# 11.3 Sensor Graph States

When the Omnipod 5 System is in Manual Mode, the mode indicator is blue.



The graph shows your most recent sensor glucose values over the last 3, 6, 12, and 24 hours.

**Note:** You can tap the? symbol in the lower right hand corner to see a Legend of symbols used in the Sensor Graph.

- 1. **Current Status:** Your current sensor glucose value and trend arrow display, along with the current IOB.
- 2. **Sensor Glucose Trend Line:** Each dot on the graph represents a sensor glucose value. Plotted values are from 40–400 mg/dL.
- 3. **Glucose Goal Range:** This shaded area shows your Glucose Goal Range. The yellow line shows the Upper Limit, and the red line shows the Lower Limit that you set in Settings.
- 4. **Target Glucose:** Dashed green line shows the Target Glucose that you set in Settings. When the Activity feature is enabled, this value changes to 150 mg/dL.
- 5. **Event area:** The row below the graph shows:
  - Purple background for periods of time that Omnipod 5 was in Automated Mode
  - Blank (white) background for the periods of time that Omnipod 5 was in Manual Mode, when there was no active Pod, or when there is no Pod communication
  - Dark gray background when Omnipod 5 was delivering insulin in Automated Mode: Limited state



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# 11 Browsing Your History and Records

- A red line during the time that SmartAdjust technology paused insulin
- An orange line during time that the maximum amount of basal insulin was delivered by the Omnipod 5 System
- Bolus button at the time you started a bolus
- 6. **View Selection:** Use the buttons to select 3-, 6-, 12-, and 24-hour views.
- 7. **Vertical axis:** Displays sensor glucose values in mg/dL.
- 8. **Time scale:** Displays hour and half-hour markings.

When the Omnipod 5 System is in Automated Mode, the mode indicator is purple.





When the Omnipod 5 System is in Automated Mode: Limited state, the mode indicator is gray.

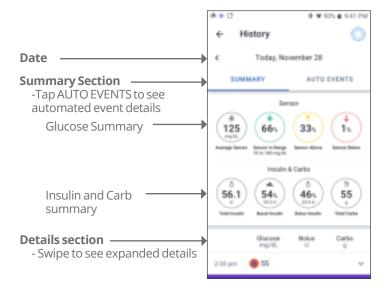


# **11.4 History Summary Section**

# **History Information Overview**

You can access the history summary and detail information, and a list of automated events from the History Detail screen.

Navigate to: Menu button ( ) > History Detail.





# 11 Browsing Your History and Records

Today's history records are displayed below the summary circles, beginning with the newest records on the top.

**Note:** Tap the "<" next to the date arrow to view an earlier day. The upper section of the History screens summarizes the records for the day.

Summary item	Description	
Row 1 - Sensor		
Average Sensor	Average of sensor glucose values for the day.	
Sensor in Range	Percentage of sensor glucose values within your Glucose Goal Range.	
Sensor Above	Percentage of sensor glucose values above your Glucose Goal Range.	
Sensor Below	Percentage of sensor glucose values below your Glucose Goal Range.	
Row 2 - Insulin & Carbs		
Total Insulin	Total insulin (basal + bolus) delivered for the day.	
Basal Insulin	Percentage of the total insulin that was delivered as basal along with the number of units of basal insulin delivered. Basal insulin includes delivery based on your Basal Program while in Manual Mode, and any automated deliveries received while in Automated Mode.	
Bolus Insulin	Percentage of the total insulin that was delivered through bolus(es) along with the number of units of bolus insulin delivered.	
Total Carbs	Sum of meal carbohydrates (in grams) that were used in bolus delivery calculations for the given day.	

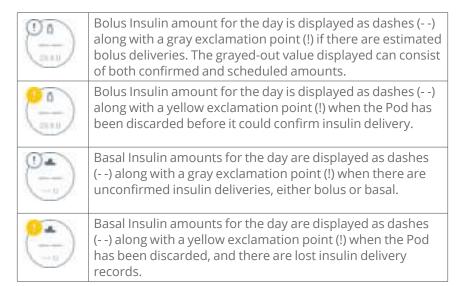
**Note:** Percentages may not add to 100 due to rounding.

For the summary of these calculations, see page 156.



#### When insulin delivery is unconfirmed

After delivering a bolus or basal dose of insulin, the Pod sends a confirmation to the Omnipod 5 App once completed. If a bolus, basal, or total insulin delivery has not been confirmed, the following icons will display:





# 11.5 Calculations for History Summaries

This section lists the calculations for the summary data shown on the History screens.

#### **Glucose Summaries**

The calculations used for the glucose summaries include sensor glucose values (including HIGH and LOW values) and exclude manually-entered readings.

Item	Calculation
Row 1	
Average Sensor	= Sum of all sensor glucose values Total number of sensor glucose values
	<b>Note:</b> Note: HIGH sensor glucose values are included as 401 and LOW sensor glucose values as 39.
Sensor in Range	= Qty of sensor glucose values within Glucose Goal Range Total number of sensor glucose values x 100
Sensor Above	Glucose Goal Ralige upper III III V 100
Sensor Below	Glucose Goal Range lower III III

# **Insulin Delivery Summaries**

Bolus insulin calculations include:

- SmartBolus Calculator boluses
- Manual boluses
- Any partial bolus amounts delivered from immediate or extended boluses that were canceled that the Pod can confirm

Basal insulin calculations include:

- Basal adjustments from SmartAdjust technology (Automated Mode)
- Basal Programs (Manual Mode)



 Any adjustments for temp basals, pause periods, or times without an active Pod

When your Omnipod 5 System has not received updates from the Pod about confirmed insulin delivery, the insulin delivery calculations are estimates based on the scheduled insulin delivery.

Summary item	Calculation
Row 2	
Total Insulin	= Sum of basal and bolus insulin delivered
Basal Insulin	Amount of basal insulin delivered in Manual  = Mode and all automated insulin deliveries in Automated Mode
Bolus Insulin	= Amount of bolus insulin delivered
Total Carbs	= Total grams of carbs entered into the SmartBolus Calculator

# 11.6 History Details Section

Scroll on the History screens to see the details section. The details section of the History screen shows individual records listed by time of day.

Tap a row with a down arrow to display more details. Tap again to hide the details.

#### **Glucose Details**

The icon displayed with a blood glucose reading indicates whether the glucose was in range.





The blood glucose icons are:

	BG entry
Above Glucose Goal Range	<b>(6)</b>
Within Glucose Goal Range	<b>(6)</b>
Below Glucose Goal Range	<b>(6)</b>

The Dexcom icon is:



The FreeStyle Libre 2 Plus Sensor icon is:



#### **Glucose Goal Range**

The goal of using the Omnipod 5 System is to keep your glucose within your Glucose Goal Range. You define this range by setting the upper and lower limits. The Sensor Graph and the Enter BG screen use the Glucose Goal Range to determine which glucose readings are within your goal and which are above or below your goal.

**Note:** The Glucose Goal Range does not impact insulin delivery.

To set the upper and lower limit of your Glucose Goal Range:

- 1. Navigate to: Menu button ( ≡ )> Settings > Glucose Goal Range.
- 2. Set the limits of the Glucose Goal Range:
  - a. Tap the **Upper Limit** field and enter the desired value.
  - b. Tap the **Lower Limit** field and enter the desired value.
- 3. Tap **SAVE**.

#### **Bolus Details**

The icon displayed with a bolus entry indicates whether the SmartBolus Calculator was used:

- The insulin bottle icon ( ) indicates that the SmartBolus Calculator was used.
- The syringe icon ( ) indicates a manual bolus was delivered.



#### Immediate and extended boluses

The bolus amount listed next to the Bolus button is the total of an immediate bolus plus any extended portion of the bolus. If you cancel an immediate or extended bolus, the amount listed is the confirmed amount delivered before cancellation.

Tapping a row with a bolus entry expands the record to show additional details about the bolus, including:

- Whether the bolus was calculated by the SmartBolus Calculator or it was a manual bolus.
- The VIEW BOLUS CALCULATIONS button if the SmartBolus Calculator was used. Tapping this button brings up a screen showing the calculation details and whether you made a manual adjustment to the calculated bolus.

You may need to scroll up or down to see all of the calculations. Tap **CLOSE** when done (see "18.1 The SmartBolus Calculator" on page 278 for details).

- The amount originally scheduled for delivery if you canceled an immediate bolus.
- For an extended bolus, the amount delivered now and extended, and the percentage (%) of the meal bolus delivered now and extended.
- If a bolus is ongoing, unconfirmed, or lost, how much of the bolus has been confirmed.

#### **Extended bolus events**



- An Extended Bolus started banner marks the time when the immediate bolus finishes and the extended bolus starts. In addition to the start time of the bolus, the banner lists the number of units extended and the duration of the extension.
- An Extended Bolus completed banner marks the end of the extended bolus.
- An Extended Bolus canceled banner marks the cancellation of an extended bolus and states the confirmed amount of the bolus that was delivered before cancellation.



## 11 Browsing Your History and Records

#### When the Pod has not confirmed a bolus delivery



After you confirm the amount of a bolus that you want to be delivered, a bolus instruction is sent to your Pod. When the Pod completes delivery, it sends a confirmation to the Omnipod 5 App that the bolus was delivered.

Before the Omnipod 5 App receives confirmation from the Pod that the bolus has been delivered, the Omnipod 5 App estimates the amount delivered. During this time, the History screens use a gray exclamation icon to indicate that the bolus is estimated.



In most cases, after the Controller or smartphone running the Omnipod 5 App and Pod are back in range, the Pod confirms the bolus delivery. However, in rare cases, the Pod is unable to confirm bolus delivery due to a communication error. If you tap the **DISCARD POD** option in this situation, the History screens use a yellow exclamation icon to mark the bolus as "unconfirmed."

If a Pod is discarded with an unconfirmed bolus, the basal and total insulin amounts for that day are also marked as unconfirmed with dashes and a yellow exclamation icon. The listed bolus amount includes the amount that was scheduled for delivery up until the Pod was discarded.

**Note:** If you have an unconfirmed bolus, the SmartBolus Calculator is disabled for the duration of insulin action.

#### **Pod Details**



A Pod icon and banner mark the activation and deactivation (or discarding) of each Pod. Tapping a Pod banner displays the Pod's lot number and sequence number.

#### **Carbs Details**

A carbs icon ( **T**) is displayed next to carbohydrate entries used by the SmartBolus Calculator. Bolus events indicate whether carbs were manually entered or from Custom Foods.

#### **Basal Rate Details**

## **Activity feature**



In Automated Mode, an Activity icon and banner indicate the start, end, or cancellation of the Activity feature.



#### **Basal Programs**



A Basal Program icon and banner indicate the start of a Basal Program and the restart of a Basal Program at the end of a temp basal or insulin pause period.

#### Temp basals



11 In Manual Mode, a temp basal icon and banner indicate the start, end, or cancellation of a temp basal.

If a temp basal was defined as a percentage (%) of the Basal Program in progress, the banner displays the percent increase or decrease as well as the duration. If a temp basal was defined as a flat basal rate (U/hr), the banner displays the temp basal rate and the duration.

Tapping a **Temp Basal started** banner displays a graph of basal rates associated with each time segment.

If a temp basal was canceled, the **Temp Basal started** banner contains the scheduled duration, and the **Temp Basal canceled** banner contains the actual duration.

#### Basal rate at midnight

The first entry for each day is a banner displaying the status of the basal insulin delivery at midnight. If a Basal Program, temp basal, or use of the Activity feature was carried over from the day before, the banner indicates that this is a continued program. If insulin was paused at midnight, the banner states this.

## **Insulin Paused and Started Details**



An **Insulin Delivery Paused** icon and banner indicate the time an insulin paused period began.



An **Insulin Delivery Started** icon and banner indicate the time insulin delivery was restarted.

# Time Change Details

A Time zone changed banner appears if you change your insulin delivery time zone.

After the time zone change has occurred, new history entries will reflect your new time zone.

Note: History entries recorded before your time zone changed will show in your prior time zone.

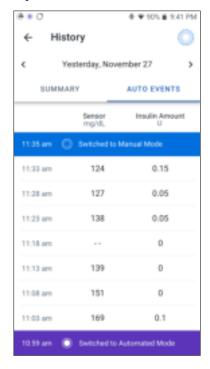


## 11 Browsing Your History and Records

# **Automated Events (Auto Events)**

Tap **AUTO EVENTS** on the history screen to display the amount of insulin delivered at each 5-minute period while in Automated Mode.

A system mode icon and banner show the time the system switched to Automated Mode or to Manual Mode.





# CHAPTER 12 Managing Software Updates

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# 12.1 Insulet-provided Controller

When connected to a network, the Omnipod 5 Controller offers over-the-air updates when a software update is available. There are two types of updates for the Omnipod 5 Controller: OS (Operating System) updates and Omnipod 5 App updates. OS update refers to updating the operating system of the Controller. Omnipod 5 App update refers to updating the Omnipod 5 App on the Controller. When an update is available, you will receive a notification prompting you to update.

**Note:** You will not be able to navigate in the Omnipod 5 App during an Omnipod 5 update; however, your insulin therapy will not be impacted. The Pod continues delivering insulin and will re-establish connection with the Omnipod 5 App once the update is complete.

**Note:** The Controller must be connected to a network to receive over-the-air updates. If you turn Airplane Mode ON, you may miss important updates.

**Note:** All updates on the Controller that are considered optional require a Wi-Fi connection.

**Note:** If you have an immediate bolus in progress, software updates will be delayed until the bolus is complete.

**Caution:** ALWAYS make sure your battery has adequate charge prior to installing a software update.

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



# **Operating System (OS) Update**

Operating System (OS) updates may be either "optional" or "required." Required updates require you to perform the update immediately before you can use the Omnipod 5 App. Optional updates may be postponed to a later time.

To download and install an OS update on the Controller:

1. Ensure your Controller is currently charging or the battery is charged to above 40%.

**Note:** If your Controller is currently charging, the battery must be above 20%.

#### 2. Tap Update Now.

The Omnipod 5 Controller begins to update.

Once the update is complete, you will see a confirmation screen.

If the update is not considered required, you may select **Not Now** to delay the update to a later time; however, it is recommended that you update the OS as soon as the update is available. If you choose to postpone an optional update, you can manually update at any time. After 72 hours have passed, you will receive a notification every 24 hours reminding you to update. To manually update the operating system of the Controller:

1. Ensure your Controller is currently charging or the battery is charged to above 40%.

**Note:** If your Controller is currently charging, the battery must be above 20%.

- 2. Go to the Home screen.
- 3. Tap the notification bell.
- 4. Tap the update notification.
- 5. Tap **Update Now.**

Once the update is complete, a confirmation screen displays to inform you that the update was completed successfully.



# 12 Managing Software Updates

## **Omnipod 5 App Update on the Controller**

Omnipod 5 App updates may be either "optional" or "required." Required updates require you to perform the update immediately before proceeding to use the Controller. Optional updates may be postponed to a later time.

To download and install an Omnipod 5 App update on the Controller:

- 1. Ensure your battery is charged to above 15%.
- 2. Select **Update Now.**

After the update is complete, a confirmation screen displays to inform you that the update was completed successfully.

If the update is not considered required, you may select **Not Now** to delay the update to a later time; however, it is recommended that you update the Omnipod 5 App as soon as the update is available. If you choose to postpone an optional update to a later time, you can manually update the Omnipod 5 App at any time. After 72 hours have passed, you will receive a notification every 24 hours reminding you to update your Omnipod 5 App.

To manually update your Omnipod 5 App:

- 1. Ensure your battery is charged to above 15%.
- 2. Go to the Home screen.
- 3. Tap the notification bell.
- 4. Tap the update notification.
- 5. Tap **Update Now.**

Once the update is complete, a confirmation screen displays to inform you that the update was completed successfully.



# 12.2 Omnipod 5 App on Smartphone

The Omnipod 5 App offers updates through Google Play. You will be notified when an update is available for download. You will not be able to navigate in the Omnipod 5 App during an update; however, your insulin therapy will not be impacted. The Pod continues delivering insulin and will re-establish connection with the Omnipod 5 App once the update is complete.

**Caution:** ALWAYS make sure your battery has adequate charge prior to installing a software update.

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

# **Automatic Updates Enabled**

If you have Automatic Updates enabled on your phone, the Omnipod 5 App updates will be downloaded and installed automatically through Google Play. If an automatic update occurs, the Omnipod 5 App informs you that an update was successfully completed when you open the app.

For more information on how to enable automatic updates, see your smartphone's user manual.



# 12 Managing Software Updates

# **Automatic Updates Disabled**

To download and install an Omnipod 5 App update on your smartphone:

- 1. Ensure your phone battery is charged to above 15%.
- 2. If prompted when using the app, select **Update Now**.
  - Or navigate to your list of apps in Google Play.

Tap **Update** next to the Omnipod 5 App.

After the update is complete and the Omnipod 5 App is reopened, a confirmation screen displays to inform you that the update was completed successfully.

If the update is not considered required, you may select **Not Now** to delay the update to a later time; however, it is recommended that you update the Omnipod 5 App as soon as the update is available. If you choose to postpone an optional update to a later time, you can manually update the Omnipod 5 App at any time. After 72 hours have passed, you will receive a notification every 24 hours reminding you to update your Omnipod 5 App.

To manually update your Omnipod 5 App:

- 1. Ensure your phone battery is charged to above 15%.
- 2. Navigate to your list of apps in Google Play.
- 3. Tap **Update** next to the Omnipod 5 App.

Once the update is complete and the Omnipod 5 App is reopened, a confirmation screen displays to inform you that the update was completed successfully.



# **CHAPTER 13**

# Alarms, Action and Reminder Notifications

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# 13.1 Types of Alarms and Notifications

**Warning:** ALWAYS contact Customer Care if your Omnipod 5 System Controller is damaged and not working properly. If a Controller replacement is needed, ALWAYS consult with your healthcare provider to get instructions on using other backup insulin delivery methods, like insulin injections. Be sure to check your glucose frequently.

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

**Caution:** AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown
- iPhone: Screen Time, Focus Mode, Hide App, Lock App

If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able see the Alarm or Notification displayed on the Omnipod 5 App.

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



The Omnipod 5 System generates the following types of alarms and notifications:

#### · Alarms:

- A Hazard Alarms are high-priority alarms that indicate a serious problem has occurred, and you may need to remove your Pod. Hazard Alarms will repeat every15 minutes until acknowledged. The audible alarm on the Pod will continue until acknowledged in the Omnipod 5 App. See "13.5 Hazard Alarm List" on page 181.
- In general, only one hazard alarm can occur at a time. In the unlikely even that a Pod and Omnipod 5 App hazard alarm occur simultaneously, the Hazard Alarm that most recently occurred will be displayed first on the Omnipod 5 App. Any Pod Hazard Alarms will be sounded on the Pod.
- • Advisory Alarms are low-priority alarms that indicate that a situation exists that needs your attention. Advisory Alarms will repeat every 15 minutes until acknowledged (see Alarm tables for additional details) and continue on the Pod until acknowledged in the Omnipod 5 App. See "13.6 Advisory Alarm List" on page 189.

#### · Notifications:

- **Action Item notifications** are for technical System tasks that need your attention. See page 173.
- Reminder notifications remind you about a diabetes management action that you may want to perform. See "13.10 Reminder Notifications List" on page 217.
- **Communication error** messages display when the Omnipod 5 App is unable to communicate with the Pod. See "27.5 Pod Communication Issues "Try Again"" on page 458.

For how to view the alarms and notifications history, see page 173.

For Dexcom G6 alarm information, see the *Dexcom G6 CGM System Instructions for Use.* 

For FreeStyle Libre 2 Plus Sensor alarm information, see "20.5. FreeStyle Libre 2 Plus Sensor Communication and Problem Messages" on page 283.



#### Alarms and Notifications Screen

To review past alarms and notifications:

 Tap Menu button ( )> Notifications.

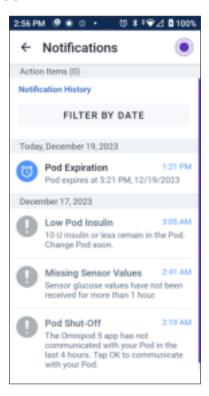
Messages from today are displayed first, with newest at the top of the screen and oldest at the bottom of the screen.

- 2. To display a specific date range, tap **FILTER BY DATE**.
  - a. Tap the starting date on the calendar.

**Note:** Tap the "<" arrow to view an earlier month.

- b. Tap **END** at the top of the screen.
- c. Tap the ending date for the date range.
- d. Tap OK.
- 3. When finished, tap the back arrow to exit ( ). Unread notifications have colored icons described in "13.1 Types of Alarms and Notifications" on page 171.

**Note:** When a notification has been displayed on this screen, and you have exited by tapping the back arrow ( ), the icon for those notifications will be gray the next time you view this screen.





#### 13.2 Sounds and Vibrations

The Omnipod 5 System uses sounds and vibrations to attract your attention to an alarm or notification.

**Caution:** AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown
- iPhone: Screen Time, Focus Mode, Hide App, Lock App

If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able see the Alarm or Notification displayed on the Omnipod 5 App.

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

**Tip:** To test the sounds and vibrations, see "Check alarms" on page 180.

#### Pod alarms

The Pod sounds a tone when it detects a problem that can affect insulin delivery.

- Pod Hazard Alarms are continuous tones broken up periodically by a set of beeps.
- Pod Advisory Alarms and notifications are intermittent beeps, which periodically repeat until you acknowledge them.

# Omnipod 5 App alarms

Omnipod 5 App alarm sounds are dependent on your Controller or smartphone sound settings, for example, silent or vibrate setting.

#### The Sound/vibrate button on your Controller

The Sound/vibrate button, located on the upper right side of the Controller, controls whether all notifications use vibrations or sounds.



- To turn vibrations ON, press and hold the lower end of the Sound/ vibrate button until the vibrate icon ( ) appears on the screen.
- To turn sound ON, press the upper end of the Sound/vibrate button until the sound icon ( ) appears on the screen.
- To increase or decrease the volume, press the upper or lower end of the Sound/vibrate button. On the screen, you can also move the volume indicator to the left to decrease the volume and move it to the right to increase the volume

# **Smartphone Sounds and Vibrations**

**Caution:** ALWAYS make sure you can hear alarms and notifications when paired to alternative audio devices (e.g. Bluetooth speaker, headphones).

Navigate to your smartphone's sound settings to ensure that all Omnipod 5 App notifications are enabled to produce a vibration and audible sound. See "4.5 General Settings on Your Smartphone" on page 75 for more information on how to adjust your smartphone sound and vibration settings.

**Note:** When paired to an alternative Bluetooth device to project sound, such as headphones or speakers, alarms/alerts/notifications may sound on your smartphone or on the Bluetooth accessory. Each accessory is different. Test yours prior to use to ensure alarms/alerts/notifications are audible. See "Check alarms" on page 180.



# 13.3 Informational Sounds and Vibrations

**Caution:** AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown
- iPhone: Screen Time, Focus Mode, Hide App, Lock App

If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able see the Alarm or Notification displayed on the Omnipod 5 App.

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

The Pod and the Omnipod 5 App can provide informational sounds (tones, beeps) or vibrations to let you know that normal activity between the Pod and the Omnipod 5 App is occurring as expected. See the tables below for descriptions of informational sounds you will encounter during use.

