

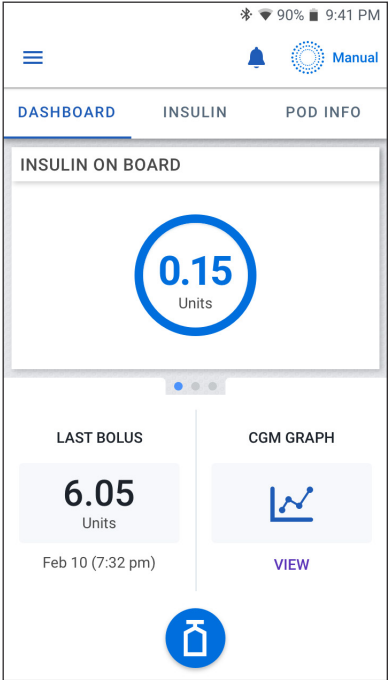
DASHBOARD Tab

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 "19.5. CGM Trend Arrows" on page 278.
- 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 "19.4. CGM Values" on page 277.
- LOW: when CGM value received from your CGM transmitter is less than 40. See "19.4. CGM Values" on page 277.

The DASHBOARD tab also displays information related to potential CGM communication issues. See page 279 for more information.

A progress bar appears when a bolus is in progress (see "16.3. Tracking the Progress of a Bolus" on page 234).



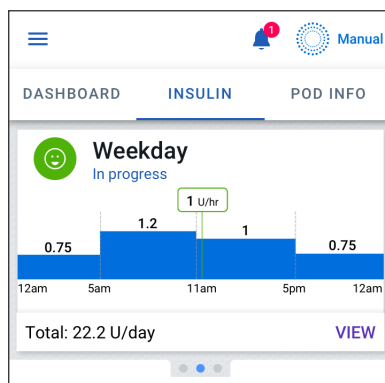
INSULIN Tab

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

Manual Mode

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

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



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

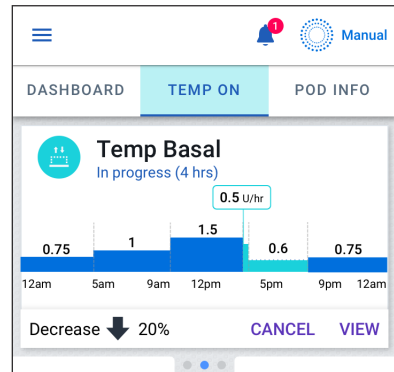
The total daily amount of basal insulin in Manual Mode is shown beneath the graph. This total is the amount of insulin that the Basal Program in progress is scheduled to deliver in a 24-hour period. This total does not account for temp basals or boluses.

To see the total amount of insulin that your Pod has actually delivered, including temp basals and boluses, see "Browsing Your History and Records" on page 133.

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

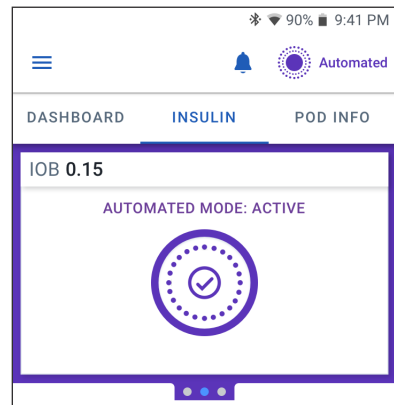
Temp basal

When a temp basal is running, the INSULIN tab label changes to TEMP ON and is highlighted in light blue. It displays the temp basal graph and allows you to cancel the temp basal. See "7.1. About Temporary Basal Rates" on page 104.



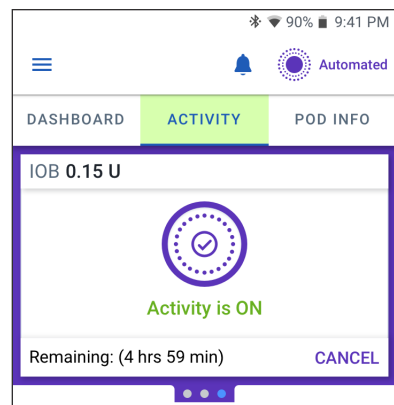
Automated Mode

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 "About Automated Mode" on page 289.



Activity feature

In Automated Mode, when the Activity feature is enabled, the INSULIN tab label changes to ACTIVITY, highlighted in green, and shows Activity is ON. See "23.1. About the Activity Feature" on page 302 for more information.

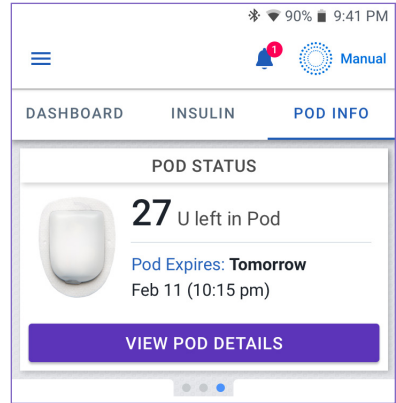


3 Omnipod 5 System Overview

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



Caution: When there is no communication between the Pod and the Controller or smartphone, the Pod continues delivering insulin according to settings active on the Pod before losing communication. For example, automated insulin delivery from the Pod will continue in Automated Mode. Restoring communication is needed to see your system status, notifications, and to send new instructions to the Pod. To restore communication, try bringing the Controller or smartphone within 5 feet (1.5 m) of the Pod. See "26.5. Pod Communication Issues – "Try Again"" on page 337.

