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Chapter 4: Setting Up Your Omnipod 5 Application

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4.1. Setting Up Your Account

The Omnipod 5 System requires you to sign in with an Omnipod ID. If you already have an Omnipod ID, use the same username and password to sign into your controller.

If you need to create an Omnipod ID:

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

4.2. Choosing a Controller or Smartphone

Before setting up your Omnipod 5 System, decide whether you want to use the Insulet-provided controller or your personal smartphone for the Omnipod 5 app. You can find a list of compatible smartphones at *omnipod.com/compatibility*.

Settings and history are stored on the device (Omnipod 5 controller or smartphone) that you choose. If you decide later to use a different device, you will need to start setup again on 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.

Using the Omnipod 5 application on your controller

If you select the Insulet-provided controller with the Omnipod 5 app, your initial shipment contains the items you need to begin using the Omnipod 5 System.

The Insulet-provided Omnipod 5 Intro Kit contains:

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

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

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



Using the Omnipod 5 application on your smartphone

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

Caution: Do not attempt to use the Omnipod 5 app on a phone modified to allow unrestricted access to its file system. You will be prevented from using the Omnipod 5 app.

Caution: If you install other apps on the same phone as your Omnipod 5 app, take care that the other apps do not contain malware. If you do not know what it is, do not install it. Only install apps from trusted sources.

Note: Your smartphone must have enough storage space for the Omnipod 5 app to work and save important information regarding your insulin therapy. If your smartphone does not have 150 MB of free space, you will be prompted to free up smartphone storage in order to use the Omnipod 5 app.

Recommended smartphone settings

The Omnipod 5 app relies on some of your smartphone's settings to function. Follow the recommendations below to ensure the Omnipod 5 System works as intended. To learn how to change your smartphone's settings, see your smartphone instructions.

Recommended Setting	ON or OFF
Bluetooth	ON
Automatic date and time	ON
Battery optimization	OFF
Notifications	ON
Smartphone security	ON
Location	ON
Sound	ON
Network connectivity (Wi-Fi or cellular)	ON

Caution: Keep the Bluetooth setting ON. If you turn this setting OFF, you may not receive important updates and alarms that rely on communication between your Omnipod 5 app and your Pod.

Note: If you do not have the setting ON or OFF as recommended, you will receive a notification to adjust the setting.

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

4.3. Preparing for Your Training

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

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

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

Charge the battery

To charge your controller:

- 1. Assemble the charger cable by attaching its wall adapter.
 - **Caution:** Only use the charger that came with your controller. Using an unapproved charger can damage the controller.
- 2. Plug the charger into an outlet.
- 3. Plug the other end of the cable into the USB port of the controller.
- 4. Charge the controller until the battery level icon shows 100% charge.
- 5. Disconnect the charger from the controller and the wall outlet.

If you are using your smartphone with your Omnipod 5 app, refer to your smartphone instruction manual for charging instructions.

Items needed for your training

- Your controller or smartphone with Omnipod 5 app and charger
- Your Dexcom G6 transmitter and sensor
- Your Dexcom G6 app
- Two Pods
- This *User Guide*
- Blood glucose meter
- Test strips and a lancing device (available from many pharmacies)
- Vial of rapid acting U-100 insulin (See page 8 for information about the approved types of insulin to use with the Pod).
- · Alcohol prep swabs
- Instructions from your healthcare provider with Omnipod 5 app settings tailored to your needs. These settings include Basal Program, IC Ratio, Correction Factor, Target BG, and Duration of Insulin Action.



4.4. General Settings

Warning: Do NOT use the Omnipod 5 System before you have been trained. Inadequate training could put your health and safety at risk.

Warning: Follow your healthcare provider's instructions for setting up your Omnipod 5 app. Improper setup could put your health and safety at risk.

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

Note: If you are using an Insulet-provided controller, steps in this section may differ from your smartphone. For example, you may see a checkmark instead of DONE on your keyboard.

Turning on and signing in to your controller

- 1. Press and hold the Power button on the right side until the device manufacturer logo appears.
- 2. The controller runs through a series of checks. If prompted, allow permissions and connect to Wi-Fi. See page 207 for more details.
- 3. Review the terms and conditions (ToU terms of use), including End User License Agreement (EULA), warranty and Legal Notices as follows:
 - Tap the HIPAA Privacy Notice, EULA, ToU, and Warranty link to read the Omnipod 5 System's legal notices and privacy policy. Then tap AGREE.
 - A checkmark is added to the checkbox to indicate agreement.
 - b. Tap CONTINUE.

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

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

Note: The username and password are case sensitive.



Setting up your controller

Personalize your controller

Follow the steps below to personalize your controller.

- Enter a personalized screen message (at least two characters), tap Done, then tap CONTINUE.
 - A screen appears showing several background images.
- 2. Swipe right or left to see more images. Tap on your preferred image, then tap CONTINUE.

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

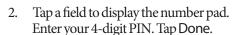
Setting the PIN on your controller

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

To set a PIN:

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

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





3. Enter the same 4 numbers again to confirm your PIN. Tap Done.

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

Once PIN has been set, continue on to "Enabling notifications and sound on your Omnipod 5 app" on page 49.

Setting your Omnipod 5 app security (on your smartphone)

If you already have a security method on your smartphone, the Omnipod 5 app will require it to enter the app.

- Read the Omnipod 5 Security screen.
 - Tap I UNDERSTAND.

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

- Tap SET UP SECURITY to continue.
- You will be taken to your smartphone's screen lock settings screen. Select your desired security method and complete security setup.

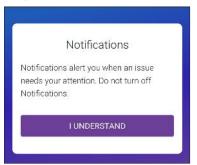


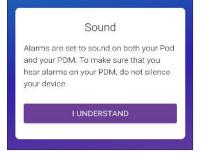
- After you successfully set your security method, you will see the Omnipod 5 Security screen on the Omnipod 5 app.
 - Tap I UNDERSTAND.

Note: To learn more about security settings on your smartphone, see your smartphone's instruction manual.

Enabling notifications and sound on your Omnipod 5 app

- Read the message explaining the importance of enabling Omnipod 5 app notifications on your Omnipod 5 app. If notifications are not enabled, you may miss important messages from the Omnipod 5 app.
 - Tap I UNDERSTAND.
- Read the message explaining the importance of enabling sound on your Omnipod 5 app. If you do not have sound enabled, you may miss important messages from the Omnipod 5 app.
 - Tap I UNDERSTAND.





4.5. Basal Settings

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

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

Set Maximum Basal Rate

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

Setup: Basal

or temp basal.

Max Basal Rate

(0.05 to 30 U/hr)

Choose Maximum Basal Rate

(You can adjust rate later if your needs change)

tap to select -

U/hr

Upper limit for basal rates in a Basal Program

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

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

Tap NEXT. 3.

Note: You can adjust your Maximum Basal Rate later, if your needs change. See "Maximum Basal Rate" on page 162

Create a Basal Program

The next step is to create a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Chapter 6: Basal Programs" on page 77.

Tap Next on the Create Basal Program description screen to continue.

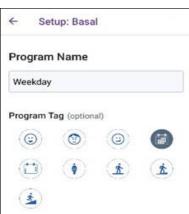
Name and tag the Basal Program

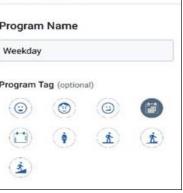
The default name for the Basal Program is Basal 1.

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

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

2. Tap NEXT.







Define the segments

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

- Tap the EndTime field and scroll to select the desired end time.
- Tap the Basal Rate field and scroll to select the basal rate for the segment.

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

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

Check the values of your start and end times and the basal rate. Then tap NEXT.

If the Basal Program does not cover 12:00AM-12:00AM you must add additional segments. Repeat steps 1-3 as needed until your final segment ends

at midnight.

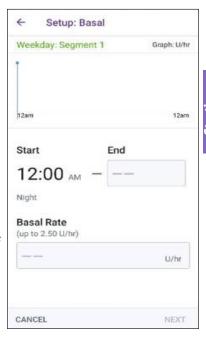
Review the Basal Program

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

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

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

- To change an end time or basal rate for a segment:
 - a. Tap the row containing the segment you would like to change.





- b. Tap the EndTime field, and enter the new end time for the segment.
- c. Tap the Basal Rate field, and enter the desired basal rate.
- d. Tap NEXT.
- Then define the end time and basal rate for any following segments, as needed.
- 4. When the Basal Program is correct, tap SAVE.
- 5. To add a new segment:
 - a. Tap the row containing the start time of the new segment.
 - b. Tap the End Time field, and enter the start time of the new segment as the end time of this segment.
 - c. Change the basal rate, if necessary.
 - d. Tap NEXT.
 - e. Then define the end time and basal rate for any following segments, as needed.
- 6. To delete a segment:
 - a. Note the end time of the segment you want to delete.
 - b. Tap the segment that precedes the segment you want to delete.
 - c. Tap the End Time field, and enter the end time of the segment you want to delete. This 'overwrites' the segment you want to delete.
 - d. Tap NEXT.
 - Then define the end time and basal rate for any following segments, as needed.
- 7. When the Basal Program is correct, tap SAVE.

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

Note: To create additional Basal Programs after setup is complete, start at page 78 and begin steps again.

Temporary basal configuration

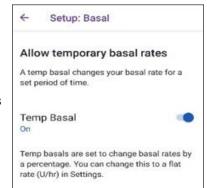
For a description of temporary basal rates, also called temp basals, see page 81.

Note: Temp basal is available in Manual Mode only.

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

If you turn temp basals on, percentages are used by default. To specify temp basal as a flat rate (U/hr), see "Temp basal" on page 163.

Tap NEXT. 2.



4.6. Bolus Settings

Next you will set Bolus Settings which allow the Bolus Calculator to suggest a bolus after you manually enter a blood glucose value, or current CGM value and trend is used, and any food you are about to eat. You can adjust your Bolus settings later, if your needs change (see "Bolus Calculator settings" on page 164 for more information).

- Tap the arrow (>) on the Bolus screen to move to the Target BG & Correct Above description screen.
- Tap NEXT to move to the segment screen.

Target BG and Correct Above values

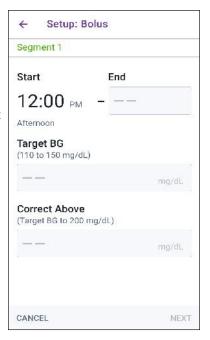
Target BG and Correct Above values are used in both Automated and Manual Modes.

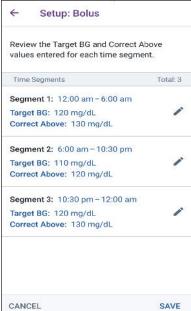
- In Automated Mode, your insulin delivery will be adjusted automatically to bring your glucose levels towards your Target BG value.
- In both Automated and Manual Modes, the Bolus Calculator aims to bring your glucose levels to the Target BG value. The Bolus Calculator delivers a correction bolus if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

Define the segments

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

- Tap the EndTime field and specify an end time for the segment.
- 2. Tap the Target BG field and specify the Target BG for that segment.
- Tap the Correct Above field and specify the Correct Above value for that segment.
- 4. Review and tap NEXT.
- Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
- 6. Review the segments for the full 24 hour profile.
- 7. To change any of the entries:
 - a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
- 8. When the segments and values are correct, tap SAVE.