#### **Confidence reminders**

Cause	Omnipod 5 App	Pod
Tones or vibrations let you know that your temp basals and boluses are working as expected. These reminders are ON by default. To turn them ON or OFF, see "Confidence Reminders" on page 147.	Tone/vibration at the start of a temp basal, bolus, or extended bolus.	Beeps once at the end of a temp basal, bolus, or extended bolus.



**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" on page 147.

# **Program reminders**

Cause	Omnipod 5 App	Pod
Beeps remind you that you have a temp basal or extended bolus running. These reminders are ON by default. To turn them ON or OFF, see page 147.	No tone/vibration	Beeps once every 60 minutes while a temp basal or extended bolus is running.

# **Basal Program changes**

Cause	Omnipod 5 App	Pod
Tones or vibrations inform you of changes to your Basal Program. You cannot turn these OFF.	Tone/vibration when a Basal Program is activated, edited, paused, or started.	Beeps once every 15 minutes after the pause period has ended.

# Canceling temp basals and boluses

Cause	Omnipod 5 App	Pod
Tone informs you that the temp basal or bolus has been successfully canceled. You cannot turn these OFF.	No tone/vibration	Beeps once when you cancel a temp basal, bolus, or extended bolus.



#### Pod activation / Pod deactivation

Cause	Omnipod 5 App	Pod
Tones or vibrations occur at various times during the Pod activation process to indicate progress. You cannot turn these OFF.	Tone/vibration when the Pod and Omnipod 5 App are successfully paired. Sounds tone/ vibrates twice when the Pod is successfully deactivated.	Beeps twice when it has been filled with the minimum amount of insulin needed for activation (see page 100).  Beginning 10 minutes after the Pod is filled with insulin, beeps every five minutes
		until insulin delivery has started.

# 13.4 Responding to Alarms

**Caution:** AVOID leaving your Controller or smartphone in a place that would prevent you from hearing alarms and notifications from your Omnipod 5 App. Delivery of insulin in Manual Mode or Automated Mode continues as programmed if you move away from your Controller or smartphone.

**Caution:** AVOID setting your Controller or smartphone to Silent, Vibrate, or any other setting that prevents you from hearing alarms and notifications from your Omnipod 5 App. Avoid the use of tools that limit sounds and notifications, including but not limited to:

- Android: Digital Wellbeing, Private Space, Notification cooldown
- iPhone: Screen Time, Focus Mode, Hide App, Lock App

If you do not hear alarms and notifications from your Controller or smartphone, you might not make the changes you need to make to your insulin therapy in a timely manner. Your Pod will still sound, and you will be able see the Alarm or Notification displayed on the Omnipod 5 App.

**Note:** The Omnipod 5 System on your smartphone requires Do Not Disturb permission and Notifications to be turned ON to ensure



you always receive important safety alarms. You cannot use the app until Do Not Disturb permission is provided and Notifications is turned ON.

To respond to a Hazard Alarm or Advisory Alarm:

- 1. Wake up your Controller or smartphone. The Lock screen shows an alarm message along with the hazard alarm (♠) icon or Advisory Alarm (♠) icon.
- 2. After unlocking your Omnipod 5 App, follow the on-screen instructions or see the individual alarm details starting on page 180.

**Note:** You can use your Omnipod 5 System even if you do not address an Advisory Alarm immediately. However, you must acknowledge a Hazard Alarm before you can use your Omnipod 5 System.

**Tip:** If you follow the Omnipod 5 App's instructions and are still not able to silence a hazard alarm, see "13.8 Silencing Unresolved Alarms" on page 215.

**Note:** If a temp basal or extended bolus is running when a Pod Hazard Alarm occurs, the Omnipod 5 App informs you that it was canceled.

# Timing of Pod Alarms on the Omnipod 5 App

If the Pod is sounding a HazardAlarm, the Pod sends a signal to your Omnipod 5 App.

- If the Controller or smartphone running the Omnipod 5 App is in range and awake within 25 seconds of the Pod's initial alarm sound, your Omnipod 5 App also sounds an alarm and displays the alarm message.
- If the Controller or smartphone running the Omnipod 5 App is in range but asleep, there could be a delay of up to 6 minutes between when the Pod sounds the alarm and when your Omnipod 5 App sounds the alarm.
- If the Controller or smartphone running the Omnipod 5 App is out of range of the Pod, your Omnipod 5 App cannot receive any communication from the Pod. Therefore, if you hear a Pod alarm or notification, bring your Controller or smartphone in range of the Pod and wake up your Omnipod 5 App. Within 25 seconds, your Omnipod 5 App sounds the alarm and displays the alarm message.



# **Diagnostics**

**Warning:** DO NOT continue using an activated Pod that fails to beep during a diagnostic test. The Pod should be changed immediately. If the Omnipod 5 App fails to beep during a diagnostic test, contact Customer Care immediately. Continuing to use the Omnipod 5 System in these situations could put your health and safety at risk.

#### **Check alarms**

Before you begin, switch to Manual Mode if currently using Automated Mode. See "23.2 Switching from Automated Mode to Manual Mode" on page 386.

**Note:** Your Controller or smartphone sound settings must be ON to hear a tone on the Omnipod 5 App.

To verify that your Omnipod 5 App and Pod's alarms and vibration functions are working properly, test them as follows:

- 2. If you have an active Pod, tap **PAUSE INSULIN** and tap **YES**.
- 3. Tap **CHECK ALARMS** to initiate the alarm check.
- 4. Listen and feel: The Controller or smartphone running the Omnipod 5 App beeps and vibrates three times. If you are wearing a Pod, the Pod beeps several times and sounds the alarm tone for several seconds.
- 5. If the Pod did not beep, tap **NO**. Then either tap **CHECK AGAIN** to retry testing the alarms, or tap **DONE** and change your Pod.
- 6. If the Omnipod 5 System alarms did not sound, tap **NO**. Then either tap **CHECK AGAIN** to retry testing the alarms or contact Customer Care.
- 7. If the beeps and vibrations worked properly, tap **YES**. If you paused insulin to check the alarms, tap **YES** to start insulin delivery.



#### 13.5 Hazard Alarm List

**Warning:** ALWAYS respond to Hazard Alarms as soon as they occur. Pod Hazard Alarms indicate that insulin delivery has stopped. Failure to respond to a Hazard Alarm could result in under-delivery of insulin which can lead to hyperglycemia.

Hazard alarms make you aware of serious situations. Always respond to a hazard alarm immediately. Some alarm messages give you a unique number called a reference number. Give that number to Customer Care if you call about that alarm.

# A Blockage Detected

**Warning:** ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA).

#### Screen Alert Description **Omnipod 5 App: Why it occurs:** A blockage (occlusion) was detected from the blocked cannula, a Pod malfunction, or from Blockage Detected using old or inactive insulin, which has stopped insulin delivery. Pod sound: Continuous tone Controller/Smartphone sound and vibration: 30 second tone Insulin delivery stopped. Change Pod. · 30 second vibration Vibration and tone repeat every Check your BG. 15 minutes until acknowledged. OK, DEACTIVATE POD NOW What to do: Tap OK, DEACTIVATE POD NOW. 2. Change your Pod. **Lock Screen:** 3. Check your blood glucose. Omniped 5 - Notifications - new W **Blockage Detected** Insulin delivery stopped. Change P.

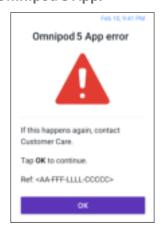


# ▲ Omnipod 5 App Error

# Cillingou 3 App El loi

# Omnipod 5 App:

**Screen Alert** 



#### Description

Why it occurs: An unexpected error is detected in the Omnipod 5 App.

**Note:** If your Omnipod App stops and restarts on its own, you may notice the app flashing white before this screen appears.

#### Pod sound: None

# Controller/Smartphone sound and vibration:

- 30 second tone
- 30 second vibration
- Vibration and tone repeat every 15 minutes until acknowledged.

#### What to do:

1. Tap **OK** to acknowledge or silence the alarm.

**Note:** Depending on the cause of this error, the Controller may restart after you tap **OK**. Whether or not that happens, continue with the following steps.

2. Check your blood glucose.

#### **Lock Screen:**





# ▲ Omnipod 5 Memory Corruption

#### **Screen Alert** Description Omnipod 5 App: Why it occurs: An unexpected error is detected in the Omnipod 5 App. Pod sound: None Omnipod 5 App memory corruption Controller/Smartphone sound and vibration: • 30 second tone • 30 second vibration Your Pod is no longer connected to Vibration and tone repeat every the ago, Remove Pod now. 15 minutes until acknowledged Tap **GK** to reset the app and delete all user settings. What to do: 1. Tap **OK** to acknowledge the alarm and reset the Omnipod 5 App. 2. Remove your Pod. Lock Screen: 3. Check your blood glucose. ▲ Granged S. Natifications | 12:25 PM ~ Omnipod 5 App memory corruption Remove Pod now. Check the Omnipod 5 App.



#### A Pod Error

**Screen Alert** 

**Caution:** ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to hyperglycemia. If another Pod is not available, use a different insulin delivery method.

# Pod Error Insulin delivery stopped. Change Pod now. Ref: 41-202-RF20-12T23 OK, DEACTIVATE POD NOW

# Description

Why it occurs: The Pod detects an unexpected error and insulin delivery has stopped.

Pod sound: Continuous tone

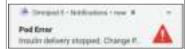
# Controller/Smartphone sound and vibration:

- 30 second tone
- 30 second vibration
- Vibration and tone repeat every 15 minutes until acknowledged.

#### What to do:

- 1. Tap **OK, DEACTIVATE POD NOW**.
- 2. Change your Pod.
- 3. Check your blood glucose.

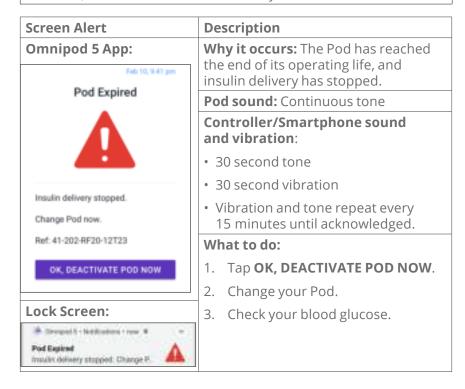
#### **Lock Screen:**





# A Pod Expired

**Caution:** ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to hyperglycemia. If another Pod is not available, use a different insulin delivery method.





#### A Pod Out of Insulin

**Caution:** ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to hyperglycemia. If another Pod is not available, use a different insulin delivery method.

# Pod empty, no insulin left in Pod. Insulin delivery stopped. Change Pod now.

# Description Why it occur

Why it occurs: The Pod's insulin reservoir is empty, and insulin delivery has stopped.

Pod sound: Continuous tone

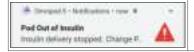
# Controller/Smartphone sound and vibration:

- 30 second tone
- 30 second vibration
- Vibration and tone repeat every 15 minutes until acknowledged.

#### What to do:

- 1. Tap **OK, DEACTIVATE POD NOW**.
- Change your Pod.
- 3. Check your blood glucose.

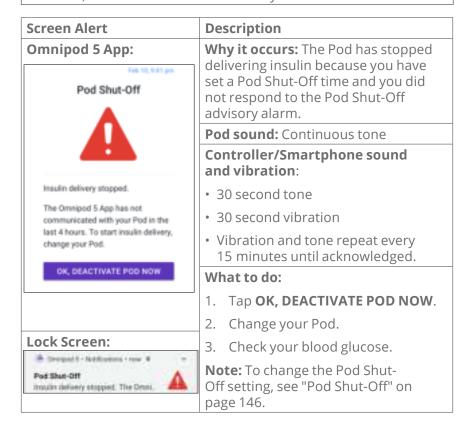
#### **Lock Screen:**





#### A Pod Shut-Off

**Caution:** ALWAYS activate a new Pod in a timely manner. Waiting too long between Pod changes could result in under-delivery of insulin which can lead to hyperglycemia. If another Pod is not available, use a different insulin delivery method.

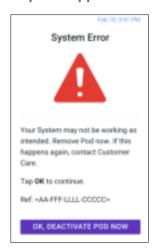




#### **▲** System Error

#### Omnipod 5 App:

**Screen Alert** 



#### **Lock Screen:**



#### Description

Why it occurs: An unexpected error is detected in the Pod or the Omnipod 5 App.

Pod sound: None

#### Controller/Smartphone sound and vibration:

- 30 second tone
- · 30 second vibration
- Vibration and tone repeat every 15 minutes until acknowledged.

#### What to do:

- 1. Tap **OK** to acknowledge the alarm.
- 2. Remove your Pod.
- 3. Check your blood glucose.



#### 13.6 Advisory Alarm List

**Caution:** ALWAYS respond to Pod Expired, Low Pod Insulin, and Pod Shut-Off Advisory Alarms when they occur. These alarms escalate to Hazard Alarms if no action is taken. When Hazard Alarms occur, insulin delivery stops.

Advisory alarms inform you of a situation that needs your attention in the near future.

#### Low Pod Insulin

#### Screen Alert Description Omnipod 5 App: Why it occurs: The amount of insulin in the Pod is below the value Aug 10, 9:41 pm specified in your settings. Low Pod Insulin Pod sound: 8 beep tone pattern Tone pattern sounds once every 3 minutes for 60 minutes. Controller/Smartphone sound and vibration: 4 U insulin or less remain in the Pod. Change Pod soon. 3 second tone OΚ · 3 second vibration Vibration and tone repeat every 15 minutes until acknowledged... What to do: Lock Screen: 1. Tap **OK**. Law Fest Insulin All books or been record to Prof. Thinks 2. Change your Pod. **Note:** This escalates to the Pod Out of Insulin hazard alarm

**Note:** This escalates to the Pod Out of Insulin hazard alarm if ignored.

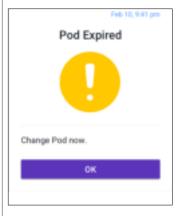
Note: To change this value, see "Low Pod Insulin" on page 146.



#### Pod Expired

## Screen Alert

#### Omnipod 5 App:



#### **Description**

Why it occurs: Your Pod will stop delivering insulin soon.

#### Pod sound:

- · 8 beep tone
- Tone issued once every 60 minutes starting after 72 hours of Pod life.
- After 79 hours of Pod life, tone is issued once every 5 minutes.

## Controller/Smartphone sound and vibration:

- · 3 second tone
- 3 second vibration
- Vibration and tone repeat every 15 minutes until acknowledged.

#### What to do:

1. Tap **OK**.

2. Change your Pod.

#### **Lock Screen:**

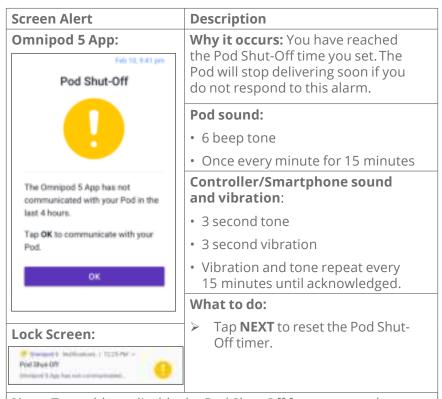


**Note:** After acknowledgment or if ignored, the alarm will repeat when there is 1 hour left of Pod life.

**Note:** This escalates to the Pod Expired hazard alarm if ignored.



#### Pod Shut-Off



**Note:** To enable or disable the Pod Shut-Off feature or to change the countdown period, see "Pod Shut-Off" on page 146.



#### Start Insulin

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

# Screen Alert Omnipod 5 App: Feb 10,9:41 pm Start Insulin Do you want to start insulin delivery with the «Basal Program Name» Basal Program? The insulin pause period has ended. START INSULIN REMIND ME IN 15 MIN

#### Description

Why it occurs: The time period that you specified to pause insulin has passed. If you do not start insulin delivery, you could develop hyperglycemia.

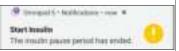
#### Pod sound:

- 8 beep tone
- Tone sounds once every minute for 3 minutes.
- Repeats every 15 minutes until acknowledged.

## Controller/Smartphone sound and vibration:

- 3 second tone
- 3 second vibration
- Vibration and tone repeat every 15 minutes until acknowledged

#### Lock Screen:



#### What to do:

Do one of the following:

- If you want to start insulin with the Basal Program, tap **START INSULIN**.
- If you want to keep insulin paused, tap REMIND ME IN 15 MIN.



#### Urgent Low Glucose

**Warning:** ALWAYS promptly treat low glucose. Glucose at or below 55 mg/dL indicates significant hypoglycemia (very low glucose). If left untreated, this could lead to seizure, loss of consciousness or death. Follow your healthcare provider's recommendations for treatment.

#### Screen Alert **Description Omnipod 5 App:** Why it occurs: Your glucose is at or below 55 mg/dL, according Am 10, but and to what your Sensor sent to the Urgent Low Glucose Omnipod 5 App. Pod sound: 4 beep tone Repeats every 5 minutes that sensor glucose value is urgently low. Controller/Smartphone sound and vibration: 3 second tone 3 second vibration Vibration and tone repeat every 15 minutes until acknowledged. What to do: Lock Screen: @ Omniped 5 - Notifications - now W Tap **OK** to acknowledge the alarm. **Urgent Low Glucose**

**Note:** This Advisory Alarm will only stop repeating after a glucose value of 56 mg/dL or greater is received. You may silence this Advisory Alarm for 30 minutes by acknowledging the on-screen message.

**Note:** After the initial Advisory Alarm is acknowledged, the Advisory Alarm will occur again if sensor glucose values are still below 55 mg/dL after 30 minutes.

**Note:** Use a blood glucose meter to confirm your blood glucose reading. Treat low glucose as needed.

**Note:** The Urgent Low Glucose Advisory Alarm has to do directly with your body's current glucose, while other alarms have to do with the Pod or Omnipod 5 App state.



#### 13.7 Action Item Notification List

Action Item notifications are technical System tasks that need your attention.

#### App Use Blocked

Warning: You will NOT be able to use the Omnipod 5 App if:

- You have not installed a required update to the Omnipod 5 App.
- An update for the Omnipod 5 App is not yet available to fix a known issue.
- Your smartphone device is no longer compatible with use of the Omnipod 5 App.
- The operating system of your smartphone has not yet been tested for safety by Insulet.

Use the Insulet-provided Controller or a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery could result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.



#### **Screen Alert**

#### **Omnipod 5 App:**

#### App use blocked



Due to a software issue, the Omnipod 5 App cannot be used. Use a different insulin delivery method until an update is available.

Check the app frequently for updates.

DEACTIVATE POD

#### **Description**

Why it occurs: The installed version of the Omnipod 5 App is no longer supported for use. You will not be able to use the app until an update becomes available.

This message may appear whether you have an active Pod or not.

#### Pod sound: None

### Controller/Smartphone sound and vibration:

- 3 second tone
- · 3 second vibration
- · No repetition

#### What to do:

- 1. If you have an active Pod, tap **DEACTIVATE POD**. (This option only appears if you have an active Pod.)
- Check your Omnipod 5 App for available update notifications frequently. When you see a notification for an available App update, follow the instructions to install the update.



#### Attention

#### **Screen Alert** Description Omnipod 5 App: Why it occurs: Your smartphone's operating system has not been completely tested for use with the Attention Omnipod 5 System. Pod sound: None Smartphone sound and vibration: 3 second tone 3 second vibration Recent updates to your device's operating system have not been No repetition tested with the Omnipod 5 App. Some areas may not work as What to do: expected. Тар **ОК**. This notification will display once per day until testing is complete. You may continue using the Omnipod 5 App on your device, as essential functions should not be affected. The notification will display once per day until testing is complete. If you notice any unexpected effects on your screen or otherwise have concerns about the way your Omnipod 5 System is working, contact Customer Care. For a list of compatible operating systems, go to https://www.omnipod. com/compatibility



#### Connect to a Wireless Network

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

## Screen Alert Omnipod 5 App: Connect to a wireless network You need network connectivity to download the latest app. Move to an area with a better signal, or connect No repetition WI-FI SETTINGS What to do:

#### Description

Why it occurs: Your Omnipod 5 App has not connected to Insulet's network for 7 or more days.

#### Pod sound: None

#### Controller/Smartphone sound and vibration:

- 3 second tone
- 3 second vibration

Tap WI-FI SETTINGS when prompted. Connect to a Wi-Fi network.

**Tip:** When you are connected to a network, your Omnipod 5 App is notified about software updates when you need them.

**Tip:** If Wi-Fi is not available, move to an area with a better cellular signal.

**Note:** The SIM Card on your Omnipod 5 Controller enables data to be sent and received via the AT&T wireless network when your Controller is not connected to a Wi-Fi network. If you stop using the Omnipod 5 App over a cellular network on your Controller, Insulet may deactivate the SIM Card.

**Note:** Please note that the Controller is still functional using Wi-Fi. If you return to using the Omnipod 5 App on your Controller after a significant period of time, please contact Customer Care to request SIM card reactivation for full coverage via both cellular network and Wi-Fi. Upon request, the SIM card is reactivated.



#### Daylight Saving Time Change

**Caution:** ALWAYS be aware of possible changes to your time zone when traveling. If you do not update your time zone, your insulin therapy will be delivered based on your old time zone which may cause disruptions in your insulin delivery schedule and inaccurate history logs. Talk to your healthcare provider about how to manage your insulin delivery while traveling between time zones.

## Daylight saving time change Daylight saving time change has been detected. Update insulin delivery to use the new time (7:35 pm)?

Screen Alert

#### **Description**

Why it occurs: The Omnipod 5 App has detected that Daylight Saving Time has started or ended.

#### Pod sound: None

### Controller/Smartphone sound and vibration:

- 3 second tone
- 3 second vibration
- No repetition

#### What to do:

Tap **UPDATE** to update your insulin delivery time.

#### Or:

Tap NOT NOW to continue using your current insulin delivery time.

**Note:** Correct time is essential for correct insulin delivery and history records. If you tap **NOT NOW**, you can find this Action Item notification at **Menu button** ( ) > **Notifications** and every 24 hours you will be reminded to update.



#### Device Has Been Modified

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

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

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

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

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

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



#### **Screen Alert**

#### Omnipod 5 App:

#### Device has been modified



This device does not match the manufacturer configuration. It cannot be used with Omnipod 5.

If you have an active Pod, remove it now.

#### **Description**

**Why it occurs:** You have modified your device and it is not safe to use with the Omnipod 5 App.

Pod sound: None

## Controller/Smartphone sound and vibration:

- 3 second tone
- 3 second vibration
- No repetition

#### What to do:

- 1. Remove your Pod if you have an active Pod.
- 2. Return your device to the unmodified configuration to continue using Omnipod 5.



#### Device Not Compatible

Warning: You will NOT be able to use the Omnipod 5 App if:

- You have not installed a required update to the Omnipod 5 App.
- An update for the Omnipod 5 App is not yet available to fix a known issue.
- Your smartphone device is no longer compatible with use of the Omnipod 5 App.
- The operating system of your smartphone has not yet been tested for safety by Insulet.

Use the Insulet-provided Controller or a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery could result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

**Note:** If you get this message while using the Controller, contact Customer Care.

#### Screen Alert Description Why it occurs: Your smartphone is Omnipod 5 App: incompatible with the Omnipod 5 Device not compatible System, and an update will not fix the problem. Pod sound: None Smartphone sound and vibration: 3 second tone 3 second vibration This Omnipod 5 App is not compatible with this device. No repetition What to do: DEACTIVATE POD 1. If you have an active Pod, tap **DEACTIVATE POD.** (This option only appears if you have an active Pod.) 2. Find out if your smartphone is on the compatible device list here: https://www.omnipod.com/ compatibility



#### Not Enough Storage

Notification again.