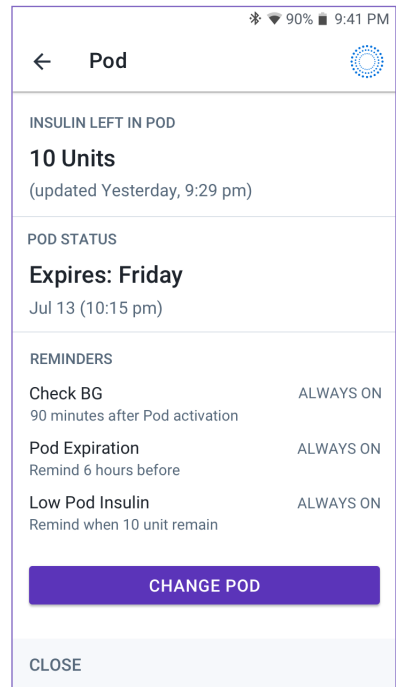
If there is no active Pod, the POD INFO tab shows "No Active Pod." To set up a new Pod, see "Activating and Changing Your Pod" on page 79.

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

The VIEW POD DETAILS screen shows:

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

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



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 6 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.

! LOW POD INSULIN



Less than 5 U

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

VIEW POD DETAILS

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

Bolus Information and Button

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

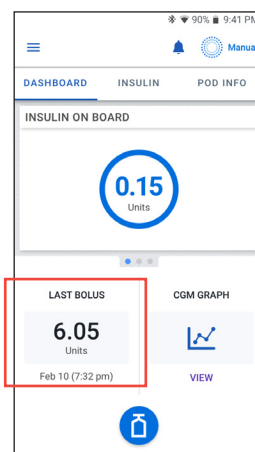
Between boluses

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

During a bolus

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

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



Bolus information if there is no Pod communication

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

Estimated and unconfirmed bolus amounts

The Omnipod 5 App estimates bolus amounts during an ongoing bolus and when the Pod is out of range. A gray icon (ⓘ) marks estimated bolus amounts. A yellow icon (⚠) marks unconfirmed bolus amounts (see "When the Pod has not confirmed a bolus delivery" on page 143).

Bolus button

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



3.6. Home Screen Main Menu

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

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

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

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

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

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

Menu Options	Manual Mode	Automated Mode
Frequent Tasks		
Switch Mode	✓	✓
Set Temp Basal	✓	
Activity		✓
Pod	✓	✓
Enter BG	✓	✓
Pause Insulin	✓	
Manage Programs & Presets		
Basal Programs	✓	
Temp Basal Presets	✓	
History		
History Detail	✓	✓
Notifications	✓	✓
Settings		
General	✓	✓
CGM Transmitter	✓	✓
Reminders	✓	✓
Glucose 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 App version number, the Customer Care contact information, the Controller serial number (if viewing on the Controller), the Pod version number, the time of the most recent Omnipod 5 App-Pod communication, and other Controller and legal information.

3.7. Notifications and Messages

Caution: DO NOT stop the Omnipod 5 App in a way that stops it from running in the background (called force stopping) on your smartphone. The Omnipod 5 App must be open or be running in the background in order to display and sound alarms on the smartphone. If the App is not running, you could miss important alarms and notifications on the smartphone. If you do not hear alarms and notifications from your smartphone, you might not make the changes you need to make to your therapy in a timely manner. Your Pod will continue to operate and sound alarms. In addition, if you stop the Omnipod 5 App while sending commands to the Pod, the command can be interrupted and may not be completed.

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App, such as Digital Wellbeing for Android tools that limit sounds and notifications. If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able to see the Alarm or Notification displayed on the Omnipod 5 App. See "13.3. Sounds and Vibrations" on page 157 to learn how to manage sounds and vibrations.

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

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

Omnipod 5 Notifications

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

Alarms

Alarms require your immediate attention (see page 160). If you ignore an alarm, you could develop hypoglycemia or hyperglycemia. When an alarm occurs, the Pod will beep and the Omnipod 5 App will beep or vibrate if sound/vibrate is on.

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

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

Action Item notifications

Action item notifications (see page 176) 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 Bluetooth wireless technology 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 "13.11. Reminder Notifications List" on page 199). 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 "Frequently Asked Questions and Troubleshooting" on page 325).

3.8. Manual and Automated Mode Overview

Available tasks in each mode

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

	Manual Mode	Automated Mode
How it works		
Basal Insulin Delivery	Insulin is delivered according to the Active Basal Program.	Insulin is delivered and adjusted automatically based on CGM values and prediction.
Bolus Insulin Delivery	Insulin is delivered using the SmartBolus Calculator or entered manually.	Insulin is delivered using the SmartBolus Calculator or entered manually.
Connected CGM	Not required. If connected, CGM values displayed, stored in history, and available for use in SmartBolus Calculator.	Required. CGM values used for automated insulin delivery, displayed, stored in history, and available for use in SmartBolus Calculator.
What you can do		
Basal Programs	Edit, create new, activate Basal Programs (Does not impact Automated Mode).	Edit Target Glucose to impact automated insulin delivery. Cannot modify Basal Programs in Automated Mode.
Basal Insulin Delivery	Start and cancel Temp Basal Rate, create Temp Basal Presets	Start and cancel the Activity feature
SmartBolus Calculator Settings	Edit Bolus Settings	Edit Bolus Settings
Bolus Insulin Delivery	Deliver, and cancel Immediate and Extended Boluses	Deliver and cancel Immediate Boluses

	Manual Mode	Automated Mode
What you can do		
Pod Changes	Activate and Deactivate Pods	Deactivate Pods Once deactivated, the system switches to Manual Mode. Pod activation occurs in Manual Mode (after activation, prompt to switch to Automated Mode is displayed)
CGM Transmitter	View, and modify CGM transmitter serial number	View CGM transmitter serial number
Pause and Start Insulin	Manually pause insulin for a specified duration of up to 2 hours. Manually Start insulin.	System automatically pauses automated insulin delivery based on CGM value/ prediction. Switch to Manual Mode to manually pause insulin delivery.
History Details	Review History Details	Review History Details
BG Entry	Enter blood glucose readings to save in History Details	Enter blood glucose readings to save in History Details
How you will be notified	See "Alarms, Action and Reminder Notifications" on page 153 for a detailed list of alarms and notifications.	