Insulin to Carb (IC) Ratio

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

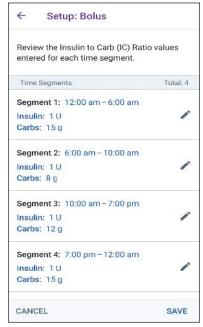
The Bolus Calculator uses the IC Ratio to calculate the meal portion of a suggested bolus. You can create up to eight IC Ratio segments per day.

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

Define the segments

- Tap the EndTime field and specify an end time for the segment.
- Tap the 1 Unit of insulin covers field 2. and specify the IC Ratio value for the segment.
- 3. Tap DONE to close the number pad.
- 4. Review and tap NEXT.
- 5. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
- 6. Review your 24-hour IC Ratio segments.
- 7. To change any of the entries:
 - a. Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
- When the segments and values are 8. correct, tap SAVE.





Correction Factor

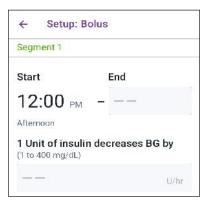
Your Correction Factor defines how much one unit of insulin lowers your blood glucose level. For example, if your Correction Factor is 50, one unit of insulin lowers your blood glucose by 50 mg/dL.

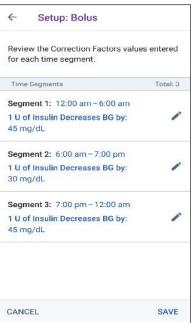
The Bolus Calculator uses the Correction Factor to calculate the correction portion of a suggested bolus. You can create up to eight Correction Factor segments per day.

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

Define the segments

- 1. Tap the End Time field and specify an end time for the segment.
- Tap the 1 Unit of insulin decreases BG by field and specify the Correction Factor for this segment.
- 3. Review and tap NEXT.
- Repeat the above steps as needed until you have specified values for the segment that ends at midnight.
- 5. Review the segments for the full 24 hour profile.
- 6. To change any of the entries:
 - Tap the row containing the entry to be changed and enter the corrected value.
 - b. Review and correct as needed any remaining segments.
- When the segments and values are correct, tap SAVE.







Duration of Insulin Action

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

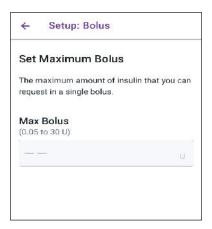
- Tap the Duration of Insulin Action field and scroll to select your Duration of Insulin Action.
- Tap NEXT.

Maximum Bolus

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

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





Extended Bolus

Extending a bolus means that a meal bolus can be delivered over a prolonged period of time.

Note: Extended bolus is available in Manual Mode only.

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



4.7. Your App Setup is Complete

Congratulations! Omnipod 5 app setup is complete.

When you are ready to activate your first Pod, go to "5.1. Beginning the Pod Activation Process" on page 60.

After successfully activating the Pod, you will be prompted to connect your CGM to the Omnipod 5 System. See "Chapter 12: Connecting CGM to the Pod" on page 123.

Note: Confidence reminders and program reminders are turned on by default. These reminders cause the Omnipod 5 app or Pod to beep at the beginning and end of boluses and temp basals, and also once an hour during an extended bolus or temp basal. For more information, see "Confidence reminders" and "Program reminders" on page 160.

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

Chapter 5: Activating and Changing Your Pod

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5.1. Beginning the Pod Activation Process

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

Warning: Do NOT use a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin.

Warning: Because the Pod uses only rapid-acting U-100 insulin, you are at increased risk for developing hyperglycemia if insulin delivery is interrupted. Severe hyperglycemia can quickly lead to diabetic ketoacidosis (DKA). DKA can cause symptoms such as abdominal pain, nausea, vomiting, breathing difficulties, shock, coma, or death. If insulin delivery is interrupted for any reason, you may need to replace the missing insulin. Ask your healthcare provider for instructions for handling interrupted insulin delivery, which may include an injection of rapid-acting insulin.

Warning: The Pod and its accessories, including the tab, contain small parts that may be dangerous if swallowed. Be careful to keep these small parts away from young children.

Warning: NEVER use insulin that is cloudy; it may be old or inactive. Always follow the insulin manufacturer's instructions for use. Failure to use rapid-acting U-100 insulin, or using insulin that has expired or is inactive, could put your health at risk.

Warning: Do NOT apply or use a Pod if the sterile packaging is open or damaged, or if the Pod has been dropped after removal from the package, as this may increase the risk of infection. Pods are sterile unless the packaging has been opened or damaged.

Warning: Do NOT apply or use a Pod that is damaged in any way. A damaged Pod may not work properly.

Warning: Do NOT use a Pod if it is past the expiration date on the package.

Warning: To minimize the possibility of site infection, do NOT apply a Pod without first using aseptic technique. This means to:

- Wash your hands.
- Clean the insulin vial with an alcohol prep swab.
- Clean the infusion site with soap and water or an alcohol prep swab.
- Keep sterile materials away from any possible germs.

Before activating a Pod,

- Gather the necessary supplies:
 - A vial of rapid-acting U-100 insulin cleared for use in the Omnipod 5 System. See "1.4. General Warnings and Safety Information" on page 8 for a list of the approved insulin types that can be used with the Omnipod 5 System.
 - An unopened Omnipod 5 Pod
 - Alcohol prep swabs
 - Controller or smartphone with Omnipod 5 app
- Wash your hands before starting and keep them clean throughout the Pod change process.
- Check the insulin for signs of deterioration according to the manufacturer's instructions for use.
- Check the Pod's packaging for damage. If undamaged, open it and inspect the Pod for signs of damage.
- If the insulin or Pod is below 50°F (10°C), allow it to warm up to room temperature before proceeding.

Confirm that you are using an Omnipod 5 Pod prior to beginning Pod activation. Look for the Omnipod 5 logo on the Pod tray lid and the clear needle tab.



5.2. Setting up a new Pod

Navigate to: Menu icon (\equiv) > Pod or

Home > POD INFO

Tap SET UP NEW POD.



Turning on location access

If you are using the Omnipod 5 app on your smartphone, Location permission must be allowed and Location setting must be on in order to activate a Pod. These are required to enable Bluetooth® to activate a Pod. If you deny the permission or

turn off the setting, you will be prompted to turn it on to activate a Pod.

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

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

Allow location access during Pod activation

Omnipod® 5 needs location access to activate a Pod.

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

> CANCEL APP INFO

Allow location access

Omnipod® 5 needs location access to activate a Pod.

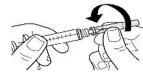
Turn device location ON and Allow location access.

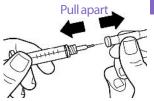
> CONTINUE CANCEL

5.3. Filling the Syringe with Insulin

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

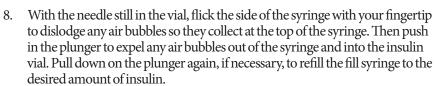
- Use an alcohol prep swab to clean the top of the 1. insulin vial.
- Securely twist the fill needle onto the fill syringe. 2.
- 3. Pull outward to remove the protective cap from the needle. Discard cap.
- Determine how much insulin you will put into the Pod. For example, to use the Pod for 72 hours,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





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

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



Warning: Make sure there are no air bubbles or pockets of air in the fill syringe before filling a Pod with insulin. Air transferred from the fill syringe into the Pod may result in interrupted insulin delivery.

Remove the needle from the vial.



MIM

fill line

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

Warning: Before filling a Pod, ensure that no other Pods are being activated within 20 feet (6 m) of your Omnipod 5 app.

Warning: NEVER use a Pod if you feel resistance when you depress the plunger. This condition can result in interrupted insulin delivery.

Warning: NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

Caution: Be sure to insert the fill syringe into the fill port and not any other location on the Pod. Do not insert the fill syringe more than once into the fill port. Only use the fill syringe and needle that came with your Pod. The fill syringe is intended for single use only and should only be used with the Omnipod 5 System.

Fill the Pod with insulin

To fill the Pod with insulin (screen step 1)



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

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

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

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

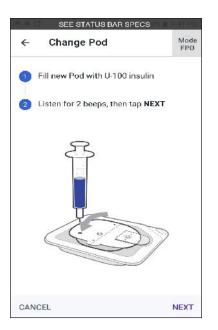
Be sure to completely empty the fill syringe, even after hearing the two beeps.

Note: The Pod must contain a

minimum of 85 units of insulin in order to function. The Pod beeps twice after it has been filled with 85 units of insulin. If you filled the Pod with more than 85 units and still do not hear the two beeps, please call Customer Care.

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

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



Activate the Pod

To activate the Pod:

Place the Omnipod 5 app (controller or smartphone) next to the Pod so they are touching. The Pod should be in its plastic tray during this process.

2. Tap NEXT.

- If more than one filled Pod is in range, the Omnipod 5 app informs you of this. Move at least 20 feet (6 m) away from any other Omnipod 5 Pod and tap TRY AGAIN.
- If only one Pod is in range, the Omnipod 5 System performs a series of safety checks and primes the Pod.
- Listen for the tone from the Omnipod 5 app that indicates that the Pod is activated and is ready to be applied.

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

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

If you see a communication error message when you attempt to activate your Pod, see "Error When Activating a Pod" on page 235.

Prepare the Pod site

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

Guidelines for Pod site selection

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

Place at least 3 inches from your CGM sensor site.

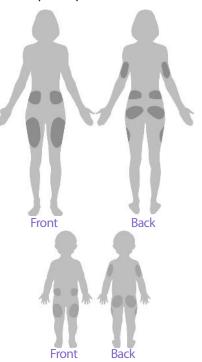


Activating and Changing Your Pod

- Place in line of sight of the CGM sensor for the best connectivity. See "13.2. CGM Placement" on page 129.
- 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 two inches (5 cm) away from your navel.
- Avoid sites where belts, waistbands, or tight clothing may rub against or dislodge the Pod.
- Avoid sites where the Pod will be affected by folds of skin.
- Avoid placing the Pod over a mole, tattoo, or scar, where insulin absorption may be reduced.
- Avoid areas of the skin with an active infection.

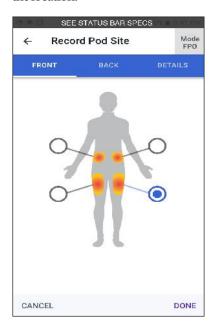
Pod site map (optional)

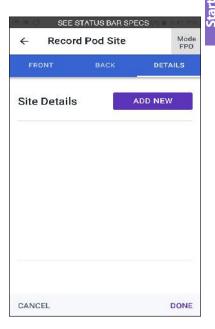
The Pod site map is an optional feature that helps you track your current and recent Pod site locations. This option only appears if the Pod Sites setting is turned on (see "17.2. Pod Sites Settings" on page 156).



Activating and Changing Your Pod 5

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





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

Note: To delete a site detail, tap the (x) next to the detail.