#### **Screen Alert Description** Omnipod 5 App: Why it occurs: You do not have enough available storage for the Omnipod 5 App to run on your Not enough storage smartphone. Your smartphone must have enough storage space for the Omnipod 5 App to work and save important information about your insulin therapy. Pod sound: None Your device must have at least 150 MB of available storage to use Controller/Smartphone sound the Omnipod 5 App. and vibration: You can free up space in Storage. 3 second tone 3 second vibration STORAGE No repetition What to do: 1. Tap **STORAGE** when prompted. 2. Clear up storage by deleting files such as photos and videos, or by deleting other apps that you are not using. **Note:** If you do not delete enough files, you will see this Action Item



#### Omnipod 5 Error

#### **Screen Alert** Description Omnipod 5 App: Why it occurs: Your Omnipod 5 App has encountered a problem. Omnipod 5 error Pod sound: None Controller/Smartphone sound and vibration: 3 second tone 3 second vibration Restart your device. If problem No repetition persists, contact Customer Care. What to do: 1-800-591-3455 1. Tap **RESTART** to restart Ref: AA-FFF-LLLL-CCCCC your device. RESTART

#### **OS Not Compatible**

Warning: You will NOT be able to use the Omnipod 5 App if:

- You have not installed a required update to the Omnipod 5 App.
- An update for the Omnipod 5 App is not yet available to fix a known issue.
- Your smartphone device is no longer compatible with use of the Omnipod 5 App.
- The operating system of your smartphone has not yet been tested for safety by Insulet.

Use the Insulet-provided Controller or a different insulin delivery method. Failure to deactivate your Pod and use another form of insulin delivery can result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.



#### **Screen Alert Description Omnipod 5 App:** Why it occurs: The Omnipod 5 App cannot be used on your device's current operating system (OS). You will Software version not not be able to use the app until you supported update the operating system of your smartphone. This message may appear whether you have an active Pod or not. Pod sound: None Go to your phone settings and Controller/Smartphone sound upgrade to your phone's newest and vibration: software version. If you still cannot use your 3 second tone Omnipod 5 App, use your Insuletprovided Controller or a different 3 second vibration insulin delivery method. If you have questions, contact No repetition Customer Care. What to do: DEACTIVATE POD 1. If you have an active Pod, tap **DEACTIVATE POD.** 2. Update your smartphone to the latest operating system. For a list of compatible operating systems, go to https://www.

omnipod.com/compatibility



#### Stop Optimizing Battery Usage

#### **Screen Alert** Description Omnipod 5 App: **Why it occurs:** Battery optimization is an Android setting that limits what apps can do in the background in order Stop optimizing battery usage to save battery life. You have turned ON battery optimization for the Omnipod 5 App on your smartphone. Battery optimization must be turned OFF in order for your Omnipod 5 App to communicate with the Battery optimization limits the Pod every 5 minutes. Your Pod Omnipod 5 App's frequency of communication with the Pod. Tap continues to deliver insulin Allow on the next screen to stop according to its program. optimization. Pod sound: None oκ Smartphone sound and vibration: 3 second tone 3 second vibration No repetition What to do: 1. Tap **OK** after reading the message. 2. Tap **ALLOW** when prompted to stop battery optimization.

**Note:** You cannot navigate within the Omnipod 5 App until you tap **ALLOW**.

**Note:** You will not be able to use the Omnipod 5 App until you stop battery optimization for the Omnipod 5 App.



#### Turn Bluetooth ON

Screen Alert	Description	
Omnipod 5 App:	Why it occurs: Bluetooth is	
Turn Bluetooth ON	turned OFF on your smartphone. Your Omnipod 5 App and Pod communicate via Bluetooth so Bluetooth must be turned ON.	
	Pod sound: None	
	Smartphone sound and vibration:	
The Omnipod 5 App needs Bluetooth to communicate with your Pod.  TURN ON	• 3 second tone	
	3 second vibration	
	No repetition	
	What to do:	
	> Tap <b>TURN ON</b> when prompted.	



#### Turn Do Not Disturb Access ON

#### 

#### Description

**Why it occurs:** Do Not Disturb access for the Omnipod 5 has been turned off.

#### Pod sound: None

#### Smartphone sound and vibration:

- 3 second tone
- 3 second vibration
- No repetition

#### What to do:

- 1. Tap **NEXT** and you will be directed to the Android list of applications.
- 2. Find the Omnipod 5 App.
- 3. Turn on Do Not Disturb Permission for the Omnipod 5 App.
- 4. Press the back button to return.

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



#### Turn Lock Screen Security ON

## Screen Alert Omnipod 5 App: Turn Lock Screen Security ON You need to set up lock screen security to use the Omnipod 5 App.

#### **Description**

**Why it occurs:** Your lock screen security has been turned OFF.

Pod sound: None

#### Smartphone sound and vibration:

- 3 second tone
- 3 second vibration
- No repetition

#### What to do:

- 1. Tap **SET UP**.
- 2. Enable your passcode or another security method.

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

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

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

Omnipod 5 Security cannot be turned off.



#### Turn ON Automatic Date and Time

#### **Screen Alert** Description Omnipod 5 App: Why it occurs: You have turned OFF Automatic Date and Time in your smartphone settings. The Turn ON Automatic date Omnipod 5 App has many therapyand time related actions that depend on time. Automatic Date and Time is a setting on your smartphone that ensures the accuracy of your time. The Omnipod 5 App uses the setting to detect if you have traveled to a different time zone. Automatic date and time on your Pod sound: None device must be set to ON to use the Omnipod 5 App. Smartphone sound and vibration: 3 second tone 3 second vibration No repetition What to do: 1. Tap **OK.** You will be taken to the Android "Date and Time" screen. 2. Tap **Automatic date and time** to turn it ON. The toggle will turn blue if it is ON.



#### Turn Notifications ON

#### **Screen Alert** Description Omnipod 5 App: Why it occurs: You have turned OFF any of the following: Turn Notifications ON Show notifications, Hazard & Advisory Alarms, or Action Item Notifications. Omnipod 5 System notifications should be turned ON in your smartphone settings so that you get important information regarding your To use the Omnipod 5 App, turn insulin therapy and alarms. Notifications on. Notifications alert Pod sound: None you when an issue needs your attention. Controller/Smartphone sound and vibration: TURN ON 3 second tone 3 second vibration No repetition What to do: 1. Tap **TURN ON** when prompted. You see the Android "App Notifications" screen. 2. Tap **Show notifications** to turn Omnipod 5 App notifications ON.

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



#### Update Omnipod 5 - App No Longer Supported

**Caution:** ALWAYS make sure your battery has adequate charge prior to installing a software update.

#### Screen Alert **Description** Omnipod 5 App: Why it occurs: The Omnipod 5 App version you are currently using is obsolete and no longer supported. Update Omnipod 5 Pod sound: None Controller/Smartphone sound and vibration: · 3 second tone 3 second vibration Your version of Omnipod 5 App is no longer supported. No repetition Update to the latest version of the What to do: Omnipod 5 App. 1. Tap **UPDATE NOW.** (This will not affect insulin delivery.) Your battery power must be above UPDATE NOW 15% before updating. 2. If you do not have enough battery power, charge your battery before continuing. You will see that the update is in progress. 3. When you see the message that the update was successful, tap **OK**. **Note:** If the update is critical (required), you will not have the

option to dismiss the notification. If you tap **NOT NOW**, you can find this Action Item notification at **Menu button** ( ) >

Notifications.



#### Update Omnipod 5 - Software Update

**Caution:** ALWAYS make sure your battery has adequate charge prior to installing a software update.

#### **Screen Alert Description** Why it occurs: An Omnipod 5 App Omnipod 5 App: software update is available. Update Omnipod® 5 Pod sound: None Controller/Smartphone sound and vibration: 3 second tone · 3 second vibration Update to the latest version of the No repetition Omnipod® 5 app. What to do: (This will not affect insulin delivery.) 1. Tap **UPDATE NOW**. UPDATE NOW Your battery power must be above 15% before updating. 2. If you do not have enough battery power, charge your battery before continuing. 3. When you see the message that the update was successful, tap **OK**.

**Note:** If the update is critical (required), you will not have the option to dismiss the notification. If you tap **NOT NOW**, you can find this Action Item notification at **Menu button** ( ) > **Notifications**.



#### Update OS

Screen Alert	De	scription		
Omnipod 5 App:		ny it occurs: An operating system date is available for your Controller.		
Update OS	Pod sound: None			
TI I	Со	ntroller sound and vibration:		
	• 3	3 second tone		
	3 second vibration			
	• 1	No repetition		
Update to the latest version of the operating system.	WI	What to do:		
(This will not affect insulin delivery.)  UPDATE NOW	1.	Tap <b>UPDATE NOW</b>		
		Your battery power must be above 40%, or be above 20% and charging, before updating.		
	2.	If you do not have enough battery power, charge your battery before continuing.		
	3.	When you see the message that the update was successful, tap <b>OK</b> .		

**Note:** If the update is critical (required), you will not have the option to dismiss the notification. If you tap **NOT NOW**, you can find this Action Item notification at **Menu button (** ) > **Notifications.** 



#### Update Time Zone

**Caution:** ALWAYS be aware of possible changes to your time zone when traveling. If you do not update your time zone, your insulin therapy will be delivered based on your old time zone which may cause disruptions in your insulin delivery schedule and inaccurate history logs. Talk to your healthcare provider about how to manage your insulin delivery while traveling between time zones.

#### Screen Alert Description **Omnipod 5 App:** Why it occurs: Your Controller or smartphone time zone does not match the Omnipod 5 App insulin Update time zone delivery time zone. Pod sound: None Controller/Smartphone sound and vibration: 3 second tone Your device time zone: 3 second vibration Los Angeles (4:30 pm) No repetition Your insulin delivery time zone: New York (7:30 pm) What to do: Update insulin delivery to your device 1. Tap **UPDATE** when prompted time zone? to update your insulin delivery time zone. UPDATE If you are in Automated NOT NOW Mode, follow the on-screen instructions to switch to Manual Mode and pause insulin delivery. 3. After the time zone is updated, you may start insulin delivery and return to Automated Mode.

**Note:** Correct time is essential for correct insulin delivery and history records. If you tap **NOT NOW**, you can find this Action Item notification at **Menu button ( ≡ ) > Notifications** and every 24 hours you will be reminded to update.



#### 13.8 Silencing Unresolved Alarms

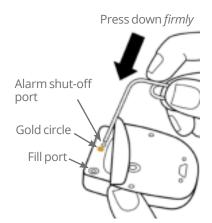
You can silence Pod or Omnipod 5 App alarms by acknowledging the alarm screen displayed on your Omnipod 5 App. If the alarm continues, follow the directions in this section.

#### **Pod Alarm**

**Caution:** Permanently silencing a Pod alarm requires the Pod to be removed from your body. Once removed and discarded, promptly activate a new Pod to avoid going too long without insulin, which could lead to hyperglycemia.

To permanently silence a Pod alarm:

- 1. If the Pod is on your body, remove it.
- 2. Peel back a little bit of the adhesive pad from the bottom of the Pod at the square end (see figure).
- 3. Locate the alarm shut-off port to the right of the gold circle. The alarm shut-off port can be felt with a fingernail or paper clip as soft plastic.
- 4. Firmly press a paper clip or similar item straight down into the alarm shut-off port. You need to apply enough force to break a thin layer of plastic. If an alarm is sounding, the alarm will stop.



#### **Controller Alarm**

If a Controller alarm is not silenced when you acknowledge the alarm:

- 1. Press and hold the Power button, then tap **Power off**.
- 2. Press and hold the Power button to turn the Controller back on.

This action silences the Controller's alarm. Your history records and personal settings are preserved. However, you may have to confirm the time zone.



#### 13.9 Responding to Reminder Notifications

Reminder Notifications remind you about diabetes management actions you may want to perform.

#### Finding out about reminder notifications

To alert you to a notification, the Pod sounds a 3-beep tone, and the Omnipod 5 App either sounds a tone or vibrates (see "13.2 Sounds and Vibrations" on page 174). When you hear a sound or feel a vibration, check your Omnipod 5 App for a message.

**Note:** Program reminders, confidence reminders, and some informational signals do not have an accompanying message.

If your Omnipod 5 App is asleep when you hear or feel a notification, wake it up. The Lock screen shows the reminder notification icon ( and the notification message.

- If there are multiple messages, the most recent message is shown at the top of the list.
- If there are more messages than can be displayed on the Lock screen, a banner beneath the messages shows the number of additional messages.

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

If you are using your Omnipod 5 App when a notification is triggered, the notification message appears at the top of the screen. To remove the message from the screen:

- Do nothing. The message disappears after several seconds and is saved as a new message.
- Swipe up to remove the message immediately and save it as a new message.
- Swipe right to remove the message immediately and save it as an acknowledged message.

#### **Acknowledging reminder notifications**

**Note:** Waking up your Omnipod 5 App and using it does not automatically acknowledge or silence notifications.

All new notifications are included in the Notifications & Alarms count ( ) in the red circle over the notification bell in the upper right of the Home screen.



To acknowledge the notification:

- 1. Wake up your Omnipod 5 App.
- 2. Tap the notification bell icon ( to bring up the Notifications & Alarms screen.
- 3. Scroll down the screen, if necessary, to see any additional notifications with blue icons (6).
- 4. Tap the back arrow ( ) in the upper left of the screen to mark the notifications as acknowledged.

**Note:** Putting the Omnipod 5 Controller to sleep by pressing the Power button does not mark the notifications as acknowledged. You must tap the back arrow ( to acknowledge the notification.

#### 13.10 Reminder Notifications List

Reminder Notifications remind you about various diabetes management actions you may want to perform. Some are automatically generated and others have settings that you control (see "10.2 Reminder Settings" on page 145).

**Tip:** Use the Sound/vibrate button on the right side of the Controller to control whether the notification sounds a tone or vibrates (see "The Sound/vibrate button on your Controller" on page 174).

The reminder notifications are:

#### No Active Pod

Screen Displayed	Omnipod 5 Notifications   T2:25 PM =  No active Pod  Activate a Pod to start insulin delivery.
Cause	Reminds you to activate a new Pod to begin basal insulin delivery.
Pod sound:	None
Controller/ Smartphone sound and vibration:	Repeats once, 15 minutes after initial notification unless acknowledged.
What to do	Unlock the Omnipod 5 App. Activate a new Pod.



#### Pod Expiration

Screen Displayed	Omnipod 5 Nutrications   12:25 PM     Pod Expiration     Pod expires at 1.15 pm, 7/24/21
Cause	Tells you how much time is left before the Pod expiration advisory alarm.
Pod sound:	<ul> <li>8 beep tone</li> <li>Tone issued once every minute for 3 minutes</li> <li>Repeats every 15 minutes until acknowledged</li> </ul>
Controller/ Smartphone sound and vibration:	Repeats once, 15 minutes after initial notification unless acknowledged.
What to do	Acknowledge the message (see "Acknowledging reminder notifications" on page 216). Change your Pod.

**Note:** To change the timing of this notification, see "Pod Expiration" on page 146. Both the Pod and the Omnipod 5 App sound the notification.



#### **CHAPTER 14**

## Taking Care of Your Controller and Pod

#### **Contents**

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#### 14 Taking Care of Your Controller and Pod

**Warning:** DO NOT expose any Omnipod 5 System products or supplies to extreme temperatures as this results in them not functioning properly. Store all Omnipod 5 System products and supplies, including unopened Pods, in a cool, dry place.

The Omnipod 5 Automated Insulin Delivery System has no user-serviceable parts. If you require assistance operating or maintaining the Omnipod 5 System, contact Customer Care.

#### 14.1 Pod and Insulin Storage and Care

This section describes proper care of your Pod.

#### **Pod and Insulin Storage**

Extreme heat or cold can damage Pods and cause them to malfunction.

It is especially important to store your insulin in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discolored. Insulin that is cloudy or discolored may be old, contaminated, or inactive. Check the insulin manufacturer's instructions for use and the insulin's expiration date.

#### **Pods and the Environment**

#### Avoid extreme temperatures

**Warning:** DO NOT expose a Pod to direct sunlight for long periods of time. Remove your Pod prior to using hot tubs, whirlpools, or saunas. These conditions could expose the Pod to extreme temperatures and may also affect the insulin inside the Pod which could lead to hyperglycemia.

The Pod's operating temperature has been tested and found to operate safely between 41°F and 104°F (between 5°C and 40°C). Under normal circumstances, your body temperature keeps the Pod within a range of 73°F and 98.6°F (23°C and 37°C).

**Caution:** NEVER use a blow dryer or hot air to dry the Controller or Pod. Extreme heat can damage the electronics.



#### Taking Care of Your Controller and Pod 14

If you remove your Pod to avoid exposing it to extreme temperatures, remember to check your glucose frequently.

**Note:** Check with your healthcare provider for guidelines if you plan on not using a Pod for extended periods.

**Note:** Check the labeling for your rapid-acting insulin, as maximum insulin exposure temperatures may vary between insulins.

#### Water and your Pod

**Warning:** DO NOT expose your Pod to water at depths greater than 25 feet (7.6 meters) or for longer than 60 minutes because damage to the Pod can occur. This could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

The Pod is waterproof up to a depth of 25 feet (7.6 meters) for up to 60 minutes (IP28). After swimming or similar exposure to water, rinse off the Pod with clean water and gently dry it with a towel.

#### **Cleaning Your Pod**

Pods are waterproof. If you need to clean a Pod, gently wash it with a clean, damp cloth, or you can use mild soap and water. However, do not use strong detergents or solvents, as they can damage the Pod's casing or irritate the infusion site.

**Caution:** Use caution while cleaning the Pod on your body. Hold the Pod securely so the cannula does not kink and the Pod does not detach from your skin.



#### 14.2 Controller Storage and Care

When you are not using your Controller, store it in a convenient, nearby location that is cool and dry.

**Caution:** ALWAYS keep your Controller safe and within your control to ensure others cannot make changes to your insulin therapy. Do not share your Controller screen lock security with anyone.

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

#### Long term storage of your Controller

If you are not going to use your Controller for an extended period of time, allow your battery to reach approximately 50% to 60% charge. Then press and hold the Power button to turn the Controller OFF.

#### Your Controller and the Environment

#### Avoid extreme temperatures

Extrem operating temperatures can affect the Controller battery and interfere with Omnipod 5 System operation. Avoid using the Controller in temperatures below 41°F (5°C) or above 104°F (40°C).

**Caution:** DO NOT expose your Controller to extreme temperatures while in storage or during use. Extreme heat or cold can cause the Controller to malfunction. Extreme heat is defined as >86°F(30°C) during storage and >104°F(40°C) during use. Extreme cold is defined as <32°F(0°C) during storage and < 41°F(5°C) during use.



#### Taking Care of Your Controller and Pod 14

#### Water and your Controller

**Caution:** DO NOT place the Controller in or near water because the Controller is not waterproof. Failure to do so may result in damage to the Controller.

#### If the Controller gets wet:

1. Dry the outside of the Controller with a clean, lint-free cloth.

**Caution:** NEVER use a blow dryer or hot air to dry the Controller or Pod. Extreme heat can damage the electronics.

- 2. Afterthe Controller has thoroughly air-dried, turn ON the Controller to see if it is working.
- 3. If the Controller is not working, contact Customer Care.

#### **Electrical interference**

The Controller and Pod are designed to withstand normal radio interference and electromagnetic fields, including airport security and cellular phones. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. In most cases, interruptions are easy to resolve by moving to a new location (for more information, see "27.5 Pod Communication Issues – "Try Again"" on page 458).

#### USB charging cable and adapter

**Caution:** Use ONLY the USB charging cable and adapter that you received in the box with your Controller. AVOID using alternative charging cables or other accessories, as they may damage the Controller or affect the way it charges in the future. If you must use a different cable, use only cables less than or equal to 4 feet (1.2 meters) in length.

**Note:** You can use the Controller while it is charging.



#### 14 Taking Care of Your Controller and Pod

#### **Cleaning Your Controller**

Always keep your Controller USB port free of debris and liquids. Dirt, dust, and liquids can impair the functionality of your Controller or damage it.

Use compressed air to clean any dust. Never blow in the port with your mouth.

**Caution:** DO NOT use solvents to clean your Controller. DO NOT immerse your Controller in water as it is not waterproof. The use of solvents or immersion in water could cause the Controller to malfunction.

To clean your Controller:

- 1. Press the Power button briefly to put your Controller to sleep.
- 2. Wipe the outer surface of the Controller with a damp, lint-free cloth. If necessary, use a solution of a mild detergent mixed in warm water on the cloth.
- 3. Dry the outer surface with a dry, lint-free cloth.

**Caution:** DO NOT allow debris or liquid to get into the USB port, speaker, sound/vibrate button, or Power button while cleaning the Controller. Failure to do so may result in damage to the Controller.

Every time you clean your Controller, examine the entire Controller for discoloration, cracks, or separations. Also, check for deteriorating performance, such as illegible messages, button malfunction, or repeated communication failures. If you notice any signs of deterioration, stop using the Controller. Contact Customer Care if you have questions.

#### If You Drop the Controller

Shock or a severe impact can damage your Controller. If you drop the Controller or if it is otherwise subjected to severe impact:

- 1. Inspect the outside of the Controller for visible signs of damage.
- 2. If the Controller has turned off, press and hold the Power button to see whether the Controller turns on and the Lock screen appears.



**Caution:** Do not use the Controller if it appears damaged or is not working as it should. Do not use the Controller if its screen is broken.

#### 14.3 Controller Battery Care

The provided Controller uses a rechargeable lithium polymer battery. The battery cannot be removed from your Controller. If there is a problem with your battery or charging cable and adapter, contact Customer Care.

#### Safe Use of the Controller Battery

**Caution:** DO NOT expose your Controller battery to high heat [> 86°F (> 30°C) during storage and > 104°F (>40°C) during use]. Do not puncture, crush, or apply pressure to your battery. Failure to follow these instructions could result in an explosion, fire, electric shock, damage to the Controller or battery, or battery leakage.

To safely use the rechargeable battery:

- Store and charge the Controller in a cool, dry place out of direct sunlight to prolong battery life. Avoid leaving the Controller in a car where temperature extremes can permanently damage the battery
- Your Controller may become warm after prolonged use or when exposed to high temperatures. If your Controller becomes hot to the touch, unplug the USB charging cable and adapter if it is plugged in, and avoid touching or holding the Controller. Place it in a cool location and allow it to cool down to room temperature
- Do not expose the charging cable and adapter to liquids, including water, rain, or snow, as this can cause malfunction. If the battery or charging cable and adapter is exposed to liquid, allow it to dry
- Do not place the Controller on or in heating devices, such as microwave ovens, stoves, or radiators. The battery may explode if overheated
- Do not drop the Controller
- Only use an Insulet approved charging cable and adapter to charge your Controller. Using unapproved charging cable and adapters



#### 14 Taking Care of Your Controller and Pod

can cause the battery to explode or damage the Controller and may void the warranty

- If the battery is damaged so that fluid leaks from the battery, do not allow the leaked fluid to make direct contact with your skin or eyes. If this happens, immediately flush your skin or eyes with clean water and consult a doctor
- Inspect your Controller battery charging cable and adapter before each use. If the adapter for the charging cable falls in water or is cracked, do not use it

### **Charging the Controller Battery**

**Caution:** ALWAYS plug in and charge your Controller when you see the low battery message. If the battery charge becomes critically low, the Controller turns itself off, and you will not receive a low battery hazard alarm. Without the use of the Controller, you will not be able to make changes to your insulin delivery, which could result in over-delivery or under-delivery of insulin that can lead to hypoglycemia or hyperglycemia.