3 Omnipod 5 System Overview

Identifying System modes

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

Graphic	Description
	Displays when there is no Pod communication or no active Pod.
	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 the loss of connectivity between the devices.
	Displays when the Omnipod 5 System is in Manual Mode and delivering the active Basal Program.

CHAPTER 4

Setting Up Your Omnipod 5 Application

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

4.1. Setting Up Your Account

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

If you need to create an Omnipod ID:

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

4.2. Preparing for Your Training

If you are a first-time Omnipod user, you may need to meet with your Omnipod 5 Trainer to set up your Omnipod 5 App, first Pod, and your Dexcom G6 sensor.

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

Note: For training information about your Dexcom G6, refer to your *Dexcom G6 CGM System User Guide*.

Omnipod 5 Intro Kit contents

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

The Insulet-provided Omnipod 5 Intro Kit contains:

- Omnipod 5 Controller and Pods
- USB cable and charger
- *User Guide* and *Quick Start Guide*

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

The Dexcom G6 CGM System and supplies must be obtained from Dexcom or an authorized distributor. Refer to the *Dexcom G6 CGM System User Guide* for instructions for use.

Items needed for your training

- Your Controller or smartphone with Omnipod 5 App and charger
- Your Dexcom G6 transmitter and sensor
- Your Dexcom G6 app
- Two Pods
- This *User Guide*
- BG meter
- Test strips and a lancing device (available from many pharmacies)
- Vial of rapid-acting U-100 insulin (See page 7 for information about the approved types of insulin to use with the Pod).
- Alcohol prep swabs
- Instructions from your healthcare provider with Omnipod 5 App settings tailored to your needs. These settings include Basal Program, Insulin to Carb Ratio, Correction Factor, Target Glucose, and Duration of Insulin Action.

Note: Ensure that your Controller is charged before training begins. To charge your Controller, see "Charging the Battery" on page 209.

4.3. Choosing a Controller or Smartphone

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

Before setting up your Omnipod 5 System, decide whether you want to use the Insulet-provided Controller or a compatible personal smartphone for the

4 Setting Up Your Omnipod 5 Application

Omnipod 5 App. You can find a list of compatible smartphones at omnipod.com/compatibility.

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

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

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

4.4. General Settings on Insulet-provided Controller

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

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

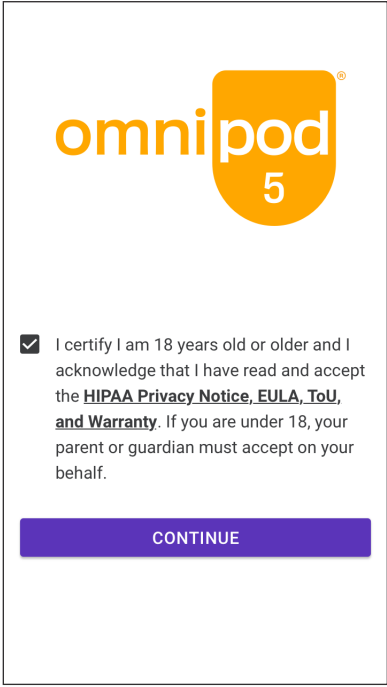
Turning On and Signing in to Your Controller

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

1. Press and hold the Power button on the right side until the device manufacturer logo appears.

2. The Controller runs through a series of checks. If prompted, allow permissions and connect to Wi-Fi. See page 179 for more details.

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



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

CONTINUE

3. Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:
 - a. Tap the HIPAA Privacy Notice, EULA, ToU, and Warranty link to read the Omnipod 5 System's legal notices and privacy policy. Then tap AGREE.

A checkmark is added to the checkbox to indicate agreement.
 - b. Tap CONTINUE.
4. Sign in with your Omnipod ID:
 - a. Enter your username.
 - b. Enter your password.
 - c. Tap SIGN IN.

Note: The username and password are case-sensitive.

4 Setting Up Your Omnipod 5 Application

Setting Up Training

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

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

After tapping the training option:

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

After signing into your Controller, you may continue setting up your Omnipod 5 System on your Controller, or sign into the Omnipod 5 App on your smartphone. If you intend to use your smartphone for the Omnipod 5 App, continue to "4.5. General Settings on Your Smartphone" on page 62. You do not need to continue with any further Controller setup at this time.

Setting Up Your Controller

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



DO NOT PROCEED

You must complete training before you can use this product!

Have you been trained to:

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

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

Please select one of the following:

I will schedule training

I am in training

I completed training

I decline training

Personalize your Controller

Follow the steps below to personalize your Controller.

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

A screen appears showing several background images.

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

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

Setting the PIN on your Controller

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

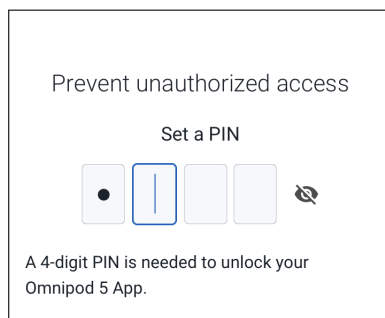
To set a PIN:

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

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

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

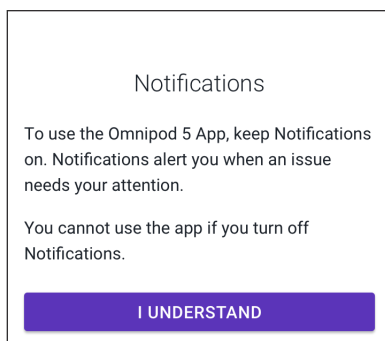
If the second PIN entry does not match the first, you must repeat the above steps.



Enabling Notifications and Sound on Your Controller

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

➤ Tap I UNDERSTAND.

