Omnipod® 5 Automated Insulin Delivery System

Resource Guide

INDICATIONS FOR USE

The **Omnipod 5 ACE Pump (Pod)** is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Omnipod 5 ACE Pump is intended for single patient, home use and requires a prescription.

SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. SmartAdjust technology is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older. SmartAdjust technology is intended for single patient use and requires a prescription.

The **Omnipod 5 SmartBolus Calculator** is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100 insulin. The Omnipod 5 SmartBolus 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. The Omnipod 5 SmartBolus Calculator is intended for single patient, home use and requires a prescription.

CONTRAINDICATIONS

The Omnipod 5 System is NOT recommended for people who:

- Are unable to monitor glucose as recommended by their healthcare provider
- Are unable to maintain contact with their healthcare provider
- Are unable to use the Omnipod 5 System according to instructions
- Are taking hydroxyurea as it could lead to falsely elevated CGM readings and result in the over-delivery of insulin that can lead to severe hypoglycemia
- Do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod 5 System, including alerts, alarms, and reminders

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

For full indications and instructions for use please consult the Omnipod 5 System User Guide available online at www.omnipod.com.

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Welcome to your Omnipod® 5 System

Before you begin using your Omnipod 5 Automated Insulin Delivery System you will need to choose to use the provided Controller or a compatible personal smartphone* for the Omnipod 5 App.

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

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 with the new device since the Pod cannot communicate with two devices at one time.

During first time setup of the Omnipod 5 App you will be directed to a website to create your Insulet profile. At this time you will create an Omnipod account, link your accounts, select training preferences and engage in eLearning courses.

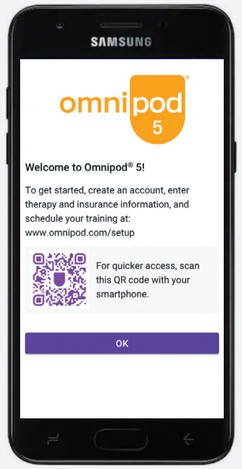
- If you already have an Omnipod account, use the same username and password to sign into your controller.

Connecting to cellular data or Wi-Fi is important when using the Omnipod 5 System. Being connected will allow you to be notified of important updates as well as allow seamless auto uploading of your data to Insulet's secure cloud. With either device, be sure to only connect to a trusted Wi-Fi network.

Dexcom CGM sold separately. You can set up and start your Dexcom G6 **before or after** setting up your Omnipod 5 App.

You must use the Dexcom G6 App, not the Dexcom G6 receiver with the Omnipod 5 System

Please consult the Dexcom G6 User Guide for more information.



If using a compatible personal smartphone:

- Download the Omnipod 5 App on Google Play.
- Ensure Bluetooth® is turned ON on your compatible smartphone so that the Omnipod 5 App and your Pod can communicate.
- In order to use the Omnipod 5 App on a compatible smartphone, you must first log into the Omnipod 5 App on the provided Controller.

GET IT ON Google Play

*For a list of compatible smartphones please visit omnipod.com/compatibility.

Preparing to Start your Omnipod® 5 System

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, which could lead to hypoglycemia or hyperglycemia.

Training

Learning how to use your Omnipod 5 System the correct way is important for safe and effective use. Different training methods to learn how to use your system are based on your and your healthcare provider's preferences.

This resource guide includes instructions for some of the key functions you may perform with the Omnipod 5 System.

Have questions at any time? We are here to help with our 24/7 Customer Care.

Customer Care: 1-800-591-3455
From Outside the US: 1-978-600-7850
omnipod.com

For more information about indications, contraindications, warnings, and full instructions please consult your *Omnipod 5 System User Guide* available online at www.omnipod.com.

In an emergency, you should call your healthcare provider.

You should also keep the following supplies on hand at all times to quickly respond to any diabetes emergency:

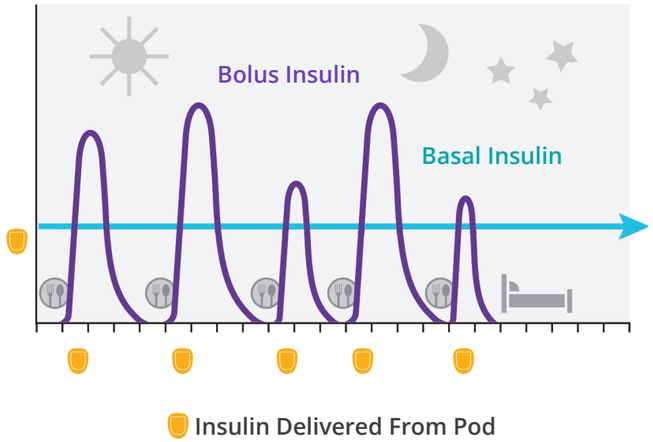
Supplies

- Several new, sealed Omnipod 5 Pods
- A vial of rapid-acting U-100 insulin
- Glucose tablets or another fast-acting source of carbohydrates
- Continuous glucose monitor (CGM) and supplies
- Blood glucose meter and test strips
- Lancing device and lancets
- Alcohol prep swabs
- Syringes or pens for injecting insulin
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- Phone numbers for your healthcare provider in case of emergency
- Ketone testing supplies
- Glucagon kit and written instructions for administration if you are unconscious

Understanding Basal, Bolus, and Automated Insulin Delivery (AID) Systems

Insulin Pump Therapy With or Without Automation

- Basal insulin covers background needs to keep glucose levels in target between meals and overnight
- Bolus insulin is an additional dose of insulin needed for food (meal bolus) and/or high glucose (correction bolus)



Automated Insulin Delivery Systems

- An insulin pump/Pod that communicates with CGM and algorithm to automatically adjust insulin delivery
- Must still bolus for meals and snacks
- Benefits of AID systems[1,2]:
  - Increase the amount of hours each day spent in time in range (70-180 mg/dL)
  - Less hypoglycemia (low glucose)
  - Less hyperglycemia (high glucose)
  - Improved quality of life

1. Cinar A. Automated insulin delivery algorithms. Diabetes Spectrum. 2019;32(3);209-214.
2. American Diabetes Association. 7. Diabetes technology: Standards of Medical Care in Diabetes - 2021. Diabetes Care 2021; 44(Suppl. 1):S85-S99.

Omnipod® 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalized recommendations.

Omnipod® 5
System

Omnipod® 5 System

The Omnipod 5 App

- Can be used on a compatible smartphone* or the provided Controller
- Used to control and monitor the Pod's operations
- Although your Omnipod 5 System does not require the Controller to be nearby to continue your insulin delivery in Manual Mode or Automated Mode, the Controller and/or smartphone provide(s) you with important information about recent insulin delivery, alerts, and alarms that come from your Pod, and allows you to use the SmartBolus Calculator to deliver a bolus

The Omnipod 5 Pod

- Small lightweight, waterproof**, Bluetooth-enabled Pod
- Enhanced with SmartAdjust™ technology which continuously adjusts glucose levels using a customized glucose target
- Provides up to 72 hours of continuous insulin delivery

Dexcom G6® CGM

- Provides real-time glucose readings every 5 minutes (up to 288 times per day)
- Consists of auto applicator, sensor, transmitter, and Dexcom app

Controller or smartphone

Omnipod 5 Pod | Dexcom G6 Transmitter

Dexcom CGM sold separately.

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

* Please go to omnipod.com/compatibility for a list of compatible smartphones
** IP28 Rating, up to 25 ft. for 60 minutes

System Communication

Bluetooth® wireless technology allows communication between the components of the Omnipod® 5 System.

Omnipod 5 App

- Activates/deactivates Pod
- Sends and receives insulin delivery info
- Receives CGM info from Pod
- Displays alerts and alarms

Dexcom App

- Starts/stops sensor session
- Displays CGM value and trends
- Display alerts and alarms
- Troubleshooting guidance

Omnipod 5 Pod

- Delivers insulin to your body
- Sends CGM values to Omnipod 5 App
- SmartAdjust™ technology in Pod automatically adjusts insulin delivery based on CGM

Dexcom G6 CGM

- Transmitter sends sensor values to the Pod and Dexcom G6 app

- **The Omnipod 5 App does not have to be near the Pod for basal insulin delivery in both Manual or Automated Mode. It is recommended to keep the Omnipod 5 App nearby as it displays important information such as alerts and alarms.**
- **The Omnipod 5 App does not communicate directly with the Dexcom app or the Dexcom transmitter.**

Starting Omnipod® 5
System Instructions

Omnipod® 5 App Setup

Depending on the device you have chosen, you may see different screens and settings as you begin to set up the Omnipod 5 App. If you have chosen to use your smartphone the Omnipod 5 System relies on some of your smartphone's settings to function. If these settings are not correctly set, you will not be able to use the App until the setting is correctly enabled or disabled. The Omnipod 5 App relies on some of your smartphone's settings to function. For recommended smartphone settings please consult your Omnipod 5 System user guide.

Your initial pump therapy settings are needed to set up your Omnipod 5 App. These settings are provided to you by your healthcare provider.

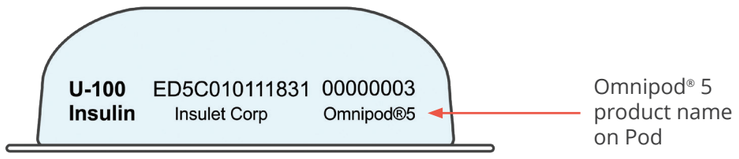
Keep a copy of your current settings in case you have to set up the Omnipod 5 App again. If you use a smartphone, you may wish to take screenshots or photos of your Omnipod 5 App settings to keep for future reference.

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

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

Caution: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms 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. Refer to Section 13 in the Omnipod 5 User Guide to learn how to manage sounds and vibrations.