Under normal use, the battery should hold its charge for more than one day.

An Omnipod 5 App message alerts you when the battery charge is low. The battery icon in the status bar tracks the remaining charge in the battery (see "3.4 Status Bar" on page 51).

**Note:** Check the charging port and the charging cable for any signs of dust or debris. Use compressed air to clean any dust. Never blow in the port with your mouth.

To charge your Controller:

1. Assemble the charging cable by attaching its wall adapter.

**Caution:** Use ONLY the USB charging cable and adapter that you received in the box with your Controller. AVOID using alternative charging cables or other accessories, as they may damage the Controller or affect the way it charges in the future. If you must use a different cable, use only cables less than or equal to 4 feet (1.2 meters) in length.

2. Plug the charging cable and adapter into an outlet. Select an outlet that you can access easily and unplug the charging cable and adapter from easily when necessary.



#### Taking Care of Your Controller and Pod 14

- 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 charging cable and adapter from the Controller and the wall outlet.

You can charge your battery many times, but all batteries have a limited lifespan. Contact Customer Care if you notice a significant deterioration in the duration of the Controller's battery charge.

**Note:** Charging times can vary depending on the surrounding temperature and the remaining battery level.

**Tip:** Develop a routine to charge the Controller battery at the same time every day. Do not wait for the low battery message.

**Note:** If the Controller battery is critically low and the Controller has turned OFF, your Pod continues to deliver Automated Mode insulin or Manual Mode basal insulin according to the Basal Program in progress or temp basal. If you do not charge your Controller battery, this insulin delivery continues until the Pod expires.

**Note:** The history records stay in memory for 1 year even if the battery power is critically low.



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# CHAPTER 15 Living with Diabetes

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#### 15.1 Infusion Site Checks

**Caution:** ALWAYS check for signs of infection often. 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.

If you see blood in your cannula, check your glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected high glucose, change your Pod.

At least once a day, use the Pod's viewing window to inspect the infusion site. Check the site for:

- Leakage or scent of insulin, which may indicate the cannula has dislodged
- Signs of infection, such as pain, swelling, redness, discharge, or heat

**Tip:** Consider making infusion site checks a part of your daily routine, like showering or brushing your teeth.



#### 15.2 Being Aware of Your Glucose

**Warning:** ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor calibration (for Sensors requiring calibration, if necessary). ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *Technical User Guide*, contact your healthcare provider.

When you routinely view your sensor glucose values and/or check your glucose, you can better identify when you need to make a treatment decision or troubleshoot an issue. If you are not wearing a Sensor, it is advisable to check your blood glucose at least 4–6 times per day (when you wake up, before each meal, and before going to bed).

#### Check your glucose:

- Whenever you feel nauseated or sick
- Before driving a car
- Whenever your glucose has been running unusually high or low
- If you suspect that your glucose is high or low
- · Before, during, and after exercise
- As directed by your healthcare provider

When using a Sensor, if your sensor glucose values are different than what you expect based on how you feel, then check your blood glucose using a BG meter to verify your sensor glucose value's



accuracy. For example, if you feel shaky and sweaty, which usually means your glucose is very low, but your sensor glucose value shows as in your acceptable range, you should confirm by checking with your BG meter.

If your blood glucose readings are verified too low or too high, consider treatment.

A sensor calibration may also be needed if you use a Dexcom Sensor; consult your compatible *Dexcom CGM System Instructions for Use* for more information.

#### 15.3 Traveling and Vacations

It is important that you check your glucose more frequently while you are traveling. Changes in time zones, activity levels, and mealtimes can all affect your glucose.

Proper preparation is important when traveling. The following sections will help you prepare for your travels.

### **Keep Supplies Accessible**

On airplanes, trains, and buses, keep these items with you, rather than checking them:

- Your Controller or your smartphone with the Omnipod 5 App
- Extra Pods
- An emergency kit
- Vials of insulin (cargo area temperatures may affect insulin)
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod 5 System
- Prescriptions for all medications
- Medications and supplies with their original prescription label
   Note: Generic medications may be easier to find than brand names outside your country.
- Snacks and hypoglycemia treatment, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of your physician and of a physician at your final destination



**Note:** For information about the recommended glucose sensing supplies to carry, see the *Instructions for Use* for your compatible glucose Sensor

**Note:** Keep your emergency kit with you during trips or vacations (see "Emergency Kit" on page 17). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

**Tip:** When you travel outside the country or for long periods of time, be sure to take extra Pod supplies. Prior to departure, contact Customer Care to inquire about additional Omnipod 5 System supplies for your trip.

#### **Plan for Changing Time Zones**

If you're planning a vacation or business trip to a different time zone, you may need to adjust Basal Programs that you would typically follow while in Manual Mode. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct Basal Program can be more challenging. Your healthcare provider can help with these adjustments.

### **Airports and Flying**

Before traveling by plane, familiarize yourself with the airport's security procedures and prepare your diabetes supplies for the security process and flight.

### **Airport security**

Prepare for your travel:

- Airport security checks and screening procedures may change, so review the airport website and the TSA website for travel updates before your trip.
- Arrive at the airport 2–3 hours before your flight.
- Have your insulin management supplies easily accessible to ensure that airport security checks run smoothly.

The airport may offer the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. You must request this before the screening process begins. Your medical supplies should be in a separate bag when you approach the security officer.



To prevent contamination or damage to your supplies, you should be asked at the security checkpoint to display, handle, and repack your own supplies during the visual inspection process. Any medication and/or associated supplies that cannot be cleared visually must be submitted for X-ray screening.

If you are concerned about going through the walk-through metal detector, notify the security officer that you're wearing an insulin pump. You should advise the security officer that the insulin pump cannot be removed because it is inserted with a catheter (tubing) under the skin.

Visit the TSA Contact Center if you have any further questions or concerns.

For information about passing glucose sensor equipment through airport X-ray machines, see the *Instructions for Use* for your compatible glucose Sensor.

#### Flying and airplane mode

**Caution:** ALWAYS check your glucose frequently during amusement park rides and flying or other situations where sudden changes or extremes of air pressure, altitude, or gravity may be occurring. Though the Omnipod 5 System is safe to use at atmospheric pressures typically found in airplane cabins during flight, the atmosphere pressure in an airplane cabin can change during flight, which may affect the Pod's insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight take-off and landing, can affect insulin delivery, leading to possible hypoglycemia or injury. If needed, follow your healthcare provider's treatment instructions.

The Omnipod 5 System sends and receives information from the Pod using Bluetooth wireless technology. Before flying, check your airline's policy regarding the use of Personal Medical Electronic Devices that communicate using Bluetooth technology.

If the use of a Personal Medical Electronic Device using Bluetooth technology is allowed, set your Omnipod 5 App to airplane mode while on the airplane (see "Airplane mode" on page 140). The Bluetooth setting remains enabled in the Controller's Airplane Mode so you can communicate with your Pod.

**Note:** The Omnipod 5 System is safe to use at atmospheric pressures typically found in airplane cabins during flight. The Omnipod 5 System can be used at atmospheric pressures as low as 700 hPa, which is lower than the typical pressure in airplane cabins.



# 15.4 Avoiding Lows, Highs, and Diabetic Ketoacidosis

You can avoid most risks related to using the Omnipod 5 System by following the instructions in this *Technical User Guide* and by promptly treating symptoms of hypoglycemia (low glucose), hyperglycemia (high glucose), or diabetic ketoacidosis (DKA) according to your healthcare provider's instructions. The easiest and most reliable way to avoid these conditions is to check your glucose often.

#### **General Precautions**

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme high glucose or low glucose, or if high glucose or low glucose are occurring more often than usual.
- If you have technical problems with your Omnipod 5 System and cannot resolve them, contact Customer Care immediately.

## Hypoglycemia (Low Glucose)

**Warning:** DO NOT wait to treat hypoglycemia (low glucose) or symptoms of hypoglycemia. Even if you cannot check your glucose, waiting to treat symptoms could lead to severe hypoglycemia, which can lead to seizure, loss of consciousness or death.

Hypoglycemia can occur even when a Pod is working properly. Never ignore the signs of low glucose, no matter how mild. If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness. If you suspect that your glucose is low, check your glucose to confirm.



#### Symptoms of hypoglycemia (low glucose)

Never ignore the following symptoms, as they could be signs of hypoglycemia:

- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling in the lips or tongue
- Anxiety

**Tip:** Hypoglycemia unawareness is a condition in which you do not realize when your glucose is low.

**Tip:** Make sure your glucose is at least 100 mg/dL before driving or working with dangerous machinery or equipment. Hypoglycemia may cause you to lose control of a car or dangerous equipment. Also, when you focus intently on a task, you may miss the symptoms of hypoglycemia.

**Tip:** Teach people you trust (like family members and close friends) how to administer glucagon dosage. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.



#### To avoid hypoglycemia (low glucose)

- Work with your healthcare provider to establish individualized Target Glucose settings and guidelines.
- Keep a fast-acting carbohydrate with you at all times to respond quickly to low glucose. Examples of fast-acting carbs are glucose tablets, hard candies, or juice.
- Teach your friends, family members, and colleagues to recognize the signs of hypoglycemia so they can help if you develop hypoglycemia unawareness or a severe adverse reaction.
- Keep a glucagon kit with your emergency supplies. Teach friends and family members how to administer a glucagon dosage in case you have severe hypoglycemia and become unconscious.

Periodically check the expiration date of your glucagon kit to make sure it has not expired.

**Note:** Always carry medical identification (such as an emergency wallet card) and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

Again, frequent glucose checks are the key to avoiding potential problems. Detecting low glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in avoiding low glucose.

Suggested action	
Confirm that the correct Basal Program is active.	
Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.	
Take bolus with food.	
Check blood glucose before giving a meal bolus. If necessary, adjust the bolus.	
Check the bolus size and timing.	
Do not overcorrect for post-meal glucose.	
Check carb intake.	
Consult your healthcare provider for guidance.	



Possible causes of hypoglycemia	Suggested action	
Incorrect Target Glucose level	Consult your healthcare provider about refining these settings as needed.	
or incorrect Correction Factor		
or incorrect IC Ratio		
Prone to severe hypoglycemia	Consult your healthcare provider about hypoglycemia unawareness and about	
or hypoglycemia unawareness	raising Target Glucose.	
Unplanned physical activity	Consult with your healthcare provider about using Temp Basal (Manual Mode) or the Activity feature (Automated Mode).	
	Adjust insulin delivery as instructed by your healthcare provider.	
	Check glucose before, during, and after activity and treat as necessary.	
Prolonged or intense exercise	<b>Note:</b> Effects of exercise can last several hours—even a full day—after activity ends.	
	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal (Manual Mode) or the Activity feature (Automated Mode) to avoid hypoglycemia.	
Low carbobydrata	Check glucose before activity.	
Low carbohydrate intake prior to activity	Consult your healthcare provider for guidance.	
Alsohol consumption	Check glucose frequently, especially before going to bed.	
Alcohol consumption	Consult your healthcare provider for guidance.	



#### To treat hypoglycemia (low glucose)

Any time your glucose is low, treat it immediately according to your healthcare provider's instructions. Your healthcare provider might recommend that you treat hypoglycemia with a different amount of carbs during Automated Mode compared to Manual Mode. Check your glucose every 15 minutes while you are treating to make sure you don't overtreat the condition and cause glucose levels to rise too high. Contact your healthcare provider as needed for guidance.

### Hyperglycemia (High Glucose)

Warning: ALWAYS monitor your glucose and follow your healthcare provider's treatment guidelines when you stop receiving insulin due to a blockage (occlusion). Not taking action promptly could result in under-delivery of insulin which can lead to hyperglycemia or diabetic ketoacidosis (DKA) (see"▲ Blockage Detected" on page 181).

Pods use rapid-acting insulin, which has a shorter duration than long-acting insulin, so you have no long-acting insulin in your body when using the Omnipod 5 System. If a blockage (interruption of insulin delivery from the Pod, or occlusion) occurs, your glucose can rise rapidly.

**Tip:** Hyperglycemia symptoms can be confusing. Always check your glucose before you treat for hyperglycemia.



#### Symptoms of hyperglycemia (high glucose)

Never ignore the following symptoms, as they could be a sign of hyperglycemia:

- Fatigue
- · Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

#### To avoid hyperglycemia (high glucose)

Check your glucose:

- At least 4–6 times a day (when you wake up, before each meal, and before going to bed); unless you are using a continuous glucose monitoring system
- If you feel nauseated or sick
- Before driving a car
- Whenever your glucose has been running unusually high or low
- If you suspect that your glucose is high or low
- · Before, during, and after exercise
- As directed by your healthcare provider



Possible causes of hyperglycemia	Suggested action
Expired insulin or insulin exposed to extreme temperatures	Deactivate and remove the used Pod. Apply a new Pod filled from a new vial of insulin.
Infusion site in or near a scar or mole	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Infortant	Deactivate and remove the used Pod.
Infected infusion site	Apply a new Pod in a different location and consult your healthcare provider.
	Deactivate and remove the used Pod.
Dislodged cannula	Apply a new Pod in a different location.
Distouged curricula	<b>Note:</b> Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.
Empty Dod	Deactivate and remove the used Pod.
Empty Pod	Apply a new Pod in a different location.
Incorrect Basal	Confirm that the correct Basal Program is active.
Program (Manual Mode)	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
	Check carb intake.
Incorrect bolus timing or bolus	Take bolus with or before eating food rather than after.
too small	Check glucose before giving meal bolus. If necessary, adjust bolus.
	Consult your healthcare provider for guidance.
High-protein or	Calculate protein/fat intake and account for it in your bolus timing and bolus type.
high-fat meal	Consult your healthcare provider about using the extended bolus option.
Less activity than usual	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal (Manual Mode).



Possible causes of hyperglycemia	Suggested action
Glucose	Do not exercise when ketones are present.
greater than 250 mg/dL (with ketones present)	<b>Note:</b> Glucose increases with exercise when ketones are present.
before exercise	Consult your healthcare provider for guidance.
Infection or illness	See "Sick Days" on page 244.
or medication change	Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain or menstrual cycle or pregnancy	Consult your healthcare provider for guidance.
Dlockago (oschusion)	Deactivate and remove the used Pod.
Blockage (occlusion)	Apply a new Pod in a different location.

#### To Treat Hyperglycemia (High Glucose)

**Warning:** NEVER drive yourself to the emergency room if you need emergency medical care. Ask a friend or family member to take you to the emergency room or call an ambulance.

Always check your glucose frequently while treating hyperglycemia. You don't want to over-treat the condition and cause your glucose to drop too low.

- 1. Check your glucose. The result will help you to find out how much insulin is needed to return your glucose to your glucose goal.
- 2. If your glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
- 3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
- 4. Check your glucose again after 2 hours.
- 5. If glucose has not decreased, do both of the following:
  - Take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3



- Replace the Pod. Use a new vial of insulin to fill the new Pod. Then contact your healthcare provider for guidance

**Note:** The Omnipod 5 System cannot track insulin that is administered outside of the system. Consult your healthcare provider about how long to wait after manually administering insulin before you start Automated Mode.

6. If you feel nauseated at any point, check for ketones and contact your healthcare provider immediately.

#### **Diabetic Ketoacidosis (DKA)**

**Warning:** DO NOT wait to treat DKA. If left untreated, DKA can quickly lead to breathing difficulties, shock, coma, or death.

Pods use rapid-acting insulin, which has a shorter duration than long-acting insulin, so you have no long-acting insulin in your body when using the Omnipod 5 System. If insulin delivery from the Pod is interrupted (a blockage or occlusion), your glucose can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but preventable—emergency that can occur if high glucose is not resolved, in times of illness, or when there is not enough insulin working in your body.

#### Symptoms of DKA

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your glucose and check for ketones to rule out DKA.



#### To avoid DKA

The easiest and most reliable way to avoid DKA is by checking your glucose at least 4–6 times a day. Routine checks allow you to identify and treat high glucose before DKA develops.

#### To treat DKA

- Once you have begun treatment for high glucose, check for ketones. Check for ketones any time your glucose is 250 mg/dL or above.
- If ketones are negative or trace, continue treating for high glucose.
- If ketones are positive and you are feeling nauseated or ill, immediately contact your healthcare provider for guidance.
- If ketones are positive but you are not feeling nauseated or ill, replace the Pod using a new vial of insulin.
- Check your glucose again after 2 hours. If your glucose has not declined or if your ketone levels have risen or remain elevated, immediately contact your healthcare provider for guidance.

#### 15.5 Handling Special Situations

#### **Sick Days**

Any physical or emotional stress can cause your glucose to rise, and illness is physical stress. Your healthcare provider can help you make a plan for sick days. The following are only general guidelines.

When you are ill, check your glucose more often to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your glucose to rule out DKA (see "To Treat Hyperglycemia (High Glucose)" on page 242).

To handle sick days:

- Treat the underlying illness to promote faster recovery.
- Eat as normally as you can. Your body still needs carbohydrates and insulin for energy.
- Adjust bolus doses, if necessary, to match changes in meals and snacks.
- Always continue your basal insulin, even if you are unable to eat.
   Contact your healthcare provider for suggested basal rate adjustments during sick days.



- Check your glucose every 2 hours and keep careful records of results.
- Check for ketones when your glucose is 250 mg/dL or higher, and/ or when you are feeling ill, as ketones can also be present when glucose is in range during illness.
- Follow your healthcare provider's guidelines for taking additional insulin on sick days.
- Drink plenty of fluids to avoid dehydration.
- Contact your healthcare provider if symptoms persist.

#### **Exercising, Playing Sports, or Working Hard**

Check your glucose before, during, and after exercising, playing sports, or doing unusually hard physical labor.

The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products.

Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

For some contact sports, if the Pod is in a location where it is likely to be knocked off, consider removing the Pod and placing a new one in a more protected location.

Make sure to check your glucose before removing the Pod and after applying a new one. Pods are designed for one-time use. Do not attempt to reapply a Pod that has been removed.

If you will need to remove the Pod for more than one hour, ask your healthcare provider to recommend appropriate guidelines.



#### X-rays, MRIs, and CT Scans

Warning: Device components including the Pod, Dexcom G6 Sensor and Transmitter, Dexcom G7 Sensor, and FreeStyle Libre 2 Plus Sensor may be affected by strong radiation or magnetic fields. Device components must be removed (and the Pod and Sensor should be disposed of) before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan (or any similar test or procedure). In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to X-ray, MRI, or CT, treatment can damage these components. Check with your healthcare provider on Pod removal guidelines.

The Pod and Controller can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

#### **Surgery or Hospitalization**

For scheduled surgeries or hospitalization, you should tell the physician/surgeon or hospital staff about your Pod. It may be necessary to remove it for certain procedures or treatments. Remember to replace the basal insulin that was missed while the Pod was removed. Your healthcare provider can help you prepare for these situations.



#### **SMARTBOLUS CALCULATOR**

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# SmartBolus Calculator Important Safety Information

# SmartBolus Calculator Warnings

Warning: AVOID changing your SmartBolus Calculator settings before consulting with your healthcare provider. Incorrect changes could result in overdelivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia. Settings that impact bolus calculations mainly include: Max Bolus, Minimum Glucose for Calculations, Correct Above, Correction Factor(s), Insulin to Carb (IC) ratio(s), Duration of Insulin Action, and Target Glucose.

Warning: ALWAYS check your glucose frequently when you use the extended bolus function to avoid hypoglycemia or hyperglycemia.

Warning: AVOID entering a blood glucose reading that is older than 10 minutes. If you use a reading older than 10 minutes, the bolus calculator could calculate and recommend an incorrect dose, which could result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

Warning: ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/ or Sensor calibration (for Sensors requiring calibration, if necessary). ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.



#### Important Safety Information

 If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this Technical User Guide, contact your healthcare provider.

Warning: Do NOT use Omnipod 5 System with a Dexcom Sensor if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom sensor glucose values could be falsely elevated and could result in overdelivery of insulin which can lead to severe hypoglycemia.

Warning: DO NOT use the Omnipod 5 System with the FreeStyle Libre 2 Plus Sensor if you are taking more than 1000mg of ascorbic acid (Vitamin C) per day, a substance found in supplements like multivitamins or cold remedies such as Airborne® and Emergen-C®. Taking more than 1000mg of Vitamin C per day may falsely raise your sensor glucose values and result in over-delivery of insulin that could result in severe hypoglycemia.

# SmartBolus Calculator Precautions

Caution: ALWAYS check your glucose prior to delivering a bolus so you are better informed on how much to take. Delivering a bolus without checking your glucose could result in the over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

Caution: DO NOT navigate away from the Omnipod 5 App while you are in the process of making changes to your insulin delivery settings. If you leave the app before you are able to save the setting change and before the app is able to put the setting change into effect, the system will continue to use your last saved settings. As a result, you may continue with therapy settings that you did not intend. If you are unsure about whether your changes were saved, review your settings.

Caution: During the first
12 hours of use of a FreeStyle
Libre 2 Plus Sensor, use a
fingerstick reading from a BG
meter before making treatment
decisions. After the first 12 hours,
you can tap "Use Sensor" to
use the value and trend in the
SmartBolus Calculator.



# CHAPTER 16 Delivering a Bolus

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### 16.1 Delivering a Manual Bolus

In certain situations, you may decide to deliver a manual bolus. A manual bolus is a bolus that you have calculated without the help of the SmartBolus Calculator. You can use manual boluses when the SmartBolus Calculator is temporarily disabled or when you choose not to use the SmartBolus Calculator. Consult your healthcare provider for instructions about how to calculate a bolus.

You can extend some or all of a manual bolus in Manual Mode.

When delivering a manual bolus, the Omnipod 5 System does not adjust the bolus amount based on your glucose value, carbohydrates being consumed, or IOB as it does when the SmartBolus Calculator is used.

**Note:** Any bolus delivered by you will be considered as IOB and may impact automated insulin delivery in Automated Mode. Current glucose values will continue to be considered in Automated Mode and may impact automated insulin delivery.

A bolus cannot be greater than your Maximum Bolus setting. See "Note: The Extended Bolus feature can only be used in Manual Mode. All other therapy settings are used similarly in both Manual and Automated Modes." on page 272.

To deliver a manual bolus:

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

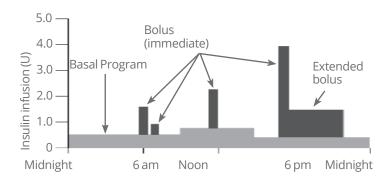
The bolus amount and bolus details are stored in your history records. The Home screen tracks the delivery of an immediate or extended bolus.



### 16.2 Delivering Immediate and Extended Boluses

A bolus is an extra dose of insulin that is delivered in addition to the continuous basal rate of insulin delivery. Use boluses to cover the carbohydrates in a meal and/or bring down a high glucose.

