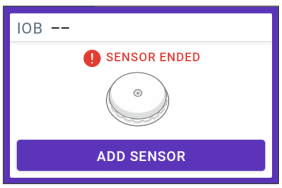
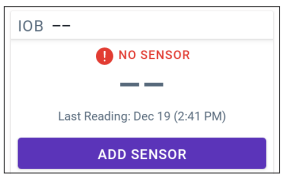
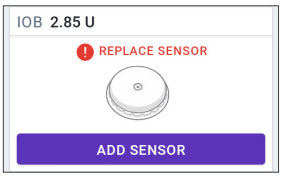
Sensor ended

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** Your Sensor has ended. Your Omnipod 5 Pod and App will receive no further information from this Sensor.
	Pod sound: None
	Controller sound and vibration: None
	What to do: To use the Omnipod 5 System in Automated Mode, you need to add a new Sensor and have an active Pod on. 1. Tap **OK.** 2. Remove the old Sensor from your body. 3. Add a new Sensor. 4. Scan the new Sensor to activate it. **Note:** For detailed instructions, see "Contents" on page 327 and "Scanning the Sensor to Activate" on page 334.

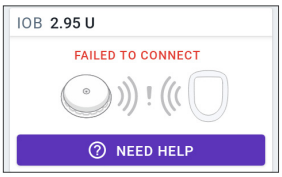
No Sensor

Screen Alert	Description
Home Screen: 	**Why it occurs:** No Sensor is detected. **Pod sound:** None **Controller sound and vibration:** None **What to do:** To use the Omnipod 5 System in Automated Mode, add a Sensor and have an active Pod on. 1. Tap **ADD SENSOR.** 2. Add the Sensor to your body. 3. Scan the new Sensor to activate it. **Note:** For detailed instructions, see "Contents" on page 327 and "Scanning the Sensor to Activate" on page 334.

Replace Sensor

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** 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.
	Pod sound: None
	Controller sound and vibration: None
	What to do: 1. Tap **OK** (from the Omnipod 5 App screen) or tap Add Sensor (from the Home screen). 2. Remove the old Sensor from your body. 3. Add a new Sensor. 4. Scan the new Sensor to activate it. **Note:** For detailed instructions, see "Contents" on page 327 and "Scanning the Sensor to Activate" on page 334.

Failed to Connect

Screen Alert	Description
Home Screen: 	**Why it occurs:** Your Sensor did not connect to the Pod.
	Pod sound: None
	Controller sound and vibration: None
	What to do: 1. Try connecting the Sensor again. 2. If the problem continues, replace your Sensor.

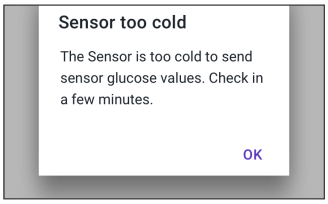
How to respond to Problem Messages

The Omnipod 5 App displays messages on your Dashboard screen when there may be a problem with your Sensor. Respond to these issues as soon as possible.

1. When a message displays, follow the screen instructions.

   For example, for the **SENSOR TOO COLD** alarm, tap the **NEED HELP** button.

2. When you tap the **NEED HELP** button, an explanation of the issue will show, with a recommendation of what to do next, e.g., Check in a few minutes.



If a problem continues and you receive multiple messages on your device, contact Customer Care.

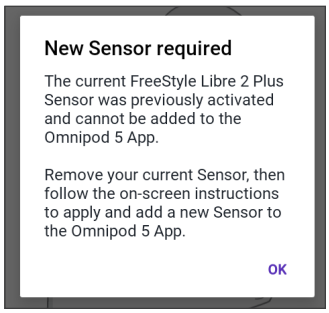
21.6 About Connecting a FreeStyle Libre 2 Plus Sensor to the Pod

The Omnipod 5 System is designed to work with the FreeStyle Libre 2 Plus Sensor. To use the FreeStyle Libre 2 Plus Sensor with the Omnipod 5 System, you will need to obtain a FreeStyle Libre 2 Plus Sensor and the *FreeStyle Libre 2 Plus Sensor Instructions for Use.*

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 a FreeStyle Libre 2 Plus Sensor. After you are 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.

The Sensor can connect to the Pod during Sensor warm-up, but needs to complete warm-up before it is able to send glucose values to the Pod.

Before you begin, consider the following:



- The Omnipod 5 System will not connect with a FreeStyle Libre 2 Plus Sensor if you started the Sensor using another device. You must start the Sensor with the Omnipod 5 App on the Insulet-provided Controller.
- If you have an existing Sensor that was previously activated outside the Omnipod 5 App, the System will let you know that a new Sensor is required. Remove your current Sensor and apply a new Sensor or wait until you are ready to start a new FreeStyle Libre 2 Plus Sensor.
- Always confirm that you are using a Pod that is compatible with a FreeStyle Libre 2 Plus Sensor. The Pod tray lid and Pod box will show compatibility with a FreeStyle Libre 2 Plus Sensor.

For additional instructions about using the FreeStyle Libre 2 Plus Sensor, see the *FreeStyle Libre 2 Plus Sensor Instructions for Use.*

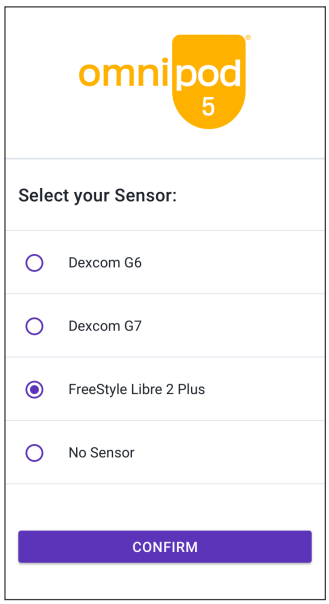
21.7 Connecting a FreeStyle Libre 2 Plus Sensor during Initial Pod Setup

To make a FreeStyle Libre 2 Plus Sensor your glucose Sensor of choice, follow these steps:

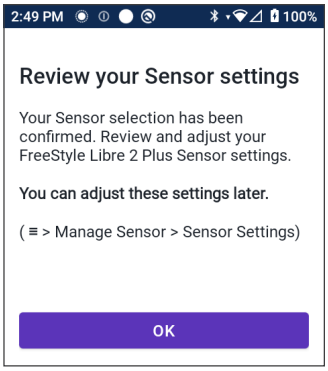
1. When prompted, select the FreeStyle Libre 2 Plus Sensor from the options on the screen.
   - Dexcom G6
   - Dexcom G7
   - FreeStyle Libre 2 Plus
   - No Sensor

   Tap **CONFIRM**.

   The App will confirm your Sensor selection. Next, the app will ask you to review your Sensor settings.

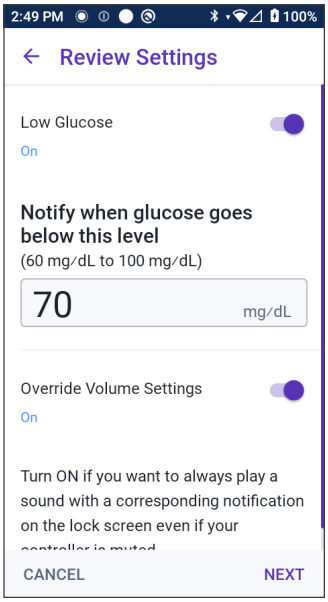


2. On the Review your Sensor settings screen, tap **OK**, to review or adjust, if necessary, your FreeStyle Libre 2 Plus Sensor settings.



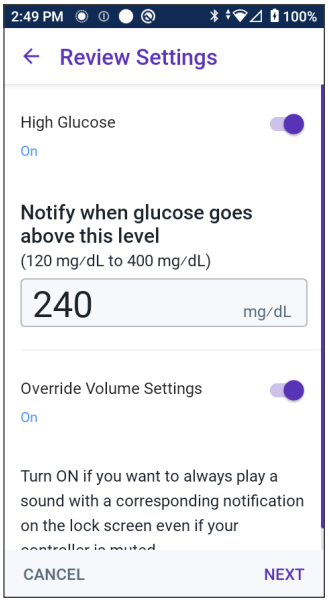
3. **Low Glucose settings:** Review or adjust your Low Glucose setting.
   - The notifications are ON by default. If the toggle is OFF (grayed out), tap the toggle to turn ON.
   - If the low glucose setting is correct, tap **NEXT** to move to the High Glucose setting screen.
   - To change the Low Glucose setting, tap the glucose field to access a scroll wheel.
4. Select a Low Glucose value, then tap **DONE** to save your selection.

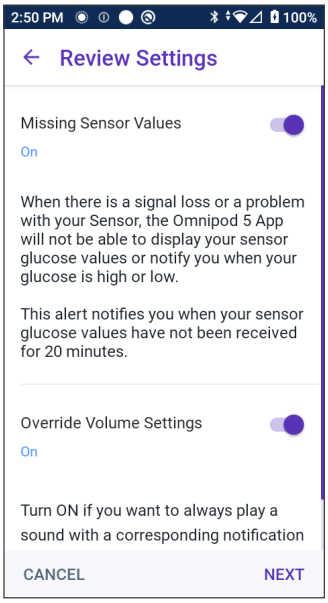
   Tap **NEXT** to move on to the High Glucose settings screen.
5. Select your alert volume preferences.



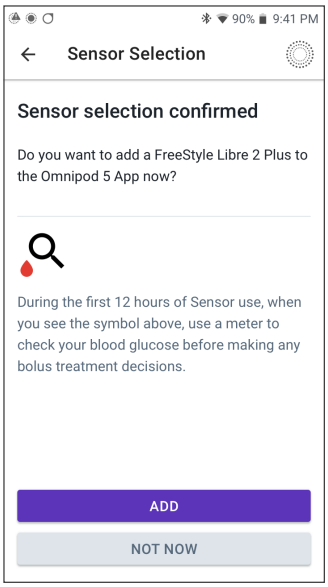
6. **High Glucose settings:** Review or adjust your High Glucose setting.
   - The notifications are ON by default. If the toggle is OFF (grayed out), tap the toggle to ON.
   - If the high glucose setting is correct, tap NEXT to move to the Missing Sensor Glucose Values setting screen.
   - To change the High Glucose setting, tap the glucose field to access a scroll wheel.
7. Select a High Glucose value from the list, then tap **DONE** to save the value.
8. Select your alert volume preferences.
9. Tap **NEXT** to move on to the Missing Sensor Glucose Values screen.
10. **Missing Sensor Glucose Values:** Turn on or adjust your Missing Sensor Glucose Values notification setting.

    Note: The Missing Sensor Glucose Values alert is designed to notify you that sensor glucose values have not been received for 20 minutes. It may mean that there has been a signal loss between your Sensor and Pod, or a problem with your Sensor.
    - The notification is ON by default. If the toggle is OFF (grayed out), tap the toggle to turn ON.
    - Select your alert volume preferences.
    - Tap **NEXT** to save your Sensor settings.
11. The System confirms that it saved your Sensor settings.





12. Next, to add your Sensor, tap **ADD**.



13. At this point, you can apply a FreeStyle Libre 2 Plus Sensor.

    If you need more help, tap How to apply a Sensor at the bottom of the screen to review step-by-step help with illustrations.

    When you have applied your Sensor, tap **CONTINUE**.

