omnipod 5

Omnipod® 5 Automated Insulin Delivery System

User Guide

for Insulet-provided Controller and Android smartphones

INDICATIONS FOR USE

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

The **Omnipod 5 algorithm** is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values. The Omnipod 5 algorithm is intended for the management of type 1 diabetes mellitus in persons 2 years of age and older and type 2 diabetes mellitus in persons 18 years of age and older. The Omnipod 5 algorithm is intended for single patient use and requires a prescription.

The **SmartBolus Calculator** is software intended for the management of diabetes in persons aged 2 and older requiring rapid-acting U-100 insulin. The SmartBolus Calculator calculates a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose 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 SmartBolus Calculator is intended for single patient, home use and requires a prescription.

COMPATIBLE INSULINS

The Omnipod 5 Automated Insulin Delivery System is compatible with the following U-100 insulins: NovoLog®, Humalog®, Admelog® , and Kirsty®.

Some insulin products are labeled for use in any pump that is compatible with the insulins listed above. To see if another insulin not listed above can be used, refer to section 2.2 of the prescribing information for that insulin product.

CONTRAINDICATIONS

The Omnipod 5 System is NOT recommended for people who:

- Are unable to monitor glucose as recommended by their healthcare provider.
- Are unable to maintain contact with their healthcare provider.
- Are unable to use the Omnipod 5 System according to instructions.
- Are taking hydroxyurea and using a Dexcom sensor as it could lead to falsely elevated sensor glucose values and result in 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.

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

WELCOME TO OMNIPOD® 5

New Omnipod 5 User

Receiving training and understanding the Instructions for Use are needed BEFORE using your new Omnipod 5 System. Follow these steps to get started:

1. **Get Started**
   Visit: **omnipod.com/setup** to create your account, link your data management accounts, and learn about training options.
2. **Receive 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 available based on your and your healthcare provider's preferences.
3. **Freedom Is Yours!**
   You'll then be ready to enjoy the benefits and flexibility of your new Omnipod 5 System.

If you have questions, please contact Customer Care at 1-800-591-3455 for support 24 hours a day, 7 days a week.

To access the complete Omnipod 5 System Technical User Guide

At any time while using Omnipod 5, you can access or request the *Omnipod 5 Technical User Guide for iPhone.*

1. Download or print a digital copy:
   - Visit omnipod.com/guides
   - Scan this QR code with your smartphone.

2. Request to receive a free printed copy:
   - Online request form at omnipod.com/guides
   - Call in to request: 800-591-3455

omnipod.com/guides

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1 Omnipod 5 System Overview

The Omnipod 5 App

- On provided Controller or a compatible smartphone.
- Sends commands to the Pod.
- Displays glucose and insulin information from the Pod.
- Used to issue meal and correction boluses.

The Pod

- Delivers insulin to your body.
- Receives commands from the Omnipod 5 App.
- Receives sensor glucose values from the sensor.
- Sends sensor glucose values to the Omnipod 5 App.
- Automatically adjusts insulin delivery in Automated Mode.

The Dexcom G6 or Dexcom G7 Sensor

- Sends sensor glucose values to the Pod and to the Dexcom G6 or G7 Continuous Glucose Monitoring System. The Dexcom G7 15 Day sensor can communicate with a display device (either a Dexcom receiver or a smartphone using the Dexcom G7 app) while paired with a Pod. Dexcom G6 and Standard Dexcom G7 sensors cannot communicate with a Dexcom receiver while paired with a Pod.
- Does not communicate directly with the Omnipod 5 App.

You can set up & start your Dexcom sensor before or after setting up your Omnipod 5 App. Please consult the Dexcom Instructions for Use for more information.

The FreeStyle Libre 2 Plus or FreeStyle Libre 3 Plus Sensor

- Sends sensor glucose values to the Pod and Omnipod 5 App.
- Sounds alarms in the Omnipod 5 App.
- Cannot communicate with another device while used with Omnipod 5.

You must scan and start Libre Plus sensors with the Omnipod 5 App.

The Libre 2 Plus sensor is compatible only with the Insulet-provided Controller when using Omnipod 5.

Sensor not included

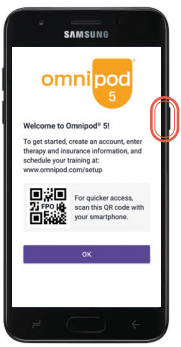
Sensor not included. For sensor-specific information, refer to the Instructions for Use for your compatible sensor.

2 Set Up Your Omnipod 5 App

Omnipod 5 App Setup

Before you set up your Omnipod 5 System, choose whether you want to use the Omnipod 5 App on the provided Controller or a compatible personal smartphone. Connectivity to cellular data or Wi-Fi is important when using the Omnipod 5 System. With either device, make sure to connect to your home or work Wi-Fi network. For a list of compatible smartphones, go to omnipod.com/compatibility.

Initial pump therapy settings, provided by your healthcare provider, are needed to set up your Omnipod 5 App.



If using the provided Controller as your Controller:

- Hold down the Power button to turn it on.

OR

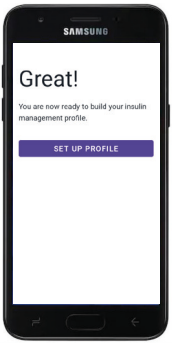
If using your compatible personal Android smartphone:

- Download the Omnipod 5 App on Google Play.
- Ensure Bluetooth® is turned ON on your compatible smartphone.

GET IT ON Google Play

- If you plan to use the Omnipod 5 App for iPhone, review the *Omnipod 5 User Guide for iPhone.*

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



The Omnipod 5 App will guide you through setup. Make sure to read each screen and carefully enter information.

An Omnipod ID is needed for setup. You will be prompted to sign in or be directed to create a new ID.

Setup is complete after entering your personalized initial pump therapy settings (provided by your healthcare provider).

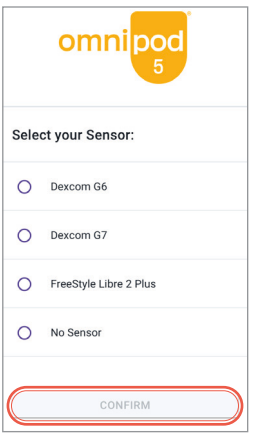
3 Connect the Sensor

Dexcom G6 Sensor

You must use the Dexcom G6 App on your smartphone to start and stop your sensor and Transmitter. If you have been using the Dexcom G6 receiver, turn it off. Your Transmitter will not pair with your Pod if it is still connected to the receiver.

Locate your Dexcom G6 Transmitter Serial Number (SN). This can be found in your Dexcom G6 mobile App Settings, on the back of the Transmitter, and on the Transmitter box.

Step 1: Select Dexcom G6 as your sensor



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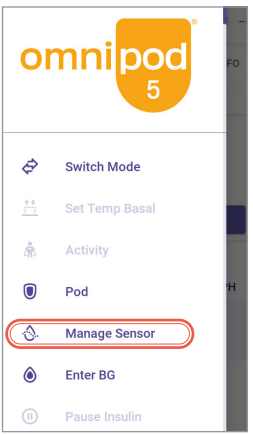
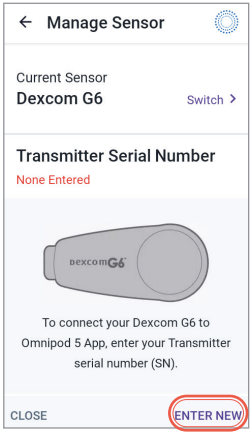


From first time setup select your sensor.

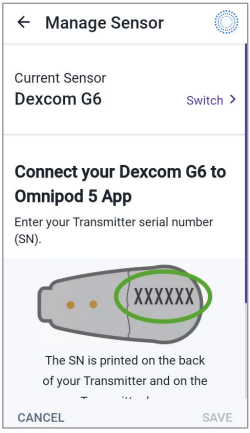
From Home screen.

- Tap the Menu button.
- Tap **Manage Sensor**.
- Select your sensor.

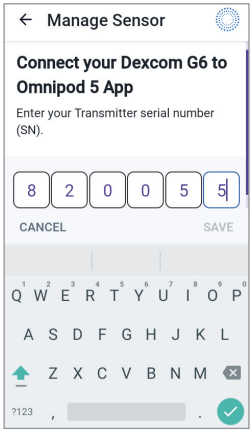
Step 2: Enter & Save New Transmitter serial number (SN)



• Tap **ENTER NEW**.