You have the option of delivering the entire bolus at once. This is referred to as an "immediate bolus" or, simply, a "bolus." In Manual Mode, you can also spread out the delivery of all or part of a meal bolus so that it is delivered steadily over a specified period of time. This is referred to as an "extended bolus."



You may want to extend a bolus if your meal contains high-fat or high-protein foods. These foods slow down digestion and therefore slow down the post-meal rise in your glucose.



## 16.3 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.

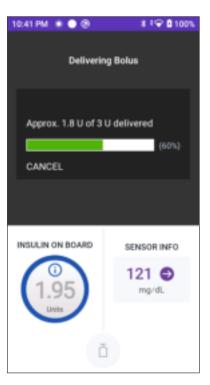
An estimate of the IOB is displayed in the lower left of the screen.

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 a bolus, see "16.4 Canceling a Bolus in Progress" on page 256.





#### **Extended bolus progress**

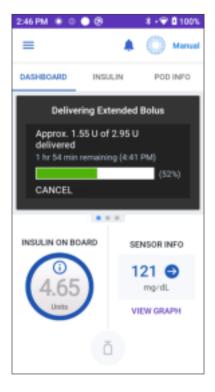
During an extended bolus, the Home screen's **DASHBOARD** tab displays a **Delivering Extended Bolus** message along with a progress bar and other details.

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 still navigate within the Omnipod 5 App during an extended bolus but some functions will be unavailable until the bolus is complete.

Unless you cancel the bolus, the Pod will finish delivering a bolus whether or not it is in range of the Controller or smartphone running your Omnipod 5 App. To cancel a bolus, see "16.4 Canceling a Bolus in Progress" in the next section.





#### 16.4 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 460.

#### Cancel a bolus

To cancel an immediate or extended bolus:

- 1. On the Home screen (immediate bolus) or the Home screen's **DASHBOARD** tab (extended bolus), tap **CANCEL**.
- 2. 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 button** ( ) > **History Detail > Summary.** For more information, see "Immediate and extended boluses" on page 159.

#### Deliver a new bolus before an extended bolus has ended

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

- 1. Cancel the extended bolus as described in the previous procedure, "Cancel a bolus."
- Find out how much insulin was remaining (not delivered) from the canceled bolus. You can find bolus details at Menu button ( )> History Detail> Summary.
- 3. From the Bolus screen, enter the carbs and glucose (or **USE SENSOR**) information.
- 4. Optional: take into consideration the amount remaining from the canceled bolus and add the amount in the Total Bolus field.
- 5. Check if the amount entered in the Total Bolus field is correct. Then tap **CONFIRM**.
- 6. Tap **START**.



## **CHAPTER 17**

# Delivering a Bolus with the SmartBolus Calculator

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#### 17 Delivering a Bolus with the SmartBolus Calculator

#### 17.1 About the SmartBolus Calculator

A bolus is a dose of insulin taken to cover carbohydrates in a meal, drink, or snack (a meal bolus) or to correct elevated glucose (a correction bolus). The SmartBolus Calculator calculates a suggested bolus amount of insulin to bring down high glucose (a correction bolus) and/or to cover carbohydrates in a meal (a meal bolus).

#### Compatible Devices for Use with the SmartBolus Calculator

Device Type	Device Manufacturer	Brand Name
Blood Glucose Meter	All FDA-cleared blood glucose meters	
iCGM	Dexcom	Dexcom G6 Continuous Glucose Monitor
		Dexcom G7 Continuous Glucose Monitor
	Abbott Diabetes Care	FreeStyle Libre 2 Plus Flash Glucose Monitoring System
Alternate Controller Enabled Insulin Pump	Insulet Corporation	Omnipod 5 ACE Pump (Pod)
(Insulin Pump)		
Interoperable Automated Glycemic Controller software	Insulet Corporation	SmartAdjust technology
(Automated Insulin Delivery Software)		



#### **About Correction Boluses and Meal Boluses**

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

Value Entered		Type of Bolus	
Blood Glucose Reading or Sensor Glucose Value Above Target	Carbohydrates	Calculated	
<b>√</b>		Correction bolus	
	V	Meal bolus	
V	<b>√</b>	Combined suggested bolus	

# **About Using a Sensor Glucose Value with Trend**

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

When sensor glucose values are	The SmartBolus Calculator tries to keep glucose 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 SmartBolus 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 SmartBolus Calculator, then enter or use your current values.

To change your personal settings used by the SmartBolus Calculator, see "SmartBolus Calculator Settings" on page 273. To use the SmartBolus 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 a Pod connection. To find out what to do when your Omnipod 5 App and Pod have a communication issue, see "Frequently Asked Questions and Troubleshooting" on page 439.

**Caution:** DO NOT navigate away from the Omnipod 5 App while you are in the process of making changes to your insulin delivery settings. If you leave the app before you are able to save the setting change and before the app is able to put the setting change into effect, the system will continue to use your last saved settings. As a result, you may continue with therapy settings that you did not intend. If you are unsure about whether your changes were saved, review your settings.

**Tip:** If you already know the number of units for the bolus you want to deliver, tap **Total Bolus**. Enter the bolus amount and tap **Done**. Then go to "17.9 Delivering an Immediate Bolus" on page 267.



# 17.2 Entering Meal Information

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

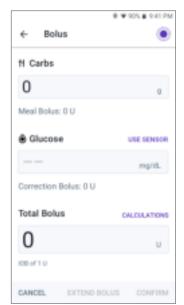
1. On the Home screen, tap the Bolus button ( 1 ).

**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.

2. 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.

**Note:** You can also pull the values in from your Custom Foods. See "Entering Meal Information Using Custom Foods" on page 263



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

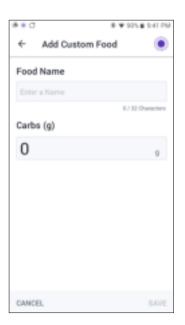


# 17.3 Creating a Custom Food

The SmartBolus Calculator allows you to save carb information for certain favourite foods, snacks or meals (Custom Foods) that you might eat frequently. You can use these carb values in your bolus calculations.

To create a Custom Food:

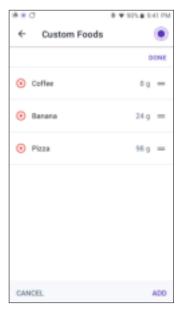
- 1. Tap Menu > Custom Foods.
- 2. Tap ADD.
- 3. Enter a name for your Custom Food.
- 4. Add the total carb count for the entry.
- 5. Tap **SAVE**. You will see a green badge that reads NEW next to your new entry.



# **17.4 Editing Custom Foods**

To edit your list, tap **EDIT** in the upper right-hand corner.

- To move an item up or down in your list, tap and hold the icon to the right of the item and drag the item to your desired location.
- To delete items, tap the (\*\*) icon to the left of the item. Tap YES to confirm that you'd like to delete the Custom Food.
- To edit the name or carb count of the Custom Food, tap the item name. Edit the item details. Tap SAVE.





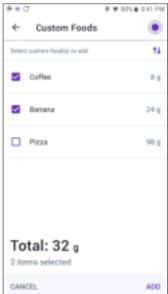
17.5 Entering Meal Information Using Custom Foods

To enter carbs from saved Custom Foods:

- On the Bolus screen, tap Custom Foods in the upper right-hand corner above the Carbs field.
- 2. You will see a list of your Custom Foods.

**Note:** Tapping the up-down arrow button allows you to change how the items are sorted and displayed. You can choose: alphabetically, by recently added, from highest to lowest carbs, or from lowest to highest carbs.

3. Select the button(s) next to the food (or foods) you'd like to select. The total amount of carbs will display at the bottom of the screen.



4. Tap **ADD**. The SmartBolus Calculator screen will appear.



# 17.6 Entering a Blood Glucose Reading or Using a Sensor Glucose Value

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

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

# **Manually Enter Your Blood Glucose Reading**

**Warning:** AVOID entering a blood glucose reading that is older than 10 minutes. If you use a reading older than 10 minutes, the bolus calculator could calculate and recommend an incorrect dose, which could result in over-delivery or under-delivery of insulin. This can lead to hypoglycemia or hyperglycemia.

To enter a blood glucose reading:

- 1. Tap the **Glucose** field.
  - If you have manually entered a blood glucose reading from a meter within the past 10 minutes, that value automatically appears in the Glucose field. If you want the SmartBolus 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.
  - For the meaning of the colors displayed on the Enter Glucose screen, see "How Blood Glucose Readings are Displayed" on page 131.
- 3. Tap **ADD TO CALCULATOR**. The SmartBolus Calculator screen appears.
- Review the suggested correction bolus, which is shown below the blood glucose reading. The correction bolus has been adjusted for any insulin on board (IOB) (see "SmartBolus Calculator Rules" on page 291).



# **Import and Use Sensor Glucose Value**

**Warning:** ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor calibration(for Sensors requiring calibration, if necessary). ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *Technical User Guide*, contact your healthcare provider.

**Caution:** During the first 12 hours of use of a FreeStyle Libre 2 Plus Sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

If a Sensor is connected, you can use the current sensor glucose value and trend in both Manual and Automated Modes:

> Tap **USE SENSOR**.



If the current sensor glucose value is below the defined Minimum Glucose for Calculations setting, you will see a message that the SmartBolus Calculator is disabled. If the sensor glucose value displays "HIGH", the SmartBolus Calculator is temporarily disabled.

**Note:** If your Omnipod 5 System does not have a valid sensor glucose value or trend at the time you open the SmartBolus Calculator, the **USE SENSOR** option is disabled.

**Tip:** If you want to replace the sensor glucose value with a blood glucose reading, tap the Sensor field. See "Manually Enter Your Blood Glucose Reading" on page 264.

# 17.7 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 SmartBolus Calculator considers the 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 "SmartBolus Calculator Rules" on page 291 and "SmartBolus Calculator Equations" on page 289.

In certain circumstances you may decide to enter only carbs or the bolus amount into the SmartBolus Calculator. This may be desired if you want to only bolus for carbs using your programmed insulin to carbohydrate ratio, or you want to deliver an amount of insulin based on your own estimate. If entering only carbs or a bolus amount without a glucose value, IOB is not subtracted from your suggested bolus dose as the calculator is not able to adjust the bolus dose if your glucose value is not known. If you want IOB to be considered, enter a glucose value. Here is an example to demonstrate when you may choose to enter only the carb or bolus amount into the SmartBolus Calculator.

Example: You are about to have lunch and you are unsure of how much you will eat. To avoid taking too much insulin, you deliver a meal and correction bolus based on the carbs you know you will eat and your glucose value. After delivering the bolus and eating the first portion, you decide you want to finish the remaining portion. Since you already delivered a correction with the previous bolus,



and you know glucose values are on the rise, you decide to deliver a second bolus for only the remaining carbs in your meal and not enter another glucose value.

# 17.8 Adjustments to Your Calculation

A suggested meal bolus that is calculated using your Insulin to Carb (IC) Ratio may be further adjusted for other values entered into and used by the SmartBolus Calculator, including: blood glucose readings, sensor glucose value and trend, and/or IOB. 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 Glucose
- · Blood glucose reading, if manually entered
- Sensor glucose value and trend (see "19.5 Sensor Glucose Trend Arrows" on page 307)

# 17.9 Delivering an Immediate Bolus

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

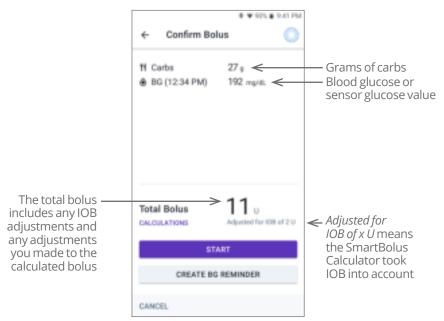
**Note:** The **EXTEND BOLUS** option is available during meal bolus entry when the system is in Manual Mode and the extended bolus setting is ON.

To review and deliver the immediate bolus:

- 1. Review the suggested bolus.
  - > To adjust it, tap 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 "SmartBolus Calculator Equations" on
  page 289 for details.
- 3. To deliver the entire bolus immediately, tap **CONFIRM**.
- 4. Review the bolus details on the Confirm Bolus screen.
- 5. Optional: Set up a reminder to check your glucose:
  - 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.
- 6. Review the bolus details on the Confirm Bolus screen.



7. Tap **START** to begin the bolus.

The Home screen tracks the delivery of an immediate or extended bolus (see "16.3 Tracking the Progress of a Bolus" on page 254).



# 17.10 Delivering an Extended Bolus

**Warning:** ALWAYS check your glucose frequently when you use the extended bolus function to avoid hypoglycemia or hyperglycemia.

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

To review, extend and deliver the bolus:

- 1. Review the suggested bolus.
  - a. To adjust it, tap the **Total Bolus** field and enter a revised bolus.
- 2. 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 "SmartBolus Calculator Equations" on page 289 for details.
- 3. Tap **EXTEND BOLUS**.
- 4. Tap the **Now** field and enter the percentage of the bolus to be delivered 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 extend only the meal portion of the bolus. A correction portion of the bolus, if any, is always delivered immediately.

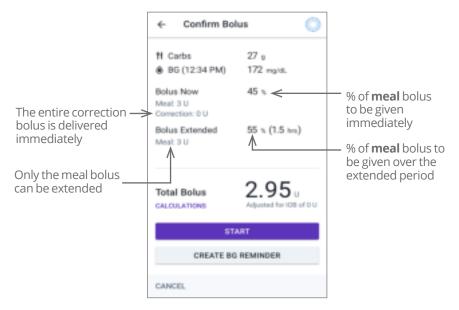
- 5. Tap the **Duration** field and enter the duration for the extended portion of the bolus.
- 6. Tap CONFIRM.

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









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

# 17.11 Bolus Settings

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

These settings allow you to change your Maximum Bolus, extended bolus, and SmartBolus Calculator settings.



# **Impacts to Suggested Bolus Calculations**

The following table describes what each SmartBolus Calculator setting does, how you can adjust them and how they are used to calculate a suggested bolus.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Carbs (grams) 0.1–225 g (0.1 g increments)	Enter in SmartBolus Calculator	Increase in carb amount value increases amount of suggested bolus dose.  Decrease in carb amount value decreases amount of suggested bolus dose.
Sensor Glucose Value (mg/dL) 40–400 mg/dL (1 mg/dL increments)	Select <b>USE SENSOR</b> within SmartBolus Calculator (Value comes from your connected Sensor)	Increase in sensor glucose value increases amount of suggested bolus dose.  Decrease in sensor glucose value decreases amount of suggested bolus dose.
Blood Glucose Reading (mg/dL) 20-600 mg/dL (1 mg/dL increments)	Enter in SmartBolus Calculator (Value comes from your blood glucose meter)	Increase in BG Reading increases amount of suggested bolus dose.  Decrease in BG Reading decreases amount of suggested bolus dose.
Maximum Bolus 0.05–30 U (0.05 U increments)  Extended Bolus (Manual Mode only)	Enter in Omnipod 5 App Settings or during First Time Setup Enter in Omnipod 5 App Settings or during First	Limits amount of single bolus dose.  Allows for bolus delivery over a user-selected period of time.
ON/OFF	Time Setup	period of time.



Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations	
Target Glucose & Correct Above Target Glucose:	Enter in Omnipod 5 App Settings or during First	Increase in setting value decreases amount of suggested bolus dose.	
110–150 mg/dL	Time Setup	Decrease in setting value increases amount	
Correct Above: Target Glucose to 200 mg/dL		of suggested bolus dose.	
(10 mg/dL increments, up to 8 segments/day)			
Minimum Glucose for Calculations	Enter in Omnipod 5 App Settings	Disables SmartBolus Calculator when	
50-70 mg/dL		glucose is at or below setting value.	
(1 mg/dL increments)		0	
Insulin to Carb Ratio	Enter in Omnipod 5	Increase in setting value decreases amount	
1–150 g	App Settings or during First	of suggested bolus dose.	
(0.1 g increments, up to 8 segments/day)	Time Setup	Decrease in setting value increases amount of suggested bolus dose.	
Correction Factor	Enter in Omnipod 5	Increase in setting	
1-400 mg/dL	App Settings or during First	value decreases amount of suggested bolus dose.	
(1 mg/dL increments, up to 8 segments/day)	Time Setup	Decrease in setting value increases amount of suggested bolus dose.	
Reverse Correction	Enter in Omnipod 5	If "On," suggested bolus	
ON/OFF	App Settings	is decreased when glucose is below Target Glucose value.	
Duration of Insulin Action	Enter in Omnipod 5 App Settings or	Increase in setting value may decrease amount of	
2–6 hours	during First Time Setup	suggested bolus dose for longer periods.	
(0.5 hour increments)	3 3 3 3 3 5	. 0 6	

**Note:** The Extended Bolus feature can only be used in Manual Mode. All other therapy settings are used similarly in both Manual and Automated Modes.



#### **Maximum Bolus**

The Maximum Bolus setting defines the upper limit for a bolus. The SmartBolus Calculator prevents you from entering a bolus over this amount. It also prevents you from entering a carb amount that will cause your calculated bolus to exceed this amount. The largest allowed value of the Maximum Bolus is 30 units.

To change your Maximum Bolus:

- Navigate to: Menu button ( ) > Settings > Bolus > Maximum Bolus.
- 2. Tap the **Max Bolus** field and enter the new Maximum Bolus value.
- 3. Tap **SAVE**.

#### **Extended Bolus**

An extended bolus is delivered over a user specified period of time. Only the meal portion of a bolus can be extended. A correction bolus cannot be extended. To turn OFF the extended bolus feature or to change your extended bolus configuration:

- 1. Navigate to: **Menu button** ( **■** ) > **Settings** > **Bolus**.
- 2. Tap the toggle next to **Extended Bolus** to turn ON or OFF the ability to extend a bolus.

# **SmartBolus Calculator Settings**

This section describes how to adjust the settings used by the SmartBolus Calculator to calculate meal and correction boluses.

**Tip:** Write a list of all of the desired settings and segments to guide you through re-entering the values for each segment.

# **Target Glucose and Correct Above**

In both Automated and Manual Mode, the SmartBolus Calculator aims to bring your glucose to your Target Glucose. However, the SmartBolus Calculator only calculates a correction bolus if your glucose is above your Correct Above setting. In Automated Mode, the Omnipod 5 System will adjust your automated insulin delivery with the goal of bringing you to your Target Glucose.

To edit Target Glucose or Correct Above values:

- Navigate to: Menu button ( ≥ ) > Settings > Bolus > Target Glucose & Correct Above.
- 2. Tap **NEXT**.



- 3. To edit a segment, tap the row containing the segment you want to edit.
  - a. Tap the **End Time** field to enter a new end time.
  - b. Tap the **Target Glucose** field to enter a new **Target Glucose**.
  - c. Tap the **Correct Above** field to enter a new **Correct Above** value.
  - d. Tap **NEXT.**
- 4. Repeat the previous step as needed for the remaining segments.
- 5. After confirming that all segments are correct, tap **SAVE**.

**Note:** You can add and delete segments by editing the existing segments.

#### **Minimum Glucose for Calculations**

Your Minimum Glucose for Calculations is used to prevent you from delivering a bolus when your glucose is too low. If your glucose is below your Minimum Glucose for Calculations, the SmartBolus Calculator is disabled and does not calculate a bolus. To edit this value:

- Navigate to: Menu button ( ) > Settings > Bolus > Minimum Glucose for Calculations.
- Tap the Minimum Glucose for Calculations field and enter the desired value.
- 3. Tap **SAVE**.

#### Insulin to Carb Ratio (IC Ratio)

The Insulin-to-Carbohydrate ratio (IC Ratio) defines how many grams of carbohydrates are covered by one unit of insulin. The SmartBolus Calculator uses your IC Ratio to calculate a meal bolus when you are going to eat. To edit this value:

- Navigate to: Menu button ( ) > Settings > Bolus > Insulin to Carb Ratio.
- 2. Tap **NEXT**.
- 3. To edit a segment, tap the row containing the segment you want to edit.
  - a. Tap the **End Time** field to enter a new end time.
  - b. Tap the 1 Unit of Insulin Covers field and enter a new IC Ratio.
  - c. Tap **NEXT.**



- 4. Repeat the previous step as needed for the remaining segments.
- 5. After confirming that all segments are correct, tap **SAVE**.

**Note:** You can add and delete segments by editing the existing segments.

#### **Correction Factor**

The SmartBolus Calculator uses your Correction Factor to calculate a correction bolus when your glucose is above your Correct Above setting. See "Target Glucose and Correct Above" on page 273. To edit this value:

- Navigate to: Menu button ( ) > Settings > Bolus > Correction Factor.
- 2. Tap **NEXT**.
- 3. To edit a segment, tap the row containing the segment you want to edit.
  - a. Tap the **End Time** field to enter a new end time.
  - b. Tap the **1 Unit of Insulin lowers glucose by** field and enter a new Correction Factor.
  - c. Tap **NEXT.**
- 4. Repeat the previous step as needed for the remaining segments.
- 5. After confirming that all segments are correct, tap **SAVE**.

**Note:** You can add and delete segments by editing the existing segments.

#### **Reverse Correction**

The Reverse Correction setting determines how the SmartBolus Calculator handles meal boluses when your glucose is below your Target Glucose.

To turn Reverse Correction ON or OFF:

- 1. Navigate to: **Menu button** ( ) > **Settings** > **Bolus**.
- 2. Tap the toggle on the **Reverse Correction** line to turn it ON or OFF.



#### **Duration of Insulin Action**

The SmartBolus Calculator uses your Duration of Insulin Action setting to calculate the amount of insulin on board (IOB) from a previous bolus.

To edit this value:

- Navigate to: Menu button ( ) > Settings > Bolus > Duration of Insulin Action
- 2. Tap the **Duration of Insulin Action** field and enter the new value.
- 3. Tap **SAVE**.

**Note:** While in Automated Mode, SmartAdjust technology does not use this Duration of Insulin Action setting to calculate automated basal insulin delivery. See "17.7 Insulin On Board (IOB)" on page 266.



# **CHAPTER 18**

# **Understanding SmartBolus Calculator Calculations**

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## 18.1 The SmartBolus Calculator

Your Omnipod 5 System's SmartBolus Calculator can do a lot of the work of calculating a bolus for you. The SmartBolus Calculator uses your personal settings and also takes into account any insulin that remains (referred to as insulin on board or IOB) from automated insulin delivery and from recent boluses.

#### **SmartBolus Calculator Boluses**

When calculating a bolus, the SmartBolus Calculator considers a bolus to be made up of the following two components:

- Correction bolus: Used to lower glucose when it gets too high.
- Meal bolus: Used to cover carbs in a meal.

#### **Extended boluses**

When using the SmartBolus Calculator, you can extend some or all of a meal bolus in Manual Mode, but a correction bolus cannot be extended. A correction bolus is always delivered immediately. In the following example, three units of insulin are extended:

Total bolus = 5 units (1 unit correction bolus + 4 units meal bolus)

```
→Deliver now = 2 units (1 unit correction + 1 unit meal bolus)

→Extend = 3 units (3 units meal bolus)
```

#### **Maximum Bolus**

The Omnipod 5 System does not allow you to enter a bolus that is above your Maximum Bolus setting. If the SmartBolus Calculator calculates a bolus amount greater than your Maximum Bolus, you will only be able to deliver up to the Maximum Bolus amount. To adjust it, tap the Total Bolus field and enter a revised bolus.