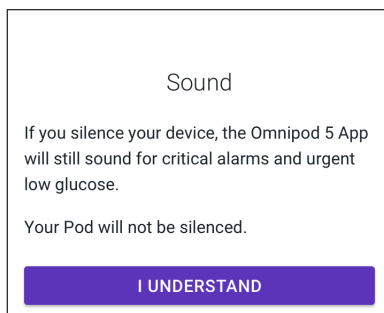


4 Setting Up Your Omnipod 5 Application

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

➤ Tap **I UNDERSTAND**.

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



4.5. General Settings on Your Smartphone

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

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

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

If you intend to use your smartphone for the Omnipod 5 App and have not yet signed into your Insulet-provided Controller, see "4.4. General Settings on Insulet-provided Controller" on page 58.

Using the Omnipod 5 App on Your Smartphone

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

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

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

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

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

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

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

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

Required smartphone settings

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

4 Setting Up Your Omnipod 5 Application

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

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

Recommended smartphone settings

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

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

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

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

Signing in to the Omnipod 5 App on Your Smartphone

1. Review the terms and conditions, including End User License Agreement (EULA), warranty and Legal Notices as follows:
 - a. Tap the HIPAA Privacy Notice, EULA, ToU, and Warranty link to read the Omnipod 5 System's legal notices and privacy policy. Then tap AGREE.

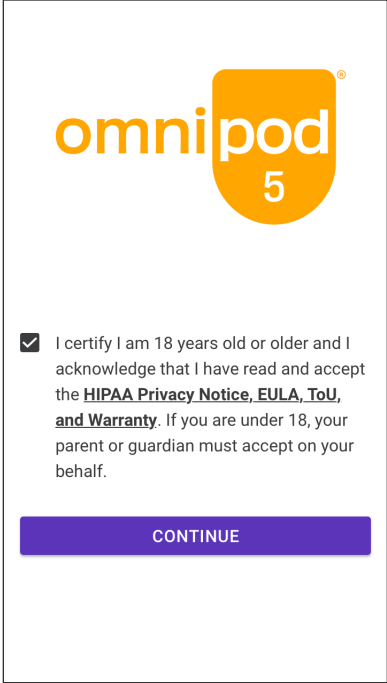
A checkmark is added to the checkbox to indicate agreement.

- b. Tap CONTINUE.

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

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

Note: The username and password are case-sensitive.



omnipod[®]
5

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

CONTINUE

Setting Your Omnipod 5 App Security (on Your Smartphone)

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

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

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

Omnipod 5 Security cannot be turned off.

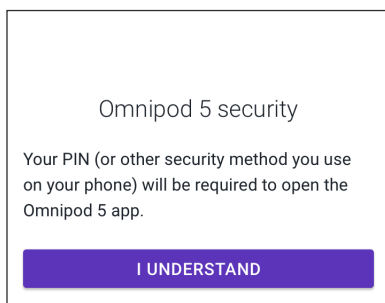
After you've signed in to the Omnipod 5 App on your smartphone for the first time, the Security screen will appear.

1. Read the Lock Screen Security screen.

➤ Tap I UNDERSTAND.

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

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



Enabling Notifications and Sound on Your Smartphone

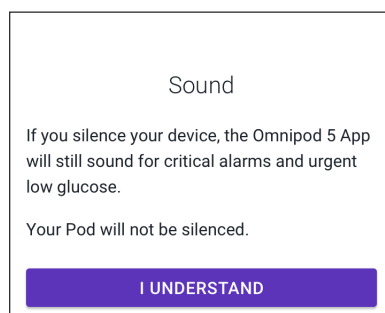
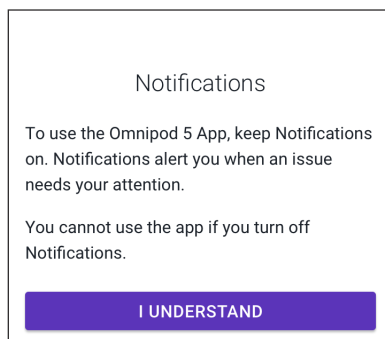
1. Read the message explaining the importance of enabling Omnipod 5 App notifications. You cannot enter or use the App if you turn Notifications off.

➤ Tap **I UNDERSTAND**.

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

➤ Tap **I UNDERSTAND**.

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



4.6. Basal Settings

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

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

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

Set Maximum Basal Rate

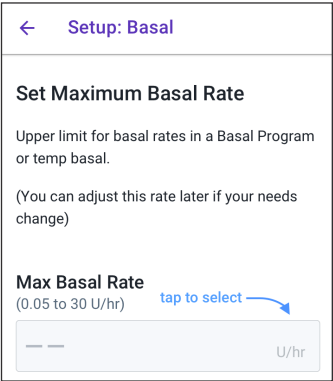
The Maximum Basal Rate sets the upper limit of any basal insulin rate you can use while in Manual Mode.

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

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

3. Tap NEXT.

Note: You can adjust your Maximum Basal Rate later, if your needs change. See "Maximum Basal Rate" on page 132.



Create a Basal Program

The next step is to create a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Basal Programs" on page 97.

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

Name and tag the Basal Program

The default name for the Basal Program is Basal 1.

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

Optional: To add a visual icon to your Basal Program, tap one of the tags. Tap the tag a second time to deselect it.

2. Tap NEXT.

Define the segments

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

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

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

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

3. Check the values of your start and end times and the basal rate. Then tap NEXT.
4. If the Basal Program does not cover 12:00 AM-12:00 AM, you must add

4 Setting Up Your Omnipod 5 Application

additional segments. Repeat steps 1-3 as needed until your final segment ends at midnight.