• Tap first box to enter Transmitter serial number (SN).



• Tap **Done**.
• Tap **SAVE**.

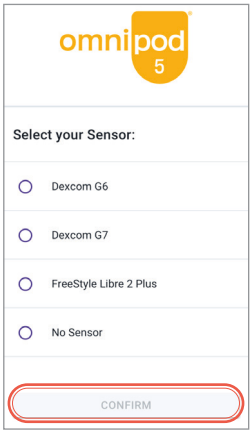
Note:
Your Pod uses the SN to connect to the correct Transmitter. You will need to enter a new SN any time you replace your Transmitter.

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

Dexcom G7 Sensor

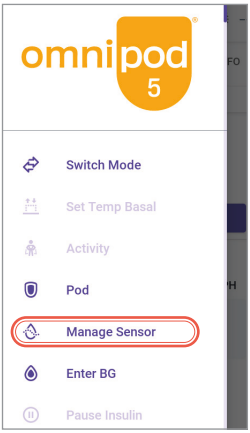
You must use the Dexcom G7 display device to start and stop your sensor.

Step 1: Select Dexcom G7 as your Sensor



From first time setup select your sensor.

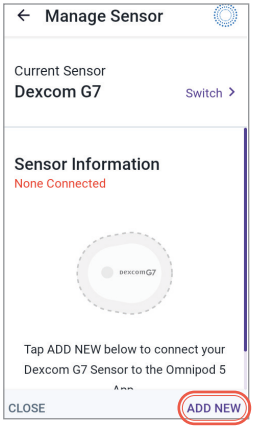
OR



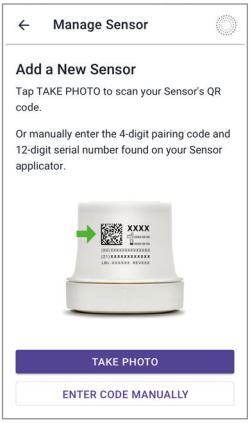
From Home screen.

- Tap the Menu button.
- Tap **Manage Sensor**.
- Select your sensor.

Step 2: Enter your Sensor pairing code and serial number



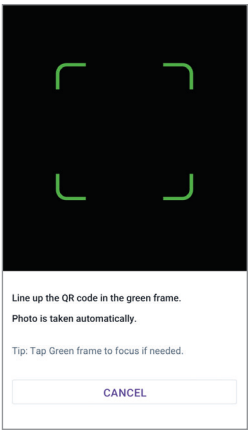
- Tap **ADD NEW**.



- To use the Take Photo option to connect, tap **TAKE PHOTO**.
- To enter the numbers, tap **ENTER CODE MANUALLY**.

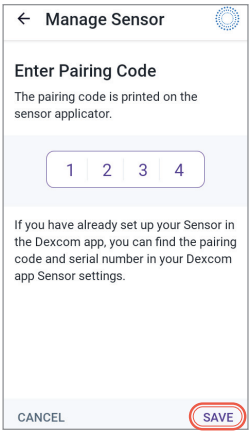
Note: You will need to connect each new Dexcom G7 sensor to both the Omnipod 5 App and Dexcom G7 display device for your Pod and sensor to stay connected.

Note:
Check that the camera lens is not blocked by your smartphone case or Controller gel skin. You will also need to have camera permission enabled.

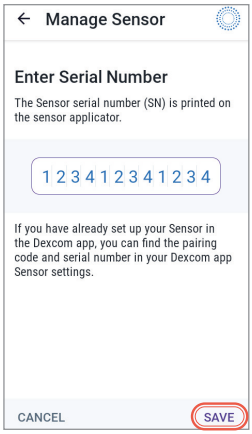


Line up the QR code in the green frame, holding both the Controller and applicator steady for several seconds. The photo is taken automatically. It will not be stored.

OR



- Enter the 4 digit pairing code on your applicator.
- Tap **SAVE**.



- Enter the 12 digit serial number printed on your applicator.
- Tap **SAVE**.

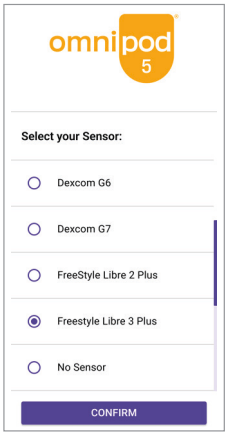
Libre 2 Plus and Libre 3 Plus Sensors

You can connect Omnipod 5 with the Libre 2 Plus or Libre 3 Plus sensors.

All Libre Plus sensor management is performed in the Omnipod 5 App, including starting a sensor and configuring and responding to alarms.

The Libre 2 Plus sensor is compatible only with the Insulet-provided Controller when using Omnipod 5.

Step 1: Select a Libre Plus as your sensor



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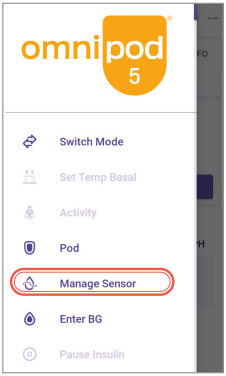


From first time setup select:

- FreeStyle Libre 2 Plus

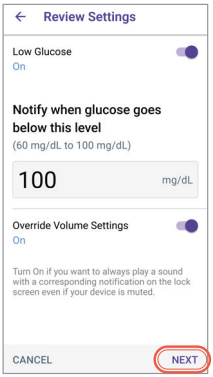
or

- FreeStyle Libre 3 Plus

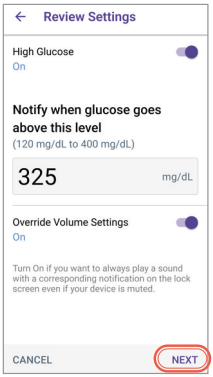
From Home screen

- Tap Menu button.
- Tap **Manage Sensor**.

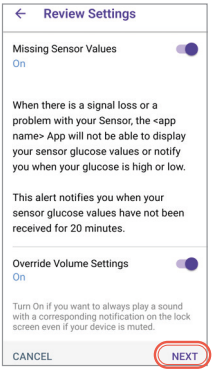
Step 2: Review your sensor settings



- Review or adjust your Low Glucose setting and volume preferences.
- Tap **NEXT**.



- Review or adjust your High Glucose setting and volume preferences.
- Tap **NEXT**.

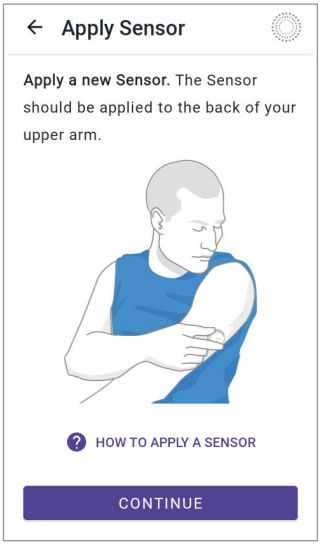


- Review or adjust your Missed sensor Values setting and volume preferences.
- Tap **NEXT**.
- Tap **SAVE**.

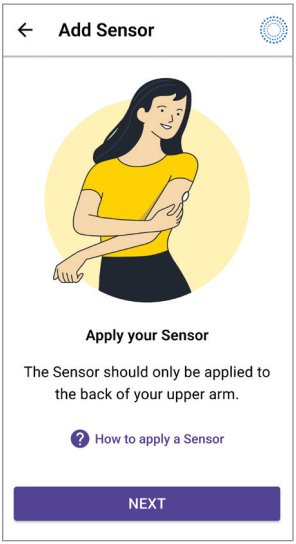
Step 3: Apply your Libre Plus sensor

- Follow the on-screen instructions.
- Tap **HOW TO APPLY A SENSOR** if you need help.

