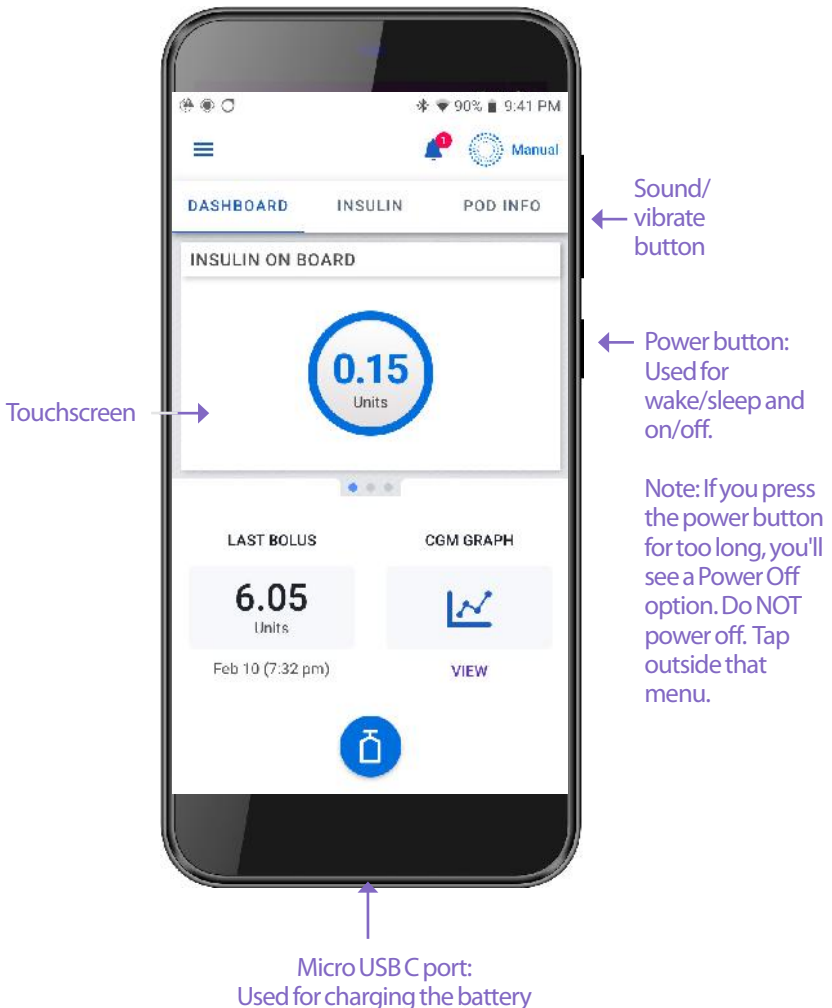


3.2. Omnipod 5 App

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

Before You
Begin

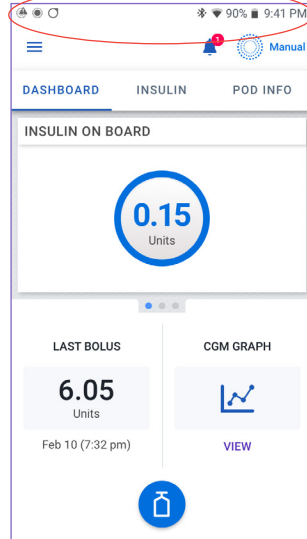
3.3. Status Bar

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.

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

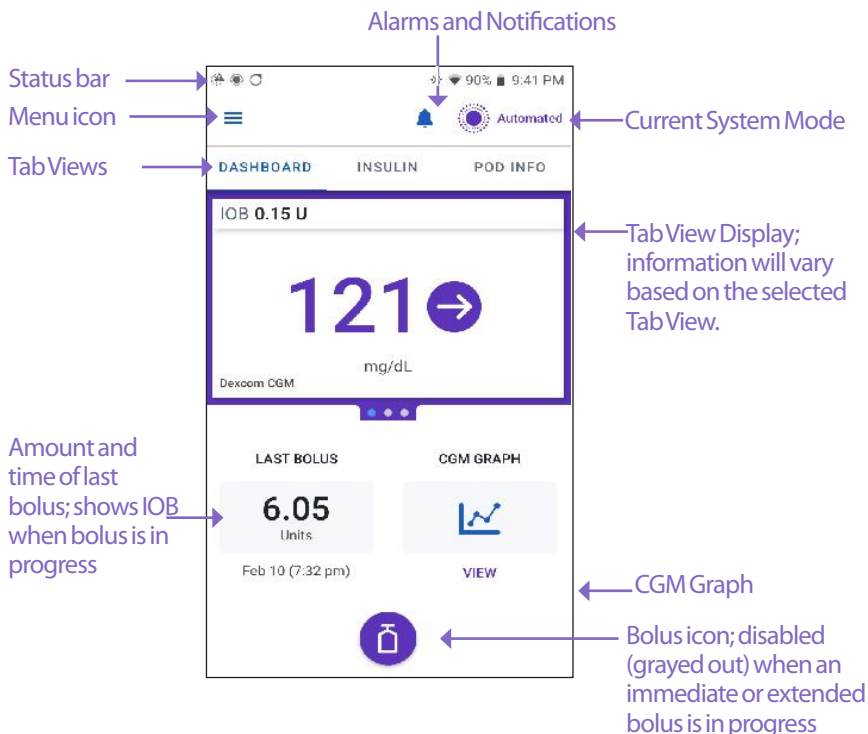
The Omnipod 5 app uses your smartphone's security settings to protect against unintended use of the app. See "Recommended smartphone settings" on page 45 for more information.