5. Tap DONE when finished to return to the Change Pod screen.

Prepare the infusion site

To reduce the risk of infection at the infusion site:

- Wash your hands with soap and water.
- Wash your selected infusion site with soap and water.

Note: Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare provider how to treat any skin irritation.

- Dry the infusion site with a clean towel.
- Use an alcohol prep swab to disinfect the infusion site. Start at the center of the site and gently rub outward in a circular motion.
- Let the infusion site air-dry thoroughly. Do not blow on the site to dry it.

Remove the Pod's tab

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

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

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

- If any of the following apply, tap CANCEL, and then dispose of the Pod and begin again with a new Pod:
 - The Pod is accidentally dropped, as this may compromise sterility.
 - The Pod or its adhesive pad is wet, dirty, or damaged.
 - The cannula extends beyond the

adhesive backing when the tab is removed.

Warning: Verify that the cannula does not extend beyond the adhesive backing once the Pod's tab is removed.

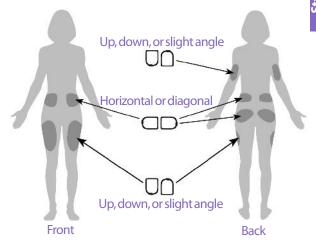
4. Using the pull tabs, remove the white paper backing covering the adhesive pad. Be careful not to remove the adhesive pad itself. Do not allow the adhesive to fold back on itself.



Apply the Pod

Inspect and apply the Pod (screen step 5):

- Examine the Pod. Tap CANCEL and dispose of the Pod if the adhesive pad is folded, torn, or damaged, and begin again with a new Pod.
- Orient the Pod so it is:
 - Horizontal or diagonal on your abdomen, hip, lower back, or buttocks.
 - Up and down or at a slight angle on your upper arm or thigh.
 - Placed within line of sight to the CGM. The Bluetooth connection between the CGM and the Pod does not travel well through



the body. Keeping both devices within line of sight allows for consistent CGM information to be available to the Pod. See "13.2, CGM Placement" on page 129.

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

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

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

Begin insulin delivery

Begin insulin delivery (screen step 6):

Warning: If you are applying a Pod in a place that does not have a lot of fatty tissue, squeeze the skin around the Pod throughout the next step. Blockages may result if you do not use this technique for lean areas.

- If you applied the Pod to a lean area, squeeze the skin around the Pod.
- Tap START to insert the cannula. 2.

Confirm Pod is securely attached

- Confirm that the Pod is securely attached to your body, then tap YES.
- If you are squeezing your skin, stop squeezing when the Omnipod 5 app asks if the cannula is properly inserted.



5.5. Checking Your Infusion Site

Following insertion of the cannula, check the Pod and infusion site:

- Look through the viewing window on the edge of the Pod to verify that the cannula is inserted into the skin. The cannula is tinted light blue.
- Verify that there is a pink color on top of Pod. This is an additional check that the cannula was inserted.
- Verify that there is no wetness or scent of insulin at the infusion site. The presence of either may indicate that the cannula has dislodged.



Warning: Check the infusion site after insertion to ensure that the cannula was properly inserted. If the cannula is not properly inserted, hyperglycemia may result.

- If the cannula is not properly inserted, tap NO. Then tap DEACTIVATE POD. 4. Restart the process with a new Pod.
- If the cannula is properly inserted, tap YES.

Activating and Changing Your Pod 5

Pod setup is complete. The screen shows details about the active Pod and a list of reminders.

Once the cannula is inserted, the Pod automatically fills the cannula with insulin. The Pod then begins delivering the basal rate of insulin according to the Basal Program in progress.

The cannula can be inserted only once with each Pod.

Review the list of active reminders, then tap CLOSE.

Note: Ninety minutes after Pod activation, a Check BG reminder prompts you to check your blood glucose level and infusion site. This additional safety feature helps ensure that the cannula was properly inserted. If a valid CGM value is received, this reminder will not display. See " Check BG After Pod Change" on page 220.

Warning: Never inject insulin (or anything else) into the fill port while the Pod is on your body. Doing so may result in unintended or interrupted insulin delivery.

Caution: Be sure to check the alarm function at every Pod change (see "Check alarms" on page 155).

5.6. Deactivating an Active Pod

To deactivate and remove an active Pod:

Navigate to the Pod change screen: Home > POD INFO tab > VIEW POD

DETAILS

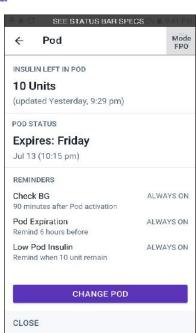
or

Menu icon $(\equiv) > Pod$

Tap CHANGE POD, then tap DEACTIVATE POD.

> If a temp basal, extended bolus, or HypoProtect[™] was running, it is canceled now.

If you see a communication error message, see "Error When Activating a Pod" on page 235.



When you deactivate your Pod, the system exits Automated Mode. When the new Pod is activated, the system will be in Manual Mode.

Warning: Do NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that has not been deactivated properly can continue to deliver insulin as programmed, putting you at risk of over infusion and possible hypoglycemia.

- 3. Remove the deactivated Pod from your body:
 - Gently lift the edges of the adhesive tape from your skin and remove the entire Pod.

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

- b. Use soap and water to remove any adhesive that remains on the skin, or, if necessary, use an adhesive remover.
- c. Check the infusion site for signs of infection (see "Avoiding infusion site infections" on page 72).
- d. Dispose of the used Pod according to local waste disposal regulations.
- 4. To activate a new Pod, tap SET UP NEW POD.

5.7. More Information about Pod Use

Avoiding infusion site infections

Check the infusion site at least once a day:

 Be aware of signs of infection, including pain, swelling, redness, discharge, or heat at the infusion site. If you suspect an infection, immediately remove the Pod and apply a new Pod in a different location. Then contact your healthcare provider.

If you observe any problems with the Pod, deactivate the Pod and activate a new



Warning: Check often to make sure the Pod and soft cannula are securely attached and in place. A loose or dislodged cannula may interrupt insulin delivery. Verify that there is no wetness or scent of insulin, which may indicate that the cannula has dislodged.

If an infusion site shows signs of infection:

- Immediately remove the Pod and apply a new Pod at a different infusion site.
- Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

Additional information

Tip: Develop a routine so you can change your Pod at a convenient time. If you know of an upcoming event that could interfere with changing your Pod, you can change your Pod early to avoid a disruption in insulin delivery.

For additional information on using your Pods as effectively as possible, see the following sections:

- For care of your Pod, see "22.1. Pod and Insulin Storage and Care" on page 242.
- To learn about the Pod alarms, see page 187.
- If a Pod alarm is sounding, first attempt to silence it with your Omnipod 5 app. If that is not successful, you can manually turn off the Pod alarm (see "20.10. Silencing Alarms" on page 217).
- To understand the Pod's informational and notification beeps, including which beeps are optional, see "20.12. Reminder Notifications List" on page 219 and "20.5. Understanding Regular Tones and Vibrations" on page 192.
- To understand how to handle situations where the Omnipod 5 app cannot communicate with your Pod, see "21.10." Try Again" - Pod Communication Issues" on page 234.
- If the Home: POD INFO tab says "No Pod Communication:"
 - To find the last time the Omnipod 5 app successfully communicated with the Pod navigate to: Menu icon $(\equiv) > Pod$.
 - If you are unable to restore communication with the Pod and want to change to a new Pod, navigate to: Menu icon (≡) > Pod > CHANGE POD.
- For a description about how the Omnipod 5 app communicates with the Pod, see "Chapter 23: Understanding Insulin Delivery and Calculations" on page 249.

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MANUAL MODE

- 6 Basal Programs
- 7 Temporary Basal Rates and Presets
- 8 Delivering a Bolus with the Bolus Calculator
- The Food Library
- 10 Blood Glucose Readings
- 11 Pausing and Starting Insulin Delivery





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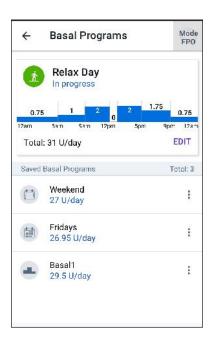
Chapter 6: Basal Programs

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6.1. Reviewing All Basal Programs

- Navigate to the list of Basal Programs:
 Menu icon () > Basal Programs
 A list of Basal Programs appears with the Basal Program in progress at the top.
- Scroll up or down as needed to see additional Basal Programs.
- Tap on the name of a saved Basal Program to see its graph and basal rates. Tap outside the graph to close that graph.



6.2. Creating New Basal Programs

While in Manual Mode, Basal Programs are used to deliver a steady amount of insulin throughout the day. This is known as your basal insulin.

To create a new Basal Program:

- Navigate to the Create Basal Program screen:
 Menuicon () > Basal Programs
- 2. Tap CREATE NEW.

Note: If you already have 12 Basal Programs, CREATE NEW does not appear. If necessary, you can delete an existing Basal Program. See "6.4. Deleting a Basal Program" on page 80.

- 3. See "Create a Basal Program" on page 50 to continue creating your new Basal Program.
- 4. If you have an active Pod and you want to use the new Basal Program now, tap START to start using the new Basal Program. If you do not want to use the new Basal Program now, tap NOT NOW.

6.3. Editing or Renaming a Basal Program

Tip: Write a list of all of the revised basal segments to guide you through re-entering the values for each segment. You can write this list on the pages at the end of this User Guide.

To edit or rename a Basal Program:

- Navigate to the list of Basal Programs:
 Menu icon () > Basal Programs
- 2. Select the Basal Program you want to edit. Scroll up or down as necessary to locate the Basal Program.
 - To edit the Basal Program in progress, tap EDIT beneath the graph of the program in process. Then tap PAUSE INSULIN.
 - To edit a saved Basal Program, tap the Options icon (*) next to the Basal Program you would like to edit. Then tap Edit.
- To rename the Basal Program, tap the Program Name field and enter the new name.
- SEE STATUS BAR SPECS 4 Mode Basal Programs FPO Relax Day In progress 0.75 EDIT Total: 31 U/day Saved Basal Programs Total: 3 Weekend 27 U/day Fridays Start 26.95 U/day Edit Basal1 29.5 U/day Delete
- 4. Optional: To change the tag, tap a different tag. Tap again to deselect a tag.
- 5. Tap NEXT.
- 6. See "Review the Basal Program" on page 51 to continue editing your Basal Program.
- 7. To activate the newly edited Basal Program:
 - If you edited the Basal Program in progress, tap START INSULIN.
 - If you edited a saved Basal Program and want to start it, tap START.

Caution: If you do not want to activate the newly edited Basal Program, tap NOT NOW.

6.4. Deleting a Basal Program

You can only delete a Basal Program that is not running; you cannot delete an in progress or paused Basal Program. To delete a Basal Program:

- 1. Navigate to the list of Basal Programs:
 - Menu icon (≡) > Basal Programs
- 2. Tap the Options icon () next to the Basal Program you want to delete.
- 3. Tap Delete.
- 4. Tap DELETE to confirm deletion of the Basal Program.

Note: Always be sure you are deleting the correct Basal Program. Once deleted, the action cannot be undone and you will have to recreate the Basal Program if needed.