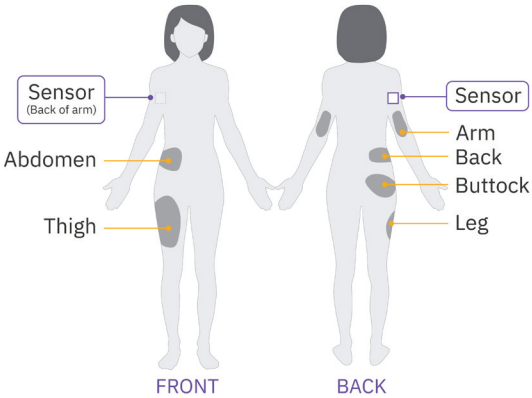
Libre 2 Plus



Libre 3 Plus



Sensor placement



Consider these Pod placements to find the locations that work best for your body for optimal line of sight to your sensor:

- On the same arm 1 inch (2.5 cm) apart
- Abdomen, same side
- Sides of abdomen, same side
- Lower back, same side
- Thigh, same side
- Upper buttocks, same side
- Back of the opposite arm

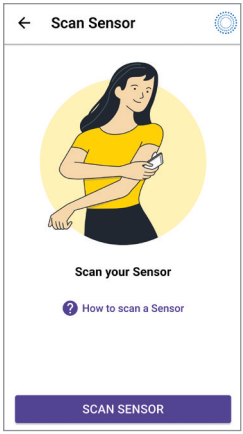
See your sensor's Instructions for Use to learn more about sensor placement.

Step 4: Scan your sensor

Place the back of your Controller or smartphone up to the sensor and scan it. The lower third of the device should almost touch the sensor.

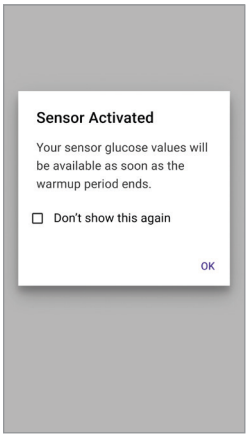
Libre 2 Plus

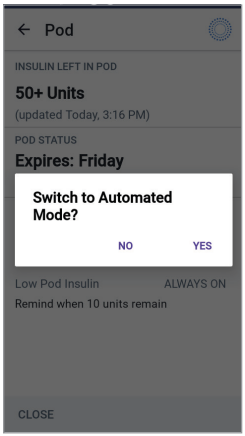
Libre 3 Plus



If the sensor scans successfully, tap **OK**. When prompted, you can switch to Automated Mode.

The Pod and sensor will connect within 20 minutes.



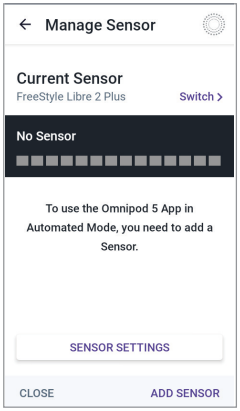


Switching Between Sensor Types

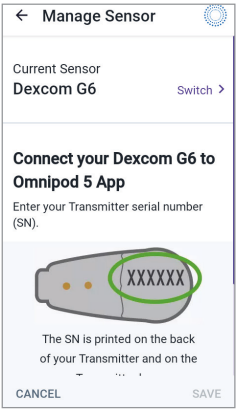
The Omnipod 5 System is compatible with more than one brand and model of sensor. If you start the System on one type of sensor and move to a different sensor in the future, you can switch your sensor type from the Manage sensor screen.

Note: Regular sensor changes do not require a Pod change, but if you are switching from one brand or model of sensor to another, you must make this switch between Pod changes. Each Pod can connect to only one type of sensor.

Step 1: Without an active Pod, tap Switch > from the Manage Sensor screen.



- To change from a Libre Plus sensor to another brand or model of sensor, tap **Switch >**.



- To change from a Dexcom sensor to another brand or model of sensor, tap **Switch >**.

Step 2: Select your new sensor brand and model, confirm your new selection, and follow the instructions on the previous pages for first-time set-up of a sensor. Check the Pod tray lid for Pod and sensor compatibility.

4 Set Up a New Pod

Prepare

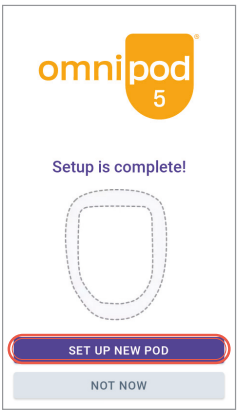
Gather the following supplies:

- Omnipod 5 Controller or smartphone.
- Unopened Omnipod 5 Pod.
- Alcohol prep swabs.
- A vial of room temperature rapid-acting U-100 insulin approved for use with Omnipod 5.

Wash your hands with soap and water.

Clean the top of the insulin vial with an alcohol prep swab.

On the Omnipod 5 App, locate the Pod activation screen.



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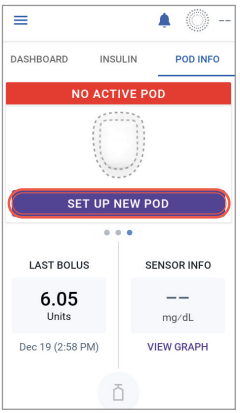


- After first time setup, tap **SET UP NEW POD**.
- From the POD INFO tab on the Home screen, tap **SET UP NEW POD**.

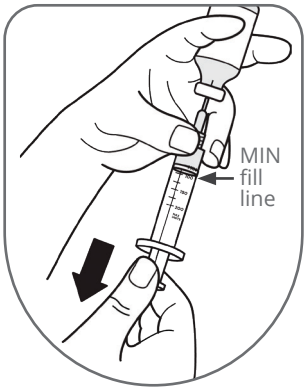
Fill the Pod

Prepare the fill syringe

- Remove the fill needle and syringe from the Pod's tray. Keep the Pod in its tray during setup. Twist the needle clockwise onto the top of the syringe for a secure fit. Do not use any other type of needle or filling device besides the syringe provided with each Pod.
- Remove the protective needle cap by carefully pulling it straight off the needle.

Fill the syringe

- Gently pull back on the plunger to draw air into the syringe equal to the amount of insulin you will use. You must fill the syringe with at least 85 units of insulin (MIN fill line). Insert the needle into the vial and push the plunger in to inject the air.
- With the syringe still in the vial, turn the vial and syringe upside down. Slowly pull the plunger to withdraw the insulin. Tap or flick the filled syringe to remove any bubbles.

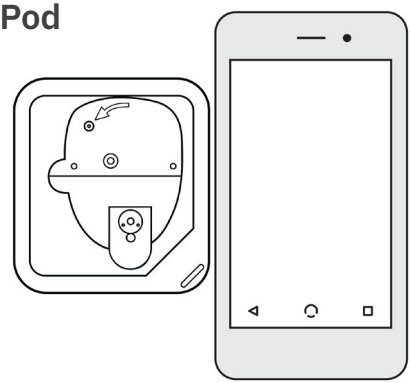


Fill the Pod

- Remove the needle from the vial and insert it straight down into the fill port. An arrow on the white paper backing points to the fill port. Slowly push the plunger down to completely fill the Pod.
- The Pod will beep twice to indicate the Omnipod 5 Pod is ready to proceed.

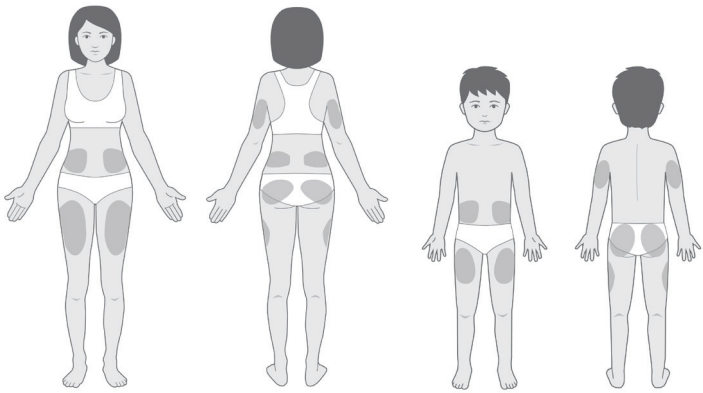
Activate the Omnipod 5 Pod

- With the Pod still in its tray, place it next to and touching the Controller to ensure proper communication. Tap **NEXT** on the Controller. The system will perform a series of safety checks and automatically primes the Pod.