Omnipod® 5 Pod

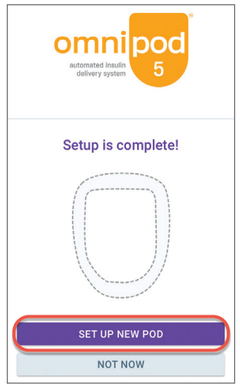


Starting Omnipod 5 System | ACTIVATE A NEW POD

Activate an Omnipod 5 Pod

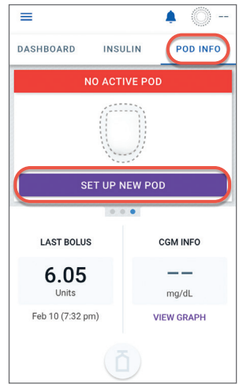
Before activating a Pod wash your hands with soap and water and gather the necessary supplies:

- An unopened Omnipod 5 Pod
  - Confirm that you are using an Omnipod 5 Pod by looking for the Omnipod 5 logo on the label or on the Pod itself
- Vial of U-100, rapid acting insulin cleared for use in Omnipod 5 System, at room temperature
- Alcohol prep swabs
- Controller or smartphone with Omnipod 5 App



- After first time setup, tap **SET UP NEW POD**

OR



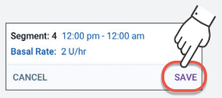
- From the POD INFO tab on the Home screen, tap **SET UP NEW POD**

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

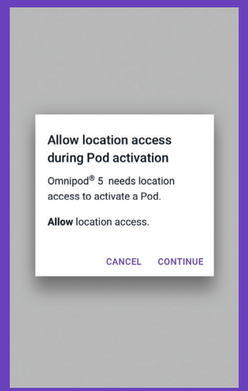
Warning: NEVER use insulin that is expired or cloudy in the Pod as it may be damaged. Using damaged or expired insulin could cause hyperglycemia and put your health at risk.

Tip

Follow the screen instructions by tapping the area highlighted by the “red circle”

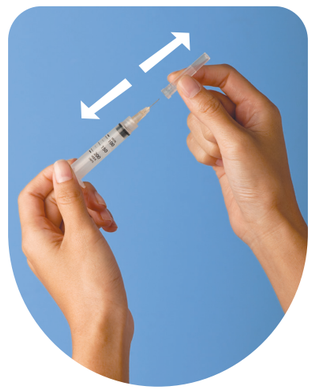


If you are using the Omnipod 5 App on your smartphone, location permission and Location setting must be on in order to activate a Pod



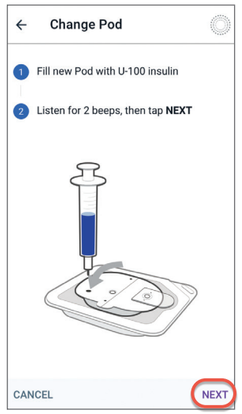
1. Fill the Pod

- Remove the fill syringe and needle. Keep the Pod in its tray during set up.
- Use the alcohol prep swab to clean the top of the insulin vial
- Securely twist the fill needle onto the fill syringe

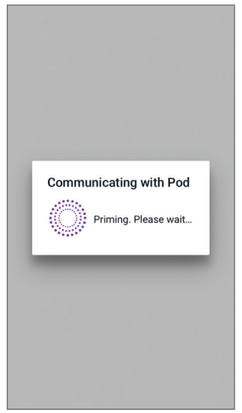


- Pull outward to remove the protective cap from the needle

- Determine how much insulin you will use over the next 72 hours
- Draw air into the fill syringe equal to the amount of insulin you want
- Insert needle into the vial of insulin and inject air. Injecting air makes it easier to withdraw insulin from the vial.
- With the syringe still in the vial, turn the vial and syringe upside down
- Pull down on the plunger to withdraw insulin from the vial and fill the syringe with the amount of insulin you want; fill at least to the MIN fill line
- With the needle still in the vial, tap or flick the syringe to dislodge any air bubbles to the top of the syringe. Then push in the plunger to expel any air bubbles out of the syringe and into the vial.
- Remove the needle from the vial



- Leave Pod in its plastic tray
- Insert the needle straight down into the fill port as indicated by the arrow, on the underside of the Pod. To ensure proper fill, do not insert fill syringe at an angle into the fill port.
- Completely empty the syringe into the Pod
- The Pod will beep twice, indicating that the Omnipod® 5 Pod is ready to proceed
- Return to the Omnipod 5 App. If the screen times out, press the Power button to wake the controller. Place the controller next to the Pod so they are touching.
- Tap **NEXT**



- The Omnipod 5 App establishes a one-to-one relationship with the Pod, which will prevent it from communicating with any other Pod while this Pod is active
- Listen for the tone from the Omnipod 5 App that indicates the Pod is activated and ready to be applied

Note

Minimum fill is 85 units,
Maximum fill is 200 units

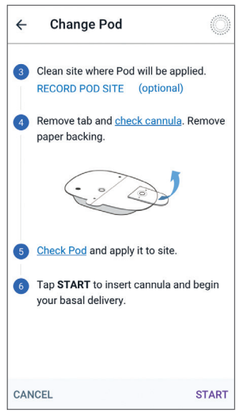
Reminder

During activation and priming, the Controller or smartphone running the Omnipod 5 App and Pod should be next to each other and touching

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

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

2. Apply the Pod



- Clean the site where the Pod will be applied
- Be careful to avoid areas where the Pod will be affected by folds of skin and clothing
- Refer to Omnipod 5 Site Preparation and Placement section for sites your healthcare provider may recommend and placement tips

Tip

When choosing sites:

Consider where your CGM is placed. Allow 3 inches between CGM and Pod.

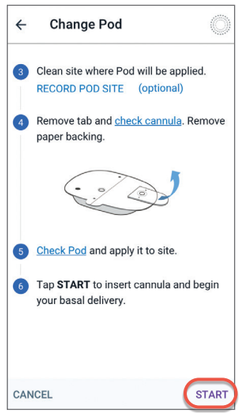
Place Pod and CGM within direct line of sight for best communication. See images for placement examples on page 21.

- Place your thumb on the bottom of the Pod and pull the tab upward. The tab will snap off.

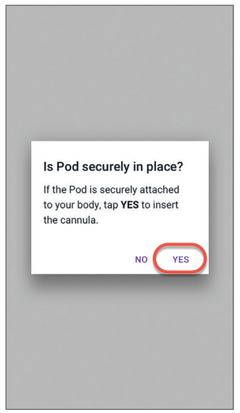
- Using the pull tabs, carefully remove white paper backing from the adhesive. Be careful not to remove the adhesive pad itself. Do not allow the adhesive to fold back on itself.

- Apply the Pod to the selected site
- Run your finger around the adhesive to secure it

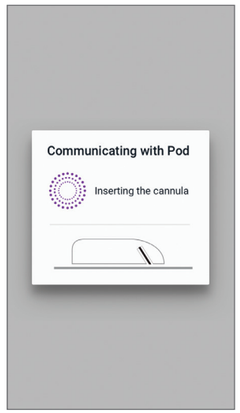
3. Start Insulin Delivery



- Tap **START**

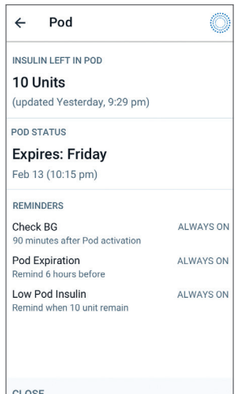


- Verify that the Pod is securely attached to your body, then tap **YES**. For best technique refer to pinching up in the Pod Preparation and Placement section of this Resource Guide.



- The Pod automatically inserts the cannula
- After insertion the cannula is filled with insulin and ready to begin insulin delivery

- Once the cannula has inserted, verify proper insertion by checking that the pink window slide insert is visible in the faint window on the top of the Pod
- Tap **YES**



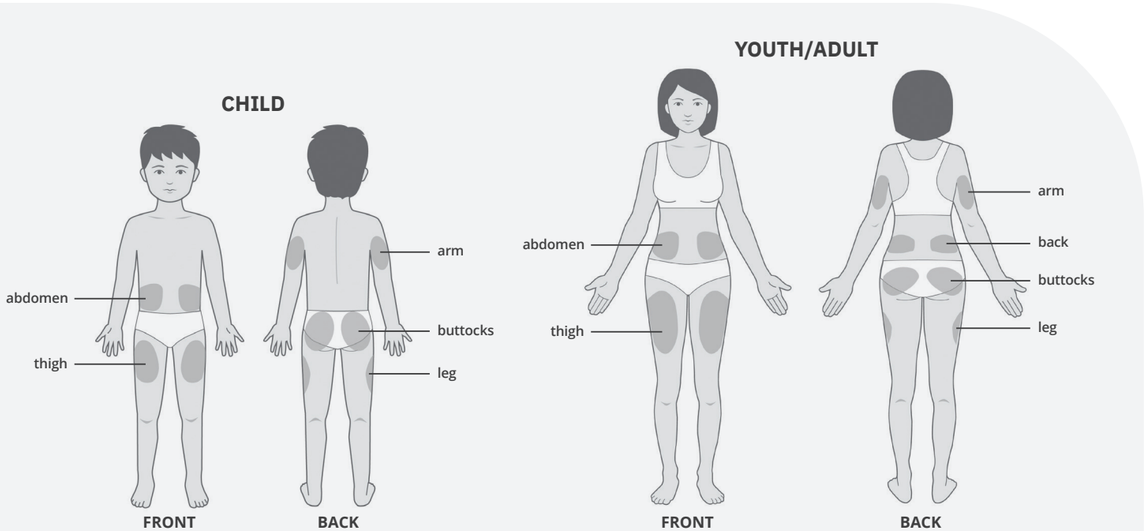
- Your Pod is now active! The Omnipod® 5 System will generate an automatic reminder to check your blood glucose 90 minutes after each Pod change. If there is a valid CGM value at that time, the alert will be dismissed.

Warning: Check the infusion site after insertion to ensure that the cannula was properly inserted. An improperly inserted cannula can result in under-delivery of insulin which could lead to hyperglycemia.

Omnipod® 5 Site Preparation and Placement

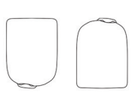
Site Selection

- Because there is **NO TUBING**, you can wear the Pod comfortably most places you would give yourself a shot. Please note the recommended Pod positioning for each body area.
- Be careful not to put it where it will be uncomfortable or dislodge when you sit or move around. For instance, don't place it near folds of skin or directly under your waistband.
- Change the site location each time you apply a new Pod. Improper site rotation may reduce insulin absorption.
- The new Pod site should be at least: 1 inch away from the previous site; 2 inches away from the navel; and 3 inches away from a CGM site. Also, never insert Pod over a mole or a scar.
- Remember to place the Pod and CGM within direct line of sight, meaning the two devices can "see" one another, for best communication.

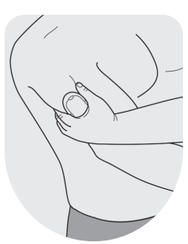


Pod Positioning

Arm & Leg:
Position the Pod *vertically* or at a slight angle.



Back, Abdomen & Buttocks:
Position the Pod *horizontally* or at a slight angle.



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.