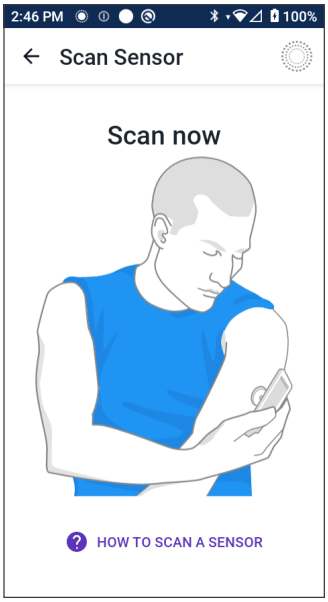
14. Scan your FreeStyle Libre 2 Plus Sensor by placing the Controller up to the Sensor, allowing it to scan the Sensor, and begin activation.

    If you need more help, tap **HOW TO SCAN A SENSOR** at the bottom of the screen for instructions on scanning.

    After scanning, the Scan successful message displays:

    Tap **OK**.

    It can take up to 20 minutes for your Sensor to connect to your Pod and display in the app.



    When Pod communication is successful: The screen will either show the number of days until your Sensor ends, or if the Sensor is still starting up, it will give the Time Remaining when your Sensor will be ready.

    If the Pod is unable to connect with the Sensor within 20 minutes: The message "Pod and Sensor failed to connect" displays. Try connecting again. If the problem continues, you may need to replace the Sensor.

15. If Pod communication is successful, you can switch to Automated Mode.

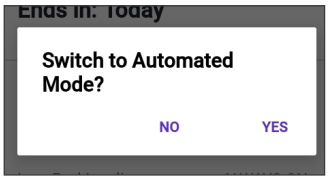
    To switch to Automated Mode, tap **YES**.

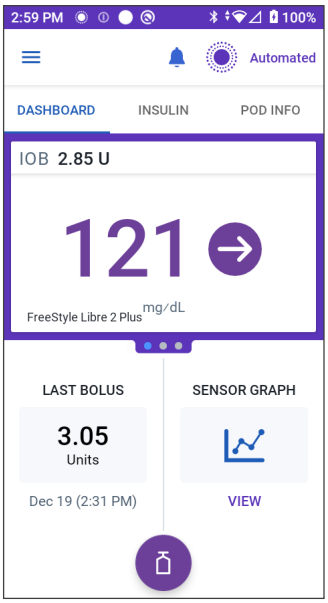
16. **Automated: Limited state**

    During Sensor warm-up, and until your Sensor can send a current glucose value to the Pod, your System will be in Automated: Limited state.

    When warm-up is complete and sensor glucose values are available, you will enter Automated Mode.

    Your sensor glucose values are updated every 5 minutes until the Sensor ends or is deleted from the System.





21.8 Sensor Removal: Expiration and Deletion

To take off the old Sensor, pull up the adhesive's edge and slowly peel it away in one motion.

The Sensor is disposable and should be disposed of according to local guidelines. For instructions about removing and disposing of Sensors, see the *FreeStyle Libre 2 Plus Sensor Instructions for Use.*

Sensor Ending

When your Sensor reaches the end of its wear duration, the Home Screen will show that your Sensor has ended with a **SENSOR ENDED** message. You can remove the Sensor from your body and apply a new Sensor. For more information about the Sensor Ended message, see "21.5 FreeStyle Libre 2 Plus Sensor Communication and Problem Messages" on page 345.

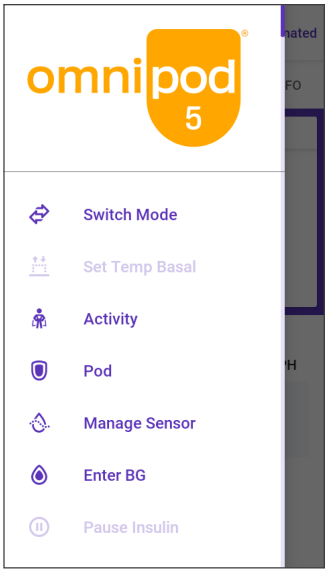
Deleting a Sensor

When you want to remove your Sensor before the end of its wear duration, you will need to delete the Sensor from Omnipod 5. Deleting a Sensor tells the Pod to stop communicating with and looking for that Sensor.

You do not need to delete a Sensor that lasts the full wear duration.

To delete a FreeStyle Libre 2 Plus Sensor through the Omnipod 5 App:

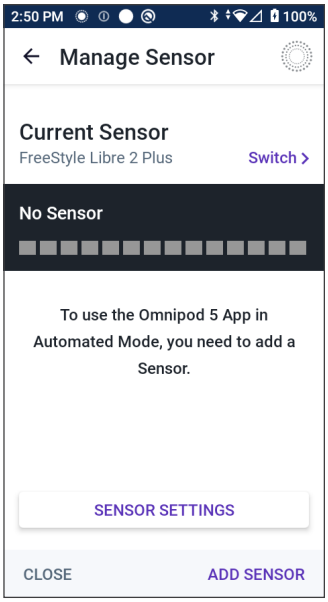
1. Tap **Manage Sensor** from the menu.



2. To delete the current Sensor, tap **DELETE SENSOR** at the bottom of the screen, so that the Pod has instructions to disconnect from the Sensor.

   If you are in Automated Mode, "Switch to Manual Mode" will display.

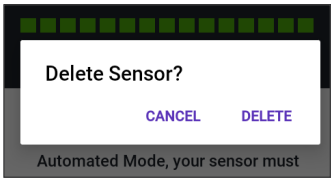
   Note: To delete a Sensor, you must be in Manual Mode.



3. Next, the Omnipod 5 App asks you to confirm that you want to delete the Sensor. Tap **DELETE**.

   If you do not want to delete the Sensor, tap **CANCEL**.

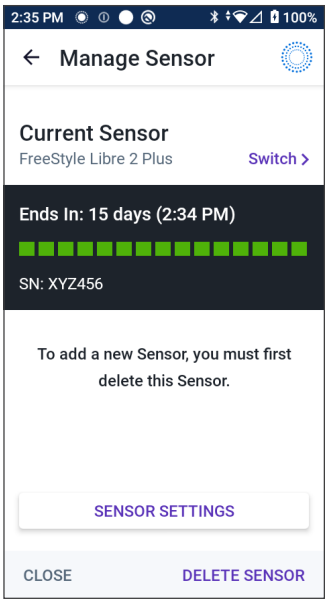
   The Omnipod 5 App confirms that the Sensor has been deleted.



4. Remove the old Sensor from your body.

   When you have deleted the Sensor, the Omnipod 5 App shows that your Pod is not connected to an active Sensor.

   Note: To add a new Sensor, tap **ADD SENSOR** and follow the instructions on the screen that will prompt you to apply, activate, and pair the Omnipod 5 System with the new Sensor.



21.9 Switching to a FreeStyle Libre 2 Plus Sensor 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 a FreeStyle Libre 2 Plus Sensor with your Omnipod 5 System from another type of compatible Sensor, you can switch Sensors in the Omnipod 5 App.

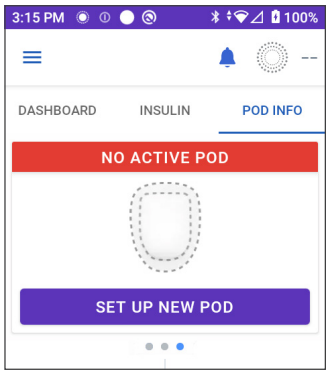
Note: Switching Sensor types must be done between Pod changes. A single Pod cannot connect with more than one brand or model of Sensor during its wear period.

To switch to the FreeStyle Libre 2 Plus Sensor from another Sensor:

1. Open the Omnipod 5 App to the **POD INFO** screen.

   Note: You cannot switch Sensor types 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.

   Navigate to **Menu button** (☰) > **Manage Sensor.**



2. The Omnipod 5 App 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 and would like to switch to using a FreeStyle Libre 2 Plus Sensor.

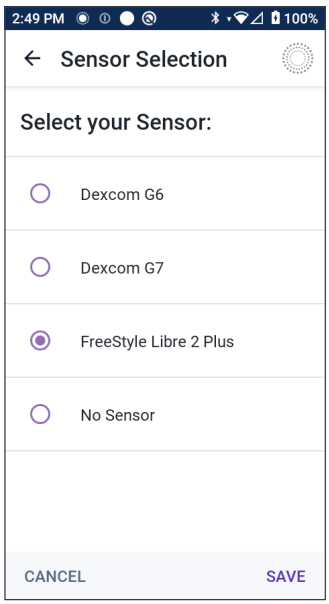
3. The Sensor Selection screen shows your options with your current Sensor model selected.

4. To switch to the FreeStyle Libre 2 Plus Sensor with the Omnipod 5 system, select FreeStyle Libre 2 Plus.

   Tap **SAVE**.

5. The Omnipod 5 App confirms your switch to FreeStyle Libre 2 Plus.

   Tap **CONFIRM** to acknowledge.



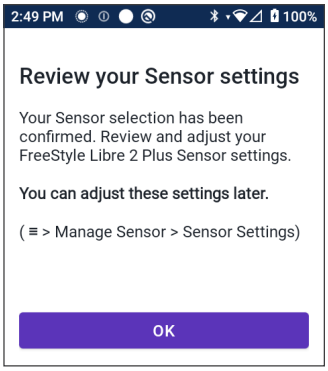
6. Review your Sensor settings.

   Tap **OK**.

   A series of screens will display allowing you to enter or adjust your notification settings for:

   - Low Glucose
   - High Glucose
   - Missing Sensor Glucose Values

   Note: For detailed instructions and screen images for reviewing your settings, see Step 3 to Step 8 in "21.7 Connecting a FreeStyle Libre 2 Plus Sensor during Initial Pod Setup" on page 345.



7. The Omnipod 5 App will ask:

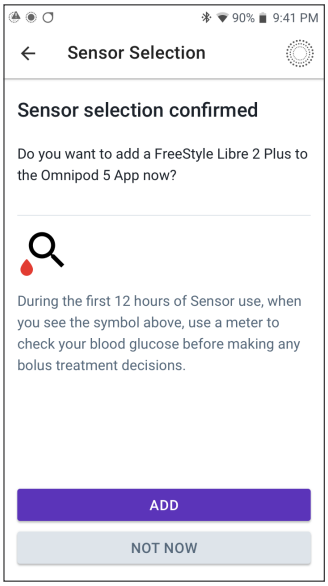
   Do you want to add a FreeStyle Libre 2 Plus Sensor to Omnipod 5 now?

   Tap **ADD** to add your FreeStyle Libre 2 Plus Sensor.

   Tap **NOT NOW** to add the FreeStyle Libre 2 Plus Sensor to the Omnipod 5 App later.

   Follow the on-screen prompts to apply, activate, and pair the Omnipod 5 System with a new Sensor.

   Note: Review Section"21.7 Connecting a FreeStyle Libre 2 Plus Sensor during Initial Pod Setup" on page 345 for more information on applying and scanning a Sensor.



8. Next, the screens will take you through the following tasks:

   a. Apply the FreeStyle Libre 2 Plus Sensor. See step 10 on page 358 for more details.

   b. Scan and activate the new Sensor. See step 11 on page 358 for more details.