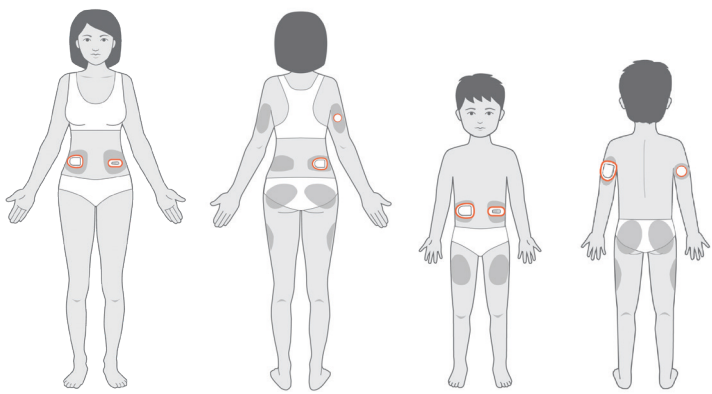
Pod Placement

Adults and Children



Sensor Placement

The Pod and sensor should be worn in line of sight, which means 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. Examples shown of various abdomen and arm sensor placements.



Guidelines for Pod Site Selection

Place your Pod and sensor as indicated in the Instructions for Use for your compatible sensor:

- At least 3 inches (8 cm) apart for your Dexcom sensor.
- At least 1 inch (2.5 cm) apart for your Libre Plus sensor.
- Place within line of sight of the sensor for the best connectivity.

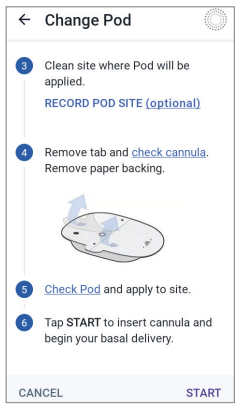
Note: Line of sight means that the Pod and sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.

- 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.

Apply the Pod

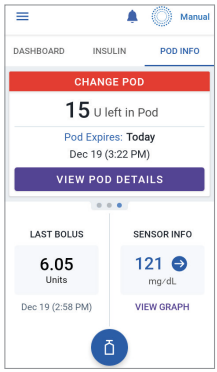
Your Pod is now ready for application and insertion.

- Carefully follow the on-screen instructions.
- Check the infusion site after insertion to ensure that the cannula was properly inserted.

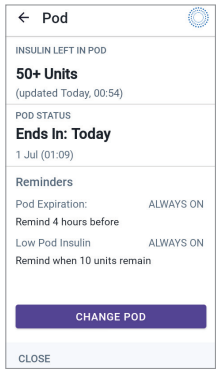


How to Change the Pod

- Tap **POD INFO**.



- Tap **VIEW POD DETAILS**.



- Tap **CHANGE POD**.
- Tap **DEACTIVATE POD**.

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 elevated glucose.
- As directed by your healthcare provider.
- If, during activation, the Pod fails to beep.

5 Omnipod 5 System Modes

System Modes

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

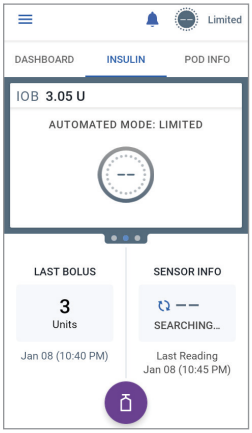
Automated Mode

- Adjusts every 5 minutes.
- Adapts by updating your total daily insulin with every Pod change.

Manual Mode

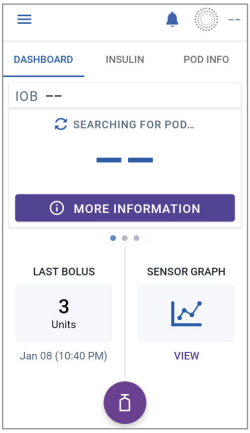
- Uses your Basal Program.

System States



Automated Mode: Limited

- Pod is not receiving sensor glucose values.
- System constantly compares Automated adaptive rate and Manual Basal Program and uses whichever is lower.



No Pod Communication

- Pod status is unknown.
- Bring Controller or smartphone closer to Pod.

	Manual Mode	Automated Mode
How it works		
Basal Insulin Delivery	Insulin is delivered according to the active Basal Program.	Insulin is delivered and adjusted automatically based on sensor glucose values and 60-minute prediction. When sensor glucose values are not available for adjustments, in Automated: Limited, the System constantly compares Automated adaptive rate and Manual Basal Program and uses whichever is lower.
Bolus Insulin Delivery	Insulin is delivered using the SmartBolus Calculator or entered manually.	Insulin is delivered using the SmartBolus Calculator or entered manually.
Connected sensor	Not required. If connected, sensor glucose values displayed, stored in history, and available for use in SmartBolus Calculator.	Required. Sensor glucose values used for automated insulin delivery, displayed, stored in history, and available for use in SmartBolus Calculator.

	Manual Mode	Automated Mode
What you can do		
Basal Programs	Edit, create new, activate Basal Programs. Does not impact Automated Mode.	Edit Target Glucose to impact automated insulin delivery. Cannot modify Basal Programs in Automated Mode.
Basal Insulin Delivery	Start and cancel Temp Basal rate.	Start and cancel the Activity feature.
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 When a Pod is deactivated, the System switches to Manual Mode. After you activate a new Pod, you'll be prompted to switch to Automated Mode.
Manage sensor	View and modify Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number. Switch between sensor brands and models (between Pod changes). Start or delete a Libre 2 Plus or Libre 3 Plus sensor, view wear duration, and configure alarms.	View Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number. View Libre 2 Plus or Libre 3 Plus sensor wear duration and configure alarms.

	Manual Mode	Automated Mode
What you can do		
Pause and Start Insulin	Manually pause insulin for a specified duration of up to 2 hours. Manually Start insulin.	System automatically pauses automated insulin delivery based on sensor glucose value/prediction. Switch to Manual Mode to manually pause insulin delivery.
History Details	Review History Details.	Review History Details. Auto Events tab shows microbolus deliveries from Automated Mode.
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 of the *Omnipod 5 System Technical User Guide* for a detailed list of alarms and notifications.	

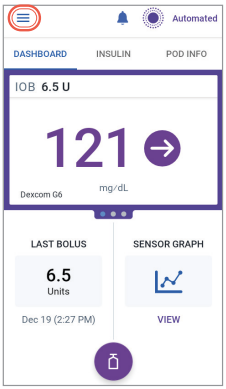
Note: In Automated Mode, your adaptive rate will be updated with every Pod change. Adaptive rate is a continuous baseline that the System can adjust up or down every 5 minutes in response to your sensor glucose values.

For your first Pod, since the System doesn't have any history yet, your total daily insulin and initial adaptive rate are estimated from the Basal Program you entered during setup.

Switch to Automated Mode

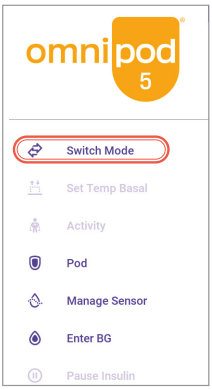
In Automated Mode, insulin delivery is adjusted based on your sensor glucose values.

1



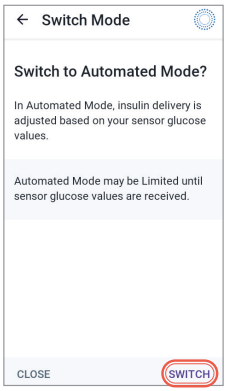
- Tap the Menu button on the Home screen.

2



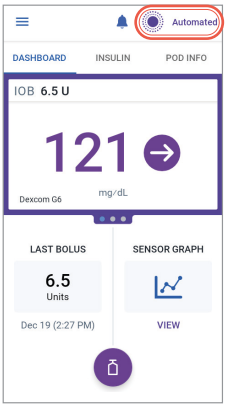
- Tap **Switch Mode**.

3



- Tap **SWITCH**.
- An active Pod and saved sensor information within the Omnipod 5 App are required.

4



- Confirm that the mode switched. Automated should be indicated at the top right of the screen.

Note: Before switching to Automated Mode, an active temp basal, extended bolus, or insulin pause must first be canceled.

Tips for Success

Great things take time

- You can begin using Automated Mode with your first Pod.
- Omnipod 5 adjusts the amount of insulin that your Pod delivers every 5 minutes.
- Over time, with every Pod change, Omnipod 5 adapts to better match your insulin needs.
- Optimizing your insulin delivery could take from a few days to a few weeks, depending on your previous therapy, starting settings, and total daily insulin delivered.