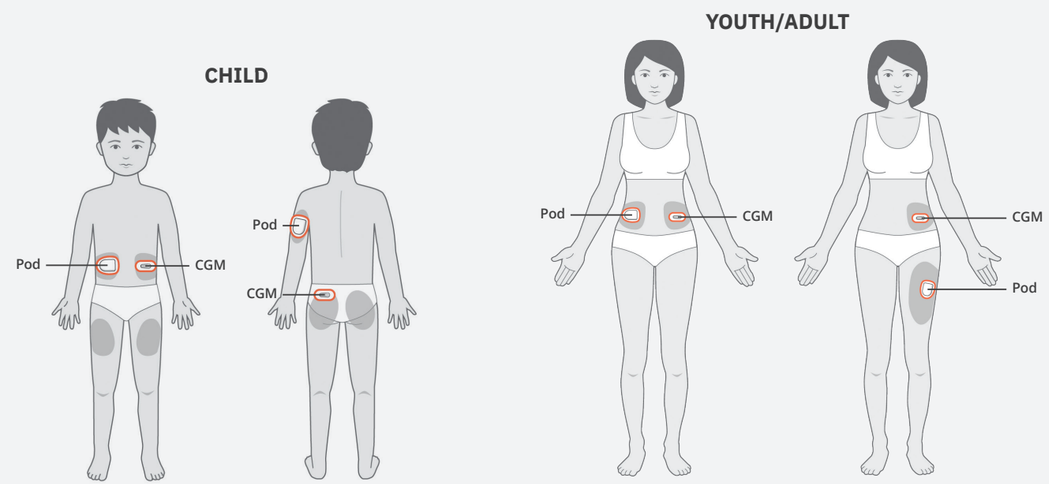
Starting Omnipod 5 System | POD SITE PREPARATION AND PLACEMENT OPTIONS

Site Preparation

- **Be cool and dry** *(not perspiring)* for Pod change.
- **Clean your skin well.** Body oils, lotions and sunscreen can loosen the Pod's adhesive. To improve adhesion, use an alcohol swab to clean the area around your site—about the size of a tennis ball. Then let it air dry completely before applying the Pod. Do not blow dry the skin.

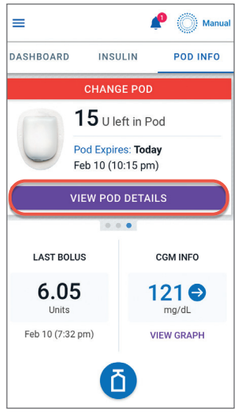
Trouble With...	Problem	Solution
Oily skin	Residue from soap, lotion, shampoo or conditioner can prevent your Pod from sticking securely.	Clean your site thoroughly with alcohol before applying your Pod—and be sure to let your skin air dry.
Damp skin	Dampness gets in the way of adhesion.	Towel off and allow your site to air dry thoroughly; do not blow on it.
Body hair	Body hair gets in-between your skin and your Pod—and if there is a lot of it, can keep the Pod from sticking securely.	Clip/shave the site with a razor to create a smooth surface for Pod adhesion. To prevent irritation, we recommend doing this 24 hrs before putting on the Pod.

Best Placement for CGM and Pod

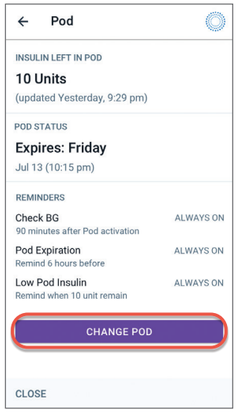


How to Change the Pod

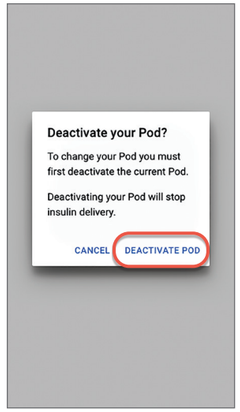
• Tap **POD INFO**



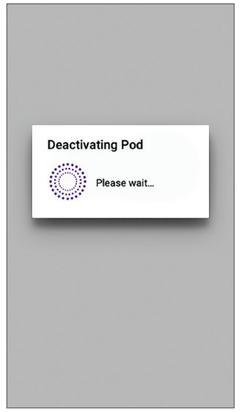
• Tap **VIEW POD DETAILS**



• Tap **CHANGE POD**



• Tap **DEACTIVATE POD**



• The Pod will take a moment to deactivate

After the Pod is deactivated, gently lift the edges of the adhesive tab from the skin and remove the entire Pod.

Tip: Remove Pod slowly to help avoid possible skin irritation.

After you have deactivated and removed the old Pod, follow the instructions on how to Activate a Pod in this guide.

DO NOT apply a new Pod until you have deactivated and removed the old Pod.

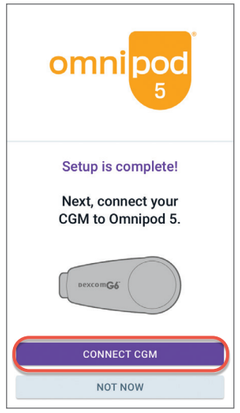
You may need to change the Pod:

- When the Pod is low on insulin or empty, or the Pod is nearing expiration or expired
- In response to an alarm
- If the Pod/cannula has become dislodged
- If you have glucose of 250 mg/dL or more and ketones are present
- If you experience unexpected elevated glucose
- As directed by your healthcare provider
- If, during activation, the Pod fails to beep

Connect Your Dexcom G6 CGM

Locate your Dexcom G6 Transmitter Serial Number (SN) from the back of the transmitter OR from the transmitter box. If you already have a sensor session started, you can also locate your SN in the Dexcom G6 app.

1. Locate CGM Transmitter Entry Screen



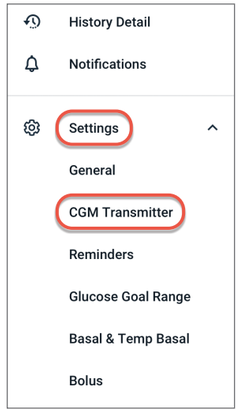
From first time setup after Pod activation:

• Tap **CONNECT CGM** in First Time Setup

OR

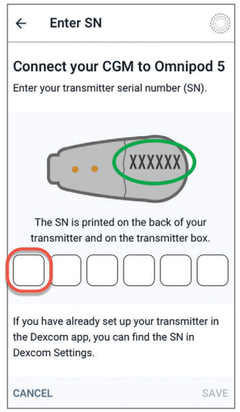
From Home screen:

• Tap the Menu button

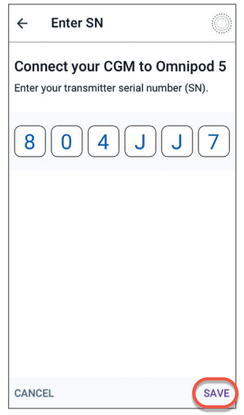


• Tap **Settings** and Tap **CGM Transmitter**

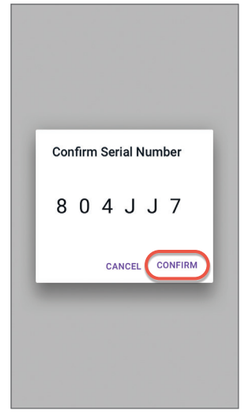
2. Enter & Save New CGM Transmitter SN



• Tap entry field within first box to begin entering transmitter SN



• Tap **SAVE**



• Tap **CONFIRM**

Omnipod 5 System Modes

The Omnipod 5 System has two operating modes: Automated Mode and Manual Mode

Automated Mode

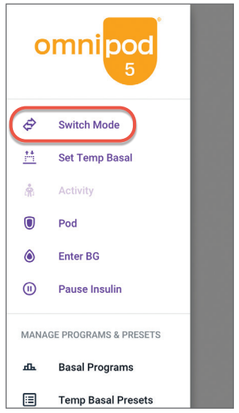
Manual Mode

	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.
Bolus Calculator Settings	Edit Bolus Settings.	Edit Bolus Settings.
Bolus Insulin Delivery	Deliver and cancel Immediate and Extended Boluses.	Deliver and cancel Immediate Boluses.
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 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	Refer to Sections 2 & 5 for a detailed list of alarms and notifications.	

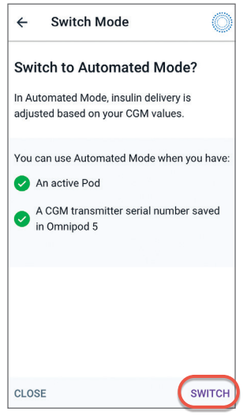
Automated Manual

Switch to Automated Mode

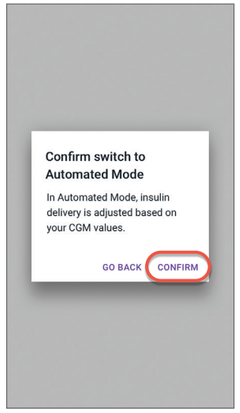
• Tap the Menu button



• Tap **Switch Mode**

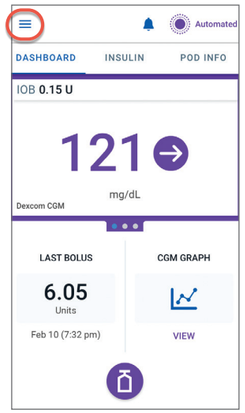


• Tap **SWITCH**

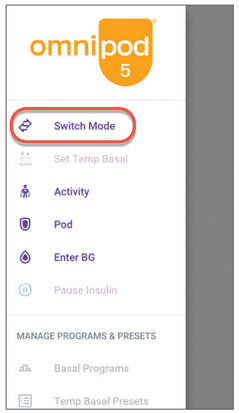


• Tap **CONFIRM**

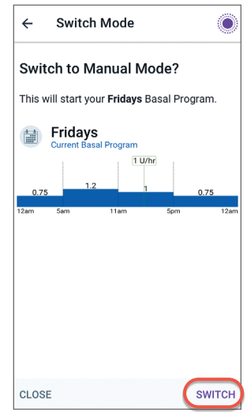
Switch to Manual Mode



• Tap the Menu button



• Tap **Switch Mode**



• Tap **SWITCH**

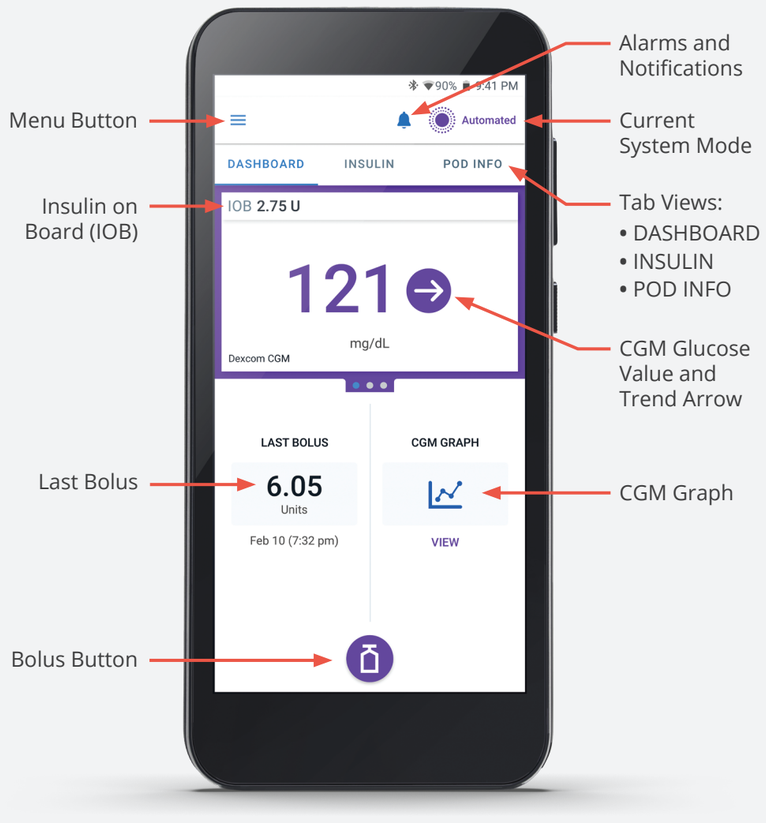
Warning: ALWAYS be aware of your current CGM value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur. If your CGM values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

Omnipod® 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalized recommendations.