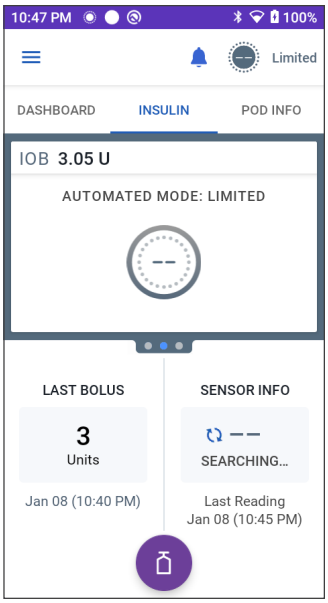
   c. Activate a new Pod and wait for the Sensor warm-up to complete. You will then be able to enter Automated Mode. See step 12 and 13 on page 359.

9. **Automated: Limited state**

   During Sensor warm-up, and until your Sensor can send a current glucose value to the Pod, your System will be in Automated: Limited state.

   When warm-up is complete and sensor glucose values are available, you will enter Automated Mode.

   Your sensor glucose values are updated every 5 minutes until the Sensor ends or is deleted from the System.



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AUTOMATED MODE

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Automated Mode Important Safety Information

Automated Mode Warnings

Warning: SmartAdjust technology should NOT be used by anyone under the age of 2 years old. SmartAdjust technology should also NOT be used in people who require less than 5 units of insulin per day as the safety of the technology has not been evaluated in this population.

Warning: DO NOT use SmartAdjust technology in pregnant women, critically ill patients, and those on dialysis. The safety of SmartAdjust technology has not been evaluated in these populations. Consult with your healthcare provider if any of these conditions apply to you before using SmartAdjust technology.

Warning: ALWAYS be aware of your current sensor glucose values, 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 can 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: AVOID administering insulin, such as by injection or inhalation, while wearing an active Pod as this could result in hypoglycemia. 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.

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

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 over-delivery 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 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.

CHAPTER 22

About Automated Mode

Contents

22.1 About Automated Mode

Warning: AVOID administering insulin, such as by injection or inhalation, while wearing an active Pod as this could result in hypoglycemia. 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.

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: 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 over-delivery or under-delivery of insulin, which can lead to hypoglycemia or hyperglycemia.

Automated Mode is the defining feature of the Omnipod 5 System. In Automated Mode, SmartAdjust™ technology (the Omnipod 5 algorithm) predicts where your glucose will be 60 minutes into the future. SmartAdjust technology uses this information, along with your current sensor glucose value and trend, to automatically adjust insulin delivery every 5 minutes. The System's goal is to help you bring your glucose to your defined Target Glucose.

SmartAdjust technology is on the Pod itself. You will stay in Automated Mode even if the Controller or smartphone running your Omnipod 5 App is out of range of the Pod. When the Pod and Controller or smartphone are in range, the Pod sends its information back to the Omnipod 5 App, updating its Home screen to show your current IOB along with recent sensor glucose value and trend.

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

How insulin is calculated and delivered during Automated Mode

The Omnipod 5 System uses your total daily insulin history over the last few Pods to determine how much insulin your body needs. The calculated amount per hour is known as the Adaptive Basal Rate, which provides a baseline for automated insulin delivery.

With each Pod change, the Omnipod 5 System will learn your recent daily insulin needs and update information about your total daily insulin, resulting in your Adaptive Basal Rate changing with each new Pod to better match your true insulin needs.

Using this Adaptive Basal Rate as a starting point, the System can automatically increase, decrease, or pause insulin delivery every 5 minutes to help you reach your Target Glucose.

Increasing Insulin Delivery

The System can increase insulin delivery by delivering a series of insulin microboluses (small amounts of insulin delivered every 5 minutes) to respond to elevated glucose or if it predicts your glucose to be above your Target Glucose in the next 60 minutes.

Decreasing and Pausing Insulin Delivery

The System can decrease or pause automated insulin delivery at any time if you are predicted to be below your Target Glucose or to protect against hypoglycemia.

It will always pause insulin when the last sensor glucose value recorded was below 60 mg/dL.

Viewing Automated Insulin Delivery

The Sensor Graph on the Home screen shows when the Omnipod 5 System paused insulin delivery or has reached the maximum delivery. See "11.2 Viewing the Sensor Graph" on page 150.

The automated insulin delivery amount given every 5 minutes while in Automated Mode can be seen in the Auto Events tab of the History Detail screen. See "Automated Events (Auto Events)" on page 162.

The Auto Events tab shows the total amount of automated insulin delivered every 5 minutes. This tab shows all automated insulin, both your baseline Adaptive Basal Rate and any adjustment up or down due to your sensor glucose value, trend, and 60-minute prediction. The values will always be small. (Remember that a basal rate of 0.60 U/hr would be like getting 0.05 U every 5 minutes.)

Note: Your sensor glucose value informs how much insulin the System will deliver in the next 5-minute time period. For example, if your sensor glucose value at 11:00 dropped to 58 mg/dL, SmartAdjust technology will not deliver a microbolus at 11:05. Your Auto Events tab will display 0 U at 11:05, as shown in the table below.

Time	Sensor (mg/dL)	Insulin Amount (U)
11:05	62	0
11:00	58	0.05

Adjusting settings for Automated Insulin Delivery

While you are using Automated Mode, the main adjustable setting affecting automated insulin delivery is Target Glucose. Target Glucose is customizable from 110–150 mg/dL (10 mg/dL increments), and you can create up to 8 different time segments per day. As you increase the Target Glucose setting value, SmartAdjust technology will deliver less automated insulin. Changing your Target Glucose can be useful if:

- There are times of the day when you are more or less sensitive to insulin (For example, you and your healthcare provider identify a time in your day when you are more at risk of hypoglycemia which may require a higher Target Glucose). Your provider can help you select different Target Glucose values for different times of day.
- You would like to gradually bring your Sensor glucose values down to a lower Target Glucose (For example, starting the system for the first time).

Consult with your healthcare provider before making any changes in your Target Glucose. See "Omnipod 5 Clinical Studies" on page 397for clinical study information at each Target Glucose.

SmartBolus Calculator settings can also be adjusted to impact your total daily insulin delivered and impact post-meal glucose. These settings include Insulin-to-Carbohydrate ratio, Correction Factor, Correct Above, Reverse Correction and Duration of Insulin Action. These all affect the bolus amounts you deliver during both Manual Mode and Automated Mode.

Note: It is important to understand that changing your Basal Programs, Max Basal, Correction Factor, or Duration of Insulin Action setting will not impact SmartAdjust technology (the Omnipod 5 algorithm).

22.2 About the Sensor in Automated Mode

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 (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.

While in Automated Mode, the Omnipod 5 System relies on your current and predicted sensor glucose values to calculate automated

insulin delivery. Sensor glucose values and trends may also be used by the SmartBolus Calculator in both Automated and Manual Modes.

It is important that your Sensor is functioning properly, delivering accurate values, and connecting to your Pod.

To ensure Sensor accuracy, be aware of your sensor glucose values. If you are experiencing symptoms that do not match your sensor glucose values, use a separate BG meter.

When your Pod and Sensor lose communication in Automated Mode, the System will enter Automated: Limited state. For more about Automated: Limited, see "22.5 About Automated Mode: Limited" on page 379.

If you experience frequent connectivity loss between the Pod and Sensor, see "27.3 Sensor FAQs" on page 449.

Connectivity issues can often be resolved by the following:

- Wear the Pod and Sensor in line of sight in such a way that the two devices can “see” one another.
- If using a Dexcom G6 Sensor:
    - Check that your current, active Transmitter is paired to the Pod by checking that the Transmitter serial number (SN) stored in both the Omnipod 5 App and in the Dexcom G6 mobile App are the same.
    - Check that your active Transmitter is not paired with a Dexcom G6 receiver or another medical device. When using Omnipod 5 , the Pod is the only medical device the Transmitter can pair with. You must use the Dexcom G6 mobile App on a smartphone to manage Sensor alarms and to start and stop Sensors and Transmitters.
- If using a Dexcom G7 Sensor:
    - Check that your current, active Dexcom G7 Sensor is paired to the Pod by checking that the pairing code and serial number stored in the Omnipod 5 App match the pairing code stored in the Dexcom G7 mobile App and the pairing code and serial number from your Dexcom G7 applicator.
- If using a FreeStyle Libre 2 Plus Sensor:
    - Check that your Sensor was started in the Omnipod 5 App. If your Sensor was started with another device, you will not be able to use the Sensor with Omnipod 5.

22.3 Bolus Settings and Importance of a Bolus

In Automated Mode, the Omnipod 5 System automatically delivers insulin every 5 minutes. However, you still need to deliver a bolus dose for meals. For information on how to deliver a bolus, see "SmartBolus Calculator" on page 247.

When delivering a bolus, it is recommended to:

- Tap **USE SENSOR** to use your Sensor glucose value in the SmartBolus Calculator. This will ensure that your sensor trend is included in the calculations and necessary adjustments are made to account for the trend.
- Review the SmartBolus Calculator calculations for accuracy. If the calculations show an amount you are not expecting, cancel the bolus and begin again.
- Always look for the progress bar to confirm that delivery has begun before exiting the Omnipod 5 App.

Note: If you leave the Omnipod 5 App for more than 5 minutes while making changes to your bolus delivery, you will lose the information you have entered into the SmartBolus Calculator.

22.4 Pod Adaptivity

In Automated Mode, automated insulin delivery adapts to your changing needs as you wear the System. As you use the Omnipod 5 System and gather insulin delivery history, SmartAdjust technology will automatically update your next Pod with information from your last few Pods about your recent total daily insulin (TDI).

Your baseline Adaptive Basal Rate is based on how much total daily insulin you have needed over the past few weeks. With each Pod change, SmartAdjust technology uses this updated TDI to set a new Adaptive Basal Rate for you.

When sensor glucose values and trend are available, SmartAdjust technology will also adjust this rate up or down every 5 minutes in response to your current and predicted glucose.

The First Pod

During your first Pod wear (or if you've gone 30 days or longer between Pods), since no recent history is available, the Omnipod 5 System estimates your total daily insulin by looking at your active Basal Program (from Manual Mode). SmartAdjust technology sets a

starting baseline Adaptive Basal Rate from that estimated TDI. That is the starting rate that will be adjusted up or down based on your current and predicted glucose and trend.

The System also sets a limit on how much insulin the first Pod's 5-minute adjustments can deliver for your safety.

At your next Pod change, if at least 48 hours of history was collected, SmartAdjust technology will start using your insulin delivery history instead of its original estimate to update the Adaptive Basal Rate.

Ongoing Use

With each Pod change, for as long as you wear the System, updated insulin delivery information is sent and saved in the Omnipod 5 App so that the next Pod that is started is updated with the new Adaptive Basal Rate.

Note: Your total daily insulin (TDI) includes all of the insulin delivered in either Automated or Manual Mode. You can view your TDI for each day by navigating to **Menu button** (☰) > **History Detail** and looking at the Total Insulin value.

22.5 About Automated Mode: Limited

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, (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.

At times, your Pod and Sensor may lose communication while you are in Automated Mode. There are several reasons this could happen, including:

- The Pod and Sensor not being within line of sight on your body.
- Temporary loss of communication due to environmental interference.
- Sensor warm-up or required calibration (for Sensors requiring calibration).
- If you use a Dexcom Sensor and your Sensor or Transmitter is still paired with a Dexcom receiver or other medical device.

When this occurs, SmartAdjust technology can no longer adjust your automated insulin delivery based on glucose because the Pod is not receiving updated glucose information from the Sensor.

After 20 minutes of the Pod not receiving sensor glucose values, you move into a state of Automated Mode called Automated: Limited. The Omnipod 5 App will display 'Limited' on the Home screen. Your System will remain in Automated: Limited until Sensor communication is restored or the Sensor warm-up period ends.