Automated Mode, explained

The Omnipod 5 algorithm predicts where your glucose will be 60 minutes into the future. You may see the System pause or increase insulin if your glucose is predicted to be below or above your Target Glucose setting in the next 60 minutes. The System might also pause or decrease insulin to protect against hypoglycemia or correct for hyperglycemia.

To see what the System is doing:

- Check the sensor Graph: A red bar shows when insulin has been fully paused. An orange bar shows when the System has reached its maximum insulin delivery.
- Check the Auto Events tab in History Detail: This tab shows all automated insulin, both your baseline adaptive rate and any adjustment up or down due to your sensor value and trend and/or the 60-minute prediction.

Help your Pod and Sensor stay connected

Omnipod 5 is built to work in Automated Mode even if the Pod is occasionally missing sensor glucose values. If you notice that Omnipod 5 is missing sensor values, but you're still in Automated Mode, that means your Pod received sensor glucose values within the last 20 minutes.

However, if you notice that Omnipod 5 is in Automated: Limited often, this might mean that your sensor and Pod are having trouble communicating. The next time you change your Pod or sensor, try placing them on the same side of the body in a way that the two devices can "see" one another (line of sight) without your body blocking their communication.

If you use a Dexcom sensor, you can also check your Dexcom display device to see if sensor glucose values are available. If they are, confirm that the Dexcom G6 Transmitter SN or Dexcom G7 pairing code and serial number match the information in your Omnipod 5 App.

Handling highs and lows

There may still be times when you have high or low glucose.

- Give correction boluses to bring down high glucose. This will help the System understand your total daily insulin needs. Try not to override the System's suggestions.
- Use the SmartBolus Calculator whenever you eat. Enter grams of carbs and tap USE SENSOR to calculate a dose based on current sensor value, trend, and Insulin on Board.

Talk to your healthcare provider about:

Treating Lows	Some people find they need to use fewer carbs to treat lows because the System has been decreasing insulin as their glucose drops.
Timing Meal Boluses	Delivering insulin 15–20 minutes before eating could help if you see high glucose after eating.
Adjusting Target Glucose	Decreasing Target Glucose can help the System deliver more automated insulin. Target Glucose is the only setting that you can change to impact automated insulin delivery. Making changes to your basal settings (like your Basal Program or Max Basal) will impact basal insulin delivery only in Manual Mode.
Adjusting Bolus Settings	If you see high glucose after eating, you may need to strengthen your Insulin to Carb ratio to give more insulin for the food you eat. Other bolus settings include Target Glucose, Correction Factor, Duration of Insulin Action, and Reverse Correction. Boluses impact your Total Daily Insulin. Bolusing for meals and to bring down high glucose will help your System learn your insulin needs as it adapts over time.

For more information about treating high and low glucose and handling sick days, see the *Omnipod 5 Automated Insulin Delivery System Important Safety Information*.

6 Get to Know the App

Omnipod 5 App Home Screen

Glucose Trends and Indicators

Automated Manual

SENSOR GLUCOSE VALUE COLOR KEY:

The sensor glucose value and trend arrow will change color depending on your Glucose Goal Range.

121 Trending steady

121 Trending steady

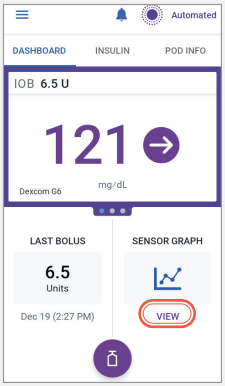
68 Rapidly falling

258 Slowly rising

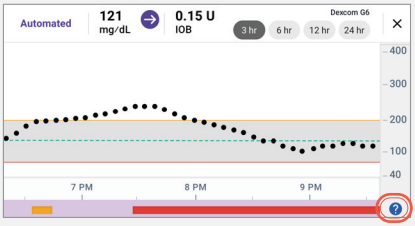
- Sensor glucose value within Glucose Goal Range (Manual Mode)
- Sensor glucose value within Glucose Goal Range (Automated Mode)
- Sensor glucose value below Glucose Goal Range (Automated & Manual Modes)
- Sensor glucose value above Glucose Goal Range (Automated & Manual Modes)

Note: A sensor glucose value will not be displayed if in Limited or No Pod Communication states.

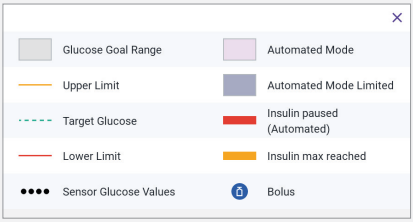
View Sensor Graph



- Tap **VIEW** on sensor Graph.



- Tap the question mark icon to view the Graph Legend.



- Sensor Graph Legend.

Note: Sensor Graph differs slightly in appearance depending on Mode.

Alarms and Notifications

The Omnipod 5 System generates different types of alarms and notifications. Alarms repeat every 15 minutes until acknowledged. Alarms that sound on the Pod must be acknowledged in the Omnipod 5 App.

Hazard Alarms

Hazard alarms are high-priority alarms that indicate a serious problem has occurred, and you may need to remove your Pod.

Hazard alarms related to the App

Omnipod 5 App Error	The System detected an error with the App. The Controller may restart.
Omnipod 5 Memory Corruption	The System detected an error with the App. The Controller will be reset. All settings will be deleted. Remove your Pod.
System Error	The System detected an error with the App. Remove your Pod.

Hazard alarms related to the Pod

Blockage Detected	The System detected a blockage (occlusion) in the Pod's cannula. Insulin delivery has stopped. Remove your Pod.
Pod Error	The System detected an error with the Pod. Insulin delivery has stopped. Remove your Pod.
Pod Expired	The Pod has reached the end of its operating life. Insulin delivery has stopped. Remove your Pod.
Pod Out of Insulin	The Pod is empty. Insulin delivery has stopped. Remove your Pod.
Pod Shut-Off	The Pod has stopped delivering insulin because you have set a Pod Shut-off time and did not respond to the Pod Shut-off Advisory alarm. Insulin delivery has stopped. Remove your Pod.

Advisory Alarms

Advisory alarms are lower-priority alarms that indicate that a situation exists that needs your attention. Advisory alarms may escalate to a Hazard alarm.

Advisory alarms related to the Pod

Low Pod Insulin	The amount of insulin in your Pod is below the value you specified in Settings. Escalates to Pod Out of Insulin Hazard alarm if ignored. Change your Pod soon.
Pod Expired	The Pod has expired and will stop delivering insulin soon. Will sound once per hour until it escalates to Pod Expired Hazard alarm. Change your Pod soon.
Pod Shut-Off	The Pod will stop delivering insulin soon because of the Pod Shut-off time you specified in Settings. Tap OK to acknowledge and avoid escalating to Pod Shut-Off Hazard Alarm.
Start Insulin	The time period you specified to pause insulin has ended. Tap **START INSULIN** to restart insulin and avoid hyperglycemia.

Advisory alarm related to Glucose

Urgent Low Glucose	Your sensor glucose value is 55 mg/dL or below. Consider eating fast-acting carbs to treat hypoglycemia.

Advisory alarms related to Automated Mode

Missing sensor Values	In Automated Mode, the Pod has not received sensor glucose values for an hour. The System will operate in Automated: Limited until new values are received.
Check blood glucose	In Automated Mode, the System has been working to bring your glucose into range but has not seen your glucose change the way it expected. This alarm can let you know to step in and check your sensor, your Pod, and your glucose. If your sensor glucose has been reading low and the System has paused your insulin for too long, the System will move into Automated: Limited until you acknowledge the alarm.
Automated Delivery Restriction	In Automated Mode, the System has been working to bring your glucose into range but has not seen your glucose change the way it expected. This alarm can let you know to step in and check your sensor, your Pod, and your glucose. Switch to Manual Mode for 5 minutes or longer to acknowledge this alarm.

Depending on the software version of your Pod, you might see the Check blood glucose alarm *or* the Automated Delivery Restriction alarm.