Everyday Use

Omnipod® 5 System

Omnipod® 5 App Home Screen



Automated Manual

Glucose Trends and Indicators

CGM Value Color Key:

The CGM value and trend arrow will change color depending on your Glucose Goal Range.*

121 Trending steady — CGM value **within** Glucose Goal Range (Manual Mode)

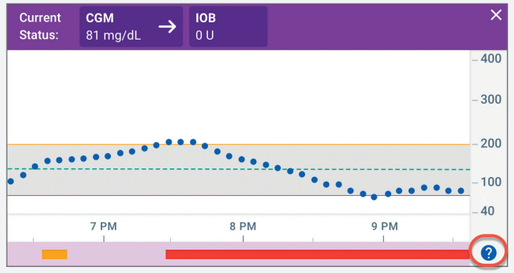
121 Trending steady — CGM value **within** Glucose Goal Range (Automated Mode)

68 Rapidly falling — CGM value **below** Glucose Goal Range (Automated & Manual Modes)

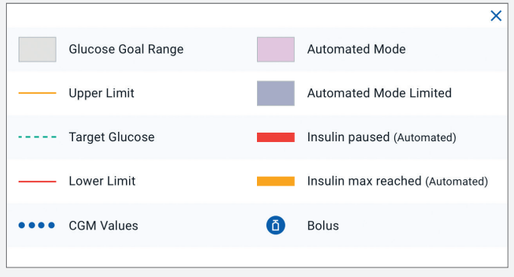
258 Slowly rising — CGM value **above** Glucose Goal Range (Automated & Manual Modes)

View CGM Graph

• Tap **VIEW** under CGM Graph



• Tap the ? symbol to see a Legend of symbols used in the CGM graph



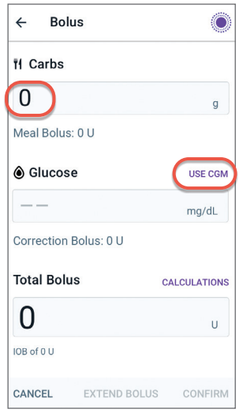
Note: CGM Graph differs slightly in appearance depending on Mode

* Refer to Section 19 for CGM trend arrows

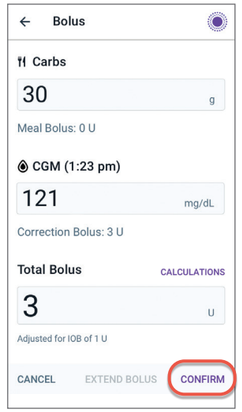
Deliver a Bolus

The Omnipod 5 SmartBolus calculator suggests a bolus (an additional dose of insulin) to correct glucose that is high (correction bolus) and/or to cover the carbohydrates in the meal or snack you may be eating (meal bolus).

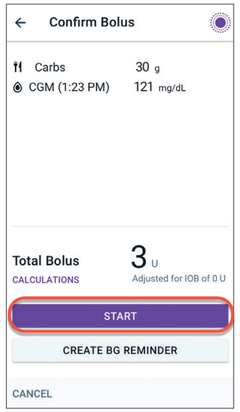
• Tap the Bolus button



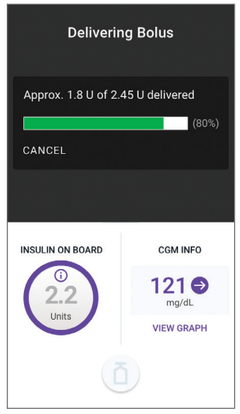
• Tap on the **Carbs** field to manually enter grams of carbs
• Tap **USE CGM** to use CGM value and trend*



• Tap **CONFIRM**



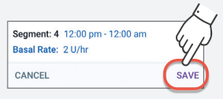
• Tap **START** to begin bolus insulin delivery



• Always look for the progress bar on the Home screen to confirm bolus delivery has started before navigating away from the Omnipod 5 App

Tip

Follow the screen instructions by tapping the area highlighted by the "red circle"



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

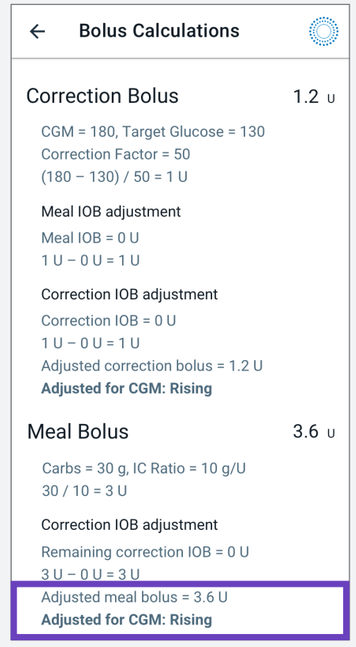
***Note:** Tap Glucose field to manually enter your blood glucose reading

Tip

When you tap **USE CGM** the SmartBolus calculator will use **BOTH CGM Value and Trend** in the bolus calculation

The SmartBolus calculator tries to keep glucose at target and adds more insulin to the correction bolus

The SmartBolus calculator tries to keep glucose at target and subtracts insulin from the correction bolus

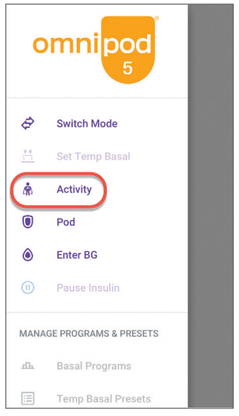


Automated

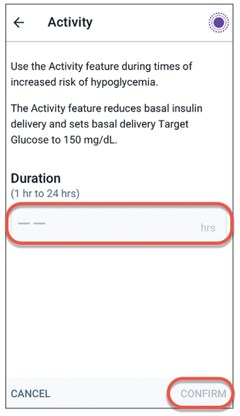
Start the Activity Feature

While in Automated Mode there may be times, like during or after exercise, activities like housework, or illness when you would like less insulin automatically delivered. When the Activity feature is enabled, the SmartAdjust™ technology reduces insulin delivery and sets the Target Glucose to 150 mg/dL for the time you choose.

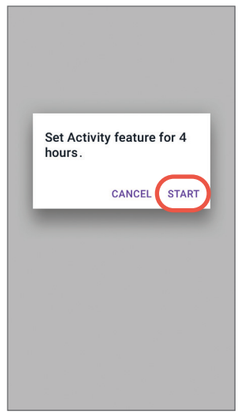
- Tap the Menu button



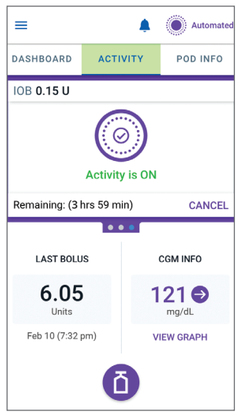
- Tap **Activity**



- Tap **Duration** field
- Set Duration (1-24 hrs)
- Tap **CONFIRM**



- Tap **START**



- The Home screen will show that the Activity feature is enabled by displaying ACTIVITY in green

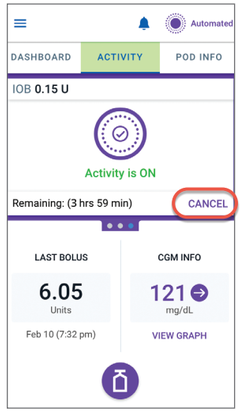
Note

The Activity feature is available only in Automated Mode

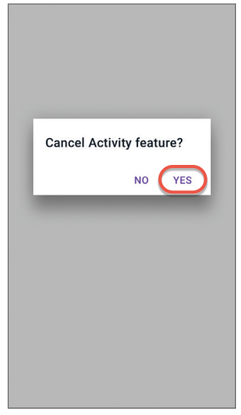
Warning: ALWAYS monitor for symptoms of hypoglycemia while the Activity feature is in progress. Hypoglycemia can still occur when using the Activity feature. Follow your healthcare provider's advice on hypoglycemia avoidance and treatment. If untreated, hypoglycemia can lead to seizure, loss of consciousness,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

Automated

Cancel the Activity Feature



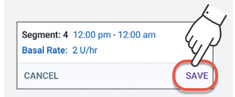
- Tap **CANCEL** on the ACTIVITY Tab



- Tap **YES**

Tip

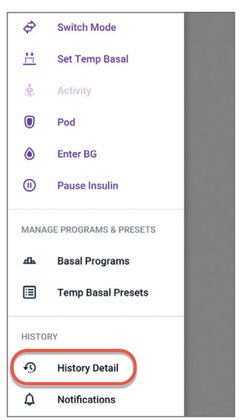
Follow the screen instructions by tapping the area highlighted by the "red circle"



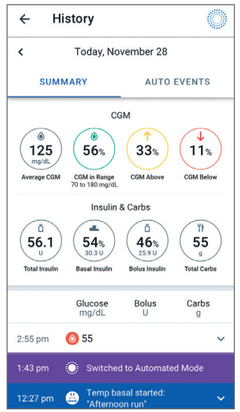
Automated Manual

View History Details

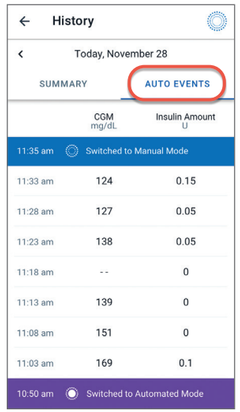
• Tap the Menu button



• Tap **History Detail**



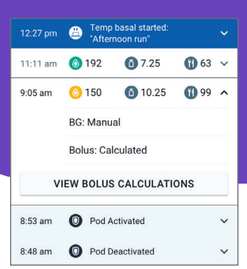
- Summary section includes:
  - Average CGM, CGM % in range, above range and below range
  - Total Insulin (basal + bolus), Basal Insulin, Bolus Insulin and Total Carbs
- Swipe up on the history screens to see the details section
- Details section shows individual records listed by time of day



- Tap **AUTO EVENTS**
- Insulin amounts delivered are shown every 5 minutes while in Automated Mode

Tip

Tapping on a specific row with a bolus entry brings up additional details about the bolus



Automated Manual

Notifications, Alerts & Alarms

Hazard Alarms

High priority alarms that indicate a serious problem has occurred and you may need to remove your Pod.