6.5. Switching to a Different Basal Program

Different days can have different routines. The Omnipod 5 app lets you create different Basal Programs for your different routines. For example, you may use one Basal Program on weekdays and a different one on weekends.

Before you begin

- Cancel your temp basal, if it is running. See "7.3. Canceling a Temp Basal or Temp Basal Preset" on page 85.
- Switch to Manual Mode, if currently using Automated Mode. See "14.2. Switching from Automated Mode to Manual Mode" on page 137.

To switch to a different Basal Program

- Navigate to: Menuicon () > Basal Programs.
 A list of Basal Programs appears with the Basal Program in progress at the top.
- 2. Select a different Basal Program in one of the following ways:
 - To see a graph of a saved Basal Program prior to activating it, tap on the name of that Basal Program. Then tap START.
 - **Tip:** Double-tap the graph to see an expanded view of the Basal Program. Swipe horizontally to view basal rates for later or earlier times.
 - Tap the Options icon (*) to the right of a saved Basal Program, then tap START.
- 3. Tap START again to start the newly selected Basal Program.



Chapter 7: Temporary Basal Rates and Presets

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Temporary Basal Rates and Presets

7.1. About Temporary Basal Rates

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 a temp basal ends, the Pod will start delivering the scheduled Basal Program.

If there is a temp basal that you use often, you can create a "temp basal preset" for rapid activation in the future. To create a temp basal preset, see page 85. You can create up to 12 temp basal presets.

To turn ON or OFF the ability to start temp basals, or to change between specifying the temp basal as a percentage or in U/hr, see page 162.

Tip: By default, the Omnipod 5 or Pod sounds a tone at the beginning and end of a temp basal and every 60 minutes while a temp basal is running. To turn these ON or OFF, see "20.5. Understanding Regular Tones and Vibrations" on page 192.

7.2. Starting a Temp Basal

Before you begin

- Temp basal setting must be ON. If it is OFF, see "17.5. Basal and Temp Basal Settings" on page 162.
- If the Omnipod 5 System is currently in Automated Mode, switch to Manual Mode. See "14.2. Switching from Automated Mode to Manual Mode" on page 137.

Note: You cannot start or cancel a temp basal during an immediate bolus, but you can start or cancel a temp basal while an extended bolus is running.

Start a temp basal

To define and start a temp basal:

Navigate to: Menu icon (\equiv) > Set Temp Basal The screen shows a graph of the Basal Program in progress.

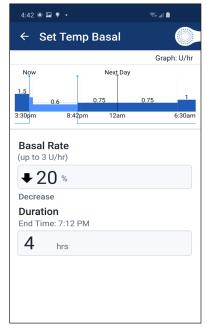
> **Note:** To start a temp basal preset, tap SELECT FROM PRESETS.

- Tap the Basal Rate field and scroll to the desired change in the basal rate:
 - If using a percent (%) change: An UP ARROW () indicates **increasing** the basal rate above that

of the Basal Program in progress.

A DOWN ARROW () indicates decreasing the basal rate below that of the Basal Program in progress.

If using a flat rate (U/hr), scroll the wheel to select the basal rate for the entire temp basal period.



Note: To change whether temp basals are configured as percent (%) or U/hr, see "17.5. Basal and Temp Basal Settings" on page 162.

Note: The scroll wheel will not scroll above your Maximum Basal Rate. To adjust your Maximum Basal Rate, see "Maximum Basal Rate" on page 162.

Tip: You can turn OFF insulin delivery for the duration of the temp basal by setting a decrease of 100% or setting the temp basal to 0 U/hr. For more information, see "Temp basal limitations" on page 253 and "Methods to temporarily pause insulin delivery in Manual Mode" on page 254.

7 Temporary Basal Rates and Presets

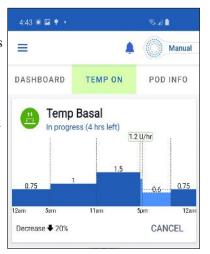
 Tap the Duration field and enter the temp basal duration (between 30 minutes and 12 hours).

Examine the temp basal graph at the top of the screen. The proposed temp basal is displayed over the Basal Program in progress.

- The lighter blue shaded area shows the proposed temp basal rate for each segment.
- If you set a decrease, the Basal Program in progress is shown as a horizontal dotted line.
- 4. Tap CONFIRM to continue.
- 5. Review the temp basal details. If corrections are needed, tap on the row that you would like to change. Then enter your corrections and confirm them.
- 6. To start the temp basal, tap START. Then tap START again.

Once the temp basal starts, the Home screen's INSULIN tab is highlighted in green and is renamed to TEMP ON which indicates that the temp basal is running. The TEMP ON tab now shows that the temp basal is in progress, what the basal rate change is, and how much time remains. At the end of the temp basal time period, the Pod will go back to delivering the scheduled Basal Program.







7.3. Canceling a Temp Basal or Temp Basal Preset

A temp basal stops automatically at the end of its time period and the last known Basal Program starts. To cancel a temp basal before the end of its time period:

- Navigate to the Home screen's TEMP ON tab.
- 2. Tap CANCEL.
- 3. Tap YES to confirm cancellation. The Omnipod 5 app cancels the temp basal and starts the last known Basal Program.

7.4. Creating a New Temp Basal Preset

To create a new temp basal preset:

- Navigate to: Menu icon $(\equiv) >$ Temp Basal Presets.
- Tap CREATE NEW. 2.

Note: If you already have 12 temp basal presets, CREATE NEW does not appear. If necessary, you can delete an existing preset.

Tap the Preset Name field and enter a descriptive name for your preset.

Optional: Tap a tag to appear beside the name of the new preset. Tap a second time to deselect the tag. If you do not select a tag, a default tag is used.

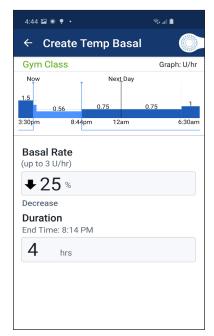
Tap DONE.

Note: The default name for the preset is "Temp Basal" followed by a number.

- 5. Tap NEXT.
- Tap the Basal Rate field and scroll to the desired value.
 - If using a percent (%) change:

An UP ARROW () indicates **increasing** the basal rate above that of the Basal Program in progress.

A DOWN ARROW () indicates **decreasing** the basal rate below that of the Basal Program in progress.



7 Temporary Basal Rates and Presets

- If using a flat rate (U/hr), scroll the wheel to select the basal rate for the entire temp basal period.
- 7. Tap the Duration field and enter a duration for the preset. The temporary change to the Basal Program is shown on the graph.
- 8. Tap CONFIRM.
- 9. Review the temp basal details. If corrections are needed, tap on the row that you would like to change. Then enter your corrections and confirm them.
- 10. Tap SAVE to save this as a temp basal preset.
- 11. If you would like to start this temp basal now, tap START. Otherwise, tap NOT NOW.

7.5. Editing or Renaming a Temp Basal Preset

Note: You cannot edit a temp basal preset that is in progress.

To edit or rename a temp basal preset

- 1. Navigate to the Temp Basal Presets screen:
 - Menu icon (≡) > Temp Basal Presets
- Find the preset that you want to edit. Then tap the Options icon (*) and tap Edit.
- 3. To rename the preset, tap the Preset Name field and enter the new name. Optional: To change the tag, tap a different tag. Tap again to deselect a tag.
- 4. Tap NEXT.
- 5. Change the basal rate and duration as desired.
- 6. Tap CONFIRM.
- 7. Review the temp basal details. If corrections are needed, tap on the row that you would like to change. Then enter your corrections and confirm them.
- 8. Tap SAVE to save your changes.
- 9. If you would like to start this temp basal now, tap START. Otherwise, tap NOT NOW.

7.6. Deleting a Temp Basal Preset

Note: You cannot delete a temp basal preset that is in progress.

To delete a temp basal preset

Delete a temp basal preset as follows:

- Navigate to the Temp Basal Presets screen:
 - Menu icon (≡) > Temp Basal Presets
- Tap the Options icon () next to the preset you want to delete. 2.
- Tap Delete. 3.
- Tap DELETE to confirm deletion of the preset.

Note: Always be sure you are deleting the correct temp basal preset. Once deleted, the action cannot be undone and you will have to recreate the temp basal preset if needed.

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Chapter 8: Delivering a Bolus with the Bolus Calculator

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8.1. About Delivering a Bolus

A bolus is a dose of insulin taken to correct an elevated blood glucose level (a correction bolus) or to cover carbohydrates in a meal, drink, or snack (a meal bolus).

About correction boluses and meal boluses

The Bolus Calculator calculates a suggested bolus amount of insulin to correct an elevated blood glucose level (a correction bolus) and/or to cover carbohydrates in a meal (a meal bolus). For additional details about how the Bolus Calculator works, see page 256.

Value E	Type of Bolus	
Blood Glucose or CGM Value Above Target	Carbohydrates	Calculated
✓		Correction bolus
	✓	Meal bolus
✓	√	Combined suggested bolus

If you enter a blood glucose or CGM value that is above target but enter no carbs, a correction bolus is calculated. If you enter carbs but not a blood glucose or CGM value, a meal bolus is calculated. If you enter both a blood glucose or CGM value and carbs, both factors are used to calculate a suggested bolus.

About using a CGM value with trend

Your CGM trend is based on the recent pattern of glucose changes. If you use your CGM value, your CGM value and trend will be used to calculate a suggested bolus amount. The CGM value and trend will be used along with your Correction Factor to determine the correction portion of your bolus. The Bolus Calculator will use the CGM trend to adjust the correction bolus amount.

When CGM Values are	The Bolus Calculator tries to keep BG within target range and
Trending up (increasing)	Adds more insulin to the correction bolus.
Trending down (decreasing)	Subtracts insulin from the correction bolus.
Steady	No adjustment to the correction bolus.

Additional information

You may choose to accept or change the final recommendation before the bolus is delivered.

After opening the Bolus Calculator, bolus delivery must be initiated within 5 minutes or values will need to be refreshed. If more than 5 minutes pass, you will see a message that values have expired. Tap CONTINUE to refresh the Bolus Calculator, then enter your current values.

To change your personal settings used by the Bolus Calculator, see "Bolus Calculator settings" on page 164.

Note: To use the Bolus Calculator, the Omnipod 5 app and the Pod must be communicating. If there is no Omnipod 5 app to Pod communication, you will be prompted to re-establish Pod connection. To find out what to do when your Omnipod 5 app and Pod have a communication issue, see "Chapter 21: Troubleshooting" on page 223.

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

8.2. Entering Meal Information

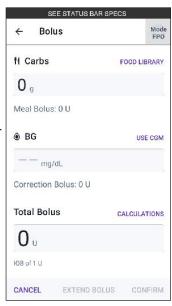
To enter the carbohydrates, or "carbs," for your meal:

On the Home screen, tap the Bolus button $(\blacksquare).$

Note: The Bolus screen is only valid for 5 minutes. After 5 minutes, if bolus delivery has not started, you must refresh and re-enter new values.