Optional, adjustable alarms related to Libre Plus Sensors

High Glucose	Your sensor glucose value is above your High Glucose setting. Optional alarm will repeat every 5 minutes until your glucose is below the setting or you acknowledge the notification.
Low Glucose	Your sensor glucose value is below your Low Glucose setting. Optional alarm will repeat every 5 minutes until your glucose is above the setting or you acknowledge the notification.
Missing Sensor Values	Sensor glucose values have not been received from your sensor for 20 minutes. Optional alarm will repeat every 5 minutes, up to 5 times, until sensor glucose values return or you acknowledge the notification.

Problem messages related to Libre Plus Sensors

Sensor Too Cold	Your sensor is too cold to provide a glucose value. Move to a warmer location.
Sensor Too Hot	Your sensor is too hot to provide a glucose value. Move to a cooler location.
Temporary Sensor Problem	Your sensor is temporarily unable to send sensor glucose values to the Pod or Omnipod 5 App. Check again in 10 minutes.
Sensor Error	Sensor glucose is unavailable. Occurs early in sensor wear when values are unable to be confirmed as accurate. Tap **Need Help**.
Sensor Ended	Your sensor has ended. Replace your sensor.
No Sensor	No sensor is detected. To use the Omnipod 5 System in Automated Mode, you need to add a sensor and have an active Pod on.
Replace Sensor	The System has detected a problem with your sensor that cannot be fixed. Replace your sensor.
Failed to Connect	Your sensor did not connect to the Pod. Try again.

Notifications

Action item notifications are for technical System tasks that need your attention, such as App settings or updates. Reminder notifications are related to diabetes management actions you may want to perform.

7 Key Insulin Delivery Actions

Deliver a Bolus

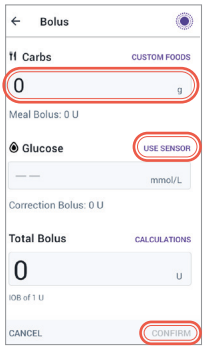
Automated Manual

Note: USE SENSOR button is active only when Omnipod 5 is receiving a sensor glucose value and trend.
Note: Extended Bolus is available only in Manual Mode.

1

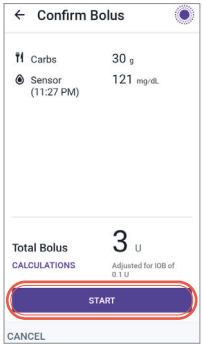
- Tap the Bolus button on the Home screen.

2



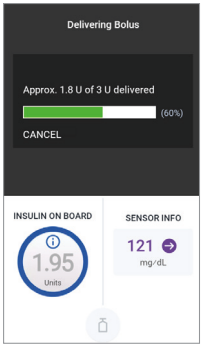
- Tap on the Carbs field to manually enter carbs.
- Tap **USE SENSOR** to use sensor glucose value and trend or add blood glucose reading by tapping the Glucose field.
- Tap **CONFIRM**.

3



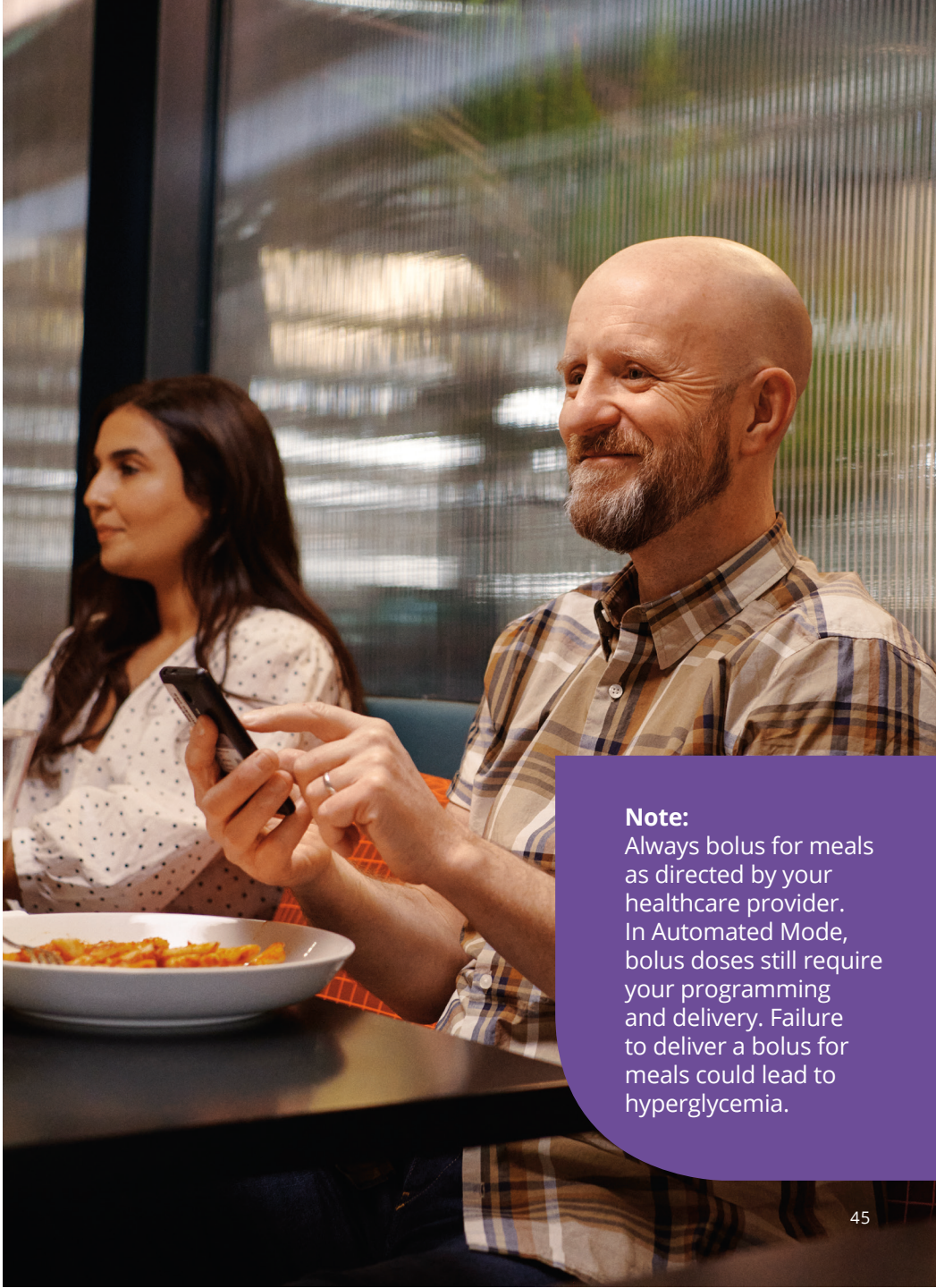
- Review entries are correct.
- Tap **START** to begin bolus insulin delivery.

4



- Home screen will display progress of bolus delivery.
- To cancel a bolus in progress, tap **CANCEL**.

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



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.

Custom Foods

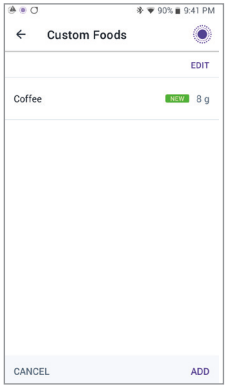
Omnipod 5 allows you to save carb information for certain favorite foods, snacks or meals (Custom Foods) that you might eat frequently.

To create or edit a Custom Food, tap Custom Foods from the Menu.

1

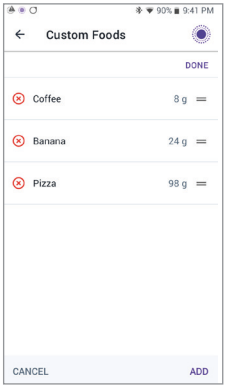
- Tap **ADD**.
- Enter a name and tap **Done**.
- Enter a carb count and tap **Done**.
- Tap **SAVE**.

2



- You will see a green badge that reads NEW next to your new entry.

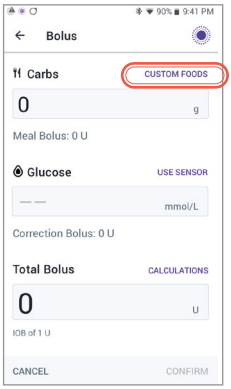
3

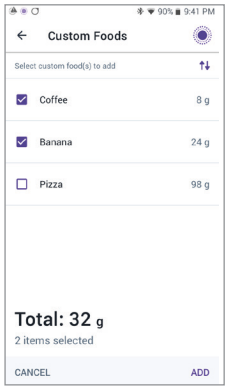


- Tap **EDIT** to edit your list. You can drag to reorder items, delete items or tap them to edit.