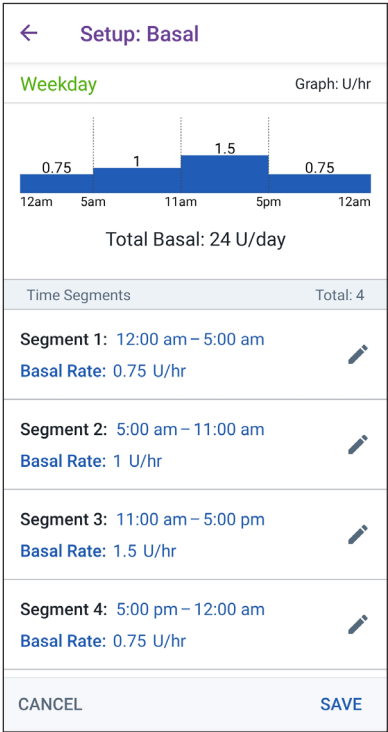
Review the Basal Program

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

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

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

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



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

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

Note: To create additional Basal Programs after setup is complete, start at page 99 and begin steps again.

Temporary Basal Configuration

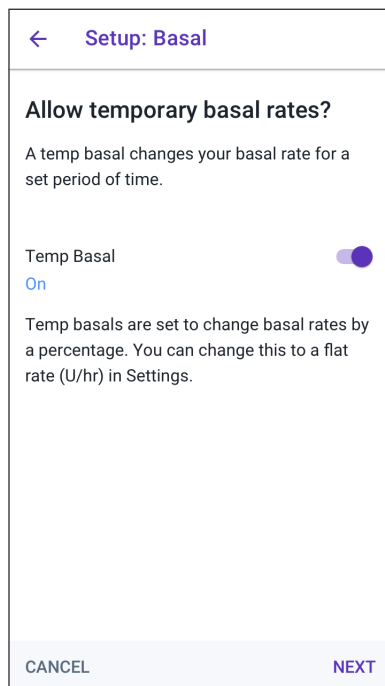
For a description of temporary basal rates, also called temp basals, see page 103.

Note: Temp basal is available in Manual Mode only.

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

If you turn temp basals on, percentages are used by default. To specify temp basal as a flat rate (U/hr), see "Temp Basal" on page 132.

2. Tap **NEXT**.



4.7. Bolus Settings

Next, you will set Bolus Settings that will be used to calculate a bolus in the SmartBolus Calculator. You can adjust your bolus settings later, if your needs change (see "17.8. Bolus Settings" on page 248 for more information).

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

Target Glucose and Correct Above Values

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

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

Define the segments

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

1. Tap the EndTime field and specify an end time for the segment.
2. Tap the Target Glucose field and specify the Target Glucose for that segment.
3. Tap the Correct Above field and specify the Correct Above value for that segment.
4. Review and tap NEXT.
5. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
6. Review the segments for the full 24-hour profile.
7. To change any of the entries:

← Setup: Bolus

Segment 1

Start

End

12:00 AM - --

Night

Target Glucose

(110 to 150 mg/dL)

-- mg/dL

Correct Above

(Target Glucose to 200 mg/dL)

-- mg/dL

CANCEL

NEXT

- a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
8. When the segments and values are correct, tap **SAVE**.

← Setup: Bolus

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

Time segments	Total: 4
Segment 1: 12:00 am - 5:00 am Target Glucose: 110 mg/dL Correct Above: 150 mg/dL	
Segment 2: 5:00 am - 9:00 am Target Glucose: 110 mg/dL Correct Above: 130 mg/dL	
Segment 3: 9:00 am - 12:00 pm Target Glucose: 120 mg/dL Correct Above: 140 mg/dL	
Segment 4: 12:00 pm - 12:00 am Target Glucose: 130 mg/dL Correct Above: 150 mg/dL	
CANCELSAVE	

Insulin to Carb (IC) Ratio

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

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

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

Define the segments

1. Tap the EndTime field and specify an end time for the segment.
2. Tap the 1 Unit of insulin covers field and specify the IC Ratio value for the segment.
3. Tap **DONE** to close the number pad.
4. Review and tap **NEXT**.
5. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.

← Setup: Bolus

Segment 1

Start

12:00 AM

End

Night

1 Unit of insulin covers

(1 to 150 g carbs)

g

4 Setting Up Your Omnipod 5 Application

6. Review your 24-hour IC Ratio segments.
7. To change any of the entries:
 - a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
8. When the segments and values are correct, tap **SAVE**.

 **Setup: Bolus**

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

Time segments	Total: 4
Segment 1: 12:00 am - 5:00 am 1 U of insulin covers: 15 g of carbs	
Segment 2: 5:00 am - 9:00 am 1 U of insulin covers: 10 g of carbs	
Segment 3: 9:00 am - 12:00 pm 1 U of insulin covers: 13 g of carbs	
Segment 4: 12:00 pm - 12:00 am 1 U of insulin covers: 15 g of carbs	
CANCELSAVE	

Correction Factor

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

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

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

Define the segments

1. Tap the **EndTime** field and specify an end time for the segment.
2. Tap the **1 Unit of insulin lowers glucose by** field and specify the Correction Factor for this segment.
3. Review and tap **NEXT**.
4. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.

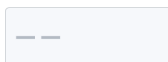
 **Setup: Bolus**

Segment 1

Start

12:00 AM

End



Night

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

 mg/dL

- 5. Review the segments for the full 24-hour profile.
- 6. To change any of the entries:
 - a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
- 7. When the segments and values are correct, tap **SAVE**.

← Setup: Bolus

Review the Correction Factor values entered for each time segment.