Tip: *If you already know the amount of units* for the bolus you want to deliver, tap Total Bolus. *Enter the bolus amount and tap* Done. Then go to "8.6. Delivering an Immediate Bolus" on page 94.

Tap the Carbs field. Enter the grams of carbs and tap Done.



Note: Consult your healthcare provider about how to calculate the grams of carbs.

Tip: To look up carbs in the Food Library, tap FOOD LIBRARY and select the food for your meal (see "9.1. About the Food Library" on page 102).

Note: Even though the Food Library may list grams of fiber in addition to grams of carbs, the Bolus Calculator does not subtract fiber from the carb value. Consult your healthcare provider about whether you should make an adjustment for fiber.

- 3. Review the suggested meal bolus, which is shown below the grams of carbs.
- Optionally, tap CALCULATIONS to see the details of the bolus calculations.

8.3. Entering a Blood Glucose Reading or Using a CGM Value

The Bolus Calculator uses your glucose information to calculate a correction portion of your bolus. The following sections describe how to give the Bolus Calculator your glucose information by either manually entering a BG reading or by obtaining and using the current CGM value.

Note: The Bolus Calculator can generate a suggested bolus dose based on the carbohydrates in a meal, BG reading, and the CGM value with trend. Entering a recent blood glucose reading or using a CGM value with trend can help with safety and accuracy.

Manually enter your blood glucose reading

To enter a blood glucose reading:

- 1. Tap the BG field.
 - If you have manually entered a BG reading within the past 10 minutes, that value automatically appears in the BG field. If you want the Bolus Calculator to use that value, skip the next step.
- 2. Tap the box in the circle and enter the blood glucose reading. Alternatively, slide the indicator along the circle to enter the blood glucose reading.

Note: While the Bolus Calculator will use any blood glucose value you enter manually, you should only enter a blood glucose value that was taken within the last 10 minutes.

For the meaning of the colors displayed on the Enter BG screen, see "How Blood Glucose Readings are Displayed" on page 115.

Optional: To tag the blood glucose reading, tap ADDTAGS and tap a tag. Tap again to deselect a tag. You can add up to four tags.

Delivering a Bolus with the Bolus Calculator 8

- 3. Tap ADDTO CALCULATOR. The Bolus Calculator screen appears.
- Review the suggested correction bolus, which is shown below the blood glucose value. The correction bolus has been adjusted for any insulin on board (IOB) (see "Bolus Calculator rules" on page 264).

Import and use CGM value

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

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

If a CGM is connected to the Omnipod 5 app, you can use the current CGM value and trend:

Tap USE CGM.

If the current CGM value is below the defined Minimum BG for Calc setting, you see a message that the Bolus Calculator is disabled. If the CGM value reads "HIGH", the Bolus Calculator is temporarily disabled.

Note: If your Omnipod 5 app does not have a valid CGM reading or trend at the time you open the Bolus Calculator, the USE CGM option is disabled.

Tip: *If you want to replace the CGM value* with a BG reading, tap the CGM field. See "Manually enter your blood glucose reading" on page 92.



8 Delivering a Bolus with the Bolus Calculator

8.4. Insulin On Board (IOB)

Insulin on board, also known as IOB or active insulin, is the amount of insulin that is still "active" in the body from a previous bolus or from automated insulin delivery.

The Bolus Calculator considers current IOB when calculating a suggested bolus. Insulin on board may come from:

- Meal IOB From previous meal boluses.
- Correction IOB Can be from previous correction boluses or from automated insulin deliveries.

For more information, see "Bolus Calculator rules" on page 264 and "Bolus Calculator equations" on page 263.

Note: If you do not enter your blood glucose or CGM value, the Bolus Calculator will not adjust the meal bolus for IOB.

8.5. Adjustments to your Calculation

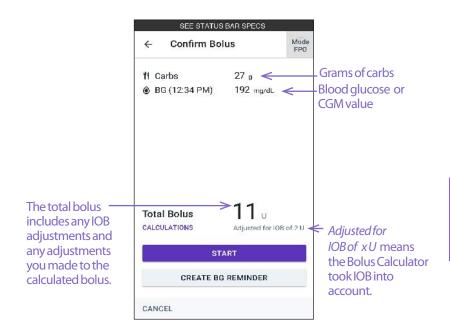
A suggested meal bolus calculated using your IC Ratio may be further adjusted for other values (such as BG, CGM value and trend, and/or IOB) entered into and used by the Bolus Calculator. These adjustments can be for the following:

- Insulin on board either meal or correction IOB
- Reverse correction, if this feature is turned ON and your glucose is below your Target BG
- BG value if manually entered
- CGM value and trend (see "13.5. CGM Trend Arrows" on page 131)

8.6. Delivering an Immediate Bolus

The Total Bolus field shows the proposed bolus. The amount of any IOB adjustment appears below the Total Bolus field.

Note: The EXTEND BOLUS option is available when the system is in Manual Mode, there is a meal bolus, and the extended bolus setting is enabled.



To review and deliver the immediate bolus:

- Review the suggested bolus. To adjust it, tap the Total Bolus field and enter a 1. revised bolus.
- To review the specifics of calculations, tap CALCULATIONS. You may need 2. to swipe up or down to see all of the calculations. Tap CLOSE when done (see "Bolus Calculator equations" on page 263 for details).
- To deliver the entire bolus immediately, tap CONFIRM. 3.
- Review the bolus details on the Confirm Bolus screen. 4.
- Optional: Set up a reminder to check your blood glucose: 5.
 - a. Tap CREATE BG REMINDER.
 - b. Tap the Check BG in field and select the number of hours you want to be reminded in.
 - c. Tap SAVE.
- Review the bolus details on the Confirm Bolus screen. 6.
- Tap START to begin the bolus.

The Home screen tracks the delivery of an immediate or extended bolus (see "8.8. Tracking the Progress of a Bolus" on page 98).

8 Delivering a Bolus with the Bolus Calculator

Delivering a Manual Bolus

A manual bolus is a bolus that you calculate yourself. If the Bolus Calculator is temporarily disabled and you need to deliver a bolus, you must enter a manual bolus.

Caution: Since your IOB and current glucose value are not taken into consideration when the Bolus Calculator is disabled, be sure to closely monitor your glucose levels after the bolus to avoid hypoglycemia or hyperglycemia.

A bolus cannot be greater than your Maximum Bolus setting (see "Maximum Bolus" on page 163).

To deliver a manual bolus:

- On the Home screen, tap the Bolus button (📵).
- 2. Tap the Total Bolus field and enter the bolus amount. Then tap Done.
- 3. To deliver the entire bolus immediately, tap CONFIRM.
- Review the bolus details on the Confirm Bolus screen. 4.
- Review the bolus details, then tap START to begin the bolus. 5.

The bolus amount and bolus details are stored in your history records. The Home screen tracks the delivery of an immediate or extended bolus.

8.7. Delivering an Extended Bolus

Warning: When using the extended bolus function, check your blood glucose levels more frequently to avoid hypoglycemia or hyperglycemia.

Note: You can only extend a bolus while in Manual Mode.

To review, extend and deliver the bolus:

- Review the suggested bolus. To adjust it, tap 1. the Total Bolus field and enter a revised bolus.
- To review the specifics of calculations, tap CALCULATIONS. You may need to swipe up or down to see all of the calculations. Tap CLOSE when done (see "Bolus Calculator equations" on page 263 for details).
- Tap EXTEND BOLUS. 3.





Delivering a Bolus with the Bolus Calculator 8

Tap the Now field and type in the percentage of the bolus to be delivered 4. immediately. Alternatively, tap the Extended field and enter the percentage to be extended.

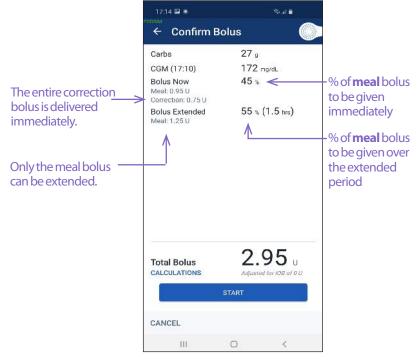
The number of units to be delivered now and over the extended period appear below the percentage (%).

Note: You can only extend the meal portion of the bolus. A correction portion of the bolus, if any, is always delivered immediately.

- 5. Tap the Duration field and enter the duration for the extended portion of the bolus.
- Tap CONFIRM. 6.

The extended bolus screen shows how much of the bolus will be delivered immediately and how much will be extended.

Review the bolus details on the Confirm Bolus screen.



8. Review the bolus details, then tap START to begin the bolus.

8.8. Tracking the Progress of a Bolus

During a bolus, the Home screen displays a progress bar.

Immediate bolus progress

During an immediate bolus, the Home screen displays a Delivering Bolus message along with a progress bar and details.

An estimate of the IOB is displayed in the lower left of the screen.

If IOB is unavailable, then the amount of the last completed bolus is displayed in the lower left of the screen.

Note: You cannot navigate within the Omnipod 5 app during an immediate bolus.

Note: Look for the progress bar to confirm the bolus delivery has started before navigating away from the Omnipod 5 app.

To cancel or replace a bolus, see "8.9. Canceling a Bolus in Progress" on page 99.

Extended bolus progress

During an extended bolus, the Home screen's DASHBOARD tab displays a Delivering Extended Bolus message along with a progress bar and other details.

An estimate of the IOB is displayed in the lower left of the screen.

If IOB is unavailable, then the amount of the last completed bolus is displayed in the lower left of the screen.

Note: You can use your Omnipod 5 app for most actions during an extended bolus.

Unless you cancel the bolus, the Pod finishes delivering a bolus whether or not it is in range of your Omnipod 5 app. To cancel or replace a bolus, see "8.9. Canceling a Bolus in Progress" in the next section.





8.9. Canceling a Bolus in Progress

When an immediate bolus is in progress, you must cancel it or allow it to finish before performing any other action.

During an extended bolus you can use your Omnipod 5 System normally except that the Bolus button will be disabled (grayed out), preventing you from delivering an additional bolus. You have the options to:

- Cancel the bolus.
- Cancel the bolus in progress and then deliver another bolus.

If you get a communication error message when canceling a bolus, see "Error When Canceling a Bolus" on page 235.

Cancel a bolus

To cancel an immediate or extended bolus:

- On the Home screen (immediate bolus) or the Home screen's DASHBOARD tab (extended bolus), tap CANCEL.
- Tap YES to confirm canceling the bolus. The Pod beeps to confirm that the bolus is canceled.

Tip: *To see how much insulin was delivered from a bolus, go to:* Menu icon (≡) > History Detail > Summary. For more information, see "Immediate and extended boluses" on page 176

Deliver a new bolus before an extended bolus has ended

To deliver a bolus while an extended bolus is in progress:

- Cancel the extended bolus as described in the previous procedure, "Cancel a 1. bolus".
- Find out how much insulin was remaining (not delivered) from the canceled bolus. You can find bolus details at Menu icon () > History Detail > Summary
- From the Bolus screen, enter the carbs and blood glucose (or Use CGM) information.
- If you want, take into consideration the amount remaining from the canceled bolus and adjust the amount in the Total Bolus field.
- Check if the amount entered in the Total Bolus field is correct. Then tap 5. CONFIRM.
- 6. Tap START.