When the System enters Automated: Limited state, SmartAdjust technology bases its insulin delivery on the following:

- It looks at your basal rate in Manual Mode at this time of day and your Adaptive Basal Rate for this Pod and chooses the lower of the two values every 5 minutes. In this way, SmartAdjust technology never gives more than the Basal Program that would be active during Manual Mode.
- If SmartAdjust technology had paused your insulin before the Pod lost connection with your Sensor, it will continue to pause insulin up to 40 minutes for a total of 1 hour paused. After 1 hour of no sensor glucose information, it will resume your insulin at your adaptive or manual basal rates, whichever is lower.
- Without sensor glucose information, the rate delivered in Automated: Limited will not adjust up or down for current or predicted glucose.

After an hour of missed sensor glucose values, the Missing Sensor Glucose Values Advisory Alarm is presented. This alarm will repeat every 15 minutes until acknowledged and every 60 minutes until Sensor communication is restored. For more information on this alarm, see "Missing Sensor Glucose Values" on page 394.

The System also enters Limited state after receiving the Automated Delivery Restriction Advisory Alarm. For more information about Automated Delivery Restriction, see "22.6 Automated Delivery Restriction" on page 381.

You may also choose to switch to Manual Mode to start your Basal Program. See "23.2 Switching from Automated Mode to Manual Mode" on page 383.

If you use Dexcom as your Sensor, check your Dexcom App. See your *Dexcom CGM System Instructions for Use.*

If you use FreeStyle Libre 2 Plus as your Sensor, check for notifications related to FreeStyle Libre 2 Plus in your Omnipod 5 App.

Note: Automated: Limited state can occur due to a loss of communication between the Sensor and Pod. If you use Dexcom, it is possible that your Dexcom App is still receiving sensor glucose values. Open your Dexcom App to check.

22.6 Automated Delivery Restriction

There may be times when the System has been working to bring your glucose into range but has not seen your glucose change the way it expected. In this case, it will switch to Automated: Limited state.

During these times, you'll see an orange bar on your Sensor Graph for "Insulin max reached" or a red bar for "Insulin paused." The System will show an Advisory Alarm that says "Automated Delivery Restriction."

For more information about this alarm, see "How insulin is calculated and delivered during Automated Mode" on page 373.

Low Glucose

If your glucose has been trending low, SmartAdjust technology may have paused insulin.

If there has been little to no impact to your sensor glucose value from pausing, the System assumes there may be a problem you need to troubleshoot. Pausing insulin for too long could put you at risk of hyperglycemia.

The Automated Delivery Restriction can let you know that you need to step in and check the following:

- Is your Sensor reporting your glucose accurately? Check your BG with a BG meter to confirm.
- Has your glucose been low despite treatment? Consider eating additional fast-acting carbs.

High Glucose

If your glucose has been trending high, SmartAdjust technology may have delivered the maximum amount of insulin microboluses allowed by the System.

Note: This maximum amount is different than your Max Basal setting in Manual Mode. Adjusting your Max Basal setting in Manual Mode will not impact the amount that SmartAdjust technology can deliver in Automated Mode. This insulin max value is unique to each person and based on your recent total daily insulin use. It may change over time as your System continually adapts with each Pod change. You cannot directly impact this setting.

If there has been little to no impact to your sensor glucose value from delivering at the insulin max, the System assumes there may be a problem you need to troubleshoot. Delivering too much insulin for too long could put you at risk of hypoglycemia.

The Automated Delivery Restriction can let you know that you need to step in and check the following:

- Is your Sensor reporting your glucose accurately? Check your BG with a BG meter to confirm. You may need to replace your Sensor.
- Could there be a problem with your Pod or cannula? Check that your Pod is securely applied, and that there are no signs of wetness or leaking around the adhesive. Check for ketones. You may need to replace your Pod.
- Do you need more insulin? Tap the bolus button, tap Use Sensor on the Bolus screen, and see if additional insulin is recommended. You may need a correction bolus.

Switch to Manual Mode

When the Automated Delivery Restriction alarm appears, the System will ask you to switch to Manual Mode for 5 minutes or longer. This step allows the System to know that you are aware of the situation and considering action. While in Manual Mode, you can check BG, review the Sensor Graph and troubleshoot your Sensor and Pod. You can then return to Automated Mode by tapping **Menu button** (☰) > **Switch Modes**.

Note: If you get this alarm often, your Target Glucose or bolus settings may need to be adjusted. Consult your healthcare provider for help adjusting these settings on Omnipod 5.

CHAPTER 23

Switching Between Manual Mode and Automated Mode

Contents

23.1 Switching from Manual Mode to Automated Mode

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.

Before you begin

First, make sure you have an active Pod and connected Sensor or Transmitter. See "Activating and Changing Your Pod" on page 93 and Chapters 19, 20, and 21 for information on connecting your Sensor to the System.

Do the following, if necessary:

- Cancel your temp basal or extended bolus, if either is running. See "7.3 Canceling a Temp Basal" on page 123 or "16.4 Canceling a Bolus in Progress" on page 256.
- Start insulin, if it is paused. See "9.3 Starting Insulin Delivery" on page 137.

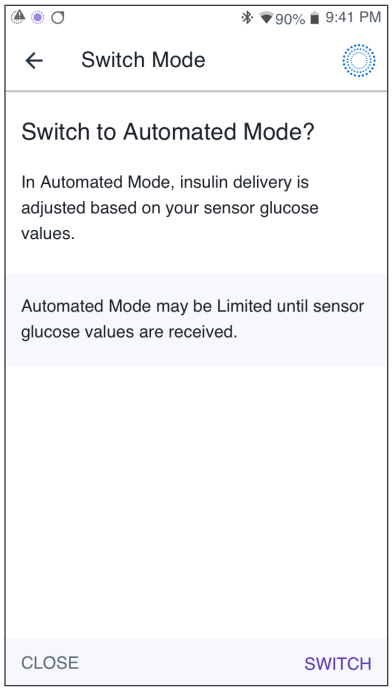
To switch to Automated Mode

To switch from Manual Mode to Automated Mode:

1. From the Home screen, tap **Menu button** (☰) > **Switch Mode**.

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

2. Tap **SWITCH.**



23.2 Switching from Automated Mode to Manual Mode

When you switch from using Automated Mode to using Manual Mode, basal insulin will be delivered based on the Basal Program scheduled for the current time. If your glucose sensor is connected, you will still be able to view these values and use them in the SmartBolus Calculator while in Manual Mode.

Before you begin, do the following:

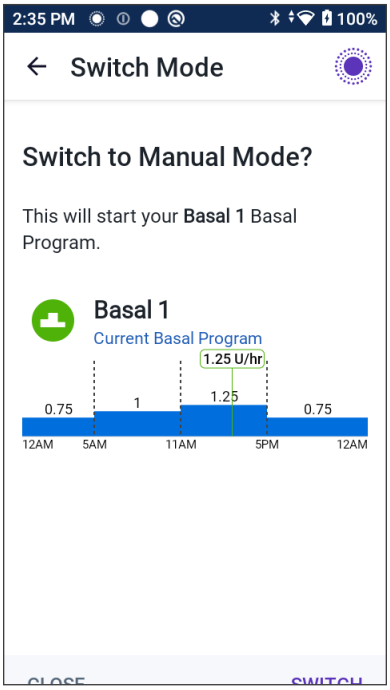
➢ Cancel the Activity feature, if it is enabled. See "24.3 Canceling the Activity Feature" on page 390.

To switch to Manual Mode

1. From the Home screen, tap **Menu button** (☰) > **Switch Mode**.

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

2. Tap **SWITCH**.



CHAPTER 24

Activity Feature

Contents

24.1 About the Activity Feature

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

While in Automated Mode, you cannot start a temp basal or manually pause insulin delivery. The Omnipod 5 System provides an option for modified automated insulin delivery through the Activity feature. The Activity feature can be useful in times when you need less insulin, for example, when you are exercising.

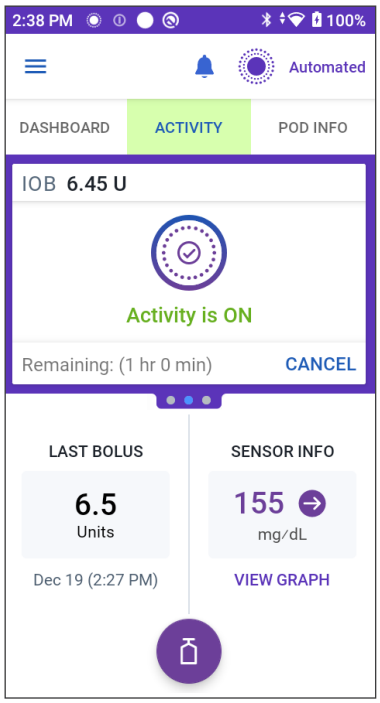
While Activity is enabled, the Omnipod 5 System does the following:

- Reduces automated insulin delivery
- Sets your Target Glucose to 150 mg/dL, regardless of your target settings

With Activity enabled, you can still deliver a bolus as you normally would.

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

Activity can be set for a duration of 1-24 hours, in increments of 1 hour. You can cancel Activity at any time. Upon cancellation or expiration of the defined time period, full automated insulin delivery starts on its own and SmartAdjust technology returns to using the Target Glucose defined in your settings.



The Activity feature ends if the Pod is deactivated. You need to re-enter Automated Mode and then enable Activity with your new Pod.

Talk to your healthcare provider about the timing of starting the Activity feature to address your anticipated period of decreased insulin needs.

Note: In the event of a loss of Pod and Sensor communication and the Omnipod 5 System enters Limited state, the Activity feature remains enabled.

Note: You may see an increase in your displayed IOB when the Activity feature starts and a decrease in your IOB when the Activity feature time period ends because of the way insulin is calculated.

24.2 Starting the Activity Feature

Before you begin, do the following:

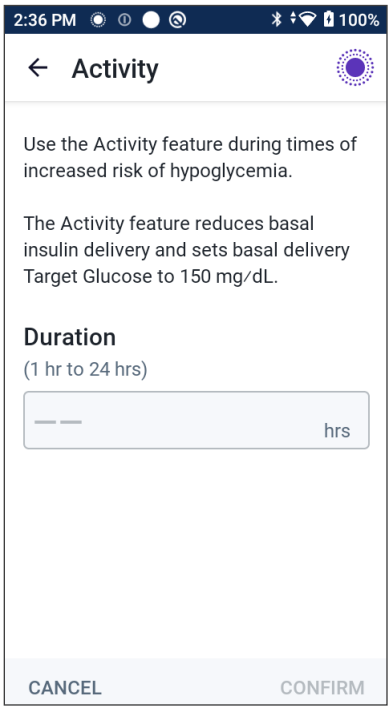
➢ Switch to Automated Mode if currently using Manual Mode. See page 384.

To enable Activity:

1. Navigate to:

   Menu button (☰) > **Activity**
2. Tap the **Duration** field and select the Activity feature duration.
3. Tap **CONFIRM.**
4. From the Confirmation screen, tap **START.**

   The **INSULIN** tab changes to a green **ACTIVITY** tab when the Activity feature is enabled.



24.3 Canceling the Activity Feature

The Activity feature automatically stops at the end of the selected duration; Automated Mode continues, using the Target Glucose defined in your user settings. The Pod beeps when the Activity feature time period completes or when you cancel it.