Examples: Pod Expired, Pod Out of Insulin, Pod Shut-Off, Blockage, Pod Error, System Error, Omnipod® 5 App Error, and Omnipod 5 Memory Corruption

WARNING: ALWAYS respond to hazard alarms as soon as they occur. Pod hazard alarms indicate that insulin delivery has stopped. Failure to respond to a hazard alarm could result in the under-delivery of insulin which can lead to hyperglycemia.

Advisory Alarms

Lower priority alarms that indicate a situation exists that needs your attention.

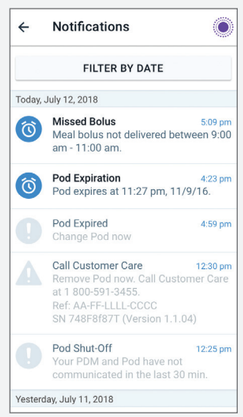
Examples: Pod Expiration, Low Pod Insulin, Pod Shut-Off, Start Insulin, Low Battery, Urgent Low Glucose, Missing CGM Values, and Automated Delivery Restriction

Notifications

Remind you of an action that you may want to perform. Some are generated automatically and others have settings that you can control.

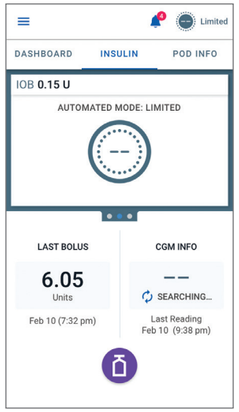
CAUTION: AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms and notifications. If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy 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 Section "13.3 Sounds and Vibrations" in the Omnipod 5 User Guide to learn how to manage sounds and vibrations.

- If your device is asleep when you hear or feel a notification, wake up your device to check if the notification is coming from the Omnipod 5 App. The lock screen will show the reminder notification icon and the message.
- Waking your device up and using the Omnipod 5 App does not automatically acknowledge or silence notifications. To acknowledge notifications, tap on the notifications icon at the top of the screen.
- Read any messages with a blue notification icon ( ). Scroll down the screen, if necessary, to see any additional notifications with blue icons.
- Tap the back arrow (←) in the top left corner to mark the notifications as acknowledged.



Missing CGM Values in Omnipod 5

- If the Pod is not receiving updated CGM values, the system can no longer fully adjust your automated insulin delivery. After 20 minutes not receiving CGM values, 'Limited' will be displayed on the Home screen.
- When the System enters Limited state, SmartAdjust™ technology never gives more than the Basal Program that would be active during Manual Mode.
- When CGM values are updated, full automated delivery resumes.



There are times when your Pod and CGM may lose connection. Some common reasons for loss of communication are:

- Pod and CGM not being in direct line of sight
- Temporary loss of communication due to environmental interference (for example, while swimming)
- Sensor warm up or required calibration

What should you do?

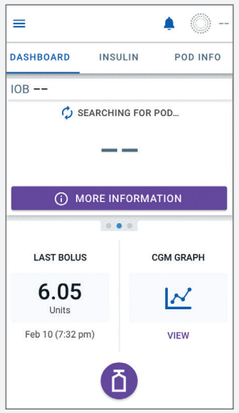
- Make sure that the Pod and CGM are in direct line of sight.
- Sometimes you can see 'Limited" if the loss of communication is between the Pod and CGM. It is possible that your Dexcom G6 app is still receiving CGM values. Open your Dexcom G6 app to check. Also look to see if there are any CGM actions that you need to take to re-establish communication.

No Pod Communication

- If the Omnipod 5 App cannot communicate with an active Pod 'No Pod Communication" will be displayed
- Follow the on-screen instructions to resolve the issue.

At times there may be communication issues between the Omnipod 5 App and your Pod. What should you do?

- Bring the device running the Omnipod 5 App and active Pod closer – within 5 feet of each other may restore communication
- Omnipod 5 App will offer you options to resolve the communication issue. Leave any options to DISCARD or DEACTIVATE POD as last choice after trying the other options.



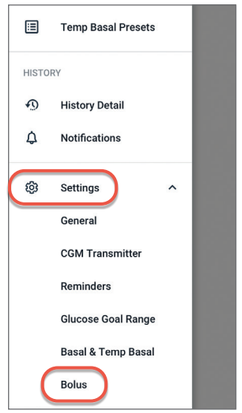
Additional Use
Omnipod® 5 System

Change Your Target Glucose

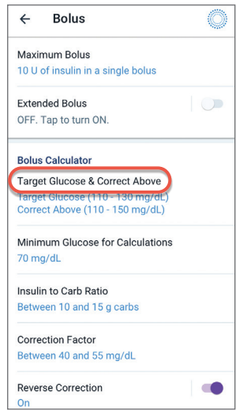
There may be a time where you want to change your Target Glucose. Check with your healthcare provider before changing your settings.

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. In both Automated and Manual Mode, when delivering a bolus the SmartBolus calculator will try to bring your glucose to the Target Glucose.

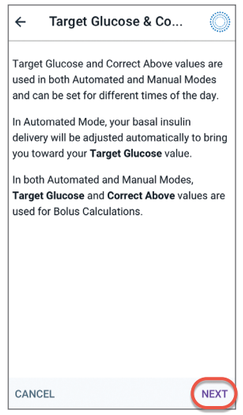
- Tap the Menu button



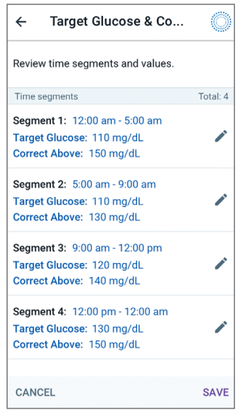
- Tap **Settings**
- Tap **Bolus**



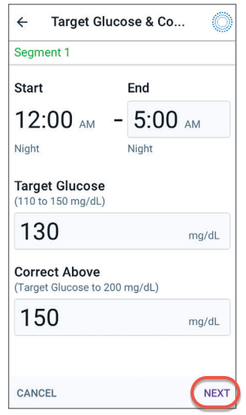
- Tap **Target Glucose & Correct Above**



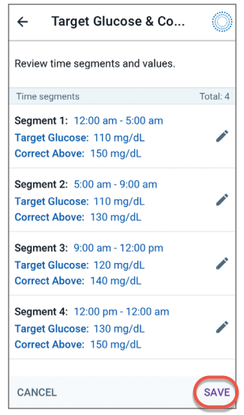
- Tap **NEXT**



- Tap on the segment you wish to change



- Edit time and/or Target Glucose or Correct Above
- Tap **NEXT**

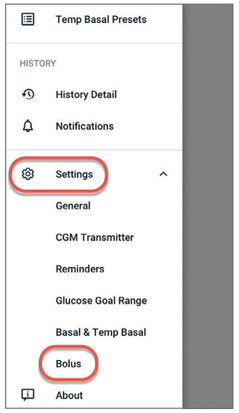


- Tap **SAVE**

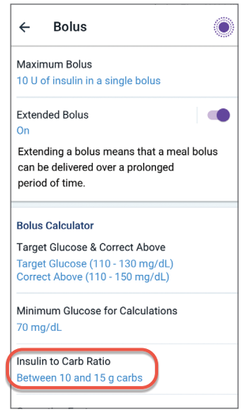
Change Your Bolus Settings

Sometimes, you may need to change the settings that are used by the SmartBolus calculator to calculate meal and correction boluses. Check with your healthcare provider before adjusting your SmartBolus calculator settings.

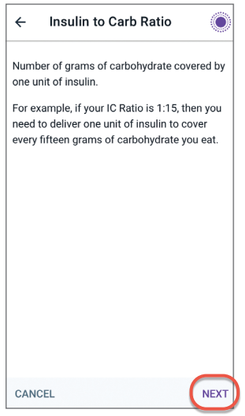
- Tap the Menu button



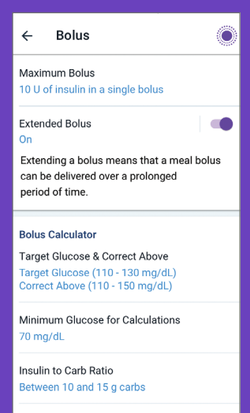
- Tap **Settings**
- Tap **Bolus**



- Tap the setting you want to change. For example, tap **Insulin to Carb Ratio**.

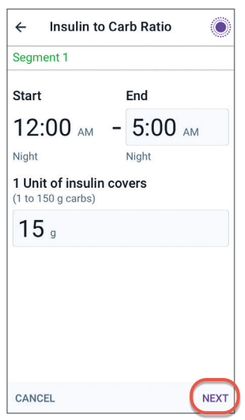


- Tap **NEXT**

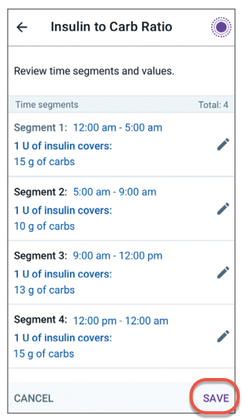


Tip

You can change other settings such as Correction Factor, Reverse Correction, or Duration of Insulin Action by tapping on that setting and following the steps on the screens



- Change the time and/or amount
- Tap **NEXT**



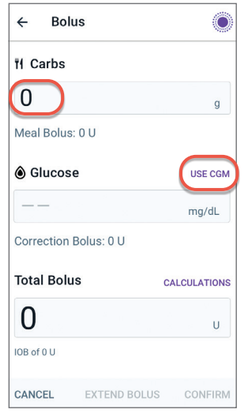
- Once you have made your changes, tap **SAVE**

Manual

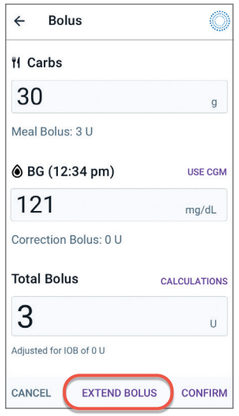
When and How to Use the Extended Bolus Feature

This feature is most commonly used for high-fat and/or high-protein meals such as pizza, cheeseburgers, or fried chicken when the digestion of carbohydrates could be delayed. Extended bolus is available only in Manual Mode.