8.10. Pediatric Bolus FAQs

Q: My child is having a second serving of an item at a meal. How should I handle delivering a bolus? Should I use the CGM value again?

A: After meals, it is common for glucose levels to rise. If you have already bolused for carbohydrates and CGM at the start of a meal, you can just enter carbohydrates for the second serving. The bolus calculator will suggest a bolus amount for the carbohydrates only.

Q: I typically deliver the bolus following the meal as it is difficult to predict how many carbs my child will eat. What is the best way to use the Bolus Calculator in this case?

A: It is difficult, especially for young children, to predict how much will be eaten at each meal. In this case, it may be best to use the bolus calculator to deliver the correction bolus by tapping USE CGM or entering the BG to deliver some insulin prior to the meal. Once you are comfortable, you can separately enter the carbohydrates only into the bolus calculator to deliver the full meal bolus.

Chapter 9: The Food Library

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9.1. About the Food Library

The Food Library contains thousands of common foods. It has a MY FOODS list and a BROWSE list.

When you are about to eat, you can use the MY FOODS list or the BROWSE list to transfer the number of carbs in a meal to the Bolus Calculator.

To access the Food Library:

• From the Bolus Calculator screen, tap FOOD LIBRARY.

Tap MY FOODS or BROWSE to switch between the lists. A blue underline indicates whether the MY FOODS or BROWSE list is showing.

All individual food items on the BROWSE list are marked with a heart. If the heart is an outline (), that food does not appear on the MY FOODS list. If the heart is solid (), you have added that food to the MY FOODS list. Foods with a solid heart () are considered "favorite" foods.



The back (<) arrow takes you to the previous screen in the Food Library.

Note: The total grams of carbs on the BROWSE list includes grams of fiber. The Bolus Calculator does not automatically subtract fiber from a carbs value when importing carbs from the Food Library. Consult your healthcare provider about how to account for fiber when calculating a bolus.

9.2. Searching for a Food

Search using the search icon

To search for a specific food:

- Tap the BROWSE list. 1.
- Tap the search icon (\bigcirc) on the upper right of the screen.
- 3. Type in a search word.

After three letters are entered, the screen shows a list of foods that begin with those letters. To narrow down a long list, you can continue typing your word.

Note: Tap the "x" next to the search term to exit the search.

- Tap Done to close the keypad. The screen displays food items matching your search term.
- Swipe up or down as needed to locate the desired food. Then tap to select it.

Search by browsing the food categories

The BROWSE list displays food categories listed in alphabetic order.

To browse food categories:

- Tap the BROWSE list.
- 2. Swipe up or down as needed and tap the desired category of food.
- Continue selecting sub-categories until a list of individual foods is displayed. 3.
- Swipe up or down as needed to locate the desired food. Then tap to select it.



9.3. My Foods List

Foods on the MY FOODS list are considered "favorites." The MY FOODS list can contain up to 50 items and can quickly be added to the Bolus Calculator. This section explains how to create food favorites on the MY FOODS list by:

- Adding foods from the BROWSE list.
- Creating a meal by combining two or more foods from the BROWSE tab.
- Creating a custom food by entering a name and number of carbs.

Add foods from the BROWSE list

To add a food item from the BROWSE list to the MY FOODS list:

- 1. Tap the BROWSE list.
- 2. On the BROWSE list, locate the food you would like to add to MY FOODS (see "9.2. Searching for a Food" on page 103).
- 3. Tap the outline of a heart () next to the food.
- 4. To change the name of the food on the MY FOODS list:
 - a. Tap the checkmark next to Keep existing name. The checkmark disappears.
 - b. Tap Enter New Name and type in a descriptive name. Tap Done.
- Optional: Tap Quantity to specify how many portions of the food you will eat.
- 6. If the food has multiple serving sizes, tap Servings to specify the serving size and measurement units.
- 7. Optional: To help locate the food in the future, tap one or more tags. Swipe up as necessary to view the tags. Tap a tag again to deselect it.
- Tap SAVETO MY FOODS. The food is marked with a solid heart ()
 indicating that the food is a "favorite" and appears in both the BROWSE and
 MY FOODS lists.

Create a meal by combining foods from the BROWSE list

To combine two or more foods into a meal on the MY FOODS list, you must first create a new meal containing only one food. Once you have an existing meal, you can add additional foods to that meal.

To create a new meal or to add foods to an existing meal:

- 1. Tap the BROWSE list.
- 2. On the BROWSE list, locate the first food you would like to add to the meal (see "9.2. Searching for a Food" on page 103).
- 3. Tap the outline of a heart (\bigcirc) next to the food.



- 4. Optional: Tap Quantity to specify how many portions of the food you will eat.
- 5. If the food has multiple serving sizes, tap Servings to specify the serving size and measurement units.
- 6. To create a new meal:
 - a. Tap Create New Meal.
 - b. Tap the Create A New Meal field. Type in a descriptive name for the meal. Tap Done.
 - c. Optional: Add one or more tags to help you find the food in the future.
 - d. Tap SAVETO MY FOODS to save this new meal.
 - The food is marked with a solid heart () indicating that the food is a "favorite" and was added to the MY FOODS list.
- 7. To add a new food to an existing meal:
 - a. Repeat steps 1 6 above.
 - b. Tap the Add To A Meal (optional) field and tap the name of the desired meal.
 - c. Optional: Add one or more tags to help you find the food in the future.
 - d. Tap SAVETO MY FOODS to add the food to the meal.
 - e. Repeat these steps to add additional food items to the meal.

Note: The food items that make up the meal are shown immediately below the meal in the MY FOODS list. To remove a food item from a meal, see "Removing foods from the MY FOODS list" on page 107.

Create a custom food

Use the custom food feature to add carb information about any food.

To add a custom food:

- 1. Tap the MY FOODS list.
- 2. Tap ADD CUSTOM FOODS.
- Tap the Food Name field and type in a descriptive name for your custom food.
- 4. Tap the Carbs field and enter the total number of carbs for the food item(s).
- 5. Optional: Tap the Fiber field and enter the amount of fiber for the food item.
- 6. To add one or more tags to your custom food, tap the desired tags.

Note: You may need to swipe up to see additional tags. The Custom tag is automatically added to a custom food. Tap any selected tag to remove it.

Tip: Tags are a quick way to filter your MY FOODS list. Select multiple tags for any foods that belong to more than one food category.



- 7. To create a different custom food, tap ADD ANOTHER ITEM. Swipe up to see a new set of name and carb fields. Repeat the previous steps.
- 8. When done, tap SAVETO MY FOODS. Your custom foods are displayed on the MY FOODS list for quick access in the future.

Removing foods from the MY FOODS list

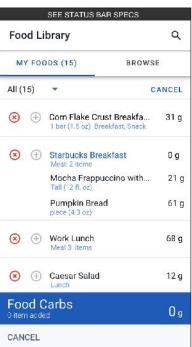
To delete a food or meal from the MY FOODS list:

- Tap the MY FOODS list.
- 2. Tap EDIT.
- 3. Locate the food or meal you would like to remove, and tap the red $x(\bigotimes)$ next to its name.
- Tap YES to remove the food item from MY FOODS.

If the food was originally added from the BROWSE list, it remains listed on the BROWSE list with an open heart icon (\bigcirc) .

If a deleted food is also part of a meal, deleting the individual food also deletes the food from that meal and subtracts the carbs from the meal's total carbs.

Note: You cannot delete or edit foods listed on the BROWSE list.



Add carbs to the Bolus Calculator

Add carbs to the Bolus Calculator from the BROWSE list

To add carbs to the Bolus Calculator from a food listed on the BROWSE list:

 Locate the food you are going to eat (see "9.2. Searching for a Food" on page 103).

2. Tap Quantity to specify how many servings of the food you will eat.

 If the food has multiple serving sizes, tap Servings to specify the serving size and measurement units.

4. Tap ADD to add the number of carbs in the food to the total carbs displayed in the Food Carbs banner.

Note: The ADD button is disabled if you have not specified a serving size.

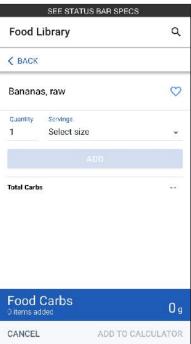
To remove the food from the Food Carbs total, tap REMOVE.

To add additional foods, tap the back
 (<) arrow and repeat the previous steps
 until all foods have been added.

Tip: *Tap the Food Carbs banner to see the foods that are included in the total.*

Tap ADDTO CALCULATOR. The Bolus
 Calculator screen appears with the total number of carbs entered in the Carbs field.

Note: The screen reads REPLACE CALCULATOR CARBS instead of ADDTO CALCULATOR if you had already entered carbs into the Bolus Calculator.



Add carbs to the Bolus Calculator from the MY FOODS list

To add carbs to the Bolus Calculator from a food listed on the MY FOODS list:

- From the Food Library, tap the MY 1. FOODS list:
- Optional: To filter the MY FOODS
 - a. Tap the down arrow beneath the MY FOODS heading. A dropdown list of food tags appears. The number of food items with each tag is shown in parentheses. The default category is All, which shows the entire MY FOODS list.
 - b. Tap a tag. The list is filtered to show only food items with that tag.
- Tap the plus sign (+) next to the food's name to add that food's carbs to the total in the Food Carbs banner. A checkmark replaces the plus (+) sign to show that the food's carbs have been added.

of carbs to the total in the Food Carbs banner.

Tip: If you want to view the food details before adding its carbs, tap the name of the food instead of tapping the plus sign (+). Then tap ADD to add the number

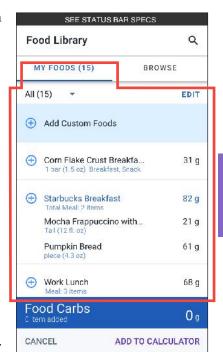
To remove a food from the Food Carbs total, tap the checkmark next to that food.

Repeat the preceding steps until the Food Carbs banner shows the total carbs for your entire meal.

Tip: *Tap the Food Carbs banner to see the foods that are included in the total.*

To transfer the total carbs from the Food Carbs banner to the Bolus Calculator, tap ADD TO CALCULATOR. The Bolus Calculator screen appears with the total number of carbs entered in the Carbs field.

Note: The screen reads REPLACE CALCULATOR CARBS instead of ADDTO CALCULATOR if you had already entered carbs into the Bolus Calculator.



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Manual Mode

Chapter 10: Blood Glucose Readings

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10.1. About Blood Glucose Readings

Warning: Follow the guidance of your healthcare provider for proper blood glucose monitoring to avoid hyperglycemia and hypoglycemia.

The Omnipod 5 System receives regular glucose values from the CGM when you have connected the CGM to an active Pod. There may be times when you need to check your blood glucose using a separate BG meter. You may want to check your blood glucose if:

- You are experiencing symptoms of hypoglycemia. See "Symptoms of hypoglycemia (low glucose)" on page 277.
- You are experiencing symptoms of hyperglycemia. See "Symptoms of hyperglycemia (high glucose)" on page 280.
- You are experiencing symptoms that are not consistent with your CGM glucose values.
- Your CGM requires calibration. For more information, refer to your compatible CGM *User Guide*.
- You are not using a CGM to monitor glucose levels.
- Your healthcare provider advises you to do so.