To cancel Activity before the end of its time period:

1. Navigate to the Home screen **ACTIVITY** tab.
2. Tap **CANCEL**.
3. Tap **YES** to confirm cancellation.
   The Omnipod 5 App cancels Activity and full automated insulin delivery starts.

Note: You may see a decrease in insulin on board (IOB) when canceling the Activity feature.

CHAPTER 25

Automated Mode Alarms

Contents

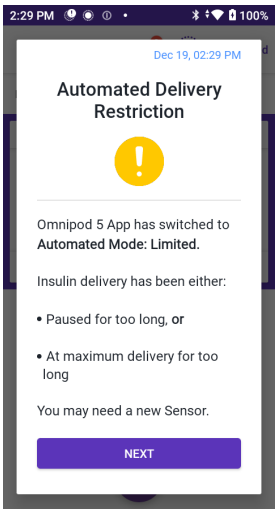
25.1 Advisory Alarm List

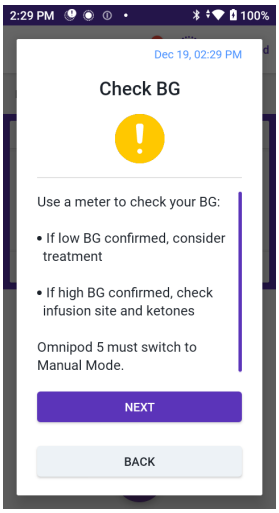
Advisory Alarms inform you of a situation that needs your attention in the near future.

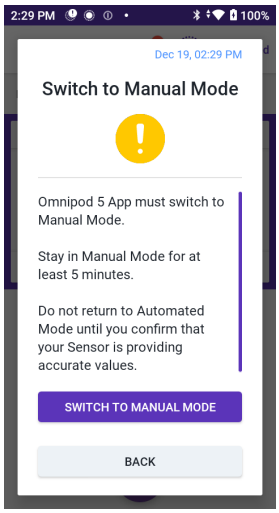
Automated Delivery Restriction

Only occurs in Automated Mode.

Omnipod 5 App Screens:







Lock Screen:

Cause	Insulin was either paused for too long or at maximum delivery for too long while the Omnipod 5 System was in Automated Mode.
Tone (Pod)	• 6 beep tone, repeats once every minute for 3 minutes • Pattern repeats every 15 minutes.
Vibration/Tone (Controller or smartphone)	• 3 second tone • 3 second vibration • Vibration and tone repeat every 15 minutes until acknowledged.
What to do	1. Tap **NEXT** to see the next screen. 2. Use a BG meter to confirm your blood glucose. - If low confirmed, consider treatment - If high confirmed, check infusion (Pod) site and ketones - If your sensor glucose value is not what you expected, you may need to replace your Sensor. 3. Tap **NEXT** after you confirm your blood glucose. 4. Tap **SWITCH TO MANUAL MODE**, then stay in Manual Mode for at least five minutes.

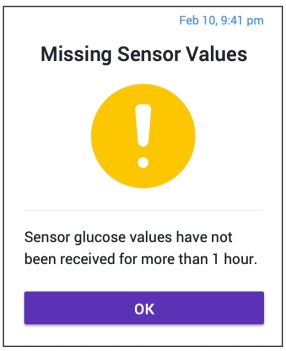
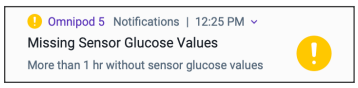
While in Manual Mode, you can check your Sensor Graph to find out whether your insulin has been paused or has been at a maximum for a long time.

After at least 5 minutes of Manual Mode, you can return to Automated Mode after you have confirmed your sensor glucose values are accurate.

For more information about Automated Mode: Limited state, see "22.5 About Automated Mode: Limited" on page 379.

Missing Sensor Glucose Values

Only occurs in Automated Mode.

<table>
<tr><th>Screen Alert</th><th>Description</th></tr>
<tr><td rowspan="3">Omnipod 5 App:
 
</td><td>Why it occurs: The Pod has not received sensor glucose values for more than one hour. The system will continue to operate in Automated Mode: Limited state until sensor glucose values are received or until you switch to Manual Mode.</td></tr>
<tr><td>Pod sound:
• 3 beep tone
• Repeats every 60 minutes</td></tr>
<tr><td>Controller/Smartphone sound and vibration:
• 3 second tone
• 3 second vibration
• Vibration and tone repeat every 15 minutes until acknowledged.
• If sensor glucose values have still not been received after 60 minutes, a new notification will be generated.</td></tr>
<tr><td>Lock Screen:
 
</td><td>What to do:
➢ Tap OK to acknowledge the alert.</td></tr>
</table>

For more information about Automated Mode: Limited state, see "21.5. About Automated Mode: Limited" on page 308.

If you use a Dexcom Sensor, check your Dexcom App to see if there are sensor glucose values present or if the cause of the loss of communication is related to the Sensor. Examples to look for within the Dexcom App include Sensor error/expiration, Transmitter error/expiration, Sensor warm-up, or signal loss alert.

If the Dexcom App is receiving sensor glucose values, there may be a temporary communication issue between your Pod and the Dexcom Sensor. You may decide to switch to Manual Mode or wait for a sensor glucose values to be received while in Automated Mode: Limited state. If this is happening often, check to see if the Pod and Sensor are located on your body at least 3 inches (8 cm) apart and within line of sight. If not, when you remove one, position the new one so that your Pod and Sensor are within line of sight to one another.

For information about your Dexcom App, refer to your *Dexcom CGM System Instructions for Use.*

If you use a FreeStyle Libre 2 Plus Sensor, check your Omnipod 5 App to see if there are sensor glucose values present or if the cause of the loss of communication is related to the Sensor. Check that your Sensor is securely applied to the back of your upper arm.

There may be a temporary communication issue between your Pod and the FreeStyle Libre 2 Plus Sensor. You may decide to switch to Manual Mode or wait for a sensor glucose value to be received while in Automated Mode: Limited state. If this is frequently occurring, check to see if the Pod and Sensor are located on your body at least 1 inch (2.5 cm) apart and within line of sight. If not, when you remove one, make sure to position the new one so that your Pod and Sensor are within line of sight to one another.

For information about your FreeStyle Libre 2 Plus Sensor, refer to your *FreeStyle Libre 2 Plus Sensor Instructions for Use.*

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CHAPTER 26

Omnipod 5 Clinical Studies

Contents

26.1 Studies in Children, Adolescents, and Adults with Type 1 Diabetes

Omnipod 5 Pivotal Study in Children, Adolescents, and Adults (6–70 years)

The goal of the US-based pivotal study of the Omnipod 5 System was to assess the safety and effectiveness of the system. This single-arm, multicenter, prospective study enrolled 112 children (6 to 13.9 years) and 128 adolescents and adults (14 to 70 years). A 2-week standard therapy phase (usual insulin regimen) was followed by 3 months of the Omnipod 5 System use in Automated Mode with a Dexcom G6 Sensor. The primary analysis consisted of A1C and sensor glucose time in range (70–180 mg/dL) results. The primary safety endpoints included an assessment of severe hypoglycemia and diabetic ketoacidosis (DKA) events. An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary, secondary, and safety results are presented in the tables below.

Of the 240 participants enrolled, 98% completed the trial (111 children and 124 adolescents and adults). The study population consisted of people with type 1 diabetes for at least 6 months. All participants were required to have a A1C < 10.0% at screening. Participants < 18 years had to be living with a parent or legal guardian. No participants with the following conditions were enrolled:

- History of severe hypoglycemia or DKA in the past 6 months
- Sickle cell disease, adrenal insufficiency , eating disorder, abnormal kidney function (eGFR < 45), hemophilia or any other bleeding disorders, untreated thyroid disease
- History of cardiovascular disease including coronary artery disease, heart attack, and cardiac intervention procedure or coronary bypass surgery in past year
- Abnormal ECG in participants > 50 years or diagnosed with diabetes >20 years
- Plans to receive blood transfusion during study
- Taking oral or injectable steroids or diabetes medications other than metformin and insulin
- Pregnant or lactating women

The safety and effectiveness of the Omnipod 5 System in users with the conditions above is unknown. Please note that the study exclusion list above is condensed and does not include every exclusion criterion.

The trial was registered at clinicaltrials.gov, a national database of clinical trials in the United States, with ID number NCT04196140. Full details of the study criteria can be found there.

Demographics

Baseline characteristics including demographics of the participants at the start of the 3-month Omnipod 5 treatment phase are provided in the table below.

Baseline Characteristics at Omnipod 5 Treatment Phase Start (n = 240)

Characteristic	Children (6 to 13.9 years)	Adolescents & Adults (14 to 70 years)
n	112	128
Age (years) ± SD	10.3 ± 2.2	36.9 ± 13.9
Duration of diabetes (years)	4.7 ± 2.6	17.9 ± 11.6
A1C[§]	7.67% ± 0.95%	7.16% ± 0.86%
Daily insulin dose (U/kg)[¥]	0.85 ± 0.24	0.61 ± 0.22
Body mass index (BMI)	18.6 ± 3.2	26.6 ± 4.7
Female sex	60 (53.6%)	78 (60.9%)
Previous[¶] or current continuous glucose monitor (CGM) use	108 (96.4%)	126 (98.4%)
Previous[¶] or current pump use	100 (89.3%)	115 (89.8%)
Race / Ethnicity[‡]		
White	110 (98.2%)	118 (92.2%)
Hispanic or Latino	8 (7.1%)	10 (7.8%)
Black or African American	5 (4.5%)	5 (3.9%)
Asian	3 (2.7%)	2 (1.6%)
Native Hawaiian or other Pacific Islander	1 (0.9%)	0 (0.0%)
American Indian or Alaska Native	0 (0.0%)	4 (3.1%)

Plus-minus values are average ± standard deviation; results reported with number in brackets afterwards represent number of participants (% of participants).

[§] *Glycated hemoglobin determined from laboratory assessment.*

[¥] *Baseline total daily insulin dose was determined from data collected during the standard therapy phase.*

Previous use is defined as having used the device for any duration in the past.

[‡] *Race and ethnicity were reported by the participants. Groups are not mutually exclusive.*

Glycemic Results

The tables below include information on the primary and secondary glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (70–180 mg/dL). Adolescents, adults, and children experienced improvements in overall A1C and time in range after 3 months of Omnipod 5 System use. This was achieved with a reduction of time > 180 mg/dL in adolescents, adults, and children as well as a reduction in median time < 70 mg/dL in adolescents and adults.

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycemic improvement; 2) standard therapy phase was shorter than the Omnipod 5 System phase; 3) minimal use of the 140 and 150 mg/dL Target Glucose settings in adults and adolescents limited the assessment of glycemic results at those settings and, for that reason, results at these Target settings were not included in this *Technical User Guide*.