# Controlling the bolus amount

The SmartBolus Calculator is a useful tool, but you have the ultimate control over the amount of a bolus to be delivered. After the SmartBolus Calculator suggests a bolus amount, you can confirm the suggested bolus or increase or decrease it. Always check the **Calculations** to confirm the amount of insulin before it is delivered.



# When the SmartBolus Calculator Does Not Work

The SmartBolus Calculator does not work when it is disabled or when there is no Pod communication. Being "disabled" means that the SmartBolus Calculator is temporarily unable to calculate a suggested bolus. Your Omnipod 5 System may disable the SmartBolus Calculator in a few situations.

Conditions that disable the SmartBolus Calculator:	The SmartBolus Calculator is disabled until:	While the SmartBolus Calculator is disabled:
Your glucose is below your Minimum Glucose for Calculations setting.	Ten minutes pass. or A new glucose reading is above your Minimum Glucose for Calculations setting.	IOB is displayed on the Home screen.
Your manually- entered blood glucose reading is greater than 600 mg/dL or "HIGH."	Ten minutes pass. or A new blood glucose reading is lower than "HIGH."	IOB is displayed on the Home screen.
There is an unconfirmed bolus when you discard a Pod.	A complete Duration of Insulin Action period passes.  For example, if your duration of insulin action is set at "2 hours", and you receive an unconfirmed bolus at 8 am you will be unable to use the SmartBolus calculator until 10 am (2 hours after the unconfirmed bolus).	IOB is not displayed on the Home screen.



# Factors Used in the SmartBolus Calculator Calculations

The SmartBolus Calculator accounts for the following when it calculates a bolus:

- Your current glucose (manually entered or from Sensor), sensor glucose trend (if sensor glucose value is used), Target Glucose, Correct Above threshold, and Correction Factor
- The carbs you are about to eat or drink and your IC Ratio
- Your Duration of Insulin Action and insulin on board (IOB)
- Your Minimum Glucose for Calculations
- Reverse Correction, if it is enabled

**Note:** In both Automated and Manual Mode, if using a sensor glucose values and trend in the Calculator, the SmartBolus Calculator may reduce the suggested insulin dose, even if your reverse correction setting is OFF.

#### Sensor glucose trend

The sensor glucose trend is used to suggest up to 30% more correction insulin when your values are rapidly rising, or up to 100% less correction insulin when your values are rapidly falling, compared to the bolus amount suggested with just a blood glucose reading alone.

# **Target Glucose**

When calculating a correction bolus, the SmartBolus Calculator aims to bring your glucose down to your Target Glucose.

#### Correct Above threshold

The SmartBolus Calculator only suggests a correction bolus if your glucose is above your Correct Above setting. This feature can prevent corrections to glucose that is only slightly higher than your Target Glucose.

#### Insulin on board

Insulin on board (IOB) is the amount of insulin still active in your body from basal insulin delivery and from earlier boluses. IOB from previous correction boluses is referred to as correction IOB. IOB from previous meal boluses is referred to as meal IOB. Additionally, in Manual or Automated Modes, the Omnipod 5 algorithm constantly calculates IOB from your basal delivery.



When calculating a new bolus, the SmartBolus Calculator may reduce the suggested bolus based on the IOB.

**Note:** The SmartBolus Calculator only subtracts IOB from a suggested bolus if your current glucose is known. You should always check your glucose prior to delivering a bolus.

#### **Duration of Insulin Action**

The SmartBolus Calculator uses your Duration of Insulin Action setting to calculate the insulin on board from prior boluses.

The Duration of Insulin Action setting represents the amount of time that insulin remains "on board" or "active" in your body.

#### Minimum Glucose for Calculations

The SmartBolus Calculator does not suggest a bolus if your glucose is below your Minimum Glucose for Calculations level. You can adjust this level down to 50 mg/dL.

#### **Reverse Correction**

If the Reverse Correction setting is turned ON and your glucose is below your Target Glucose, the SmartBolus Calculator reduces the meal bolus. This allows part of the meal to be used to raise the glucose towards the Target Glucose.

If the Reverse Correction setting is turned OFF, the SmartBolus Calculator suggests the full meal bolus even if your glucose is below your Target Glucose.

**Note:** In Automated Mode, if using a sensor glucose value and trend in the Calculator, the SmartBolus Calculator may subtract insulin even if your Reverse Correction setting is OFF in situations with a decreasing sensor glucose trend.



The below table shows how each value is used in the SmartBolus Calculator to calculate the total bolus volume:

	Accepted Value	How does the SmartBolus Calculator use this value?		
Using Omnipod 5 System with an FDA-Cleared Blood Glucose Meter				
<b>Blood Glucose</b>	20-600	To calculate total bolus volume.		
Reading from a BG Meter	mg/dL	You can enter a blood glucose reading directly into the SmartBolus Calculator. If 5 or more minutes have passed since entering the reading, it will expire. A reading saved to the Omnipod 5 System history may be used for up to 10 minutes after entry.		
	Omnipo	d 5 Insulin Pump		
Minimum Glucose for	50-70 mg/dL	Disables bolus delivery when glucose is below this value.		
Calculations		You can adjust this value in your Omnipod 5 System settings.		
Correction	1-400	To calculate total bolus volume.		
Factor	mg/dL	You can adjust this value in your Omnipod 5 System settings. The value indicates how much one unit of insulin will lower your blood glucose.		
Correct Above	Target	To calculate total bolus volume.		
	Glucose to 200 mg/dL	You can adjust this value in your Omnipod 5 System settings. The value indicates the minimum glucose at which a Correction Bolus will be included in the total bolus volume.		
Carbohydrates	0.1-225	To calculate total bolus volume.		
	grams	You can enter your Carbohydrates value directly into the calculator to inform the Meal Bolus.		



Insulin to	1-150	To calculate total bolus volume.
Carb Ratio	grams	You can adjust this value in your Omnipod 5 System settings. The value indicates the grams of carbohydrate covered by one unit of insulin.
Duration of	2-6	To calculate total bolus volume.
Insulin Action	hours	You can adjust this value in your Omnipod 5 System settings. The value indicates how long insulin remains in effect after the bolus has been delivered.
Meal	0-X	To calculate total bolus volume.
IOB Portion	Units	The value is known by the Omnipod 5 System and used by the Calculator to indicate any previously delivered Meal Boluses that may still be in effect.
Target Glucose	110–150	To calculate total bolus volume.
	mg/dL	You can adjust this value in your Omnipod 5 System settings. In Automated Mode, basal insulin delivery will be adjusted automatically to bring you towards your Target Glucose. The value informs the Correction Bolus volume.
Smart	Adjust™ tech	nnology (Automated Mode)
Target Glucose	110-150	To calculate total bolus volume.
	mg/dL	You can adjust this value in your Omnipod 5 System settings. In Automated Mode, basal insulin delivery will be adjusted automatically to bring you towards your Target Glucose. The value informs the Correction Bolus volume.



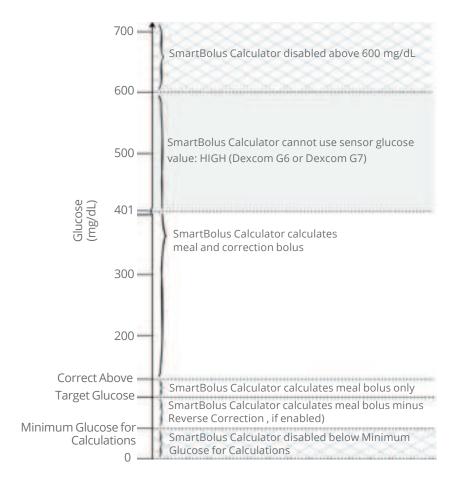
Correction IOB Portion	0-X Units	To calculate total bolus volume.  This value is known by the Omnipod 5 System and used by the Bolus Calculator to indicate any previously delivered Correction Boluses that may still be in effect.	
Usin	Using Omnipod 5 with a compatible iCGM		
Sensor Glucose Value	40-400 mg/dL	To calculate total bolus volume.  If you elect to use a Sensor, you can select USE SENSOR directly in the Bolus Calculator. As a safety constraint, the Calculator will only accept sensor glucose values that are on trend with previous sensor glucose values.	



# **Boundaries of the SmartBolus Calculator suggestions**

The following figure shows the boundaries between the types of calculations performed by the SmartBolus Calculator depending on your glucose. Some examples of how to read the figure are provided below:

- When your glucose is between your Target Glucose and your Correct Above the SmartBolus Calculator calculates a meal bolus only
- When your sensor glucose value is over 400 mg/dL the value is recorded as "HIGH" and cannot be used for bolusing
- When your blood glucose reading is above 600 mg/dL the reading is recorded as "HIGH" and the SmartBolus calculator is disabled





# Considerations about SmartBolus Calculator Recommendations

Keep the following in mind when using the SmartBolus Calculator and reviewing its recommendations:

- The SmartBolus Calculator uses your SmartBolus Calculator settings for the time you are requesting a bolus (See "SmartBolus Calculator Settings" on page 273)
- The SmartBolus Calculator refreshes values every 5 minutes.
   If you do not start your bolus within 5 minutes of entering the
   SmartBolus Calculator, the Omnipod 5 System will need to clear
   the screen so that it has the latest IOB and Sensor information
- When changing time zones, always check your IC Ratio and Correction Factor settings for the new time to ensure it still meets your body's true insulin needs
- The SmartBolus Calculator will suggest doses depending on the carbs you enter and the glucose at that time. Check the nutritional content of your meals to ensure the carbs entered is as accurate as possible. Only enter BG readings that have been obtained within the last 10 minutes or tap **USE SENSOR**. These factors will make sure that the SmartBolus Calculator suggests a bolus dose that is suitable for you

If your sensor glucose value or trend does not match your symptoms or expectations, use a fingerstick blood glucose reading in the SmartBolus Calculator.

When programming and delivering boluses, always confirm that the values you enter and the suggested bolus dose you receive are what you intend and align with what you want at that time. The Omnipod 5 System has features that help with preventing unintended delivery amounts.

<b>Delivery Limitations</b>	Description
Maximum Bolus Setting	The SmartBolus Calculator will not deliver boluses that exceed the Maximum Bolus Setting you entered (0.05 -30 U). For example, if you rarely deliver more than 5 U boluses, and you set the Maximum Bolus Setting at 5 U, the system will prevent you from delivering anything greater than this amount.



Blood Glucose Reading Time Out	The SmartBolus Calculator will not calculate a suggested bolus dose using a blood glucose reading you entered from the Main Menu ( ) that is older than 10 minutes. You will need to enter a more recent blood glucose reading within the SmartBolus Calculator.
SmartBolus Calculator Time Out	The SmartBolus Calculator considers the values you input for a given bolus calculation valid for up to 5 minutes from initial entry of the value into the SmartBolus Calculator. If 5 minutes or more have elapsed, you will be notified that you must refresh the SmartBolus Calculator and input the values again.
Time Zones	The SmartBolus Calculator relies on accurate, updated insulin delivery history and data logging from your Omnipod 5 System. If a time zone change is detected by the Controller or smartphone, the system will notify you. Update time zones on your Omnipod 5 App according to your healthcare provider's guidance.

# **Insulin on Board (IOB)**

After a bolus is delivered, the amount of insulin that is active in the body decreases over several hours. The IOB from a bolus decreases based on your defined Duration of Insulin Action value within your profile settings.

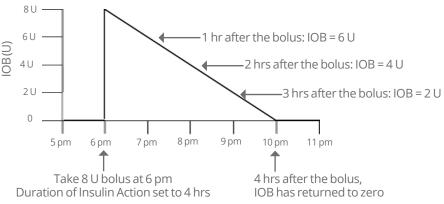
When using the SmartBolus Calculator, your Omnipod 5 System may, due to IOB, decrease your suggested bolus amount to help prevent giving too much insulin.

**Note:** You must bring your Controller or smartphone running the Omnipod 5 App near the Pod to get the most recent IOB value on your Omnipod 5 App Home screen.



# **Bolus IOB depletion**

The graph below shows the IOB from an 8 unit bolus depleting over the set Duration of Insulin Action of 4 hours.



In the Omnipod 5 System, the correction IOB can also change depending on the SmartAdjust technology calculations. It can increase or decrease automatically.

#### Insulin on board (IOB) calculations

<u>Duration of Insulin Action – time since previous bolus</u> x previous bolus Duration of Insulin Action

IOB from a previous correction bolus is called a "correction IOB."

IOB from a previous meal bolus is called a "meal IOB."

# **Correction IOB example**

Duration of Insulin Action: 3 hours

Time since previous correction bolus: 1 hour

Previous correction bolus: 3 U

$$\frac{3 \text{ hours} - 1 \text{ hour}}{3 \text{ hours}} \times 3 \text{ U} = 2 \text{ U correction IOB}$$

Final IOB shown to you:

2U correction IOB + 1U automatic adjustment = 3U overall IOB

In other words, one hour after your previous correction bolus, your body has used up 1 unit from the correction bolus. The remaining 2 units of insulin are still working in your body to lower glucose. Additionally, the system can automatically adjust the correction IOB based on its estimate of your insulin needs. In this example, the automatic adjustment added 1 unit for a total of 3 units working to lower your glucose.



#### **Correction Meal IOB example**

Duration of Insulin Action: 3 hours Time since previous meal bolus: 2 hours

Previous meal bolus: 4.5 U

$$\frac{3 \text{ hours} - 2 \text{ hours}}{3 \text{ hours}} \times 4.5 \text{ U} = 1.5 \text{ U} \text{ meal IOB}$$

In other words, two hours after your previous meal bolus, your body has used up 3 units from the meal bolus. The remaining 1.5 units of insulin are still in your body, working to cover your meal.

# **SmartBolus Calculator Equations**

The SmartBolus Calculator first calculates a preliminary correction and meal bolus. It adjusts these values for IOB, if necessary. It then suggests a final total bolus that includes the adjusted correction bolus and meal bolus.

**Note:** Your adjustments from the sensor glucose trend can add or subtract insulin from the correction and/or the meal portion.

Correction Factor

Example: Current BG or Sensor: 200 mg/dL,

Target Glucose: 150 mg/dL Correction Factor (CF): 50

$$\frac{200 \text{ mg/dL} - 150 \text{ mg/dL}}{50} = 1 \text{ U prelim. correction bolus}$$

Carb intake Preliminary meal bolus = Insulin-to-Carb (IC) ratio

**Example**: Carb intake: 45 grams of carb, IC ratio: 15

$$\frac{45}{15}$$
 = 3 U prelim. meal bolus

**Correction bolus** = (prelim. correction bolus-meal IOB) correction IOB

The meal IOB is subtracted first. If the preliminary correction bolus is still above zero, then the correction IOB is subtracted.

Meal bolus = prelim. meal bolus-remaining correction IOB

Meal IOB is never subtracted from a meal bolus. Only a remaining correction IOB is subtracted from a meal bolus.

Calculated bolus = correction bolus + meal bolus



**Reverse Correction bolus calculation**: If the Reverse Correction feature is turned ON and if your current glucose is below your Target Glucose but above your Minimum Glucose for Calculations, the SmartBolus Calculator subtracts a correction amount from the preliminary meal bolus.

**Meal bolus with Reverse Correction** = Reverse Correction + prelim meal bolus

Example: Current BG or Sensor: 75 mg/dL,

Target Glucose: 150 mg/dL

Correction Factor: 50, Preliminary meal bolus: 2.5 U

$$\frac{75 \text{ mg/dL} - 150 \text{ mg/dL}}{50} = -1.5 \text{ U Reverse Correction}$$

- 1.5 U (Reverse Correction) + 2.5 U (prelim meal bolus) = 1.0 U meal bolus

A Reverse Correction is only applied to the meal bolus. In this example, the meal bolus is reduced by 1.5 units, resulting in a meal bolus of 1.0 U.



# **SmartBolus Calculator Rules**

The SmartBolus Calculator applies the following rules to the suggested bolus doses:

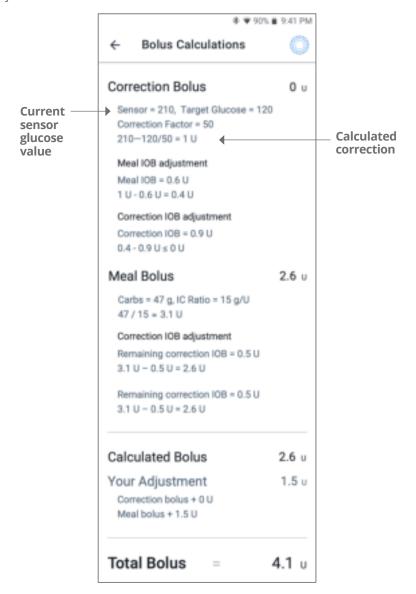
Rule	Detail			
Rounding	Boluses will always be rounded <i>down</i> to the nearest 0.05 U and will never be below 0 U.			
	IOB will always be rounded <i>up</i> to the nearest 0.0 U and will never be below 0 U.			
Factors that	Factor	Increase	Decrease	
influence the size of your bolus	Carbs entered	V		
	Sensor glucose or BG value	V	<b>√</b>	
	IOB		<b>√</b>	
	Sensor glucose trend (if using Sensor)	V	V	
	Target Glucose	V	V	
	Reverse Correction setting		<b>√</b>	
Correction IOB	Correction IOB is subtracted from both meal and correction boluses.			
Meal IOB	Meal IOB is subtracted only from the correction boluses.			



#### **Overview of the Bolus Calculations Screen**

You can tap **VIEW BOLUS CALCULATIONS** from the Insulin & BG history screen or tap **CALCULATIONS** from the SmartBolus Calculator screen if you want to view bolus calculation details.

When a sensor glucose value and trend are used for a bolus, the SmartBolus Calculator will not only consider the value but may also adjust the bolus amount for the trend. You will see these adjustments labeled in the Bolus Calculations Screen.

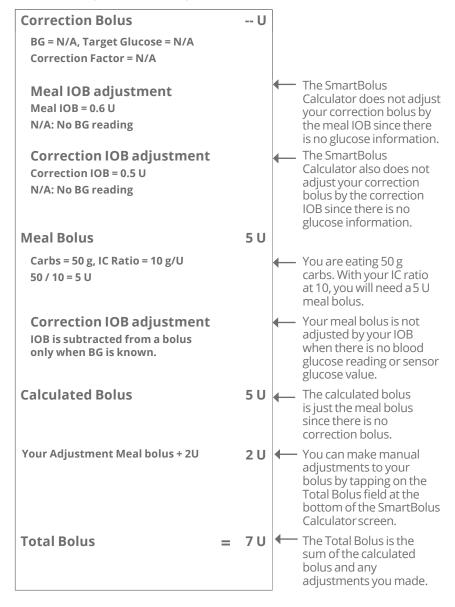




# 18.2 SmartBolus Calculator Examples

#### **Example 1**

Eating 50 g carbs, and 0.6 U meal IOB and 0.5 U correction IOB from previous meal and correction boluses. Sensor glucose is not available and a blood glucose reading is not entered.





# Example 2

Eating 30 g carbs, no meal or correction IOB. Used sensor glucose value of 180 mg/dL, with a rising trend.

Correction Bolus  Sensor = 180, Target Glucose = 130  Correction Factor = 50  (180-130) / 50 = 1 U  Meal IOB adjustment  Meal IOB = 0 U  1 U - 0 U = 1 U	1.2 U	<b>—</b>	Your glucose is 180 mg/dL which is 50 mg/dL over your target. Because your correction factor is 50, the initial correction bolus is 1 U.  The SmartBolus Calculator does not adjust your correction bolus by the meal IOB since there is no meal IOB.
Correction IOB adjustment Correction IOB = 0 U 1 U-0 U = 1 U Adjusted correction bolus = 1.2 U Adjusted for Sensor: Rising  Meal Bolus Carbs = 30 g, IC Ratio = 10 g/U 30 / 10 = 3 U	3.6 U	<b>← ←</b>	The SmartBolus Calculator also does not adjust your correction bolus by the correction IOB since there is no correction Bolus is increased to account for your rising sensor glucose trend.  You are eating 30 g carbs. With your IC ratio at 10, you will need a 3 U meal bolus. The SmartBolus Calculator does not adjust your meal bolus by the correction IOB since there is no correction IOB.
Correction IOB adjustment Remaining correction IOB = 0 U 3 U-0 U = 3 U Adjusted meal bolus = 3.6 U Adjusted for Sensor: Rising		<b>←</b>	The SmartBolus Calculator does not adjust your meal bolus by the correction IOB since there is no correction IOB. The meal bolus is increased to account for your rising sensor glucose trend.
Calculated Bolus	4.8 U	<b>—</b>	The calculated bolus is the sum of your correction bolus and meal bolus that has been adjusted for rising sensor glucose value.
Total Bolus	4.8 U	_	The total bolus is the sum of the calculated bolus and any adjustment you made.



#### **Understanding SmartBolus Calculator Calculations 18**

#### Example 3

No carbs entered, used sensor glucose value of 180 mg/dL with decreasing trend. There is 0.8 U meal IOB and 0.5 U correction IOB from the previous meal and correction boluses.

Correction Bolus	0 U	7
Sensor = 180, Target Glucose = 130 Correction Factor = 50 (180–130) / 50 = 1 U		Your glucose is 180 mg/dL, which is 50 mg/dL over target. Because your correction factor is 50, the initial correction bolus is 1 U.
Meal IOB adjustment Meal IOB = 0.8 U 1 U-0.8 U = 0.2 U		Since you have 0.8 U of meal IOB remaining from a previous meal bolus, this is subtracted from the initial correction bolus of 1 U, and you have 0.2 U of correction bolus remaining.
Correction IOB adjustment Correction IOB = 0.5 U 0.2 U-0.5 U < = 0 U		You also have 0.5 U of correction IOB from previous insulin action. This is subtracted from the remaining correction bolus of 0.2 U, driving the final calculated correction bolus to 0 U. Note that 0.3 U of correction IOB still remains after driving correction bolus to 0 U, and this is used in the meal bolus calculations.
Meal Bolus Carbs = 0 g, IC Ratio = 10 g/U 0/10 = 0 U	0 U	You did not enter any carbs, so you do not receive any calculated meal bolus dose.
Correction IOB adjustment  Remaining correction IOB = 0.3 U 0 U-0.3 U <= 0 U		Although there is a remaining correction IOB of 0.3 U, your initial meal bolus is already at 0 U, so it is not adjusted further, and your meal bolus remains at 0 U.
Calculated Bolus	0 U	Even though your glucose is above target, you have enough IOB. As a result, the SmartBolus Calculator recommends that you do not deliver any additional insulin.
Total Bolus	0 U	



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#### **USING A SENSOR WITH OMNIPOD 5**

Sensor Important Safety Information

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- 20 Connecting a Dexcom Sensor to the Pod
- 21 Using a FreeStyle Libre 2 Plus Sensor with Omnipod 5



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# Sensor Important Safety Information

#### **Sensor Warnings**

Warning: ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/ or Sensor calibration (for Sensors requiring calibration, if necessary). ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *Technical User Guide*, contact your healthcare provider.

Warning: ALWAYS make sure you are using the Sensor per manufacturer's instructions. Do not extend the Sensor wear beyond the recommended duration and do not start a Sensor past its Use By date. The Omnipod 5 System relies on accurate, current sensor glucose values to determine your insulin needs. Incorrect use of the Sensor could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

ALWAYS confirm the Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses a Dexcom Sensor, mis-matching numbers could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia and hyperglycemia.