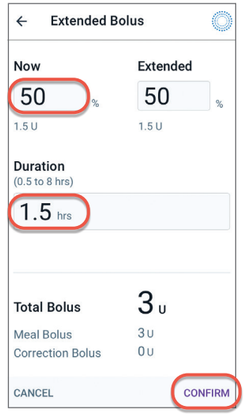
- Tap the Bolus button



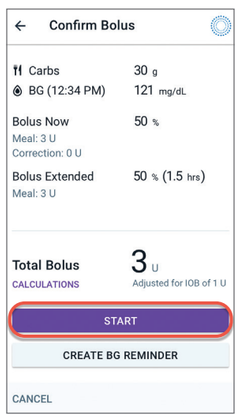
- Tap **Carbs**. Enter grams of Carbs.
- Tap **USE CGM** to use CGM value and trend*



- Tap **EXTEND BOLUS**



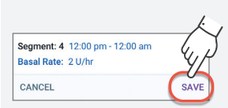
- Tap the **Now** field and enter the amount of the meal bolus to deliver now. The extended amount will automatically fill in.
- Tap **Duration** field. Enter the amount of time for the extended bolus.
- Tap **CONFIRM**



- Confirm values entered
- Tap **START**

Tip

Follow the screen instructions by tapping the area highlighted by the “red circle”



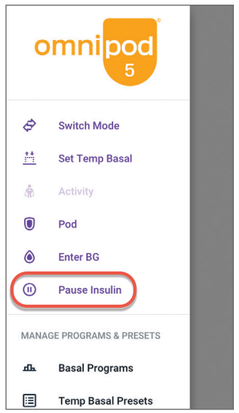
***Note:** Tap Glucose field to manually enter your glucose

Manual

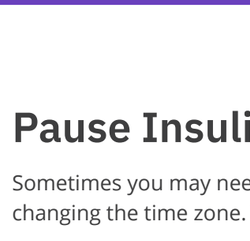
Pause Insulin Delivery

Sometimes you may need to pause insulin delivery briefly. For example, you must pause insulin delivery before changing the time zone. You can pause insulin only in Manual Mode.

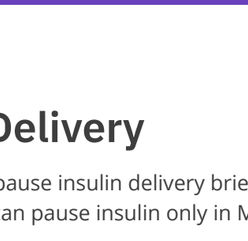
• Tap the Menu button



• Tap **Pause Insulin**



• Tap **Pause Insulin** to enter the amount of time to pause insulin
• Tap **PAUSE**



• Tap **YES** to confirm pause insulin

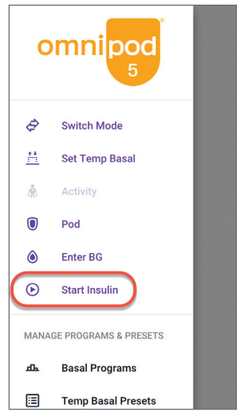
Caution: ALWAYS tap START INSULIN to start insulin delivery after a pause period has ended during Manual Mode use. Insulin delivery does not automatically start after a pause. If you do not start insulin delivery, you could develop hyperglycemia.

Manual

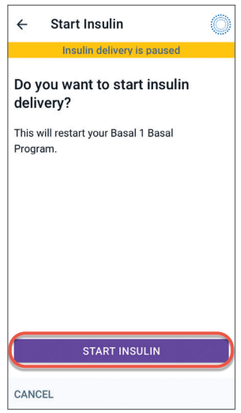
Start Insulin Delivery

Insulin delivery does not automatically restart when paused. To start insulin delivery before the pause period ends, follow these instructions. You can start insulin only in Manual Mode.

• Tap the Menu button



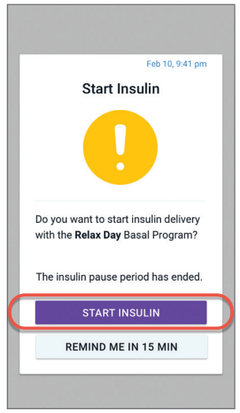
• Tap **Start Insulin**



• Tap **START INSULIN**

Reminder
Insulin delivery must be manually started if paused

If the pause period ends, the Omnipod 5 App beeps to remind you to start insulin delivery. If you do not start insulin delivery immediately, this warning reappears and the Omnipod 5 App and Pod beep every 15 minutes until insulin delivery is started.



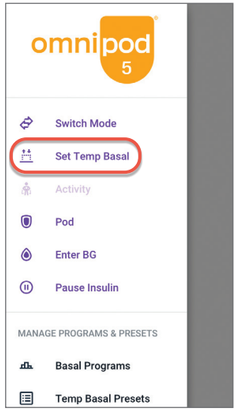
• Tap **START INSULIN** or tap **REMIND ME IN 15 MIN**

Manual

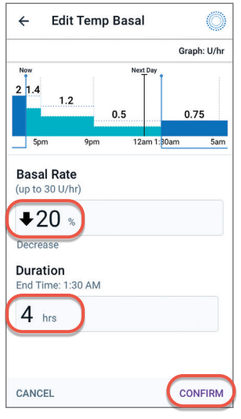
Start a Temporary Basal Rate

When in Manual Mode, you can use a temporary basal rate, or "temp basal," to handle a temporary change in your routine. For example, a temp basal can be used when you are exercising or when you are sick. When the temp basal ends, the Pod will start delivering the scheduled Basal Program.

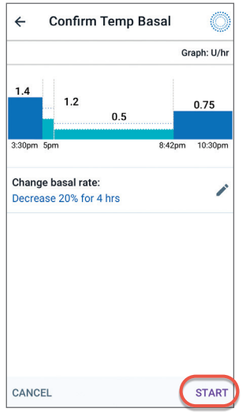
- Tap the Menu button



- Tap **Set Temp Basal**



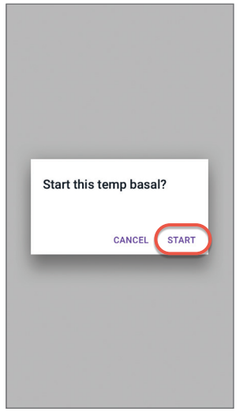
- Tap **Basal Rate** field and select % change. Using an up arrow (⬆) indicates increasing the basal rate. Using a down arrow (⬇) indicates decreasing the basal rate.
- Tap **Duration** field and select time duration
- Tap **CONFIRM**



- Review the details and tap **START**

Tip

In order to switch to Automated Mode, you must cancel an active temp basal



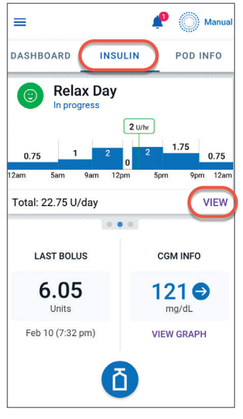
- Tap **START**

Note: Temp basal can only be used in Manual Mode

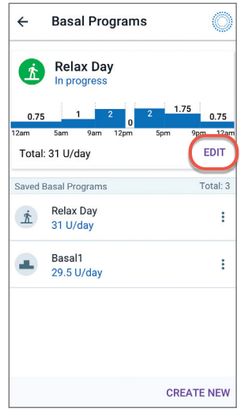
Manual

Edit a Basal Program

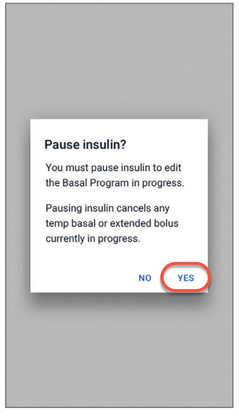
Editing a basal program will only change your basal insulin delivery in Manual Mode. You can only edit a basal program in Manual Mode. Check with your healthcare provider before changing basal settings.



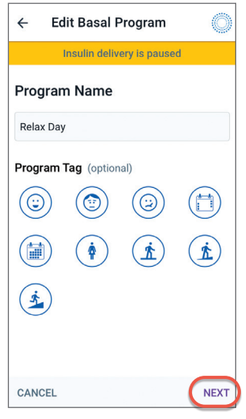
- Tap the INSULIN tab
- Tap **VIEW**



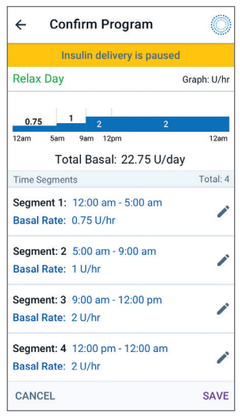
- Tap **EDIT**



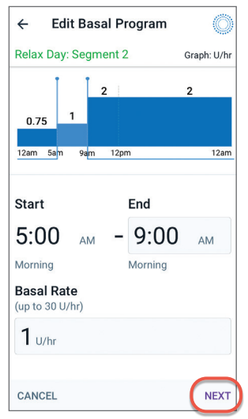
- Tap **YES**



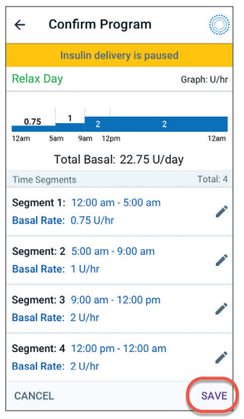
- Tap to edit program name, choose program tag, or tap **NEXT** to edit basal time segments and rates



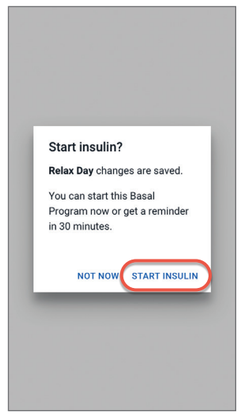
- Tap the segment to edit



- Tap to edit on the end time and/or basal rate
- Tap **NEXT**



- Tap **SAVE** after reviewing the basal program

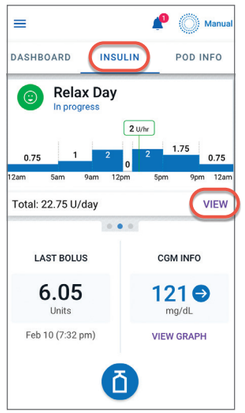


- Tap **START INSULIN**

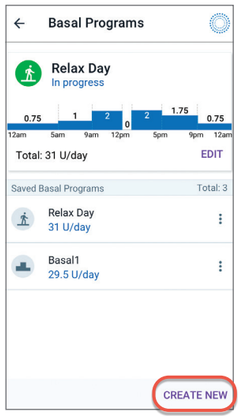
Manual

How to Create and Use Additional Basal Programs

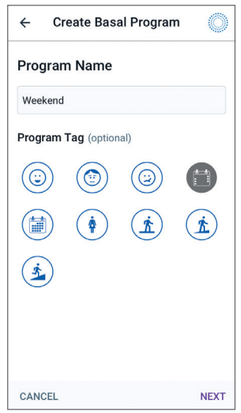
Different days can have different routines. The Omnipod 5 App lets you create different Basal Programs for your different routines (e.g. weekends vs weekdays). Consult your healthcare provider about creating additional basal programs. You can create and use additional basal programs only in Manual Mode.