Glycemic Results Overall (24 hours)

Characteristic	Children (6 to 13.9 years) (n = 112)			Adolescents & Adults (14 to 70 years) (n = 128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	7.67% (0.95%)	6.99% (0.63%)	-0.71%*	7.16% (0.86%)	6.78% (0.68%)	-0.38%*
Avg % time 70–180 mg/dL (std dev)	52.5% (15.6%)	68.0% (8.1%)	15.6%*	64.7% (16.6%)	73.9% (11.0%)	9.3%*
Avg sensor glucose, mg/dL (std dev)	183 (32)	160 (15)	-23*	161 (28)	154 (17)	-8*
Avg standard deviation of sensor glucose, mg/dL (std dev)	68 (13)	60 (10)	-9*	57 (14)	49 (11)	-8*
Avg coefficient of variation of sensor glucose, % (std dev)	37.5% (5.1%)	37.0% (3.9%)	-0.4%	35.2% (5.7%)	31.7% (4.7%)	-3.5%*
% Time in Glucose Range						
Median % < 54 mg/dL (Q1, Q3)	0.10% (0.00, 0.41)	0.23% (0.08, 0.42)	0.04%	0.22% (0.00, 0.77)	0.17% (0.06, 0.28)	-0.08%*
Median % < 70 mg/dL (Q1, Q3)	1.38% (0.42, 2.67)	1.48% (0.65, 2.23)	0.06%	2.00% (0.63, 4.06)	1.09% (0.46, 1.75)	-0.89%*
Avg % > 180 mg/dL (std dev)	45.3% (16.7%)	30.2% (8.7%)	-15.1%*	32.4% (17.3%)	24.7% (11.2%)	-7.7%*
Avg % ≥ 250 mg/dL (std dev)	19.1% (13.1%)	9.6% (5.4%)	-9.4%*	10.1% (10.5%)	5.8% (5.5%)	-4.3%*
Avg % ≥ 300 mg/dL (std dev)	8.5% (8.9%)	3.5% (2.9%)	-5.1%*	3.7% (5.5%)	1.7% (2.5%)	-2.0%*

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range < 70 mg/dL and < 54 mg/dL is reported as medians with interquartile ranges in brackets (Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic Results Overnight (12:00AM to 6:00AM)

Characteristic	Children (6 to 13.9 years) (n = 112)			Adolescents & Adults (14 to 70 years) (n = 128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg % time 70–180 mg/dL (std dev)	55.3% (19.0%)	78.1% (10.8%)	22.9%*	64.3% (19.5%)	78.1% (13.9%)	13.8%*
Avg sensor glucose, mg/dL (std dev)	177 (35)	149 (17)	-29*	160 (34)	149 (21)	-11*
Avg standard deviation of sensor glucose, mg/dL (std dev)	61 (15)	48 (12)	-13*	56 (17)	44 (13)	-12*
Avg coefficient of variation of sensor glucose, % (std dev)	34.6% (7.1%)	31.9% (5.6%)	-2.8%*	35.0% (7.9%)	28.9% (5.8%)	-6.2%*
Percentage time in glucose range, %						
Median % < 54 mg/dL (Q1,Q3)	0.00% (0.00, 0.30)	0.09% (0.02, 0.32)	0.02%	0.00% (0.00, 1.06)	0.09% (0.02, 0.30)	0.00%*
Median % < 70 mg/dL (Q1,Q3)	0.78% (0.00, 2.84)	0.78% (0.37, 1.49)	0.01%*	2.07% (0.50, 5.54)	0.82% (0.31, 1.62)	-0.86%*
Avg % > 180 mg/dL (std dev)	42.2% (20.0%)	20.7% (10.8%)	-21.5%*	32.1% (20.2%)	20.7% (14.1%)	-11.3%*
Avg % ≥ 250 mg/dL (std dev)	16.3% (15.0%)	5.4% (5.1%)	-10.9%*	10.6% (12.7%)	4.8% (7.0%)	-5.7%*
Avg % ≥ 300 mg/dL (std dev)	6.7% (9.1%)	1.8 (2.5%)	-4.8%*	4.2% (8.0%)	1.5% (3.1%)	-2.7%*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C% from baseline to the end of the 3-month Omnipod 5 System treatment phase analyzed by baseline A1C% in children (6 to 13.9 years) and adolescents and adults (14 to 70 years). Adolescents, adults, and children experienced a reduction in A1C after 3 months of Omnipod 5 System use regardless of baseline A1C < 8% or ≥ 8% category.

Subgroup Analysis of Change in Average A1C (%) by Baseline A1C (%)

Adolescents & Adults	Baseline A1C < 8% (n = 105)			Baseline A1C ≥ 8% (n = 23)		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)‡	6.86% (0.59%)	6.60% (0.53%)	-0.27%*	8.55% (0.42%)	7.63% (0.67%)	-0.91%*
Children	**Baseline A1C < 8% (n = 73)**			**Baseline A1C ≥ 8% (n = 39)**		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)	7.11% (0.50%)	6.69% (0.44%)	-0.45%*	8.73% (0.63%)	7.56% (0.54%)	-1.18%*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡ *Average A1C values are reported with standard deviation values in brackets.*

Glycemic Results by Baseline Treatment

The table below provides information on the average glycemic results at baseline (or during standard therapy phase) and the 3-month Omnipod 5 System treatment phase analyzed by baseline treatment (standard therapy). Standard therapy consisted of multiple daily insulin injections (MDI) or insulin pump use. Time in range (70–180 mg/dL) and A1C were improved after 3 months of Omnipod 5 System use regardless of baseline treatment type. After 3 months of Omnipod 5 System use, time < 70 mg/dL improved in adolescents and adults regardless of baseline therapy, but remained unchanged in children.

Subgroup Analysis of Average Glycemic Results by Baseline Treatment in Children (6 to 13.9 years)

Characteristic	MDI (n = 13)		Insulin Pump (n = 99)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70–180 mg/dL	52%	69%*	53%	68%*
% Time < 70 mg/dL‡	1.54%	1.41%	1.38%	1.49%
A1C%	7.7%	6.7%*	7.7%	7.0%*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡ *Values presented for % Time < 70 mg/dL are medians, the remaining values in the table are averages.*

Subgroup Analysis of Average Glycemic Results by BaselineTreatment in Adolescents and Adults (14 to 70 years)

Characteristic	MDI (n = 20)		Insulin Pump (n = 105)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70–180 mg/dL	60%	72%*	66%	74%*
% Time < 70 mg/dL‡	2.38%	0.79%*	1.93%	1.16%*
A1C%	7.6%	7.0%*	7.1%	6.7%*

* *Change between baseline/standard therapy and the Omnipod 5 System phase was statistically significant.*

‡ *Values presented for % Time below 70 mg/dL are medians, the remaining values in the table are averages.*

An analysis by baseline demographic characteristics, including those mentioned in the subgroup analyses above, demonstrated similar glycemic improvement as the overall study population. Please note that the study was not designed to determine differences in benefit or risk from each subgroup.

Insulin Requirements

The table below provides information on the average insulin requirements during the standard therapy phase and the 3-month Omnipod 5 System phase. Total daily insulin requirements increased in children and decreased slightly in adolescents and adults.

Characteristic	Children (6 to 13.9 years) (n = 112)			Adolescents & Adults (14 to 70 years) (n = 128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg total daily insulin (U) (std dev)	34.4 (17.5)	37.2 (19.6)	2.9*	48.2 (21.0)	46.4 (18.1)	-1.8*
Avg total daily insulin, U/kg (std dev)	0.85 (0.24)	0.92 (0.25)	0.07*	0.61 (0.22)	0.59 (0.21)	-0.02*
Avg total daily basal insulin, U/kg (std dev)	0.36 (0.13)	0.47 (0.15)	0.10*	0.31 (0.11)	0.30 (0.11)	-0.01
Avg total daily bolus insulin, U/kg (std dev)	0.48 (0.18)	0.45 (0.13)	-0.03*	0.31 (0.16)	0.29 (0.12)	-0.01

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Body Mass Index Results

The table below provides information on the average body mass index (BMI), which is a measure of weight adjusted for height, and BMI z-score, which is a measure of weight adjusted for height, sex, and age, during the standard therapy phase and the 3-month Omnipod 5 System phase in children. Although BMI increased in children, the BMI z-score remained unchanged.

Characteristic	Children (6 to 13.9 years) n = 112		
	Standard Therapy	Omnipod 5	Change
BMI, kg/m2 (std dev)	18.6 (3.2)	19.2 (3.6)	0.54*
BMI z-score (std dev)	0.4 (0.8)	0.4 (0.8)	0.03

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Omnipod 5 System Use

The table below provides information on the average % of time study participants used the Omnipod 5 System in Automated Mode.

Percent Time Spent in Automated Mode

	Children (6 to 13.9 years) n = 112	Adolescents & Adults (14 to 70 years) n = 128
% Time in Automated Mode (std dev)	95.2% (4.0%)	94.8% (6.0%)

Adverse Events

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase. There were 3 severe hypoglycemia events not attributable to the Omnipod 5 System automated insulin delivery or system malfunction and 1 DKA event from a suspected infusion site failure. Other related, but non-glycemic adverse events included infection or irritation at infusion site (2 children, 2 adolescents/adults).

Adverse Events during the Omnipod 5 System Phase

Adverse Event Type	Children (6 to 13.9 years) (n = 112)	Adolescents & Adults (14 to 70 years) (n = 128)	Total (6 to 70 years) (n = 240)
Hypoglycemia‡	1	0	1
Severe Hypoglycemia§	1	2	3
DKA	1	0	1
Hyperglycemia‖	1	2	3
Prolonged Hyperglycemia**	13	5	18
Other	8	8	16

Results reported as number of events.

‡ *Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia.*

§ *Required the assistance of another person.*

‖ *Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event.*

***Meter blood glucose measuring ≥300 mg/dL and ketones >1.0 mmol/L.*

Glycemic Results at Target Glucose Settings in Pivotal Study

The tables below provide information on the glycemic results at various self-selected Target Glucose settings during the 3-month Omnipod 5 System phase of the pivotal study. Of the customizable Glucose targets, the most selected was 110 mg/dL.

Overall (24 hours) Glycemic Results at Target Glucose Settings in Children (6 to 13.9 years) from Pivotal Study

Characteristic	110 mg/dL Target Glucose (n = 98)	120 mg/dL Target Glucose (n = 74)	130 mg/dL Target Glucose (n = 47)	140 mg/dL Target Glucose (n = 12)	150 mg/dL Target Glucose* (n = 9)
Avg % time 70–180 mg/dL (std dev)	68.4% (9.1%)	67.5% (9.7%)	64.2% (14.3%)	59.2% (16.9%)	53.3% (18.2%)
Avg sensor glucose, mg/dL (std dev)	159 (17)	163 (16)	169 (24)	178 (24)	183.6 (23.9)
% Time in glucose range					
Median % < 54 mg/dL (Q1, Q3)	0.22% (0.06, 0.49)	0.18% (0.05, 0.33)	0.09% (0.00, 0.21)	0.04% (0.00, 0.34)	0.00% (0.00, 0.00)
Median % < 70 mg/dL (Q1, Q3)	1.51% (0.76, 2.38)	1.16% (0.58, 1.94)	0.71% (0.26, 1.63)	0.59% (0.05, 1.52)	0.12% (0.00, 0.21)
Avg % > 180 mg/dL (std dev)	29.7% (9.6%)	31.1% (10.0%)	34.5% (14.8%)	39.9% (16.6%)	46.4% (18%)
Avg % ≥ 250 mg/dL (std dev)	9.7% (5.8%)	10.0% (6.3%)	11.8% (9.0%)	14.6% (11.1%)	13.3% (11.9%)
Cumulative number of person-days	6,289	2,716	941	99	73

Overall (24 hours) Glycemic Results at Target Glucose Settings in Adolescents and Adults (14 to 70 years) from Pivotal Study