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

CANCEL

SAVE

Duration of Insulin Action

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

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

← Setup: Bolus

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

Duration of Insulin Action
(2 to 6 hrs)

— —

hrs

CANCEL

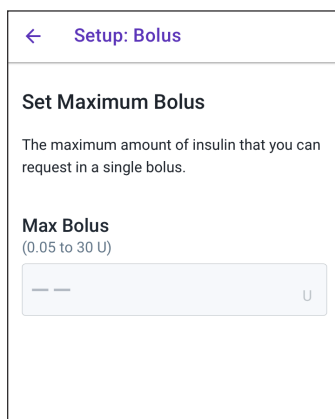
NEXT

4 Setting Up Your Omnipod 5 Application

Maximum Bolus

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

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



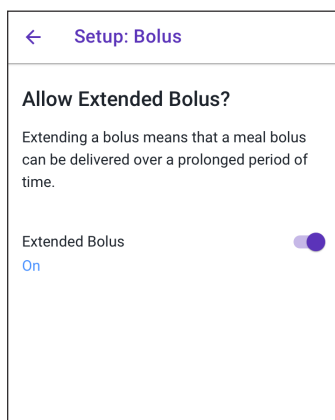
The screenshot shows the 'Setup: Bolus' screen. At the top is a back arrow and the title 'Setup: Bolus'. Below is the section 'Set Maximum Bolus' with the text 'The maximum amount of insulin that you can request in a single bolus.' Underneath is the 'Max Bolus' label with the range '(0.05 to 30 U)' and a numeric input field showing '— —' and a unit 'U'.

Extended Bolus

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

Note: Extended bolus is available in Manual Mode only.

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



The screenshot shows the 'Setup: Bolus' screen. At the top is a back arrow and the title 'Setup: Bolus'. Below is the section 'Allow Extended Bolus?' with the text 'Extending a bolus means that a meal bolus can be delivered over a prolonged period of time.' Underneath is the 'Extended Bolus' label with the word 'On' and a toggle switch that is turned on (blue).

4.8. Your App Setup is Complete

Congratulations! Omnipod 5 App setup is complete.

When you are ready to activate your first Pod, go to "5.1. Beginning the Pod Activation Process" on page 80.

After successfully activating the Pod, you will be prompted to connect your CGM to the Omnipod 5 System. See "Connecting CGM to the Pod" on page 281.

4.9. Saving Your Settings for Reference

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

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

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

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

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

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

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

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CHAPTER 5

Activating and Changing Your Pod

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5.1. Beginning the Pod Activation Process

Warning: DO NOT wear a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin. Applying a Pod under these circumstances could put your health at risk.

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

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

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

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

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

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

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

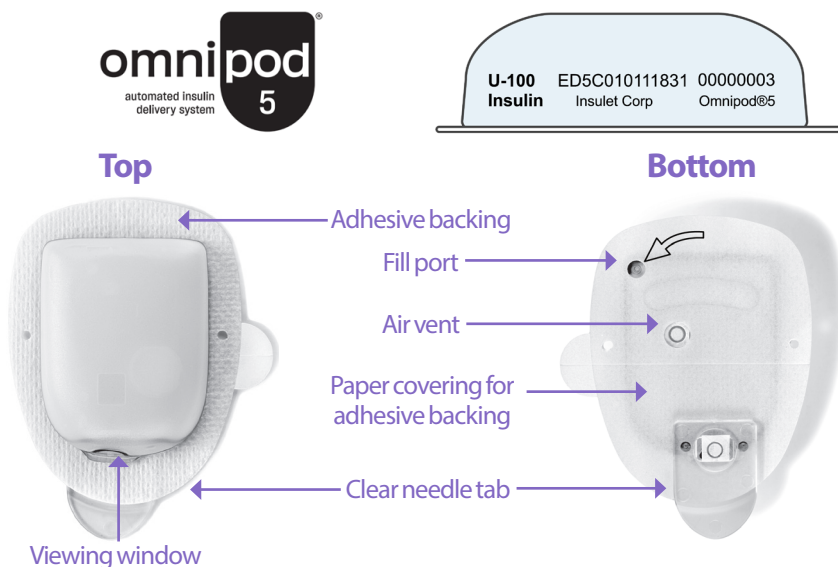
Caution: ALWAYS rotate insulin infusion sites to help prevent infusion site complications like scar tissue and infection. Rotating insulin infusion sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption.

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

Before activating a Pod, do the following:

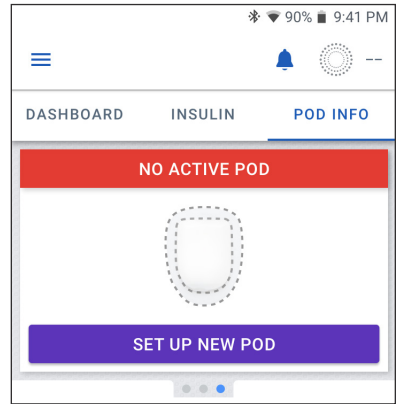
1. Gather the necessary supplies:
 - A vial of rapid-acting U-100 insulin cleared for use in the Omnipod 5 System. See "1.4. Compatible Insulins" on page 7 for a list of the approved insulin types that can be used with the Omnipod 5 System.
 - An unopened Omnipod 5 Pod
 - Alcohol prep swabs
 - Controller or smartphone with Omnipod 5 App
2. Wash your hands before starting and keep them clean throughout the Pod change process.
3. Check the insulin for signs of deterioration according to the manufacturer's instructions for use.
4. Check the Pod's packaging for damage. If undamaged, open it and inspect the Pod for signs of damage.
5. If the insulin or Pod is below 50°F (10°C), allow it to warm up to room temperature before proceeding.

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



5.2. Setting Up a New Pod

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



Turn on location access

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

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

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

Allow location access during Pod activation

Omnipod 5 needs location access to activate a Pod.

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

CANCEL **APP INFO**

Allow location access during Pod activation

Omnipod 5 needs location access to activate a Pod.

Allow location access.