To use Custom Foods for a bolus, tap Custom Foods on the SmartBolus Calculator screen.

During a bolus, you can sort foods using the up-down arrow button and add them to your bolus.





- You can choose which foods to add to your calculation. Tap **ADD**.

Start the Activity Feature

Automated

Note: The Activity feature is available only in Automated Mode.

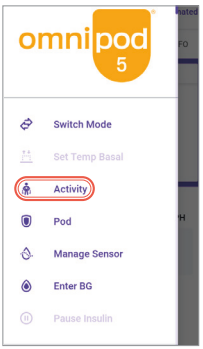
The Activity feature of the Omnipod 5 System can be enabled for times when there may be a decrease in insulin needs, like exercise. It will set the Automated Mode Target Glucose to 150 mg/dL and reduce insulin delivery.

Note: The Activity feature does not change the Target Glucose used in bolus calculations.

1

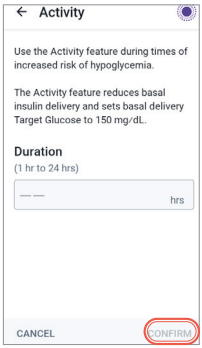
- Tap the **Menu** button on the Home screen.

2



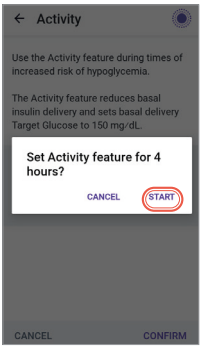
- Tap **Activity**.

3



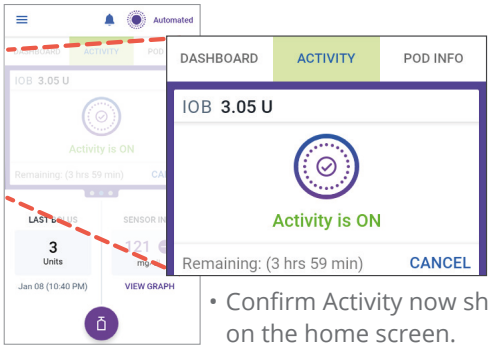
- Set Duration (1-24 hrs).
- Tap **CONFIRM**.

4



- Tap **START**.

5



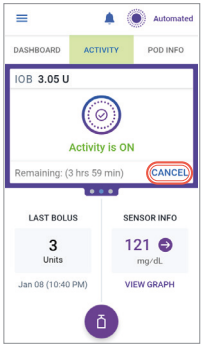
- Confirm Activity now shows on the home screen.

Cancel the Activity Feature

Automated

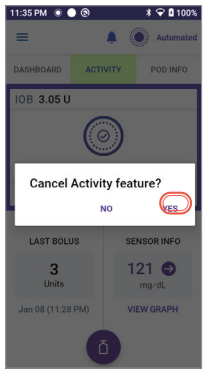
You can cancel the Activity feature at any time. Upon cancellation or expiration of the defined time period, full automated basal delivery starts on its own, and the Omnipod 5 System returns to using the user-defined Target Glucose.

1



- Tap **CANCEL** on the ACTIVITY Tab.

2



- Tap **YES**.

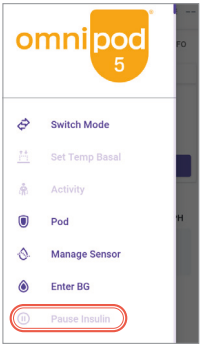
Pause Insulin Delivery

Manual

1

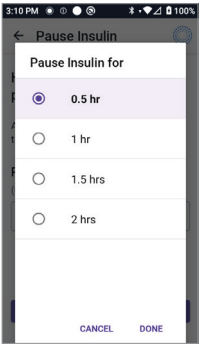
- Tap the Menu button on the Home screen.

2



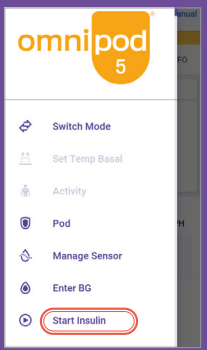
- Tap **Pause Insulin**.

3



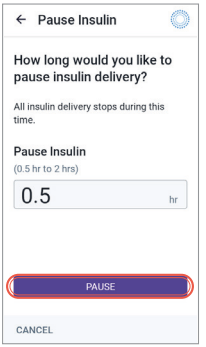
- Use scroll wheel to tell the System how long you'd like to pause insulin for.

Start Insulin Delivery



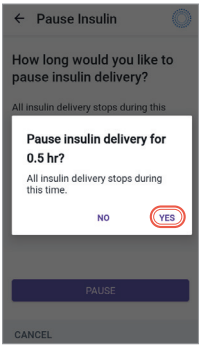
- Tap **Start Insulin**.
- Follow the Menu instructions to start insulin.

4



- Tap **Pause**.

5



- Tap **YES** to confirm insulin pause.

Insulin delivery does not automatically start at the end of the paused period. You must tap **START INSULIN** to start insulin delivery.

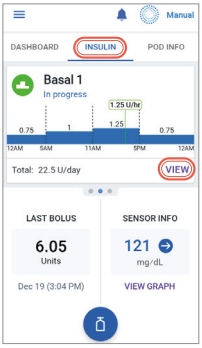
Editing a Basal Program

Manual

On occasion, you and your healthcare provider might want to update your basal program to better reflect your current insulin needs.

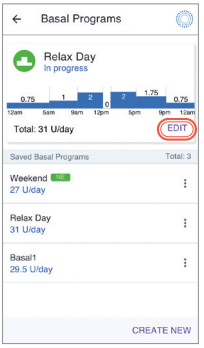
Note: Editing a Basal Program will NOT affect Automated Mode insulin delivery. To edit a Basal Program, you must be in Manual Mode, and the changes will impact only Manual Mode.

1



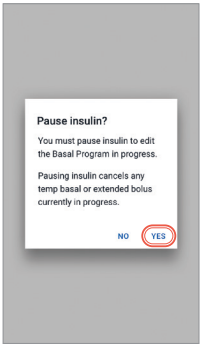
- Tap the INSULIN tab on the Home screen.
- Tap **VIEW**.

2



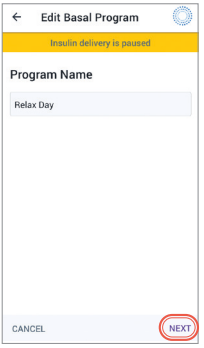
- Tap **EDIT**.

3



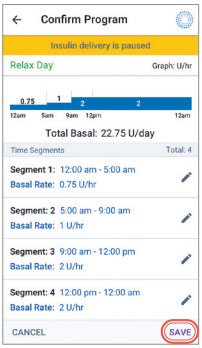
- Tap **YES**.

4



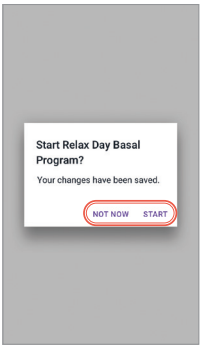
- Tap to edit program name or tap **NEXT** to edit basal time segments and rates.

5

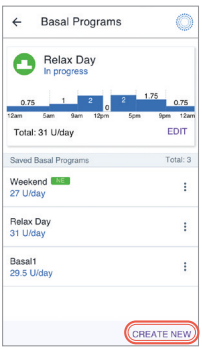


- Tap the time segment to edit.
- Tap **SAVE** after confirming edits in the basal program.

6



- To start the Basal Program now tap **START**. Otherwise tap **NOT NOW** to save to use at a later time.



Additional Basal Programs

Some people have additional basal programs to help with varying routines, like weekends or work days. These can be used only in Manual Mode.

- Additional Basal Programs can be created by navigating to the Menu button> Basal Programs and tapping **CREATE NEW**.
- Tap the Program Name field to enter a descriptive name for the new Basal Program.
- Tap **NEXT** and define the basal segments one at a time.