Characteristic	110 mg/dL Target Glucose (n = 121)	120 mg/dL Target Glucose (n = 54)	130 mg/dL Target Glucose* (n = 9)
Avg % time 70–180 mg/dL (std dev)	75.6% (9.9%)	73.4% (12.1%)	63.6% (25.9%)
Avg sensor glucose, mg/dL (std dev)	151 (15)	156 (18)	172 (33)
% Time in glucose range			
Median % < 54 mg/dL (Q1, Q3)	0.16% (0.05, 0.26)	0.11% (0.00, 0.33)	0.00% (0.00, 0.00)
Median % < 70 mg/dL (Q1, Q3)	0.99% (0.47, 1.67)	0.91% (0.31, 1.68)	0.26% (0.05, 0.63)
Avg % > 180 mg/dL (std dev)	23.1% (10.2%)	25.4 % (12.3%)	35.9% (26.1%)
Avg % ≥ 250 mg/dL (std dev)	5.1% (4.6%)	5.8% (6.4%)	9.6% (12.3%)
Cumulative number of person-days	9,278	1,827	178

* *Results for the 140 mg/dL and 150 mg/dL (with the Activity feature OFF) Target Glucose settings in adults are not shown due to too few participants selecting them (n ≤ 2).*

Omnipod 5 System Pre-Pivotal Glycemic Results at Target Glucose Settings

Glycemic Results at Target Glucose Settings in Pre-Pivotal Study

The goal of the pre-pivotal study of the Omnipod 5 System was to assess the safety and efficacy of the system. This single-arm, multicenter, prospective study enrolled 18 children (6 to 13.9 years) and 18 adults (14 to 70 years) with type 1 diabetes. A 2-week standard therapy phase (usual insulin regimen) was followed by 2 weeks of Omnipod 5 System use in Automated Mode with a Dexcom G6 Sensor. The 2-week Omnipod 5 phase included 3 days of required use at each of the Target Glucose settings of 130 mg/dL, 140 mg/dL, and 150 mg/dL for a total of 9 days, followed by 5 days of free choice of Target Glucose ranging from 110–150 mg/dL.

Overall (24 hours) Glycemic Results at Target Glucose Settings in Children (6 to 13.9 years) from Pre-Pivotal Study

Characteristic	110 mg/dL Target Glucose (n = 11)	120 mg/dL Target Glucose (n = 3)	130 mg/dL Target Glucose (n = 18)[a]	140 mg/dL Target Glucose (n = 18)	150 mg/dL Target Glucose (n = 18)[b]
Avg % time 70–180 mg/dL (std dev)	71.2% (10.2%)	66.8% (12.9%)	61.5% (7.7%)	64.8% (11.6%)	53.5% (11.0%)
Avg sensor glucose, mg/dL (std dev)	155.2 (18.2)	170 (16)	174.1 (11.4)	172.7 (17.2)	182.9 (15.3)
% Time in glucose range					
Median % < 54 mg/dL (Q1, Q3)	0.1% (0.0, 0.4)	0.2% (0.0, 0.3)	0.0% (0.0, 0.3)	0.0% (0.0, 0.0)	0.0% (0.0, 0.1)
Median % < 70 mg/dL (Q1, Q3)	0.9% (0.4, 2.8)	0.3% (0.2. 2.2)	0.5% (0.1, 0.8)	0.1% (0.0, 0.5)	0.5% (0.0, 0.8)
Avg % > 180 mg/dL (std dev)	27.1% (11.4%)	32.3% (11.9%)	37.7% (7.9)	34.6% (12.1%)	45.9% (11.0%)
Avg % ≥ 250 mg/dL (std dev)	6.8% (6.3%)	14.4% (6.2%)	13.2% (5.8%)	10.6% (7.3%)	12.8% (8.1%)
Cumulative number of person-days	47.7	8.7	73.3	56.3	61.5

[a] *All participants initiated the system at the 130 mg/dL Target Glucose for 3 days.*

[b] *The glycemic results at the 150 mg/dL Target Glucose setting include times with the Activity feature ON and OFF, meaning the results recorded during this time may include those when participants felt their insulin needs were reduced.*

Overall (24 hours) Glycemic Results at Target Glucose Settings in Adolescents and Adults (14 to 70 years) from Pre-Pivotal Study

Characteristic	110mg/dL Target Glucose (n = 12)	120mg/dL Target Glucose (n = 7)	130mg/dL Target Glucose (n = 18)[a]	140mg/dL Target Glucose (n = 18)	150mg/dL Target Glucose (n = 18)[b]
Avg % time 70–180 mg/dL (std dev)	72.5% (9.4%)	70.9% (11.3%)	75.1% (11.6%)	67.6% (9.2%)	63.7% (7.8%)
Avg sensor glucose, mg/dL (std dev)	153.8 (14.8)	159.7 (11)	153.8 (14.9)	165.4 (11.5)	169.8 (9.4)
% Time in glucose range					
Median % < 54 mg/dL (Q1, Q3)	0.0% (0.0, 0.0)	0.0% (0.0, 0.0)	0.0% (0.0, 0.2)	0.0% (0.0, 0.1)	0.0% (0.0, 0.2)
Median % < 70 mg/dL (Q1, Q3)	0.5% (0.0, 1.4)	0.4% (0.0, 0.6)	0.9% (0.4, 1.2)	0.1% (0.0, 0.6)	0.2% (0.0, 0.9)
Avg % > 180 mg/dL (std dev)	26.4% (10.0%)	28.7% (11.2%)	23.4% (11.4%)	31.7% (9.2%)	35.7% (7.9%)
Avg % ≥ 250 mg/dL (std dev)	4.1% (3.4%)	5.2% (5.5%)	5.0% (4.6%)	5.1% (4.5%)	6.0% (4.8%)
Cumulative number of person-days	41.1	28	58.8	58.4	60.3

[a] *All participants initiated the system at the 130 mg/dL Target Glucose for 3 days.*

[b] *The glycemic results at the 150 mg/dL Target Glucose setting include times with the Activity feature ON and OFF, meaning the results recorded during this time may include those when participants felt their insulin needs were reduced.*

CGM-Informed SmartBolus Calculator Clinical Study in Children, Adolescents, and Adults

A study was conducted on 25 participants with type 1 diabetes aged 6–70 years to assess the Omnipod 5 Sensor-informed SmartBolus Calculator. During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected Sensor (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected Sensor (CGM-informed SmartBolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/or either a manually entered glucose value (standard SmartBolus Calculator) or an imported current sensor glucose value and trend (CGM-informed SmartBolus Calculator). Both versions of the SmartBolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the sensor glucose trend. The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by Sensor between the two study phases. The results indicate that the use of the Sensor-informed SmartBolus Calculator was associated with less time in hypoglycemia within 4 hours of bolusing. The study was conducted using a Dexcom G6 Sensor.

Comparison of Glycemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (n = 25)

Percent time in glucose range as measured by Sensor	Standard SmartBolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70–180 mg/dL	65.1% (15.4)	63.8% (15.7)	-1.3%
< 70 mg/dL	2.8% (2.7)	2.1% (2.0)	-0.6%*
< 54 mg/dL	0.5% (1.0)	0.3% (0.7)	-0.2%
> 180 mg/dL	32.1% (15.7)	34.0% (16.0)	1.9%
≥ 250 mg/dL	8.2% (6.9)	9.7% (10.3)	1.4%
≥ 300 mg/dL	2.0% (2.6)	2.6% (3.7)	0.6%

Data is presented as average (standard deviation). Significant differences ($p<0.05$) are highlighted with an asterisk.

26.2 Studies in Very Young Children with Type 1 Diabetes

Omnipod 5 Clinical Study in Very Young Children

The goal of this study was to assess the safety and effectiveness of the Omnipod 5 System in children with type 1 diabetes aged 2 to 5.9 years. This single-arm, multicenter, prospective study enrolled 80 children.

A 2-week standard therapy phase (usual insulin regimen) was followed by 3 months of the Omnipod 5 System use in Automated Mode with a Dexcom G6 Sensor. The primary analysis consisted of A1C and sensor glucose time in range (70–180 mg/dL) results.

The primary safety endpoints included the incidence of severe hypoglycemia and diabetic ketoacidosis (DKA). An analysis of the secondary endpoints and additional metrics was also performed. An analysis of the primary, secondary, and safety results are presented in the tables below.

Of the 80 participants enrolled, 100% completed the trial. The study population consisted of children diagnosed with type 1 diabetes based on the investigator's clinical judgement. All participants were required to have an A1C < 10.0% at screening. Participants had to be living with a parent or legal guardian. No participants with the following conditions were enrolled:

History of severe hypoglycemia or DKA in the past 6 months

- Sickle cell disease, adrenal insufficiency, abnormal kidney function (eGFR < 45), hemophilia or any other bleeding disorders, untreated thyroid disease
- Plans to receive blood transfusion during study
- Taking oral or injectable steroids or diabetes medications other than metformin and insulin

The safety and effectiveness of the Omnipod 5 System in users with the conditions above is unknown. Please note that the study exclusion list above is condensed and does not include every exclusion criterion. The trial was registered at clinicaltrials.gov, a national database of clinical trials in the United States, with ID number NCT04476472. Full details of the study criteria can be found there.

Demographics

Baseline characteristics, including demographics of the participants at the start of the 3-month Omnipod 5 treatment phase, are provided in the table below.

Baseline Characteristics at Omnipod 5 Treatment Phase Start

Characteristic	
n	80
Age (years) ± std dev	4.7 ± 1.0
Duration of diabetes (years)	2.3 ± 1.1
A1C[§]	7.4% ± 1.0%
Daily insulin dose (U/kg) [¥]	0.69 ± 0.18
Body mass index (BMI) (kg/m2)	16.7 ± 1.5
Female sex	34 (42.5%)
Previous[¶] or current continuous glucose monitor (CGM) use	78 (97.5%)
Previous[¶] or current pump use	68 (85.0%)
Using multiple daily injection as standard therapy method	12 (15.0%)
Race/Ethnicity[‡]	
White	67 (83.8%)
Hispanic or Latino	5 (6.3%)
Black or African American	4 (5.0%)
Black or African American, White	3 (3.8%)
Asian	3 (3.8%)
Asian, White	2 (2.5%)
Hispanic or Latino	1 (1.3%)
Not Hispanic or Latino	1 (1.3%)
Other (Dominican)	1 (1.3%)
Hispanic or Latino	1 (1.3%)

Plus-minus values are average ±standard deviation; results reported with number in brackets afterwards represent number of participants (% of participants).

[§] *A1C determined from laboratory assessment.*

[¥] *Baseline total daily insulin dose was determined from data collected during the standard therapy phase.*

[¶] *Previous use is defined as having used the device for any duration in the past.*

[‡] *Race and ethnicity were reported by the participants. Groups are not mutually exclusive.*

Glycemic Results

The tables below include information on the primary and secondary glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (70–180 mg/dL). Participants experienced improvements in A1C and overall time in range after 3 months of Omnipod 5 System use. This result was achieved with a reduction of time >180 mg/dL as well as a reduction in median time <70 mg/dL.

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycemic improvement; 2) standard therapy phase was shorter than the Omnipod 5 System phase.