#### **Important Safety Information**

Warning: Device components including the Pod, Dexcom G6 Sensor and Transmitter, Dexcom G7 Sensor, and FreeStyle Libre 2 Plus Sensor may be affected by strong radiation or magnetic fields. Device components must be removed (and the Pod and Sensor should be disposed of) before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan (or any similar test or procedure). In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to X-ray, MRI, or CT, treatment can damage these components. Check with your healthcare provider on Pod removal guidelines.

Warning: DO NOT use Omnipod 5 System with a Dexcom Sensor if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom sensor glucose values may be falsely elevated and result in over-delivery of insulin that can result in severe hypoglycemia.

Warning: DO NOT use the Omnipod 5 System with the FreeStyle Libre 2 Plus Sensor if you are taking ascorbic acid (Vitamin C), a substance found in supplements like mutlivitamins or cold remedies such as Airborne and Emergen-C. Your FreeStyle Libre 2 Plus sensor glucose values may be falsely elevated at levels of more than 1000 mg of ascorbic acid per day

and result in over-delivery of insulin that could result in severe hypoglycemia.

#### **Sensor Precautions**

Caution: You cannot use the Dexcom receiver with the Omnipod 5 System because the Omnipod 5 System is compatible only with the Dexcom G6 or Dexcom G7 App on a smartphone.

Caution: During the first 12 hours of use of a FreeStyle Libre 2 Plus Sensor, sensor glucose values are not avaialble for use with the SmartBolus Calculator. You will need to enter a blood glucose reading from a BG meter during those first 12 hours and any time the [VSV] icon appears.



#### **CHAPTER 19**

# Using a Dexcom Sensor with Omnipod 5

#### **Contents**

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#### 19.1 Dexcom Sensor Overview

**Warning:** ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your sensor glucose value do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor calibration (for Sensors requiring calibration, if necessary). ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *Technical User Guide*, contact your healthcare provider.

The Omnipod 5 System is designed to connect with the Dexcom G6 or Dexcom G7 CGM Systems. When connected to the Dexcom Sensor, the Pod receives glucose values and trends from the Dexcom Sensor. In Automated Mode, the Pod uses sensor glucose values to make automated insulin dosing decisions every 5 minutes. In both Manual Mode and Automated Mode, a sensor glucose value and trend can be used in the SmartBolus Calculator to calculate a suggested bolus.

Read and follow all Dexcom product instructions, including Safety Statements, in the *Dexcom CGM System Instructions for Use*.

**Note:** All Sensor and Transmitter-specific actions and alerts are controlled through your Dexcom G6 or Dexcom G7 App. See your *Dexcom CGM System Instructions for Use* for additional information.

**Note:** The Dexcom App and Omnipod 5 App do not directly communicate with each other. They have their own separate communication channels to acquire sensor glucose values. As a result, you may notice that, at times, the sensor glucose values may slightly differ in each App.



#### Using a Dexcom Sensor with Omnipod 5 19

When connecting and using a Sensor, be aware of the following:

- Always check the Dexcom expiration dates for the Sensor and Transmitter. Do not start a Sensor past its Use By date.
- Adhere to Dexcom's approved site placements for Dexcom Sensor wear.
- All Dexcom alerts are configured and driven by your Dexcom App. Set your Low and High alerts, as well as any other alerts in your Dexcom G6 or Dexcom G7 App before using the Omnipod 5 System.

**Note:** The Omnipod 5 System also alerts you when your sensor glucose values are at or below 55 mg/dL.

 Always ensure the Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number entered in the Dexcom G6 and Omnipod 5 Apps match the one you are wearing.

#### 19.2 Dexcom Sensor Placement

The Bluetooth connection between the Sensor and the Pod is optimal when the signal does not pass through the body. Keeping both devices at least 3 inches (8 cm) apart and within line of sight allows for consistent Sensor communication with the Pod.

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

Consider these Pod placements to find the locations that work best for your body:

### Sensors indicated for the abdomen:

- Abdomen, on the same side, 3 inches (8 cm) apart
- Abdomen, opposite side
- Lower back, same side
- Thigh, front sides or outer same side
- Lovehandles, same side
- Upper buttocks, same side

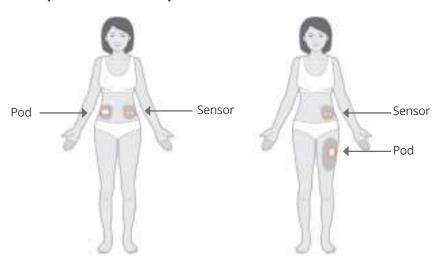
## Sensors indicated for the back of the upper arm:

- On the same arm, 3 inches (8 cm) apart
- Abdomen, same side
- Lower back, same side
- Thigh, same side
- Lovehandles, same side
- Upper buttocks, same side
- Back of the opposite arm

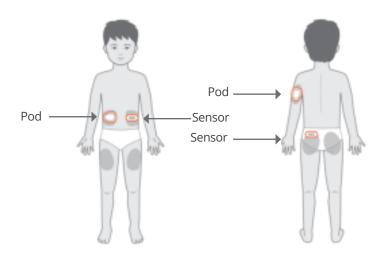


#### 19 Using a Dexcom Sensor with Omnipod 5

#### Adult placement examples



#### Pediatric placement examples



Consult the *Dexcom CGM System Instructions for Use* for more information on approved Sensor placement locations. Images show Dexcom G6 examples only.



#### 19.3 Using a Dexcom Sensor with Omnipod 5

When using Omnipod 5 System with the Dexcom CGM System, you need to use the Dexcom G6 or Dexcom G7 App to control your Sensor.

**Caution:** You cannot use the Dexcom receiver with the Omnipod 5 System because the Omnipod 5 System is compatible only with the Dexcom G6 or Dexcom G7 App on a smartphone.

#### 19.4 Sensor Glucose Values

Sensor glucose values are displayed on the **DASHBOARD**. The **DASHBOARD** also displays a sensor glucose trend arrow to indicate whether sensor glucose values are trending up, down, or holding steady. In Automated Mode, the system takes your sensor glucose trend into account every 5 minutes when making automated insulin delivery decisions.

In Manual Mode and Automated Mode, the sensor glucose value and trend can be used in the SmartBolus Calculator. The SmartBolus Calculator can increase or decrease your bolus as needed based on your sensor glucose value and trend.





#### **High and Low Sensor Glucose Values**

The Omnipod 5 App indicates high and low sensor glucose values as follows.

Sensor Glucose Value	Screen display
Above 400 mg/dL	HIGH
Below 40 mg/dL	LOW

**Note:** Sensor glucose values are automatically recorded on the Omnipod 5 System and do not need to be entered on the Enter BG screen.

#### **Urgent Low Glucose**

**Warning:** ALWAYS promptly treat low glucose. Glucose at or below 55 mg/dL indicates significant hypoglycemia (very low glucose). If left untreated, this could lead to seizure, loss of consciousness or death. Follow your healthcare provider's recommendations for treatment.

When your sensor glucose value is at or below 55 mg/dL, your Dexcom Sensor will send the value to your Pod. The Pod will sound an Advisory Alarm to let you know that your glucose is very low. You can acknowledge the alarm from your Controller or smartphone. See "13.6 Advisory Alarm List" on page 189.

**Note:** This Alarm will occur again if another sensor glucose value of 55 mg/dL or lower is received after the initial Advisory Alarm was acknowledged.

**Note:** This Advisory Alarm will only stop repeating after a glucose value of 56 mg/dL or greater is received. You may silence this Advisory Alarm for 30 minutes by acknowledging the onscreen message.

**Note:** Use a BG meter to confirm your glucose. Treat low glucose as needed.

**Note:** The Urgent Low Glucose Advisory Alarm has to do directly with your body's current glucose, while other alarms have to do with the Pod or Omnipod 5 App state.



#### 19.5 Sensor Glucose Trend Arrows

Trend arrows display per Dexcom specifications. The arrow color matches the sensor glucose value color. For more information, refer to the *Dexcom CGM System Instructions for Use*.

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

Sensor Glucose Value Color	Description
Purple	Sensor glucose value is within Glucose Goal Range (Automated Mode)
Blue	Sensor glucose value is within Glucose Goal Range (Manual Mode)
Red	Sensor glucose value is below Glucose Goal Range
Orange	Sensor glucose value is above Glucose Goal Range

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

Sensor Glucose Trend Arrows	Description
9	Steady; decreasing/increasing less than 1 mg/dL per minute
00	Slowly falling/rising; glucose could decrease/increase 30–60 mg/dL in 30 minutes
00	Falling/rising; glucose could decrease/increase 60–90 mg/dL in 30 minutes
<b>8</b>	Rapidly falling/rising; glucose could decrease/increase more than 90 mg/dL in 30 minutes



#### 19 Using a Dexcom Sensor with Omnipod 5

### 19.6 Dexcom G6 Communication Messages

Communication Message	Description
CONNECTING TRANSMITTER	Occurs after you have entered a Transmitter serial number (SN) and the Pod is attempting to connect with the Transmitter.
DEXCOM ISSUE DETECTED	When sensor glucose 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 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 SENSOR	When the Sensor is active and connected to the Omnipod 5 Pod but the most recent sensor glucose value was not acquired within the 5-minute window. There may be no valid sensor glucose value available due to a Pod/Sensor communication issue or a temporary Sensor issue (recoverable without any user action). Tap MORE INFORMATION for recommended action. Review Pod and Sensor placement. Pod and Sensor should be at least 3 inches (8 cm) apart and within line of sight.



#### Using a Dexcom Sensor with Omnipod 5 19

TRANSMITTER ERROR	When the Transmitter connected with the Omnipod 5 System has expired or experienced a non-recoverable error. Tap <b>NEED HELP</b> for potential causes and recommended actions. To set up a new transmitter, see "20.3 Connecting the Dexcom G6 Transmitter" on page 316.
TRANSMITTER NOT FOUND	When the Pod tried to connect with a Transmitter but after 20 minutes was unable to do so. This can also happen when a Transmitter is still connected to a discarded Pod. Tap <b>NEED HELP</b> for potential causes and recommended actions. See "27.3 Sensor FAQs" on page 449 for additional information.
WAITING FOR DEXCOM SETUP	When the Transmitter is connected but sensor glucose 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.

**Note:** For all Sensor-related issues, refer to your *Dexcom G6 CGM System Instructions for Use.* 

### 19.7 Dexcom G7 Communication Messages

Communication Message	Description
CONNECTING SENSOR	Occurs after you have entered a pairing code and serial number
	from the Dexcom G7 applicator
	and the Pod is attempting to
	connect with the Sensor.



#### 19 Using a Dexcom Sensor with Omnipod 5

Communication Message	Description
DEXCOM ISSUE DETECTED	When sensor glucose values are not available due to a Sensor error. See the Dexcom G7 App for details. No action is required within the Omnipod 5 App.
SENSOR ERROR	When the Sensor connected with the Omnipod 5 System has experienced a non-recoverable error. Tap <b>NEED HELP</b> for potential causes and recommended actions. To set up a new Sensor, see "20.6 Connecting the Dexcom G7 Sensor" on page 320.
SENSOR EXPIRED	When the Sensor has reached the end of its wear. Remove the Sensor from your skin and dispose of it. Start a new Dexcom G7 Sensor using your Dexcom G7 App. To connect the new Sensor to your Omnipod 5 App, see "20.6 Connecting the Dexcom G7 Sensor" on page 320.
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.



#### Using a Dexcom Sensor with Omnipod 5 19

Communication Message	Description
SEARCHING FOR SENSOR	When the Sensor is active and connected to the Omnipod 5 Pod but the most recent sensor glucose value was not acquired within the 5-minute window. There may be no valid sensor glucose value available due to a Pod/Sensor communication issue or a temporary Sensor issue (recoverable without any user action). Tap MORE INFORMATION for recommended action. Review Pod and Sensor placement. Pod and Sensor should be at least 3 inches (8 cm) apart and within line of sight.
SENSOR NOT FOUND	When the Pod tried to connect with a Sensor but after 25 minutes was unable to do so. Tap <b>NEED HELP</b> for potential causes and recommended actions. See "27.3 Sensor FAQs" on page 449 for additional information.
WAITING FOR DEXCOM SETUP	When the Sensor is connected but sensor glucose values are unavailable because the Dexcom G7 Sensor warm-up is not complete. See the Dexcom G7 App for details. No action is required within the Omnipod 5 App.

**Note:** For all Sensor-related issues, refer to your Dexcom G7 CGM System Instructions for Use.



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#### **CHAPTER 20**

# Connecting a Dexcom Sensor to the Pod

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#### 20.1 About Connecting a Dexcom Sensor to the Pod

The Omnipod 5 System is designed to work with the Dexcom G6 or Dexcom G7 CGM. To use a Dexcom CGM with the Omnipod 5 System, you will need to obtain the Dexcom G6 Sensor and Transmitter or Dexcom G7 Sensor, *Dexcom CGM System Instructions for Use*, and download the Dexcom G6 or Dexcom G7 App on your personal smartphone.

Before you can view and use sensor glucose values in the Omnipod 5 System, you must first set up the Omnipod 5 System to allow the Pod to communicate with the Sensor. Once connected, you will be able to use the system in Automated Mode, view sensor glucose values in the Omnipod 5 App, and use sensor glucose values in the bolus calculator in both Manual and Automated Modes.

**Note:** The Dexcom Sensor must be started in the Dexcom App in order to use sensor glucose values and trends in the Omnipod 5 System.

**Note:** Note: Always confirm that the Pod you are activating is compatible with the Sensor you intend to use. The Pod tray lid and Pod box will show the Sensor compatibility.

#### Before you begin, do the following:

➤ The Omnipod 5 System will not connect with the Sensor if you are using the Dexcom receiver. If you have an existing Sensor or Transmitter that is connected to your receiver, turn off your receiver. You will need to use the Dexcom G6 or Dexcom G7 App on your smartphone. For instructions about using a Dexcom CGM System, see the Dexcom CGM System Instructions for Use.



## 20.2 Connecting the Dexcom G6 during Initial Pod Setup

To connect the Transmitter during initial Pod setup:

1. After activating your Pod during initial setup, tap **CONNECT SENSOR**.

**Note:** If you tap **NOT NOW** after activating your Pod during initial setup, you can connect the Sensor and Transmitter at a later time. See "Connecting the Dexcom G6 Transmitter" in the next section.

2. Go to step 3 of "Connecting the Dexcom G6 Transmitter" in the next section.



#### 20.3 Connecting the Dexcom G6 Transmitter

Warning: ALWAYS confirm the Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses the Dexcom Sensor, mis-matching numbers could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia and hyperglycemia.

If you had previously connected a Transmitter and your Transmitter has expired, or you have deleted the Transmitter serial number (SN) and wish to reconnect, you must enter a new SN. You must be in Manual Mode to manage your Transmitter SN.

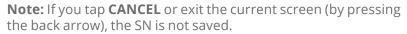
To connect the Dexcom G6 Transmitter:

 From the Home screen, tap Menu button ( ≡ ) > Manage Sensor.

The Manage Sensor screen displays the saved SN.

**Note:** If the Transmitter SN was previously deleted, the SN field is empty. (See "20.4 Disconnecting the Transmitter from the Pod" on page 317).

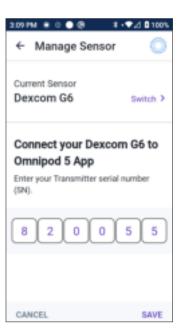
- 2. Tap ENTER NEW.
- 3. Tap the SN field to display the alphanumeric keypad.
- 4. Enter the SN printed on the back of your Transmitter or on the Transmitter box, then tap **Done**.
- 5. Tap **SAVE**.



6. Tap **CONFIRM** to start connecting your Transmitter to your Pod. 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 Transmitter within 20 minutes, the message "Transmitter Not Found" displays.





Tap **NEED HELP** for more information. See "27.3 Sensor FAQs" on page 449 for additional information.

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

#### 20.4 Disconnecting the Transmitter from the Pod

To stop the Pod from communicating with the Transmitter, delete the SN. If you delete the SN, you will no longer be able to enter Automated Mode until a new Transmitter SN is added.

To delete the serial number (SN):

- 2. Tap **DELETE**.
- 3. Tap **OK**, **DELETE** to confirm.

#### 20.5 Switching to Dexcom G6 from Another Sensor

The Omnipod 5 System is compatible with more than one brand or model of Sensor. If you want to switch to using the Dexcom G6 Sensor with your Omnipod 5 System from another type of compatible Sensor, you can switch Sensors in the Omnipod 5 App.

**Note:** Switching Sensors must be done between Pod changes. A single Pod cannot connect with more than one brand or model of Sensor during its wear.





To switch from another Sensor to Dexcom G6, follow the steps below:

Navigate to the Menu button ( ≡ )
 > Manage Sensor.

**Note:** You cannot switch Sensors while wearing an active Pod. If you have an active Pod, Wait for next Pod change will display on the screen when you try to switch.

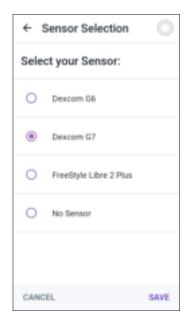
2. The Manage Sensor screen shows your current Sensor.

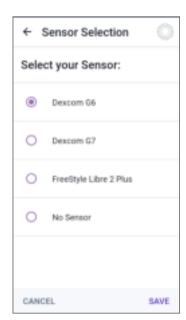
Tap **Switch** > to switch to a different (or to no) Sensor.

For example, you may have been using a Dexcom G7 Sensor and would now like to switch to a Dexcom G6 Sensor.

- 3. The Sensor Selection screen shows your options with your current Sensor selected.
- 4. To switch to the Dexcom G6 Sensor, select Dexcom G6.

Tap **SAVE**.







- Confirm your switch to Dexcom G6.Tap **CONFIRM** to acknowledge.
- 6. The Omnipod 5 App will ask: **Do**you want to add the Dexcom **G6**Sensor to Omnipod 5 now?
  - Tap ADD to begin the process of adding your Dexcom G6 Sensor to Omnipod 5.
  - b. Tap **NOT NOW** to add a Dexcom G6 Sensor to Omnipod 5 later.
- 7. Add your Dexcom G6 Transmitter by entering your Transmitter serial number (SN) into the Omnipod 5 App. The SN must match the SN of the Transmitter connected to the Dexcom G6 mobile App. See "20.3 Connecting the Dexcom G6 Transmitter" on page 316.
- 8. Activate a new Pod. Check the Pod tray lid and Pod box for compatibility with the Dexcom G6 Sensor.

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

If the Pod is unable to connect with the Dexcom G6 Transmitter within 20 minutes, the message "**Transmitter Not Found**" displays. Tap **NEED HELP** for more information. See "27.3 Sensor FAQs" on page 449.

If you do not have an active Pod, the Transmitter serial number (SN) will be saved and sent to the next Pod you activate.

#### Confirm switching to Dexcom G6

You are switching from Dexcom G7 to Dexcom G6.

If you have an active Sensor, remove and discard the old Sensor because the Omnipod 5 App will no longer be able to communicate with it.

CANCEL CONFIRM



#### 20.6 Connecting the Dexcom G7 Sensor

If you had previously connected a Dexcom G7 Sensor and your Sensor has expired, or you have deleted the Sensor pairing code and serial number (SN) and wish to reconnect, you must enter the Dexcom G7 Sensor information from the applicator for your current Sensor.

To connect the Dexcom G7 Sensor:

From the Home screen, tap Menu button ( ≡ ) > Manage Sensor.

**Note:** If you are starting the Omnipod 5 System for the first time, you will be prompted to enter the Sensor information during first-time setup.

The Manage Sensor screen displays the saved pairing code and serial number.

**Note:** If the Sensor information was previously deleted, the pairing code and serial number fields are empty. (See "20.7 Disconnecting the Dexcom G7 from the Pod" on page 323).

2. Tap ADD NEW.





3. To use the Take Photo option to connect, tap **TAKE PHOTO**.

To enter the numbers, tap **ENTER CODE MANUALLY**.

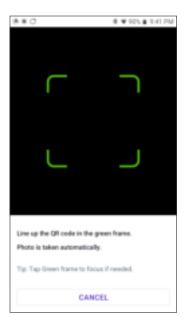
**Note:** You will need to connect each new Dexcom G7 Sensor to both the Omnipod 5 App and Dexcom G7 App for your Pod and Sensor to stay connected.



4. If taking a photo, line up the QR code in the green frame. The photo is taken automatically. The photo will not be stored.

**Note:** If you tap **CANCEL**, the information is not saved.

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





#### OR

If entering manually, enter the 4-digit pairing code printed on your applicator:

Tap SAVE.

Tap CONFIRM.

**Note:** Note: You can find both the 4-digit pairing code and the 12-digit serial number in your Dexcom G7 mobile app.

Next, enter the 12-digit serial number printed on your applicator.

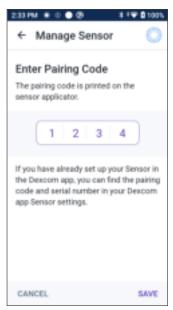
Tap SAVE.

**Note:** If you tap **CANCEL** or exit the current screen (by pressing the back arrow), the information is not saved.

5. Tap **CONFIRM** to start connecting your Sensor to your Pod. The connection process can take up to 25 minutes.

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

If the Pod is unable to connect with the Sensor within 25 minutes, the message "Sensor Not Found" displays. Tap NEED HELP for more information. See "27.3 Sensor FAQs" on page 449 for additional information.









#### 20.7 Disconnecting the Dexcom G7 from the Pod

To stop the Pod from communicating with the Sensor, delete the Sensor information. If you delete the pairing code and serial number, you will no longer be able to enter Automated Mode until a new Sensor pairing code and serial number are added.

To delete the Sensor:

- From the Home screen, tap
   Menu button ( ≡ ) > Manage Sensor.
- 2. The Manage Sensor screen displays the saved Sensor information.

Tap **DELETE**.

3. Tap **OK**, **DELETE** to confirm.



## 20.8 Switching to the Dexcom G7 from another Sensor

The Omnipod 5 System is compatible with more than one brand or model of Sensor. If you want to switch to using the Dexcom G7 Sensor with your Omnipod 5 System from another type of compatible Sensor, you can switch Sensors in the Omnipod 5 App.

**Note:** Switching Sensors must be done between Pod changes. A single Pod cannot connect with more than one brand or model of Sensor during its wear.

To switch from another Sensor to Dexcom G7, follow the steps below:

Navigate to the Menu button ( ) > Manage Sensor.

**Note:** You cannot switch Sensors while wearing an active Pod. If you have an active Pod, Wait for next Pod change will display on the screen when you try to switch.



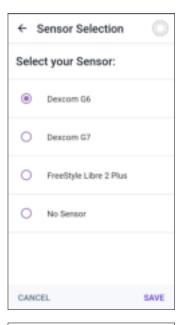
2. The Manage Sensor screen shows your current Sensor.

Tap **Switch** > to switch to a different (or to no) Sensor.

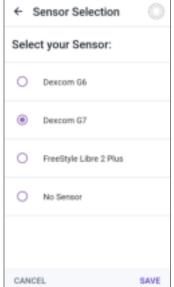
For example, you may have been using a Dexcom G6 Sensor and would now like to switch to a Dexcom G7 Sensor.



3. The Sensor Selection screen shows your options with your current Sensor selected.



 To switch to the Dexcom G7 Sensor, select Dexcom G7.
 Tap SAVE.