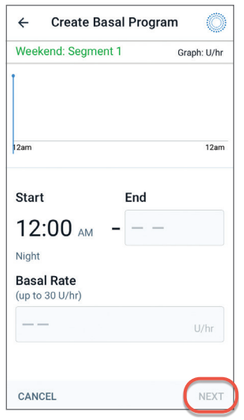
- Tap the INSULIN tab
- Tap **VIEW**



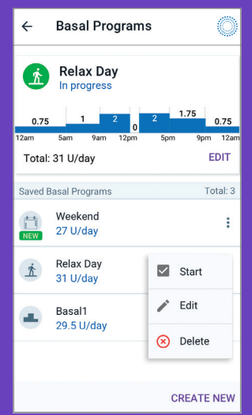
- Tap **CREATE NEW**



- Rename your program or keep the default name. Example “Weekend”
- Tap to choose a program tag

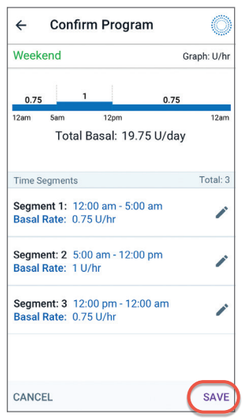


- Edit End Time and Basal Rate
- Tap **NEXT**
- Continue to add segments for the entire 24 hours

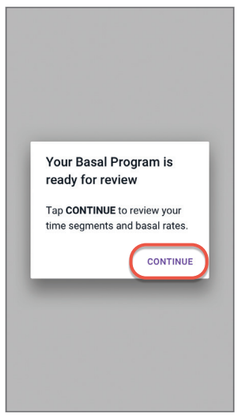


Tip

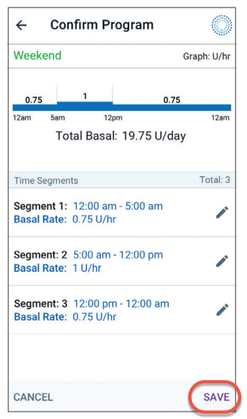
In Basal Programs, you can start, edit or delete the different basal programs you have saved by tapping on the Options icon (⋮)



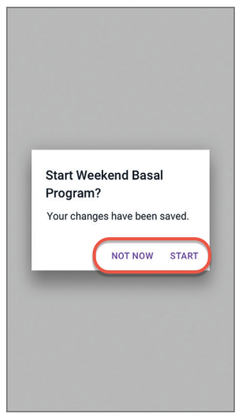
- Confirm segments Tap **SAVE**



- Tap **CONTINUE** to review your Basal Program



- Review your time segments and basal rates
- Tap **SAVE**



- Tap **START** or Tap **NOT NOW**

The Pod has an IP28 rating for up to 25 feet for 60 minutes. The controller is not waterproof. The Dexcom G6 sensor and transmitter ware water-resistant and may be submerged under eight feet of water for up to 24 hours without failure when properly installed.

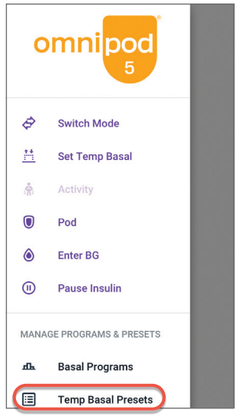
 Omnipod® 5 App screens are for educational purposes only. Consult your healthcare professional before using these features and for personalized recommendations.

Manual

How to Create and Use Temp Basal Presets

Temp Basal presets are best used for "temporary" routine activities, such as an exercise class that occurs twice a week. The Omnipod 5 App can store up to 12 temporary basal presets. You will be able to access your temp basal presets when you select **Temp Basal Presets** from the Menu. Temp basal presets can be created and used only in Manual Mode.

- Tap the Menu button

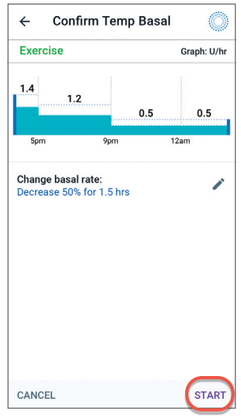


- Tap **Temp Basal Presets**

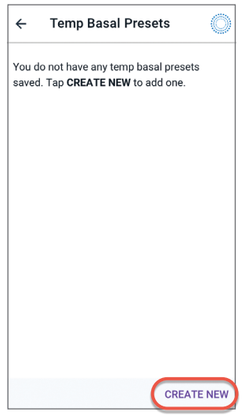
Tip

Presets can be created for commonly-used activities. For instance, if you find yourself setting the same temp basal rates for a particular activity, presets can be a real time saver.

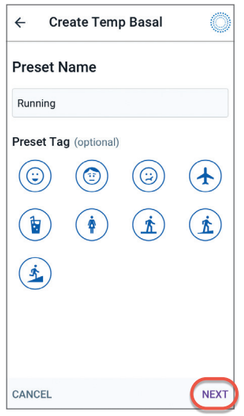
On any preset you can name the preset, for example running, for even more personalization.



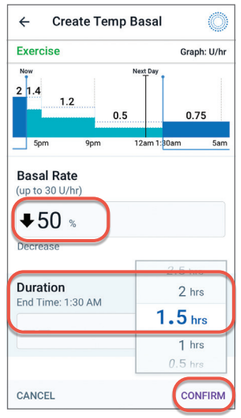
- Tap "**START**" to save temp basal preset



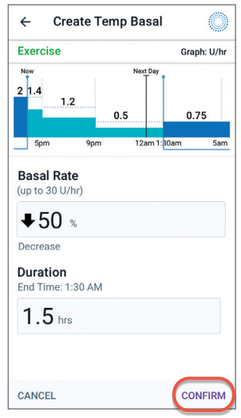
- Tap **CREATE NEW** to enter a new temp basal preset



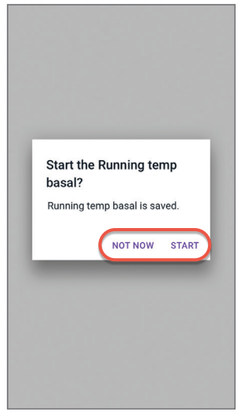
- Tap to enter preset name, choose program tag or Tap **NEXT** to edit basal rates and duration



- Tap **Basal Rate** field and select % change. Using an up arrow (⬆) indicates increasing the basal rate. Using a down arrow (⬇) indicates decreasing the basal rate.
- Tap **Duration** field and select time duration
- Tap **CONFIRM**



- Tap "**CONFIRM**"



- Tap **START** or Tap **NOT NOW**

Tip

- If you have already created Temp Presets, you can access them from Set Temp Basal
- Tap "**SELECT FROM PRESETS**"
- Tap on the Options icon (⋮) to activate, edit or delete your Temp Basal Presets

Understanding **Diabetes Therapy**

Why Carbohydrates Matter

What are Carbohydrates?

Starches Starchy vegetables like potatoes, corn and peas, dried beans and lentils, grains like oats, barley, rice, and items made from grain flour.

Sugars Naturally occur in milk and fruit, or added during cooking or processing. Common names for sugar are table sugar, brown sugar, molasses, honey, cane sugar, maple syrup, high fructose corn syrup, and agave nectar

Fiber Can be found in fruits, vegetables, whole grains, nuts and legumes. Most dietary fiber is not digestible. Fiber contributes to digestive health, keeps you regular, and helps make you feel full and satisfied after eating.

Impact on Blood Glucose

Carbohydrates (carbs) are important because they provide us with energy and essential vitamins and minerals. Proteins and fats also contain calories, vitamins, and minerals, but do not contain carbohydrates unless the food is a mixed item like a casserole.

Carbohydrates are the primary foods that affect glucose. Proteins and fats take longer to digest and are slower to affect your glucose. Higher consumption of protein or fat at meals can delay glucose absorption and create higher glucose later. Using an extended bolus can be helpful with these types of meals. The section "When and How to Extend a Bolus" can provide more information about extending a bolus while in Manual Mode.

Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0 mg	**0%**
Sodium 160 mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice

Source: US Food and Drug Administration Website

How do I figure out the amount of carbohydrates in my meal?

Check the Label

The two key pieces of information on the Nutrition Facts label for carb counting are the serving size and total carbohydrates.