Set a Temporary Basal Rate

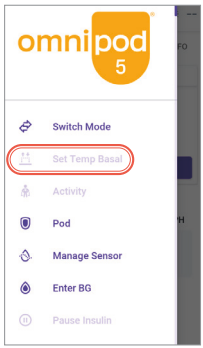
Manual

On occasion, you might want to temporarily change your basal rate for illness or activity.
Note: Temp Basal is available only in Manual Mode.

1

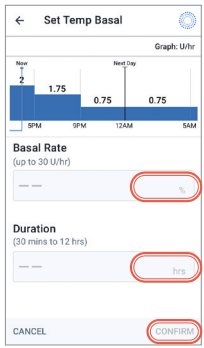
- Tap the Menu button on the Home screen.

2



- Tap **Set Temp Basal**.

3

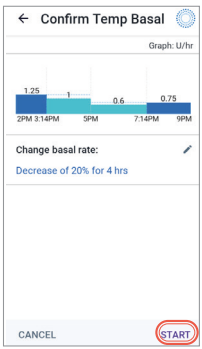


- Tap Basal Rate entry box and select % change.

Note: The up arrow indicates an increase. The down arrow indicates a decrease.

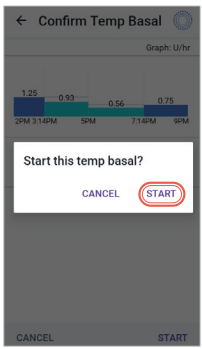
- Tap **DURATION** entry box and select time duration.
- Tap **CONFIRM**.

4



- Review selections are correct and tap **START**.

5



- Tap **START**.

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

8 My Omnipod 5 Information

My next 3 Pod Placements

Make a plan for where you'll place your next few Pods.
(Example: left abdomen, right lower back)

Pod 2: _____

Pod 3: _____

Pod 4: _____

My Custom Foods

Record the carb value for some of your most frequent meals.
(Example: bedtime snack: 20 grams)

Custom Food: _____**=** _____ **grams**

Custom Food: _____**=** _____ **grams**

Custom Food: _____**=** _____ **grams**

Custom Food: _____**=** _____ **grams**

Custom Food: _____**=** _____ **grams**

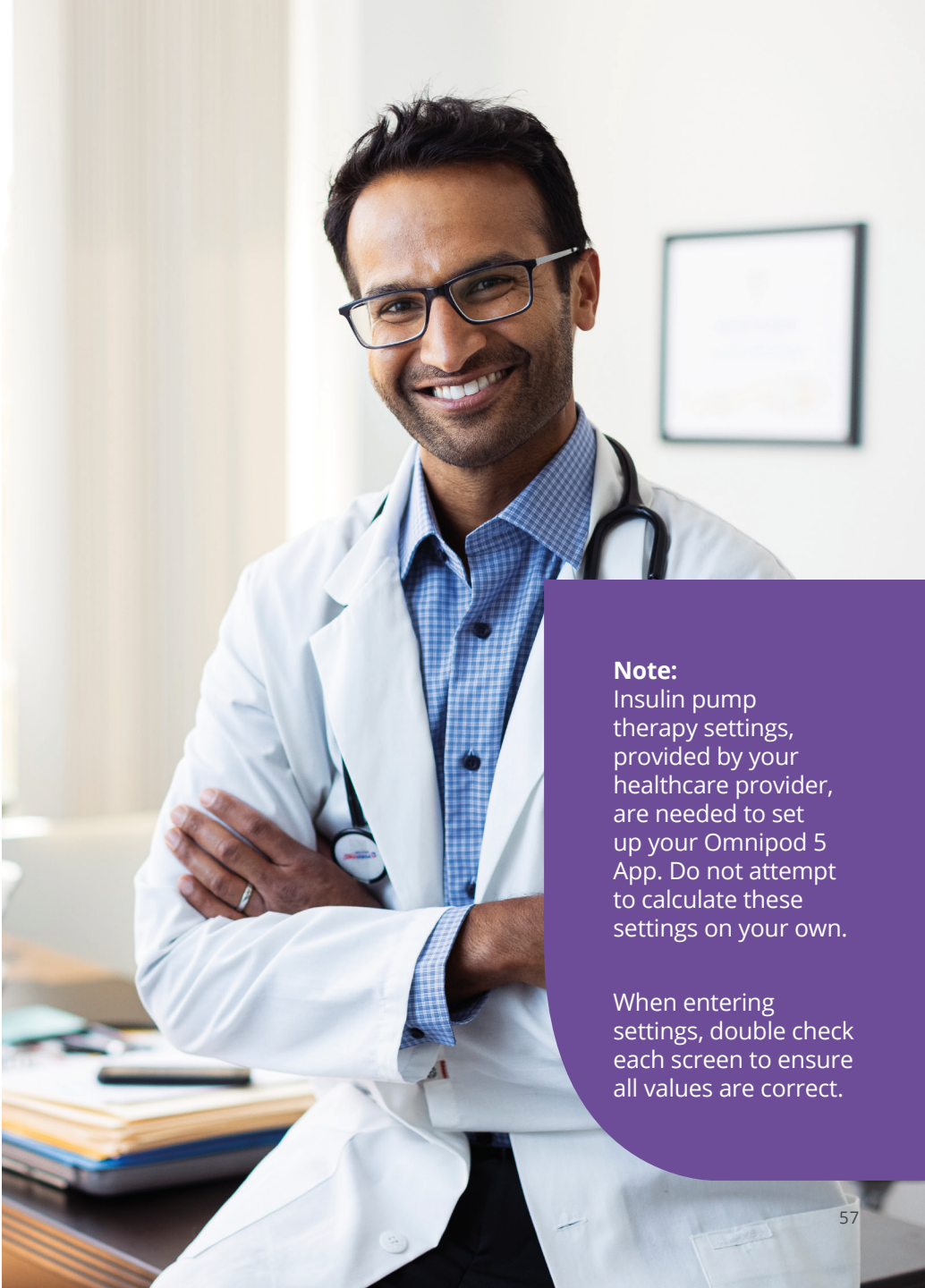
MY INITIAL INSULIN THERAPY SETTINGS

Basal Settings			
Max Basal Rate	_____ U/hr		
Basal Programs	**Start Time**	**End Time**	**Basal Rate**
	12:00 AM	_____	_____ U/hr
	_____	_____	_____ U/hr
	_____	_____	_____ U/hr
Temp Basal	ON or OFF (circle one)		

Bolus Settings				
Target Glucose & Correct Above	**Start Time**	**End Time**	**Target Glucose**	**Correct Above**
	12:00 AM	_____	_____ mg/dL	_____ mg/dL
	_____	_____	_____ mg/dL	_____ mg/dL
	_____	_____	_____ mg/dL	_____ mg/dL
Insulin to Carb (IC) Ratio	**Start Time**	**End Time**	**1 Unit of Insulin Covers**	
	12:00 AM	_____	_____ g of carbs	
	_____	_____	_____ g of carbs	
	_____	_____	_____ g of carbs	
Correction Factor	**Start Time**	**End Time**	**1 Unit of Insulin Lowers Glucose by**	
	12:00 AM	_____	_____ mg/dL	
	_____	_____	_____ mg/dL	
	_____	_____	_____ mg/dL	
Duration of Insulin Action	_____ hours			
Max Bolus	_____ Unit			
Extended Bolus	ON or OFF (circle one)			

Reverse Correction is not part of First Time Setup.
(Go to **Menu > Settings > Bolus**)

Reverse Correction	ON or OFF (circle one)



Note:
Insulin pump therapy settings, provided by your healthcare provider, are needed to set up your Omnipod 5 App. Do not attempt to calculate these settings on your own.

When entering settings, double check each screen to ensure all values are correct.

omnipod® 5

For More Information

Please refer to your Omnipod® 5 Automated Insulin Delivery System Technical User Guide

Visit us online at omnipod.com/guides

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Controller FCC ID: 2ADINN5004L
Controller FCC ID: 2ADINN5004LR1
Pod FCC ID: RBV-029
Pod FCC ID: RBV-029C
Pod FCC ID: RBV-029D
Pod FCC ID: RBV-029E

Patent: www.insulet.com/patents

PT-002952-AW Rev. 03 12/25

REF PDM-H001-G-XX

PT-002952