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.

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).

3 Omnipod 5 System Overview

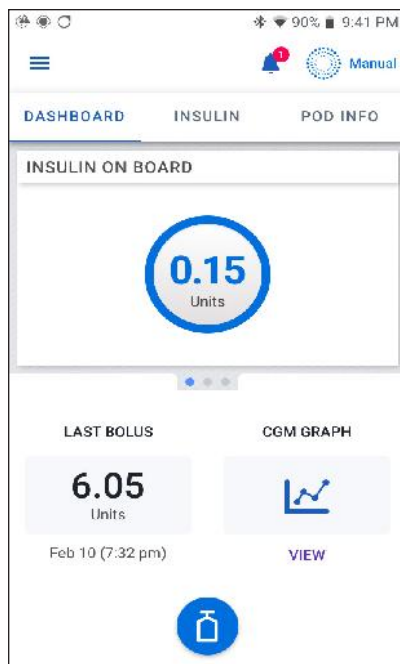
DASHBOARD tab

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.



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).

3 Omnipod 5 System Overview

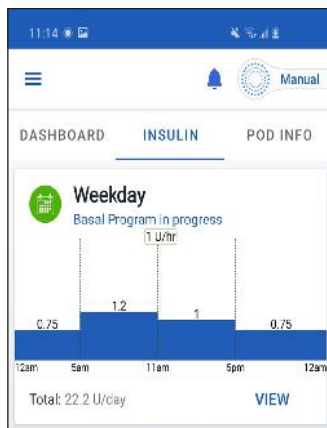
INSULIN tab

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.

Temp basal

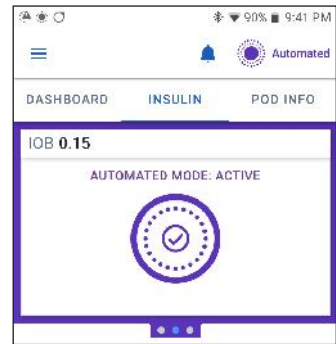
If a temp basal is running, the INSULIN tab label changes to **TEMP ON** and is highlighted in green. It displays the temp basal graph and allows you to cancel the temp basal. See "7.1. About Temporary Basal Rates" on page 82.



Before You Begin

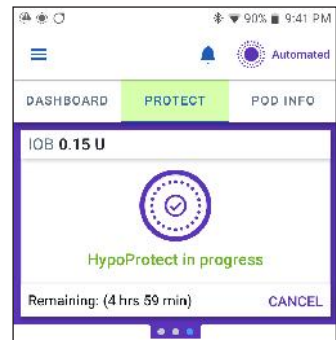
Automated Mode

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.



3 Omnipod 5 System Overview

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.

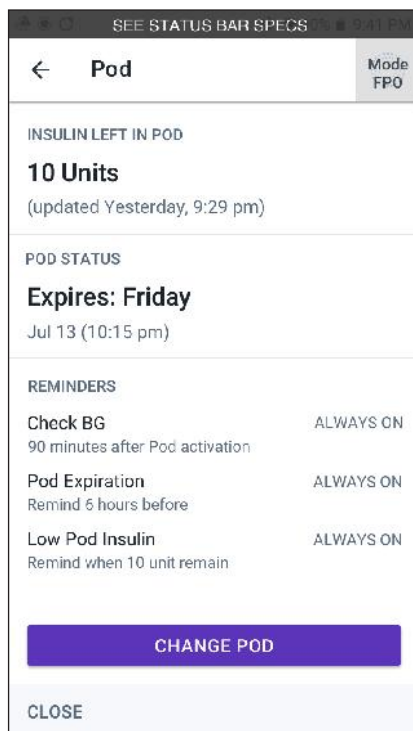
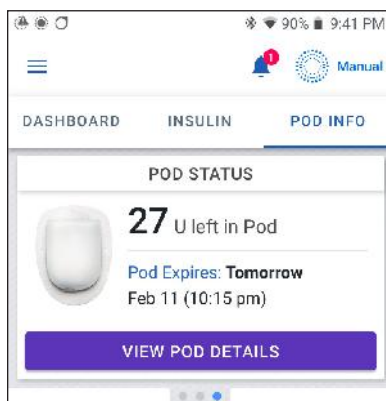
If there is no active Pod, the POD INFO tab says "No Active Pod." To set up a new Pod, see "Chapter 5: Activating and Changing Your Pod" on page 59.

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

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.



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
Frequent Tasks		
Switch Mode	✓	✓
Set Temp Basal	✓	
HypoProtect™		✓
Pod	✓	✓
Enter BG	✓	✓
Pause Insulin	✓	
Manage Programs & Presets		
Basal Programs	✓	
Temp Basal Presets	✓	
History		
History Detail	✓	✓
Notifications	✓	✓
Settings		
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).

3.8. Manual and Automated Mode Overview

Available tasks in each mode

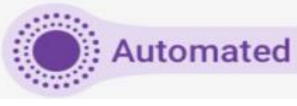
The following table defines the tasks that can be performed in Manual Mode and Automated Mode.

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	✓	✓

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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STARTING OMNIPOD 5

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