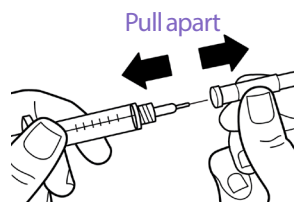
CANCEL **CONTINUE**

5.3. Fill the Syringe with Insulin

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

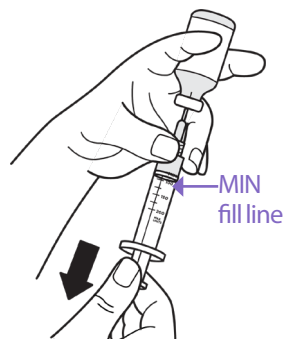
The next step is to fill the syringe that came with the Pod (the "fill syringe") with insulin:

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



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

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



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

5.4. Filling, Activating, Applying, and Starting the Pod

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

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

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

Fill the Pod with Insulin

To fill the Pod with insulin (screen step 1)

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

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

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

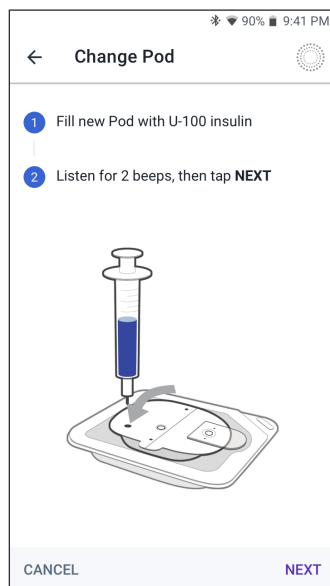
Listen for two beeps from the Pod during the filling process (screen step 2):

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

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

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

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



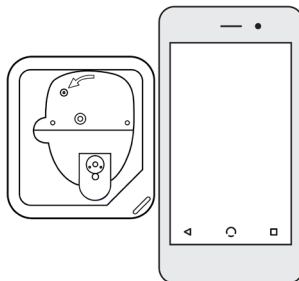
Activate the Pod

To activate the Pod:

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

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

2. Tap NEXT.



5 Activating and Changing Your Pod

- If more than one, non-paired, filled Omnipod 5 Pod is in range, the Omnipod 5 App informs you of this and prevents you from completing activation. Move at least 20 feet (6 m) away from any other filled Omnipod 5 Pod and tap TRY AGAIN.
- Only Omnipod 5 Pods are compatible with the Omnipod 5 System. If you try to use an older Pod that cannot communicate with the system, the Omnipod 5 App informs you of this and prevents you from completing activation. Tap DISCARD POD and restart Pod activation with an Omnipod 5 Pod.
- If the Omnipod 5 App is able to communicate with the Pod but detects an incompatible Pod, the Omnipod 5 App informs you of this and prevents you from completing activation. Tap DISCARD POD and restart Pod activation with an Omnipod 5 Pod.

More than one Pod found

Move away from other Pods and try again.

CANCEL TRY AGAIN

Pod communication error

If the problem persists, discard this Pod and set up a new one.

TRY AGAIN DISCARD POD

Pod not compatible

Your Pod is not compatible.

Discard this Pod.

DISCARD POD

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

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

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

If you see a communication error message when you attempt to activate your Pod, and you are not using an older Pod, see "Error when activating a Pod" on page 339.

Prepare the Pod Site

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

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

Guidelines for Pod site selection

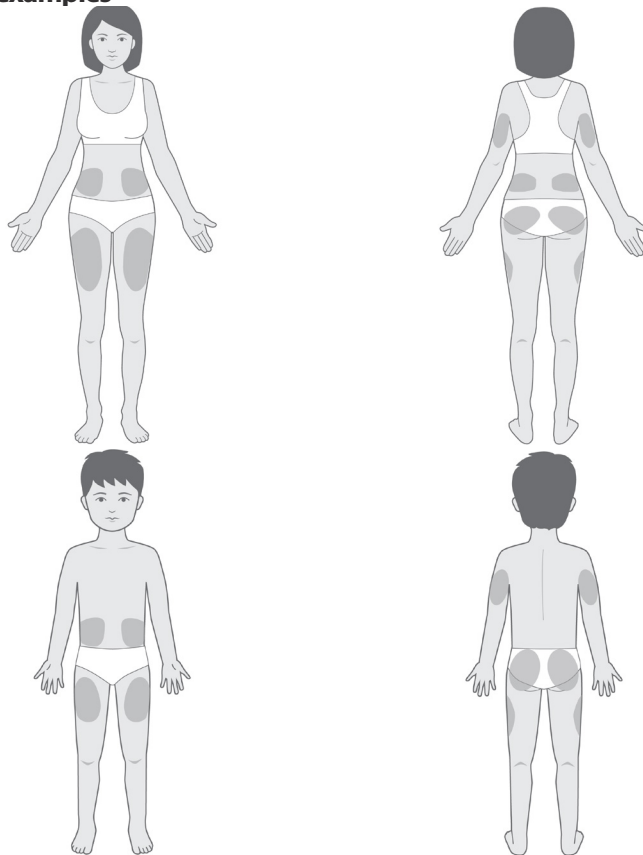
Discuss suitable Pod placement sites with your healthcare provider using the following guidelines:

- Place at least 3 inches (7.62 cm) from your CGM sensor site, as indicated in your *Dexcom G6 System User Guide*.
- Place within line of sight of the CGM sensor for the best connectivity. See "19.2. CGM Placement" on page 275.

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

- Ideal sites have a layer of fatty tissue.
- Ideal sites offer easy access and viewing.
- The site should be at least 1 inch (2.5 cm) away from the previous site to avoid skin irritation.
- The site should be at least 2 inches (5 cm) away from your navel.
- Avoid sites where belts, waistbands, or tight clothing may rub against or dislodge the Pod.
- Avoid sites where the Pod will be affected by folds of skin.
- Avoid placing the Pod over a mole, tattoo, or scar, where insulin absorption may be reduced.
- Avoid areas of the skin with an active infection.