- Confirm your switch to Dexcom G7.Tap **CONFIRM** to acknowledge.
- 6. The Omnipod 5 App will ask: Do you want to add the Dexcom G7 Sensor to Omnipod 5 now?
  - Tap ADD to begin the process of adding your Dexcom G7 Sensor to Omnipod 5.
  - Tap **NOT NOW** to add a Dexcom G7 Sensor to Omnipod 5 later.
- 7. Add your Dexcom G7 Sensor to Omnipod 5 by selecting **TAKE**

**PHOTO** and taking a photo of the QR code on the side of the Dexcom G7 applicator. Or you can manually enter the pairing code and serial number into the Omnipod 5 App. See "20.7 Disconnecting the Dexcom G7 from the Pod" on page 323.

The pairing code and serial number must match the numbers on the Dexcom G7 applicator. The pairing code must match the pairing code of the Sensor connected to the Dexcom G7 mobile App.

8. Activate a new Pod. Check the Pod tray lid and Pod box for compatibility with the Dexcom G7 Sensor.

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

If the Pod is unable to connect with the Dexcom G7 Sensor within 25 minutes, the message "**Sensor Not Found**" displays. Tap **NEED HELP** for more information. See "27.3 Sensor FAQs" on page 449.

If you do not have an active Pod, the Sensor pairing code and serial number will be saved and sent to the next Pod you activate.

#### Confirm switching to Dexcom G7

You are switching from Dexcom G6 to Dexcom G7.

If you have an active Dexcom G6 Sensor, remove and discard the old Sensor because the Omnipod 5 App will no longer be able to communicate with it.

CANCEL CONFIRM



#### **CHAPTER 21**

# Using a FreeStyle Libre 2 Plus Sensor with Omnipod 5

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#### 21.1 FreeStyle Libre 2 Plus Sensor Overview

**Warning:** ALWAYS be aware of your current sensor glucose value, trust how your body feels, and do not ignore symptoms of high and low glucose. Even though insulin delivery adjusts automatically in Automated Mode with the goal of bringing your glucose level to your defined Target Glucose, severe hypoglycemia or hyperglycemia may still occur.

If your sensor glucose values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or Sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate sensor glucose values.

- Erroneously high sensor glucose values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low sensor glucose values can cause prolonged insulin suspension leading to hyperglycemia, DKA, or death.

If you are having symptoms that are not consistent with your blood glucose readings and you have followed all instructions described in this *Technical User Guide*, contact your healthcare provider.

The Omnipod 5 System is designed to connect with the FreeStyle Libre 2 Plus Sensor. When connected to the FreeStyle Libre 2 Plus Sensor, the Pod receives glucose values and trends directly from the FreeStyle Libre 2 Plus Sensor. In Automated Mode, the Pod uses sensor glucose values to make automated insulin dosing decisions every 5 minutes. In both Manual Mode and Automated Mode, a sensor glucose value and trend can be used in the SmartBolus Calculator to calculate a suggested bolus.

Read and follow all FreeStyle Libre 2 Plus Sensor instructions, including Safety Statements, in the *FreeStyle Libre 2 Plus Sensor Instructions for Use.* 

**Note:** All Sensor-specific actions and alerts are controlled through your Omnipod 5 App on the Insulet-provided Controller. The Sensor must be started by the Omnipod 5 App on the Insulet-provided Controller to pair with a Pod.



#### 21 Using a FreeStyle Libre 2 Plus Sensor with Omnipod 5

When connecting and using a FreeStyle Libre 2 Plus Sensor, be aware of the following:

- Do NOT use if the Sensor Kit package, Sensor Pack, or Sensor applicator appear to be damaged or already opened due to risk of no results and/or infection.
- Do NOT use if Sensor Kit contents are past their expiration date.
- Check that the Sensor codes match on the Sensor Pack and Sensor applicator before using. Different Sensor codes will result in incorrect sensor glucose values.
- The FreeStyle Libre 2 Plus Sensor is worn on the back of the upperarm.
- All FreeStyle Libre 2 Plus Sensor alerts are configured and driven by your Omnipod 5 App. You will set your Low and High Glucose and Missing Sensor Values alerts during first-time setup of your Sensor with your Omnipod 5 System.

The FreeStyle Libre 2 Plus Sensor continuously monitors glucose and, when used with the Omnipod 5 System, sends glucose values and trends wirelessly to your Pod. The FreeStyle Libre 2 Plus Sensor requires no fingersticks.

The FreeStyle Libre 2 Plus Sensor includes:

- Sensor Pack: Contains one sterile Sensor.
- **Sensor:** Circle-shaped Sensor worn on the back of the upper arm. The Sensor has a thin, flexible filament that is painlessly inserted just under the skin.
- **Applicator:** Used to pick up the Sensor from the Sensor Pack and to apply the Sensor to your arm.
- **Controller:** Sensors are started and managed using the Omnipod 5 App running on the Insulet-provided Controller. You cannot use a FreeStyle Libre 2 Plus Sensor with the Omnipod 5 App on a personal smartphone.

When used with an active Pod: Sensor glucose values and trend are sent directly to the Pod for use in automating insulin delivery. The value and trend are displayed in the Omnipod 5 App.

When used without an active Pod: If you choose to use your Omnipod 5 App without a Pod, such as if you're returning to injections for a few days, you can still use the Omnipod 5 App to manage your glucose. Without an active Pod, the Sensor will send sensor glucose values and trend directly to the app. You can use the app in this way for up to 30 days.





# 21.2 FreeStyle Libre 2 Plus Sensor Application and Placement

After you have activated a Pod, you will set up a FreeStyle Libre 2 Plus Sensor as your Sensor of choice.

**Note:** Always confirm that the Pod you are activating is compatible with the FreeStyle Libre 2 Plus Sensor. The Pod tray lid and Pod box will show the words "FreeStyle Libre 2 Plus."

#### **Sensor Placement**

The Bluetooth connection between the Sensor and the Pod is optimal when the signal does not pass through the body. Keeping both devices within line of sight allows for consistent Sensor communication with the Pod.

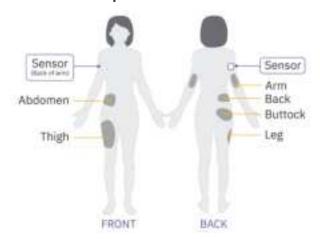
Line of sight means that the Pod and Sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.



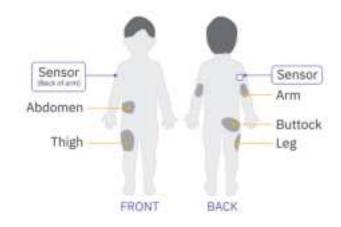
For Sensors indicated for the back of the upper arm, for example, consider these Pod placements to find the locations that work best for your body:

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

#### Adult placement examples



#### Pediatric placement examples





#### **Applying the Sensor**

To apply a Sensor:

- 1. Clean, disinfect, and dry the intended site.
  - a. Select a site on the back of your upper arm that stays flat during normal activity.
  - b. Clean the skin with non moisturizing, fragrance-free soap and water.



- c. Use an alcohol wipe to disinfect the skin and let it air dry before proceeding.
- d. Choose a site that is in line of sight to and at least 1 inch away from your Pod.

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

**Note:** Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

- 2. Prepare the applicator.
  - Open the Sensor Pack by peeling back the lid.
  - Unscrew the cap from the bottom of the Sensor applicator.
  - Line up the marks on the Sensor applicator as you insert it into the Sensor Pack.
  - Press down firmly on the applicator on a hard surface until it comes to a stop. Then lift the applicator.

The Sensor applicator is now ready to apply the Sensor.





**Caution:** The Sensor applicator contains a needle. Do not touch the inside of the Sensor applicator or put it back into the Sensor Pack.

- 3. Apply the Sensor.
  - Place the Sensor applicator over the selected site on the back of your upper arm and press firmly to apply.
  - Gently pull the Sensor applicator away from your body.
  - Make sure the Sensor is secure by pressing down on the Sensor and running your finger along the Sensor adhesive.



**Caution:** Do not push down on Sensor applicator until placed over prepared site to prevent unintended results or injury.

#### **Scanning the Sensor to Activate**

To activate the Sensor:

 To add the FreeStyle Libre 2 Plus Sensor to the Omnipod 5 App, tap ADD SENSOR.

If you are not in Manual Mode, you will be prompted to switch to Manual Mode.

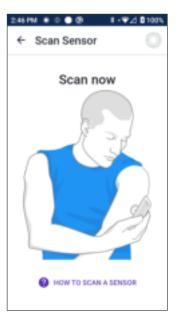
**Note:** If you have not already applied your Sensor to your body, you will be prompted to do so before continuing.

2. Scan the FreeStyle Libre 2 Plus Sensor by holding the bottom third of your Controller up to the Sensor.

Hold the Controller near the Sensor, and do not move it until the Controller vibrates to show that the scan is complete.

**Note:** It can scan through your clothes.

3. When you place the Controller up to the Sensor, it will activate the scan.





When the scan successfully completes, a message shows that you will not need to scan again until you start a new Sensor.

#### Tap OK.

**Note:** The Pod receives an updated sensor glucose value and trend every 5 minutes. You will not need to scan the Sensor for a new value. If you do not have an active Pod, the Omnipod 5 App will update its displayed glucose value from the Sensor.

# Scan successful You do not need to scan again until you start a new Sensor. The Omnipod 5 App updates your sensor glucose values every 5 minutes. Don't show this again

4. The Sensor will begin its 1-hour warm-up.

You can watch the progress of the warm-up on the Omnipod 5 App Home screen.

At the end of the warm-up period, your sensor glucose values are available to view in the app and for use in Automated Mode to adjust your insulin delivery.

**Caution:** During the first 12 hours of use of a FreeStyle Libre 2 Plus Sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

# 21.3 Using FreeStyle Libre 2 Plus Sensor with the Omnipod 5 App

After you have connected the FreeStyle Libre 2 Plus Sensor to the Omnipod 5 System, the Pod will receive a sensor glucose value from the Sensor every 5 minutes. These values are sent from the Pod to the Omnipod 5 App, allowing you to monitor your glucose and insulin delivery. If you use the Sensor without an active Pod, the app receives glucose values directly from the Sensor.



# Using FreeStyle Libre 2 Plus Sensor without an active Pod (Sensor-only state)

There may be times when you want to continue using a Sensor but take a break from using a Pod in favor of another insulin therapy, like injections. Since you typically use the Omnipod 5 App to start your Sensor and view your sensor glucose information, you can continue to do that even without an active Pod.

For the Sensor-only state (no active Pod), the Omnipod 5 App will update glucose Sensor values every 5 minutes directly from the FreeStyle Libre 2 Plus Sensor, rather than from a Pod. You will be able to view your Sensor graph, as well as alerts about high or low glucose. You will not receive information on insulin status until you activate a new Pod.

**Note:** You can use the Omnipod 5 App in the Sensor-only state for up to 30 days. If you plan to use an alternative insulin therapy, like injections, for more than 30 days, ask your healthcare provider about moving to a standalone FreeStyle Libre 2 Plus system. Remember that, to use a Sensor with the Omnipod 5 App, it must be scanned and started by the Omnipod 5 App.

**Note:** In the Sensor-only state, the Omnipod 5 Controller must be nearby and in line of sight with the Sensor for sensor glucose values to appear on the screen. Bring the Controller closer to the Sensor if you don't see values displayed.



To add a Sensor to the Omnipod 5 App, follow the 5 steps below:

1. Home screen shows no Sensor is detected.

**Note:** Before applying and scanning the FreeStyle Libre 2 Plus Sensor, the Omnipod 5 App will ask you to review and adjust (if necessary) your Sensor settings.



After you have reviewed and adjusted (if necessary) your Sensor settings.

#### Tap **ADD SENSOR**.

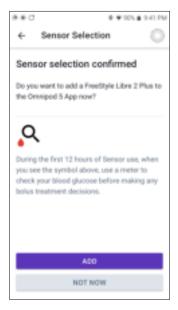
- 3. Apply a FreeStyle Libre 2 Plus Sensor. After you have applied the Sensor, tap **CONTINUE**.
- 4. Next, you will scan the FreeStyle Libre 2 Plus Sensor by placing the Controller up to the FreeStyle Libre 2 Plus Sensor, allowing it to scan the Sensor and begin activation. Do not move the Controller until the scan is complete.

#### Tap OK.

 After you have selected FreeStyle Libre 2 Plus as your Sensor option and you have reviewed your Sensor settings, confirm that you want to add your Sensor to the Omnipod 5 App.

#### Tap **ADD** to proceed.

Or tap **NOT NOW** to add the FreeStyle Libre 2 Plus Sensor to the Omnipod 5 App later.





#### **Review Sensor Glucose Values**

The Omnipod 5 App is where you can review and adjust your settings for high and low sensor glucose value alarms.

There are 3 optional, adjustable Sensor alarms to alert you to out-of-range glucose.

#### **High Glucose Alarm**

Screen Displayed:	Onverped 5 - Notifications - new: #  High Glacose Your sensor glucose value is above.
Cause:	The notification is set to ON and your sensor glucose value is above your High Glucose setting.
Controller sound	• 3 second tone
and vibration:	3 second vibration
	Alarm repeats every 5 minutes until your sensor glucose value is below your High Glucose setting or you acknowledge the notification
What to do:	Acknowledge the alarm by viewing the notification in the Notification bell or by dismissing the notification from the lock screen.
	Check your blood glucose     with a BG meter to confirm     your glucose value.



# Low Glucose Alarm

Screen Displayed:	Constport 5 - Notifications - new W      Law Glacose     Your sensor glucose value is below .
Cause:	The notification is set to ON and your sensor glucose value is below your Low Glucose setting.
Controller sound	• 3 second tone
and vibration:	• 3 second vibration
	<ul> <li>Alarm repeats every 5 minutes until your sensor glucose value is above your Low Glucose setting or you acknowledge the notification</li> </ul>
What to do:	Acknowledge the alarm by viewing the notification in the Notification bell or by dismissing the notification from the lock screen.
	Check your blood glucose with a BG meter to confirm your glucose value.



# Missing Sensor Glucose Values Alarm

Screen Displayed:	Ommond 5 - Notifications - new 8     Missing Sensor Values High and Low Glucose notifications.	
Cause:	The notification is set to ON and sensor glucose values have not been received for 20 minutes.	
	It may indicate that there has been a signal loss or a problem with your Sensor, and the Omnipod 5 App is not able to display your sensor glucose values or notify you when your sensor glucose is high or low.	
Controller sound	• 3 second tone	
and vibration:	• 3 second vibration	
	<ul> <li>Alarm repeats every 5 minutes for a total of 5 repeats until sensor glucose values are restored or you acknowledge the notification</li> </ul>	
What to do:	<ol> <li>Acknowledge the alarm by viewing the notification in the Notification bell or by dismissing the notification from the lock screen.</li> </ol>	
	2. Check that your Sensor is still applied to your skin.	
	3. To minimize the risk of interruption, make sure your FreeStyle Libre 2 Plus Sensor and Pod are worn on the same side of the body. Wireless communications do not travel well through the body. If you experience frequent connectivity loss between the Pod and Sensor, see "27.3 Sensor FAQs" on page 449.	



#### **Urgent Low Glucose**

**Caution:** ALWAYS promptly treat low glucose. Glucose at or below 55 mg/dL indicates significant hypoglycemia (very low glucose). If left untreated, this could lead to seizure, loss of consciousness and death. Follow your healthcare provider's recommendations for treatment.

When your sensor glucose value is at or below 55 mg/dL, your FreeStyle Libre 2 Plus Sensor will send the value to your Pod. The Pod will sound an Advisory Alarm to let you know that your glucose is very low. You can acknowledge the alarm from your Controller.

If you do not have an active Pod, the Omnipod 5 App will issue the Advisory Alarm. See "21.1 FreeStyle Libre 2 Plus Sensor Overview" on page 329.

**Note:** This Alarm will occur again if another sensor glucose value of 55 mg/dL or lower is received after the initial Advisory Alarm was acknowledged. You may silence (snooze) this Advisory Alarm for 30 minutes by acknowledging the on-screen message.

**Note:** This Advisory Alarm will stop repeating only after a glucose value of 56 mg/dL or greater is received.

**Action to Take:** Use a BG meter to confirm your glucose. Treat low glucose as needed.



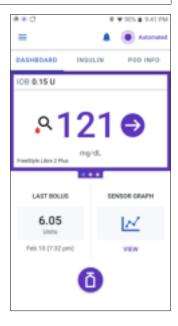
#### Using Sensor Glucose Values in the First 12 Hours

**Caution:** During the first 12 hours of use of a FreeStyle Libre 2 Plus Sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

Your sensor glucose values can be used by the Omnipod 5 System in Automated Mode to adjust your insulin as soon as the 1-hour warm-up is complete, but your sensor glucose values and trend cannot be used with the SmartBolus Calculator for the first 12 hours of Sensor wear.

During the first 12 hours after connecting a Sensor, you cannot tap **USE SENSOR** to import your sensor glucose value and trend into the SmartBolus Calculator.

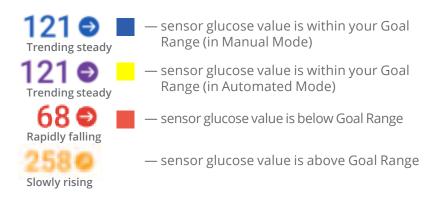
You can manually enter a BG reading from a BG meter during the first 12 hours of Sensor use and whenever you see the Verify Sensor Values icon on the Home screen.





#### 21.4 Sensor Glucose Trends and Indicators

Colors and trend arrows display on the Home Screen to show your sensor glucose value and trend. They will change depending on your Glucose Goal Range.



#### **Glucose Trend Arrows**

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

Trend Arrows	Description
•	Glucose is rising quickly (more than 2 mg/dL per minute)
<b>2</b>	Glucose is rising (between 1 and 2 mg/dL per minute)
9	Glucose is changing slowly (less than 1 mg/dL per minute)
<b>(2)</b>	Glucose is falling (between 1 and 2 mg/dL per minute)
•	Glucose is falling quickly (more than 2 mg/dL per minute)



#### **View Sensor Glucose Graph**

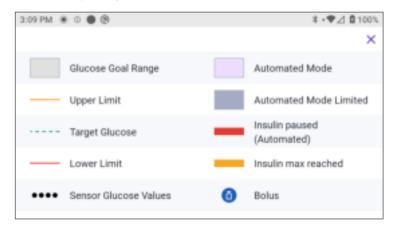
You can view the Sensor Graph from the Home Screen by tapping VIEW under the Sensor Graph icon in the lower right side of the Home screen.

When you tap **VIEW**, the Sensor Graph will display.



To display the Sensor Graph legend, tap the question mark icon in the lower right of the graph.

The Sensor Graph Legend will show:



The Sensor Graph Legend explains the colors and use of lines on the graph which show your sensor glucose and insulin delivery over the past few hours.



# 21.5 FreeStyle Libre 2 Plus Sensor Communication and Problem Messages

# **Communication Messages**

The following are the communication messages that show on the Dashboard of the Omnipod 5 App that are associated with the FreeStyle Libre 2 Plus Sensor.

Communication Message	Description
CONNECTING	Appears after you have applied and scanned a FreeStyle Libre 2 Plus Sensor and your device or Pod are connecting to the Sensor.
SENSOR READY AT 2.76 PM	Appears when the Sensor is connected and starting up and sensor glucose values are unavailable.
	No action is required within the Omnipod 5 App.
SENSOR CONNECTED AND READY SENSOR CONNECTED AND READY	Sensor has recently completed start-up and glucose values will be available in a few minutes.
SEARCHING FOR POD	Appears when Pod communication was not established within the most recent 5-minute update interval.
	Tap <b>MORE INFORMATIO</b> N for potential causes and recommended actions.



Communication Message	Description
SEARCHING FOR SENSOR	Appears when a Sensor is being used with or without a Pod and the most recent sensor glucose value was not acquired within a 5-minute window.
	There may be no valid sensor glucose value available due to a communication issue between Pod and Sensor, or it could be a temporary Sensor issue (recoverable without any user action).
	Tap <b>MORE INFORMATION</b> for recommended action. Review Pod and Sensor placement.
	Pod and Sensor should be at least 1 inch apart and within line of sight.



## **Problem Messages**

The following is a summary of the Sensor problem messages associated with the FreeStyle Libre 2 Plus Sensor that display on the Home screen Dashboard and indicate a problem and a need for action. These messages show with a red alarm icon and are in red text. More specific information for each message follows the summary.

Dashboard Message and Display	Description of Problem	Action to Take
Sensor too cold	Your Sensor is too cold to provide a glucose value.	Move to a warmer location and try again in a few minutes.
Sensor too hot	Your Sensor is too hot to provide a glucose value.	Move to a cooler location and try again in a few minutes.
Temporary Sensor problem  TEMPORARY SENSOR PROBLEM	Your Sensor is temporarily unable to send sensor glucose values to the Pod or Omnipod 5 App.	Check again in 10 minutes.
Sensor Error  SEMSOR ERROR	Sensor glucose value is unavailable. Occurs early in Sensor wear when values are unable to be confirmed as accurate.	Tap <b>Need Help</b> .
Sensor Ended      srusce runn	Your Sensor has ended. Your Omnipod 5 Pod and App will receive no further information from this Sensor.	To use the Omnipod 5 System in Automated Mode, add a new Sensor and have an active Pod on.



Dashboard Message and Display	Description of Problem	Action to Take
No Sensor	No Sensor is detected.	To use the Omnipod 5 System in Automated Mode, add a Sensor and have an active Pod on.
Replace Sensor  Replace Sthsps	The System has detected a problem with your Sensor that cannot be fixed. Your Omnipod 5 Pod and App will receive no further information from this Sensor.	Remove old Sensor. Add a new Sensor.
Failed to Connect	Your Pod and Sensor were not able to connect.	Try connecting again. If the problem continues, reboot your Controller or replace the recently applied Pod or Sensor.

#### Sensor too cold

Screen Alert	Description
Home Screen:	Why it occurs: Your Sensor is too cold to provide a glucose value.
<b>©</b> Mwon 1to (o.6·	Pod sound: None
·	Controller sound and vibration: None
⊕ HEXO HEIDS	What to do:
	1. Move to a warmer location.
	2. Try again in a few moments.



#### Sensor too hot

Screen Alert	Description
Home Screen:	<b>Why it occurs:</b> Your Sensor is too hot to provide a glucose value.
O directs fire ser	Pod sound: None
0	Controller sound and vibration: None
Ф нехо нель	What to do:
	1. Move to a cooler location.
	2. Try again in a few moments.

# **Temporary Sensor problem**

Screen Alert	Description
Home Screen:  108 8.15 U TEMPORARY SENSOR PROBLEM	Why it occurs: Your Sensor is temporarily unable to send sensor glucose values to the Pod or Omnipod 5 App.
	Pod sound: None
① MEED HELP	Controller sound and vibration: None
	What to do:
	Wait and try again in 10 minutes.



# **Sensor Error**

Screen Alert	Description
Sensor Error:	Why it occurs: Your sensor glucose value is unavailable. This usually occurs early in the Sensor's life when values may be less accurate.
0	Pod sound: None
© MIDHEP	Controller sound and vibration: None
	What to do:
	Tap <b>NEED HELP</b> for a time to check back for a glucose value.
	1. Try again when glucose values are available.