10.2. Entering Your Blood Glucose Reading

To enter your blood glucose reading:

- 1. Check your blood glucose following your BG meter's instructions for use.
- Manually enter or edit a blood glucose value as follows:
 - a. Tap the box inside the circle.
 - b. Use the number pad to enter and confirm your blood glucose reading.
 - c. Tap Done to close the number pad.

Note: Alternatively, you can enter a blood glucose reading using the circular slider (see "Using a slider" on page 19). When using the slider, "+" and "-" buttons appear briefly. Tap these buttons to make small adjustments to the glucose number.

Note: When you enter a blood glucose reading above 600 mg/dL, the Omnipod 5 app stores it as "HI". When you enter a blood glucose reading below 20 mg/dL, the Omnipod 5 app stores it as "LO".



- 4. After the blood glucose reading and any tags are entered, do one of the following:
 - Tap ADDTO CALCULATOR to save any tags and enter the blood glucose reading into the Bolus Calculator.

Note: Until a BG value has been entered, or if insulin is paused, ADDTO CALCULATOR is disabled.

- Tap SAVE to save the blood glucose reading and any tags in the history records. If you accessed this screen from the Bolus Calculator, SAVE does not appear.
- Tap CANCEL, then YES, to exit the screen without saving the blood glucose reading or tags.

The Omnipod 5 app records the current time as the time of the blood glucose reading.

10.3. High and Low Blood Glucose Readings

The Omnipod 5 app indicates high and low blood glucose readings as follows.

Glucose reading	Screen display
Above 600 mg/dL or HI	HI
20-600 mg/dL	<bg reading=""></bg>
0-19 mg/dL or LO	LO

If the blood glucose reading is HI or above 600 mg/dL, the Omnipod 5 app records "HI" in the history. This indicates severe hyperglycemia (high glucose). If the blood glucose reading is LO or below 20 mg/dL, the Omnipod 5 app records "LO" in the history. This indicates severe hypoglycemia (low glucose).

Warning: Blood glucose readings below 70 mg/dL may indicate hypoglycemia (low blood glucose). Blood glucose readings above 250 mg/dL may indicate hyperglycemia (high blood glucose). Follow your healthcare provider's suggestions for treatment.

Warning: If you get a low BG reading and feel symptoms such as weakness, sweating, nervousness, headache, or confusion, follow your healthcare provider's recommendation to treat hypoglycemia.

Warning: If you get a high BG reading and feel symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your healthcare provider's recommendation to treat hyperglycemia.

Warning: "LOW" or "HIGH" CGM values and "LO" or "HI" blood glucose readings can indicate potentially serious conditions requiring immediate medical attention. If left untreated, these situations can quickly lead to diabetic ketoacidosis (DKA), shock, coma, or death.

How Blood Glucose Readings are Displayed

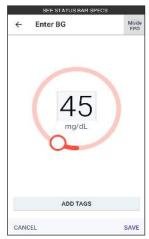
The Omnipod 5 app displays the blood glucose reading inside a colored circle. The circle is:

- Yellow if your blood glucose is above your CGM/BG Goal Range.
- Green if your blood glucose is within your CGM/BG Goal Range.
- Red if your blood glucose is below your CGM/BG Goal Range.

To change your CGM/BG Goal Range, see page 162.





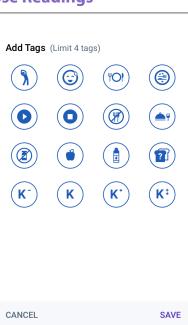


10.4. Tagging Your Blood Glucose Readings

You can add informational tags to your blood glucose reading for future reference. For example, you may tag the blood glucose reading as pre-meal.

To add a tag to the current blood glucose reading:

- Tap ADDTAGS.
- 2. Tap a tag to select it. You can add up to four tags.
- 3. To remove a tag, tap the tag again to deselect it.



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Chapter 11: Pausing and Starting Insulin Delivery

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11 Pausing and Starting Insulin Delivery

11.1. Pausing Insulin Delivery

Sometimes you may need to pause insulin delivery briefly. For example, you must pause insulin delivery prior to editing a Basal Program in progress or changing the time zone. The Omnipod 5 app lets you pause all insulin delivery for up to two hours.

For the difference between pausing insulin delivery using the pause feature or the temp basal feature, see "Methods to temporarily pause insulin delivery in Manual Mode" on page 254.

Before you begin

You must be in Manual Mode to pause insulin. If you are currently using Automated Mode, see "14.2. Switching from Automated Mode to Manual Mode" on page 137.

Warning: Insulin delivery does not automatically start at the end of the paused period. You must tap START INSULIN to start insulin delivery. If you do not start insulin delivery, you could develop hyperglycemia.

Pause insulin delivery

To pause insulin delivery:

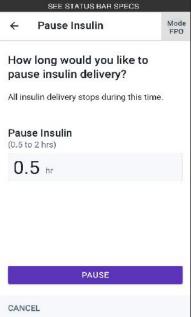
- Navigate to: Menu icon (=) > Pause Insulin
- Tap the Pause Insulin field. Scroll to specify how long to pause insulin. The paused time can last 0.5 hours, 1 hour, 1.5 hours, or 2 hours.
- 3. Tap PAUSE.
- Tap YES to confirm that you want to pause all insulin delivery.

All basal insulin delivery is paused.

The Home screen displays a yellow banner stating that "Insulin delivery is paused."

Note: The Pod beeps every 15 minutes

CANCEL throughout the paused period. At the end of the paused period, insulin delivery does not automatically start. The Pod and Omnipod 5 app notify you every minute for three minutes, and repeat this notification every 15 minutes until you have started insulin delivery.



11.2. Starting Insulin Delivery

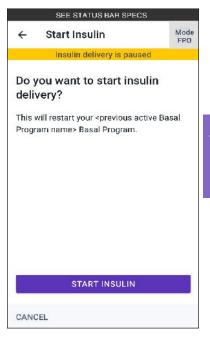
Start insulin delivery before the pause period ends

1. Navigate to:

Menu icon (≡) > Start Insulin

 Tap START INSULIN to confirm restarting the Basal Program scheduled for the current time.

The Omnipod 5 app beeps to confirm that insulin delivery has started.



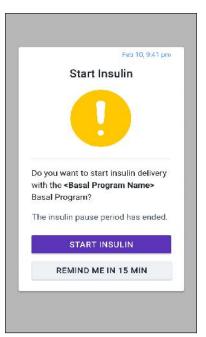
Start insulin delivery after the pause period ends

Tap START INSULIN to start insulin delivery.

The Omnipod 5 app starts the Basal Program that is scheduled for the current time and beeps to alert you that insulin delivery has started.

If you do not start insulin delivery immediately, this screen reappears and the Omnipod 5 app and Pod beep every 15 minutes until insulin delivery is started.

Warning: Insulin delivery does not automatically start at the end of the paused period. You must tap START INSULIN to start insulin delivery. If you do not start insulin delivery, you could develop hyperglycemia.



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USING A CGM WITH OMNIPOD 5

- 12 Connecting the Dexcom G6 CGM to the Pod
- 13 About the Dexcom G6



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USING a CGM with OmniPod 5

Chapter 12: Connecting Dexcom G6 CGM to the Pod

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12 Connecting Dexcom G6 CGM to the Pod

12.1. About Connecting Dexcom G6 to the Pod

Before you can operate the Omnipod 5 System in Automated Mode, you must first set up the Omnipod 5 app to allow the Pod to communicate with the CGM transmitter.

Note: The Dexcom G6 transmitter must be connected and active within the Dexcom G6 app in order to send CGM values to the Pod. The sensor does not have to be warmed up in order to connect the transmitter.

Before you begin

➤ The Omnipod 5 System will not connect with the CGM if you are using the Dexcom receiver. If you have an existing CGM transmitter that is connected to your receiver, use the Dexcom G6 app on your smartphone and turn off your receiver. For instructions about using the Dexcom G6 CGM System, see the Dexcom G6 CGM System User Guide.

12.2. Connecting the Dexcom G6 during Initial Pod Setup

To connect the CGM transmitter during initial Pod setup:

- After activating your Pod during initial setup, tap CONNECT CGM.
 Note: If you tap NOT NOW after activating your Pod during initial setup, you can connect the CGM at a later time. See "Connecting the Dexcom G6 Transmitter" below.
- 2. Go to step 3 of "Connecting the Dexcom G6 Transmitter" below.

12.3. Connecting the Dexcom G6 Transmitter

If you had previously connected a transmitter and your CGM transmitter has expired, or you have deleted the transmitter serial number and wish to reconnect, you must enter a new serial number.



Connecting Dexcom G6 CGM to the Pod 12

To connect the Dexcom G6 transmitter

Connect CGM transmitter and enter the serial number as follows:

From the Home screen, tap Menu icon (\equiv) > Settings > CGMTransmitter.

The CGM Transmitter screen displays the saved serial number.

Note: If the transmitter serial number was previously deleted, the serial number field is empty. (See "12.4. Disconnecting the CGM from the Pod" on page 126).

- 2. Tap ENTER NEW.
- Tap the serial number field to display the alphanumeric keypad.
- Enter the serial number printed on the back of your transmitter or on the transmitter box, then tap Done.

Warning: Confirm the transmitter serial number you entered into the Omnipod 5 app is the same as the one in your Dexcom G6 app and the transmitter you are wearing. In cases where more than one person in the household is wearing a CGM, it is critical to ensure the correct transmitter serial number is entered. Mixing up CGM transmitter entries could lead to serious cases of hyperglycemia or hypoglycemia



Tap SAVE.

Note: If you tap CANCEL while the system is attempting to connect, the serial number is not saved. If you exit the current screen, but do not cancel, the Pod continues connecting to the transmitter in the background.

Tap CONFIRM to start the connection process. The connection process can take up to 20 minutes.

When Pod communication is successful, the screen displays "Connecting Transmitter".

If the Pod is unable to connect with the CGM transmitter within 20 minutes, the message "Transmitter Not Found" displays. Tap NEED HELP for more information.

12 Connecting Dexcom G6 CGM to the Pod

If you do not have an active Pod or you are changing your Pod, the transmitter serial number will be saved and sent to the next Pod that is activated.

12.4. Disconnecting the CGM from the Pod

To stop the Pod from communicating with the CGM, delete the serial number. If you delete the serial number, you will no longer be able to enter Automated Mode.

To delete the serial number:

- From the Home screen, tap Menu icon () > Settings > CGM Transmitter.
 The CGM Transmitter screen displays the currently saved serial number.
- 2. Tap DELETE.
- 3. Tap OK, DELETE to confirm.



Using a CGM with OmniPod 5

Chapter 13: About the Dexcom G6

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13.1. CGM Overview

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

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

The Omnipod 5 System is designed to connect with the Dexcom G6 CGM System. When connected to the Dexcom G6, the Pod receives glucose values and trend from the Dexcom G6. In Automated Mode, the Pod uses the CGM values to make automated insulin dosing decisions every 5 minutes. In both Manual Mode and Automated Mode, a CGM value and trend can be used in the Bolus Calculator to calculate a suggested bolus.