Beaser RS. Joslin's Diabetes Deskbook: A guide for primary care providers. 3rd ed. Boston, MA. Joslin Diabetes Center; 2014

Know Your Favorites

Food Category	Food	Serving Size	Carbohydrate Grams
Breads	White or wheat bread	2 slices (2 oz)	25 – 30
	Hotdog or hamburger bun	1 whole (2oz)	25
	Bagel	1 whole (3-4 oz)	52
	Dinner roll whole wheat	1 roll (1 oz)	15
	Saltine crackers	5 crackers	11
	Flour tortilla	1 tortilla (8" dia)	25
	Corn tortilla	1 tortilla (8" dia)	13
Cereals/ Grains/ Pasta	White or brown rice	2/3 cup	30
	Pasta cooked	1 cup	38
	Dry cereal (plain Cheerios)	1 cup	20
	Instant oatmeal (regular cooked in water)	1 packet	20
	Grits cooked in water	1 cup	32
Starchy Vegetables	Corn	1 cup	35
	Mashed potatoes	1 cup	35
	Backed potato 3-4" diameter	1 large (10 oz)	64
Dried Beans, Peas, Lentil	Cooked black beans	1/2 cup	20
	Cooked peas	1/2 cup	12
	Cooked chick peas	1/2 cup	16

Food Category	Food	Serving Size	Carbohydrate Grams
Fruit and Fruit Juices	Apple	1 small (4 oz)	17
	Banana	1 small (6")	23
	Watermelon	1 cup	12
	Strawberries	1 cup halves	12
	Grapes	1 cup	27
	Canned fruits (in juice)	1 cup	28
	Apple, orange, grapefruit, or pineapple juice	1/2 cup (4 oz)	15
	Cranberry, grape, or prune juice	1/2 cup (4 oz)	20
Milk and Milk Products	Low-Fat (fat-free, 2%, whole)	1 cup (8 oz)	12
	Plain low-fat yogurt	1 cup (8 oz)	16
	Plain low-fat greek yogurt	1 cup (8 oz)	8
Sweets, Desserts & Snacks	Regular soda	1 can (12 oz)	38
	Vanilla ice cream (regular)	1/2 cup	15 – 20
	Vanilla wafers	8	22
	Popcorn (regular, microwave)	1 cup, popped	5
	Potato chips (plain, lightly salted)	1 oz (15 chips)	15

For a more extensive list, visit the USDA Food Composition Databases: http://ndb.nal.usda.gov/ndb/search/list

Automated Manual

Hypoglycemia (Low Glucose)

Glucose < 70 mg/dL

SmartAdjust technology in the Omnipod 5 System automatically decreases or pauses insulin delivery every 5 minutes when glucose levels are below the Target Glucose. The System can pause automated insulin delivery at any time to protect against hypoglycemia and will always pause when your glucose is below 60mg/dL.

Mild to Moderate Hypoglycemia Symptoms

- Shakiness
- Fatigue
- Hunger
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision
- Headache
- Rapid heartbeat
- Confusion
- Tingling
- Anxiety
- Drowsiness
- Dizziness
- Personality change

Verify and Check Glucose Level

↓

Glucose less than 70 mg/dL

Treat with 5- 15 grams of carbohydrate*
(Fast acting carbs: glucose tablets or gel, juice, regular soda (not diet), sugary candy (not chocolate), honey)

Recheck BG in 15 mins

↓

If Glucose is less than 70 mg/dL or symptoms persist repeat above steps†

* If glucose was dropping while in Automated Mode, SmartAdjust technology may have decreased or paused insulin for some time already and sometimes a smaller amount of carbohydrate can be used to prevent or treat mild hypoglycemia.

* Boughton, CK, Harnell S, et. Al Training and Support for Hybrid Closed-Loop Therapy. J Diabetes Sci Technol. Published online September 11, 2020.

† If glucose remains low after repeated treatments, notify your healthcare provider immediately and/or go to the nearest emergency room.

Never leave a person who is hypoglycemic unattended!

Important Notes: Make sure your glucose is at least 100mg/dL before driving or working with dangerous machinery or equipment. Even if you cannot check glucose, do not wait to treat symptoms of hypoglycemia. Avoid hypoglycemia unawareness by checking your glucose more frequently.

The above are general guidelines. For further guidance please consult with your healthcare provider for individualized advice.

Understanding Diabetes Therapy | HYPOGLYCEMIA

Automated Manual

Action Plan

Warning: DO NOT wait to treat hypoglycemia (low glucose) or symptoms of hypoglycemia. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe hypoglycemia, which can lead to seizure, loss of consciousness, or death. If loss of consciousness, inability to swallow glucose treatment or seizures are experienced or observed take the following action immediately:

- Give glucagon as instructed by healthcare provider
- Call 911
- Notify healthcare provider
- Pause insulin delivery

Troubleshooting Frequent Hypoglycemia

Check Settings

- Are you in Automated Mode?
- Are you in Manual Mode?
- If in Manual Mode, is the correct basal program in progress?
- If in Manual Mode, is the temp basal (if active) correct?
- Is Target Glucose correct?
- Is the insulin correction factor set correctly?
- Is the insulin-to-carb ratio correct?

Consult your healthcare provider about adjusting settings.

Review Recent Activity

Physical activity

- Has your exercise been unusually long or strenuous?
- Have you been unusually physically active? (e.g., extra walking, housework, heavy or repetitive tasks, lifting or carrying?)
- Did you use the Activity feature?
- Did you use a decreased temp basal during this activity?
- Did you consume carbs before, during, and/or after activity?

Meals/Snacks

- Did you count the carbs correctly?
- Did you bolus with food?
- Did you consume alcohol?

WARNING:
Hypoglycemia can occur even when a Pod is working properly. If left untreated, severe hypoglycemia can cause seizure or lead to unconsciousness. If you suspect your glucose level is low, check your glucose level to confirm

Automated Manual

Hyperglycemia (High Glucose)

Glucose ≥ 250 mg/dL

Every 5 minutes the Pod's SmartAdjust technology automatically increases insulin delivery by delivering a series of microboluses to respond to elevated glucose.

Hyperglycemia Symptoms

- Fatigue
- Frequent urination (i.e. at night)
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

↓

Verify and Check Glucose

↓

If Glucose is Over 250 mg/dL
Check Urine/Blood for Ketones

A	B	C
Trace or negative • Take a bolus using the Omnipod 5 App* • Address possible causes • Recheck BG in 2 hours	**Small urine or 0.6-0.9 mmol/L blood ketones** • Take bolus with syringe.* Change your Pod. • Address possible causes • Recheck urine ketones in 2 hours or blood ketones in 1 hour and BG in 2-3 hours	**Moderate – large urine or ≥ 1.0 mmol/L blood ketones** • Take bolus using syringe.* Change your Pod. • Address possible causes • Recheck urine ketones in 2 hours or blood ketones in 1 hour and BG in 2-3 hours
If BG unchanged or higher: Recheck for ketones • If neg ketones, take a bolus with a syringe*. Change your Pod. • If ketones small/0.6-0.9 mmol/L, or mod/large/>1.0 mmol/L, follow steps B or C above	**If Glucose unchanged or higher: Recheck for ketones** • If neg ketones take a bolus using your Omnipod 5 App* • If ketones small/0.6-0.9 mmol/L, or mod large/ >1.0 mmol/L, follow steps B or C above	If Glucose unchanged or higher, contact your healthcare provider
If glucose decreased, return to normal dosing schedule and continue to monitor glucose frequently	If glucose remains >250 mg/dL after 2 correction boluses by syringe, contact your healthcare provider	If Glucose decreased, return to normal dosing schedule and continue to check glucose every 3-4 hours and monitor ketones if glucose is >250 mg/dL

* Follow the dosing guidelines provided to you by your healthcare provider.

The above are general guidelines. For further guidance please consult with your healthcare provider for individualized advice.

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

Understanding Diabetes Therapy | HYPERGLYCEMIA

Automated Manual

Troubleshooting Frequent Hyperglycemia

Check Settings
- Are you in Automated Mode?
- Do you have the Activity feature enabled?
- Is your Target Glucose correct?
- In Manual Mode, is the correct basal program in progress?
- Temp basal: Do you have a temp basal running that you should have turned off?

Check my records
- Alarm history: Did you ignore or not hear alarms that should have been addressed?
- Last bolus: was the bolus too small?
  - Was the bolus timing correct?
  - Did you account for high-protein or high-fat meal?

Check Pod

Check your cannula through the viewing window
- Did the cannula slip out from under your skin?
- Is there blood in the cannula?
- Is there redness, drainage, or other signs of infection around the cannula?

If YES, change your Pod. If you suspect an infection, then call your healthcare provider.

Check your Pod site
- Is there redness or swelling around the Pod and adhesive?
- Is insulin leaking from your Pod site or is there odor of insulin?

If YES, change your Pod. If you suspect an infection, then call your healthcare provider.

Check your adhesive
- Is the adhesive dressing coming loose from your skin?
- Is the Pod becoming detached from the adhesive dressing?

If YES, and if cannula is still inserted properly, you may tape down the Pod or adhesive to prevent further detachment.

If cannula is no longer under your skin, change your Pod.

Check your insulin
- Is the insulin used expired?
- Has the insulin used been exposed to extreme temperatures?

If YES, change Pod using a new vial of insulin.

Reminder

If you are experiencing persistent nausea and/or vomiting, or have diarrhea over two hours, contact your healthcare provider immediately.

Action Plan

There are several factors that can cause hyperglycemia. Common causes include illness, stress, infection, and missed insulin doses. With the Omnipod 5 System, only rapid-acting insulin is used in your Pod, so you have no long-acting insulin in your body. If a blockage (occlusion) or other interruption of insulin delivery occurs, your glucose may rise rapidly. It is important you do not ignore the signs and symptoms of hyperglycemia.

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

Sick Day Management

Action Plan

Discuss sick day management with your healthcare provider. Always follow your healthcare provider's guidelines for your individual needs. Below are only general guidelines.

Emergency situations

- For glucose of 250 mg/dL or more see: Hyperglycemia Action Plan
- For glucose of 70 mg/dL or less (and/or symptoms) see: Hypoglycemia Action Plan

Throughout an illness

If you have a cold, stomach virus, toothache or other minor illness:

- Check glucose more often (every 2-4 hours or at least 4 times a day)
- Check ketones—any time glucose is 250 mg/dL or more
- Use temp basal as directed by your healthcare provider
- Stay hydrated
- Monitor urine output
- Keep a record of information (BG, ketone checks, fluids, and time/amount of urine, vomiting, diarrhea, temperature)

Call your healthcare provider immediately if you have:

- Persistent nausea and/or if you are vomiting/or have diarrhea over two hours
- Difficulty breathing
- Unusual behavior (such as confusion, slurred speech, double vision, inability to move, jerking movements)
- Persistent high glucose and/or positive ketones after treating with extra insulin and drinking fluids
- Persistent low glucose that is not responsive to decreasing insulin and drinking carbohydrate-containing fluids
- A fever above 100.5°F
- Moderate to large urine ketones or ≥ 1.0 mmol/L blood ketones

Reminder

The symptoms of DKA (diabetic ketoacidosis) are much like those of the flu. Before assuming you have the flu, check your glucose to rule out DKA. Consult your healthcare provider for further information. Always consult with your healthcare provider when experiencing hyperglycemia and sick days. Always follow your healthcare provider's guidelines.

Insulet Corporation
100 Nagog Park
Acton, MA 01720
1-800-591-3455 | 1-978-600-7850

Medical Disclaimer: This handout is for information only and is not a substitute for medical advice and/or services from a healthcare provider. This handout may not be relied upon in any way in connection with your personal health care related decisions and treatment. All such decisions and treatment should be discussed with a healthcare provider who is familiar with your individual needs.

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