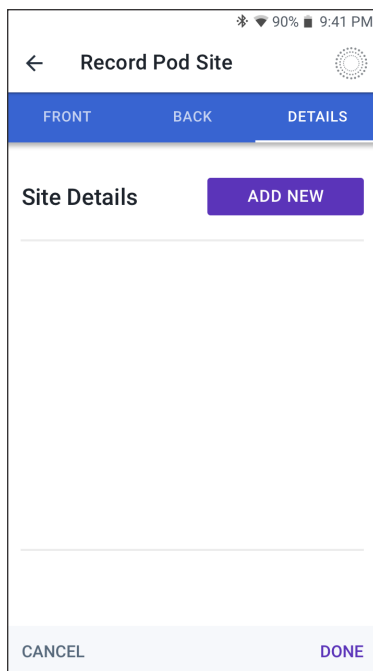
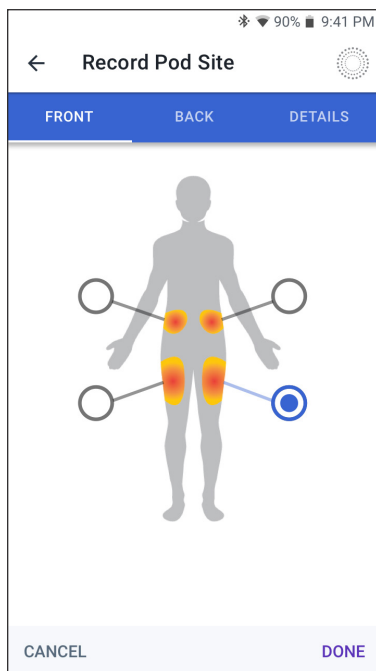
Pod site examples



Pod site map (optional)

The Pod site map is an optional feature that helps you track your current and recent Pod site locations. This option only appears if the Pod Sites setting is turned on (see "10.2. Reminder Settings" on page 128).

1. Tap **RECORD POD SITE** to bring up the Record Pod Site screen.
2. Tap the **FRONT** or **BACK** tab to select an area of your body for your Pod. To help you avoid recent Pod sites, the screen shows the two most recent dates that each site was selected.
3. Tap a circle to indicate the location on your body where you will place your new Pod. A blue dot appears inside the selected circle. Tap again to deselect the location.



4. Tap the **DETAILS** tab to add a detail about the placement of this Pod. For example, you could add a detail that says "Facing up" or "Facing down" to describe the Pod's orientation.
 - a. To add a new detail, tap **ADD NEW** and type in the new detail. Tap **ADD** when done. The new detail is added to the list.
 - b. Select a detail for the new Pod by tapping the circle next to that detail. You may only add one detail for each Pod. Tap again to deselect the detail.

Note: To delete a site detail, tap the  next to the detail.
5. Tap **DONE** when finished to return to the Change Pod screen.

Prepare the infusion site

To reduce the risk of infection at the infusion site:

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

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

5 Activating and Changing Your Pod

Remove the Pod's Tab

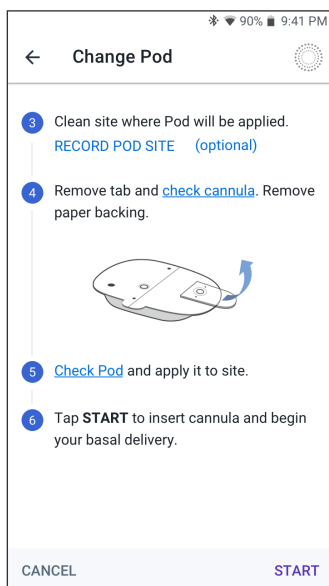
Warning: DO NOT apply a Pod if you see the cannula is extended beyond the adhesive backing after the tab on the Pod is removed. This cannula cannot be inserted resulting in under-delivery of insulin which could lead to hyperglycemia.

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

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

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

3. If any of the following apply, tap **CANCEL**, and then dispose of the Pod and begin again with a new Pod:
 - The Pod is accidentally dropped, as this could mean the Pod is no longer sterile.
 - The Pod or its adhesive pad is wet, dirty, or damaged.
 - The cannula extends beyond the adhesive backing when the tab is removed.
4. Using the pull tabs, remove the white paper backing covering the adhesive pad. Be careful not to remove the adhesive pad itself. Do not allow the adhesive to fold back on itself.



Apply the Pod

Inspect and apply the Pod (screen step 5):

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

2. Orient the Pod so it is:

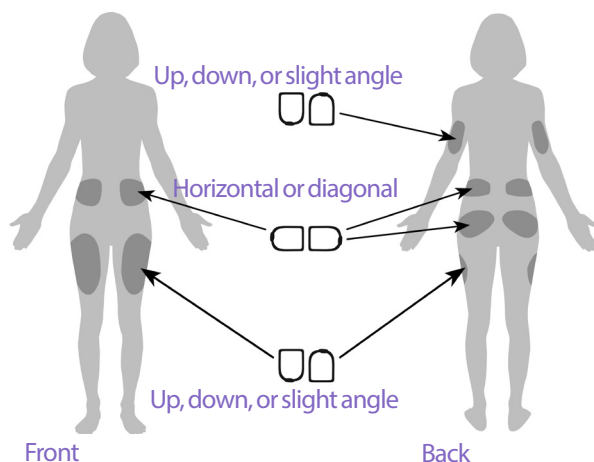
- Horizontal or diagonal on your abdomen, hip, lower back, or buttocks.

- Up and down or at a slight angle on your upper arm or thigh.

- For optimal connectivity, the Pod should be placed at

least 3 inches (7.62 cm) from and within line of sight to the CGM. The Bluetooth connection between the CGM and the Pod does not travel well through the body. Keeping both devices within line of sight allows for consistent CGM communication with the Pod. See "19.2. CGM Placement" on page 275.

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



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

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

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

Begin Insulin Delivery

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