Read and follow all Dexcom G6 product instructions, including Safety Statements, in the *Dexcom G6 User Guide*. If you do not, you could have a severe high or low glucose event.

Note: All sensor and transmitter-specific actions and alerts are controlled through your Dexcom G6 app. See your *Dexcom G6 User Guide* for additional information.

Note: The Dexcom G6 app and Omnipod 5 application do not directly communicate with each other. They have their own separate communication channels to acquire CGM readings. As a result, you may notice that, at times, the CGM readings may slightly differ in each app.

When connecting and using a CGM transmitter, it is important to be aware of the following:

- Always check the Dexcom G6 expiration dates for the sensor and transmitter.
 Only use a sensor and transmitter that are within their use-by date.
- Adhere to Dexcom's approved site placements for Dexcom G6 wear.
- All Dexcom G6 alerts are configured and driven by your Dexcom G6 app. Set your Low alert and High alert, as well as any other alerts in your Dexcom G6 app before using the Omnipod 5 System.

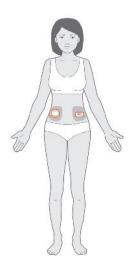
Note: The Omnipod 5 application will also alert you when your CGM values are below 55 mg/dL.

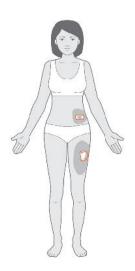
 Always ensure the transmitter serial number entered in the Dexcom G6 and Omnipod 5 apps match the transmitter on your body.

13.2. CGM Placement

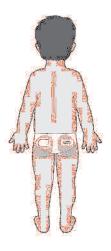
The Bluetooth connection between the CGM and the Pod does not travel well through the body. Keeping both devices within line of sight allows for consistent CGM information to be available to the Pod.

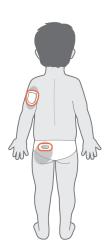
Adult placement examples





Pediatric placement examples





13.3. Using the Dexcom G6 with Omnipod 5

When using Omnipod 5 System with the Dexcom G6 CGM System, you will need a separate app to control your CGM.

There are different options available to control your Dexcom G6:

- Using the Dexcom G6 app on your smartphone.
- Using the Dexcom G6 Receiver.

Caution: The Omnipod 5 app will not be compatible with Dexcom G5 or G6 sensors used with a receiver.

13.4. CGM Values

CGM values display on the DASHBOARD tab. The Omnipod 5 app displays a CGM trend arrow to indicate whether CGM values are trending up, down, or holding steady. In Automated Mode, the system takes your CGM trend into account every 5 minutes when making automated insulin delivery decisions.

In Manual Mode and Automated Mode, a CGM trend is needed to add a CGM value into the Bolus Calculator. The Bolus Calculator can increase or decrease your bolus as needed based on your CGM value and trend.



High and low CGM values

The Omnipod 5 app indicates high and low CGM values as follows.

CGM Value	Screen display
Above 400 mg/dL	HIGH
40 - 400 mg/dL	<cgm value=""></cgm>
Below 40 mg/dL	LOW

Note: CGM values are automatically recorded on the Omnipod 5 app and should not be entered on the Enter BG screen.

13.5. CGM Trend Arrows

Trend arrows display per Dexcom specifications. The arrow color matches that of the CGM value color. For more information, refer to the *Dexcom G6 CGM System User Guide*.

The color of the CGM value and trend arrow can vary as follows:

CGM Value Color	Description
Blue	CGM value is within CGM/BG Goal Range (Manual Mode)
Red	CGM value is below CGM/BG Goal Range
Yellow	CGM value is above CGM/BG Goal Range
Purple	CGM value is within CGM/BG Goal Range (Automated Mode)

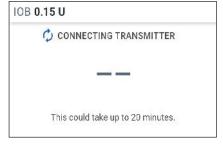
The following table describes the CGM trend arrows. The trend arrows are shown in blue for example purposes only.

	•
CGM Trend Arrows	Description
(-)	Steady; decreasing/increasing less than 1 mg/dL per minute
90	Slowly falling/rising; glucose could decrease/increase 30-60 mg/dL in 30 minutes
O	Falling/rising; glucose could decrease/increase 60-90 mg/dL in 30 minutes
8	Rapidly falling/rising; glucose could decrease/increase more than 90 mg/dL in 30 minutes

13.6. Communication Messages

The DASHBOARD displays the following communication messages:

- CONNECTINGTRANSMITTER: Occurs after you have entered in a transmitter serial number and the Pod is attempting to connect with the transmitter.
- WAITING FOR DEXCOM SETUP: When the transmitter is connected but CGM values are unavailable because the Dexcom G6 is in sensor warm-up or requires calibration. See the Dexcom G6 app for details. No



action is required within the Omnipod 5 app. SEARCHING FOR POD: When Pod communication was not established

- within the most recent 5-minute update interval. Tap MORE INFORMATION for potential causes and recommended actions.
- SEARCHING FOR CGM: When the CGM is active and connected to the Omnipod 5 Pod but the most recent CGM value was not acquired within the 5-minute window. There may be no valid CGM value available due to a Pod/ CGM communication issue or a temporary CGM sensor issue (recoverable without any user action). Tap MORE INFORMATION for recommended action. Review Pod and CGM placement. Pod and CGM should be within line of sight. IOB 0.15 U
- **DEXCOM ISSUE DETECTED: When** CGM values are not available due. to a sensor error (including sensor expiration). See the Dexcom G6 app for details. No action is required within the Omnipod 5 application.
- TRANSMITTER ERROR: When the transmitter that was connected with the Omnipod 5 System has expired or experienced a non-recoverable error. Tap NEED HELP for potential causes and recommended actions. To set up a new transmitter, see "Chapter 12: Connecting CGM to the Pod" on page 123.
- TRANSMITTER NOT FOUND: When the Pod has tried to connect with a transmitter but after 20 minutes was unable to do so. Tap NEED HELP for potential causes and recommended action.

Note: For all CGM related issues, refer to your compatible CGM *User Guide*.



AUTOMATED MODE

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- 15 About Automated Mode
- 16 HypoProtect™



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Chapter 14: Switching Between Manual Mode and Automated Mode

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14.1. Switching from Manual Mode to Automated Mode

Before you begin

First, ensure you have an active Pod and connected CGM. See "Chapter 5: Activating and Changing Your Pod" on page 59 and "Chapter 12: Connecting CGM to the Pod" on page 123.

Do the following, if necessary:

- Cancel your temp basal or extended bolus, if either are running. See "7.3. Canceling a Temp Basal or Temp Basal Preset" on page 85 or "8.9. Canceling a Bolus in Progress" on page 99.
- Start insulin, if it is paused. See "11.2. Starting Insulin Delivery" on page 119.

To switch to Automated Mode

To switch from Manual Mode to Automated Mode:

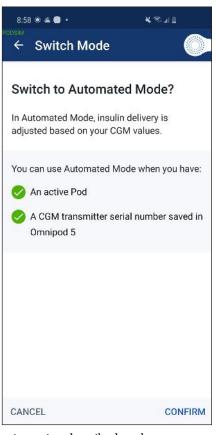
From the Home screen, tap Menu icon (≡) > Switch Mode.

Note: If the screen displays a red circle with an exclamation point and SWITCHTO AUTOMATED

is disabled (grayed out), take the corrective action described on the screen before you try again.

Tap SWITCHTO AUTOMATED.

Warning: The Omnipod 5 System relies on accurate, current CGM values to determine your insulin needs. Despite using an automated insulin delivery system, you should always be aware of your current CGM value because severe hypoglycemia and hyperglycemia may still occur. If your CGM readings do not match your symptoms or expectations, use a BG meter to perform a fingerstick check to make appropriate diabetes treatment decisions.



14.2. Switching from Automated Mode to Manual Mode

When you switch from using Automated Mode to using Manual Mode, basal insulin will be delivered based on the Basal Program scheduled for the current time.

Before you begin

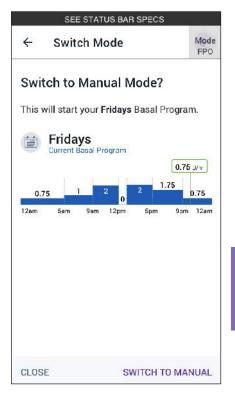
Cancel HypoProtect[™], if it is running. See "16.3. Canceling HypoProtect[™] on page 147.

To switch to Manual Mode

From the Home screen, tap Menu icon (\equiv) > Switch Mode.

> **Note:** If the screen displays a red circle with an exclamation point and SWITCHTO MANUAL is disabled (grayed out), take the corrective action described on the screen before you try again.

Tap SWITCHTO MANUAL.



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Chapter 15: About Automated Mode

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15.1. About Automated Mode

Warning: In Automated Mode, bolus doses for meals still require your programming and delivery based on your healthcare provider's recommendations. Failure to deliver a bolus when needed could result in hyperglycemia.

Warning: The Omnipod 5 System cannot track insulin that is administered outside of the system. Administering insulin, such as by injection, while wearing an active Pod could result in hypoglycemia. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.

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

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

Caution: Always check your glucose prior to delivering a bolus.

Automated Mode is the defining feature of the Omnipod 5 System. In Automated Mode, the system will automatically adjust your insulin delivery every 5 minutes, based on current CGM value and trend, with the goal of bringing your glucose level to your defined Target BG.

How insulin is calculated and delivered during Automated Mode

The Omnipod 5 System uses your insulin delivery history to determine how much insulin your body needs. The calculated amount is known as the adaptive basal rate, which provides a baseline for automated delivery.

The System can automatically increase, decrease or pause insulin delivery. The System can pause automated insulin delivery at any time to protect against hypoglycemia and will always pause when your glucose is below 60 mg/dL. The System can increase insulin delivery, by delivering a series of microboluses, to respond to elevated glucose levels.

The maximum automated insulin delivery that can be given while in Automated Mode is based on your insulin history and your current insulin on board. This value is not related to your maximum basal rate setting.

About Automated Mode 15

Your baseline adaptive basal rate is based on how much insulin you needed in the past. Over time, the Omnipod 5 System will learn your daily insulin needs and adapt, resulting in your adaptive basal rate changing to better match your true insulin needs at every Pod change.

The Pod contains the Omnipod 5 algorithm which adjusts your adaptive basal rate. You can stay in Automated Mode when the Omnipod 5 app is out of range from the Pod. When the Pod and Omnipod 5 app are in range, the Pod sends its information back to the Omnipod 5 app, updating its home screen to show your current IOB along with recent CGM value and trend.

The automated insulin delivery amount given every 5 minutes while in Automated Mode can be seen in the 'Auto Events' tab of the History Detail screen. See "Automated events (Auto Events)" on page 179.

The CGM graph on the Home screen shows when the Omnipod 5 System paused insulin delivery or has reached the maximum delivery. See "18.2. Viewing the CGM Graph" on page 168.

Note: The Omnipod 5 app must be in Pod communication range to receive the most up-to-date information.