Glycemic Results Overall (24 hours)

Characteristic	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	7.4% (1.0%)	6.9% (0.7%)	-0.55%*
Avg % time 70-180 mg/dL (std dev)	57.2% (15.3%)	68.1% (9.0%)	10.9%*
Avg sensor glucose, mg/ dL, (std dev)	171.1 (30.5)	157.4 (16.8)	-13.7*
Avg standard deviation of sensor glucose, mg/dL (std dev)	64.9 (13.4)	59.6 (10.3)	-5.3*
Avg coefficient of variation of sensor glucose, % (std dev)	38.1% (5.5%)	37.7% (4.0%)	-0.4%
% Time in Glucose Range			
Median % < 54 mg/dL (Q1, Q3)	0.24% (0.05, 0.84)	0.26% (0.16, 0.60)	0.06%
Median % < 70 mg/dL (Q1, Q3)	2.19 (0.89, 4.68)	1.94 (1.18, 3.43)	-0.27%*
Avg % >180 mg/dL (std dev)	39.4% (16.7%)	29.5% (9.8%)	-9.9%*
Avg % ≥ 250 mg/dL (std dev)	14.8% (12.1%)	9.2% (5.6%)	-5.6%*
Avg % ≥ 300 mg/dL (std dev)	6.0% (7.3%)	3.2% (2.8%)	-2.7%*

Most of the primary and secondary results are presented as averages (avg) with standard deviation (std dev) values in brackets. Time in range < 70 mg/dL and < 54 mg/dL is reported as medians with interquartile ranges in brackets (Q1, Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic Results Overnight (12:00AM to 6:00AM)

Characteristic	Standard Therapy	Omnipod 5	Change
Avg % time 70–180 mg/dL (std dev)	58.2% (18.7%)	81.0% (10.0%)	22.8%*
Avg sensor glucose, mg/dL, (std dev)	168.1 (33.3)	140.7 (16.4)	-27.4*
Avg standard deviation of sensor glucose, mg/dL (std dev)	58.0 (14.0)	45.5 (10.8)	-12.5*
Avg coefficient of variation of sensor glucose, % (std dev)	34.7% (6.6%)	32.1% (5.2%)	-2.6%*
% Time in Glucose Range			
Median % < 54 mg/dL (Q1, Q3)	0.00% (0.00, 0.97)	0.18% (0.06, 0.53)	0.00%
Median % < 70 mg/dL (Q1, Q3)	1.66% (0.40, 4.21)	1.58% (0.65, 2.89)	-0.44%*
Avg % > 180 mg/dL (std dev)	38.4% (20.1%)	16.9% (10.3%)	-21.5%*
Avg % ≥ 250 mg/dL (std dev)	13.0% (13.2%)	3.9% (3.9%)	-9.1%*
Avg % ≥ 300 mg/dL (std dev)	4.3% (6.7%)	1.2% (1.6%)	-3.1%*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C% from baseline to the end of the 3-month Omnipod 5 System treatment phase analyzed by baseline A1C%. Participants experienced a reduction in A1C after 3 months of Omnipod 5 System use regardless of baseline A1C < 8% or ≥ 8% category.

Subgroup Analysis of Change in Average A1C (%) by Baseline A1C (%)

	Baseline A1C < 8% (n = 55)			Baseline A1C ≥ 8% (n = 25)		
	Baseline	Omnipod 5	Change	Baseline	Omnipod 5	Change
A1C% (std dev)‡	6.9% (0.6%)	6.6% (0.6%)	-0.31%*	8.5% (0.5%)	7.5 (0.4%)	-1.06%*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡ *Average A1C values are reported with standard deviation values in brackets.*

Glycemic Results by Baseline Treatment

The table below provides information on the average glycemic results at baseline (or during standard therapy phase) and the 3-month Omnipod 5 System treatment phase analyzed by baseline treatment (standard therapy). Standard therapy consisted of multiple daily insulin injections (MDI) or insulin pump use. Time in range (70–180 mg/dL) and A1C were improved after 3 months of Omnipod 5 System use regardless of baseline treatment type. Time < 70 mg/dL improved in participants on an insulin pump at baseline and remained low in those on MDI at baseline.

Subgroup Analysis of Average Glycemic Results by Baseline Treatment

Characteristic	MDI (n = 12)		Insulin Pump (n = 68)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70–180 mg/dL	48%	62%*	59%	69%*
% Time < 70 mg/dL‡	1.45%	1.48%	2.44%	2.00%*
A1C%	8.4%	7.5%*	7.3%	6.8%*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

‡ *Values presented for % Time <70 mg/dL are medians, the remaining values in the table are averages.*

Insulin Requirements

The table below provides information on the average insulin requirements during the standard therapy phase and the 3-month Omnipod 5 System phase. Total daily insulin requirements remained unchanged except for an increase in total daily basal insulin.

Characteristic	Standard Therapy	Omnipod 5	Change
Avg total daily insulin (U) (std dev)	13.7 (4.4)	14.1 (4.0)	0.4
Avg total daily insulin, U/kg (std dev)	0.69 (0.18)	0.71 (0.15)	0.02
Avg total daily basal insulin, U/kg, (std dev)	0.28 (0.12)	0.32 (0.10)	0.04*
Avg total daily bolus insulin, U/kg, (std dev)	0.41 (0.15)	0.39 (0.10)	-0.02 (0.10)

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Body Mass Index Results

The table below provides information on the average body mass index (BMI) and BMI z-score during the standard therapy phase and the 3-month Omnipod 5 System phase. BMI and BMI z-score did not change between the two phases.

Characteristic	Standard Therapy	Omnipod 5	Change
BMI, kg/m2 (std dev)	16.7 (1.5)	16.7 (1.4)	0.1
BMI z-score (std dev)	0.74 (0.95)	0.76 (0.89)	0.05

Omnipod 5 System Use

The median (Q1, Q3) % of time study participants used the Omnipod 5 System in Automated Mode was 97.8% (95.8, 98.5).

Adverse Events

The table below provides a full list of the adverse events that occurred during the 3-month Omnipod 5 System treatment phase. Other related, but non-glycemic adverse events included skin irritation (n = 2), cellulitis (n = 1), and ketosis not meeting the DKA definition (n = 2).

Adverse Events during the Omnipod 5 System Phase

Adverse Event Type	Omnipod 5
Hypoglycemia‡	0
Severe Hypoglycemia§	0
DKA	0
Hyperglycemia‖	4
Prolonged Hyperglycemia **	20
Other	5

Results reported as number of events.

‡ *Hypoglycemia resulting in a serious adverse event, but otherwise not meeting the definition of severe hypoglycemia.*

§ *Required the assistance of another person.*

‖ *Hyperglycemia requiring evaluation, treatment or guidance from intervention site, or hyperglycemia resulting in a serious adverse event.*

** *Meter blood glucose measuring ≥ 300 mg/dL and ketones >1.0 mmol/L*

Glycemic Results at Target Glucose Settings

The tables below provide information on the glycemic results at various self- selected Target Glucose settings during the 3-month Omnipod 5 System phase of the pivotal study. The most commonly selected target glucose values were 110 mg/dL and 120 mg/dL, which were used 33% and 42% of the time, respectively.

Overall (24 hours) Glycemic Results at Target Glucose Settings

Characteristic	110 mg/dL Target Glucose (n = 47)	120 mg/dL Target Glucose (n = 61)	130 mg/dL Target Glucose (n = 47)	140 mg/dL Target Glucose (n = 20)	150 mg/dL Target Glucose* (n = 16)
Avg % time 70–180 mg/dL, (std dev)	69.3% (9.5%)	68.3% (11.3%)	67.3% (14.6%)	63.0% (11.9%)	65.0% (15.0%)
Avg sensor glucose, mg/dL, (std dev)	153 (18)	157 (21)	161 (25)	169 (18)	169 (20)
% Time in glucose range					
Median % < 54 mg/dL, (Q1, Q3)	0.3% (0.2, 0.7)	0.2% (0.1, 0.5)	0.2% (0.05, 0.7)	0.2% (0.03, 0.5)	0.06% (0.0, 0.2)
Median % < 70 mg/dL, (Q1, Q3)	2.4% (1.5, 3.9)	1.6% (1.1, 2.7)	1.4% (0.6, 2.9)	1.4% (0.4, 2.7)	0.8% (0.1, 2.0)
Avg % > 180 mg/dL (std dev)	27.6% (10.5%)	29.3% (12.1%)	30.4% (15.4%)	35.4% (12.2%)	33.9% (15.0%)
Avg % ≥ 250 mg/dL (std dev)	7.7% (5.9%)	8.9% (6.2%)	10.6% (9.4%)	12.6% (6.2%)	11.4% (7.2%)
Cumulative number of person-days	2438.4	3083.5	1066.6	404.0	237.0

* *Glycemic measures reported at the 150 mg/dL Target Glucose setting only included those with the Activity feature turned OFF.*

CGM-Informed SmartBolus Calculator Clinical Study in Very Young Children

A study was conducted on 5 participants with type 1 diabetes aged 2–5.9 years to assess the Omnipod 5 CGM-informed SmartBolus Calculator in Manual Mode. During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected Sensor (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected Sensor (CGM-informed SmartBolus Calculator) for 7 days. Boluses were calculated using stored pump settings plus user-estimated meal size and/ or either a manually entered glucose value (standard SmartBolus Calculator) or an imported current sensor glucose value and trend (CGM-informed SmartBolus Calculator). Both versions of the SmartBolus Calculator considered insulin on board (IOB) in the bolus calculations. The CGM-informed calculator automatically increased or decreased the suggested bolus amount based on the sensor glucose trend. The primary analysis of the study was to compare the percent of time spent < 70 mg/dL and > 180 mg/dL for the 4 hours after any bolus as measured by Sensor between the two study phases. The results showed that the CGM-informed SmartBolus Calculator provided similar glycemic results as the standard SmartBolus calculator when used in Manual Mode.

Comparison of Glycemic Measures from Phase 1 (Standard SmartBolus Calculator) and Phase 2 (CGM-Informed SmartBolus Calculator) for the 4 hours After any Bolus (n = 5)

Percent time in glucose range as measured by Sensor	Standard Smart- Bolus Calculator	CGM-Informed SmartBolus Calculator	Difference
70–180 mg/dL	59.6% (7.1%)	62.8% (15.5%)	3.15%
< 70 mg/dL	5.16% (4.99%)	4.03% (3.28%)	-1.13%
< 54 mg/dL	1.47% (1.88%)	0.81% (0.91%)	-0.66%
> 180 mg/dL	35.2% (10.3%)	33.2% (18.5%)	-2.03%
≥ 250 mg/dL	9.4% (5.7%)	7.9% (6.4%)	-1.55%
≥ 300 mg/dL	2.33% (2.69%)	1.99% (2.05%)	-0.34%

Data is presented as average (standard deviation).

26.3 Studies in Adults with Type 2 Diabetes

Omnipod 5 Pivotal Study in Adults with Type 2 Diabetes (18–75 years)

The goal of this U.S.-based pivotal study was to assess the safety and efficacy of the Omnipod 5 System in adults with type 2 diabetes aged 18 to 75 years. This study enrolled 343 participants.

A 2-week standard therapy phase where participants used their usual insulin delivery method was followed by 3 months of participants using the Omnipod 5 System. The system was used in Automated Mode with a Dexcom G6 continuous glucose monitor (CGM). The primary safety outcome is that Omnipod 5 does not worsen A1C compared to baseline/standard therapy. The primary effectiveness outcome is that Omnipod 5 lowers A1C compared to baseline/standard therapy.

The study also tested other outcomes for safety and benefit. The results for the primary, secondary, and safety results and other study data are presented in the tables below.

Of the 343 participants enrolled, 305 started Omnipod 5 and 289 completed the study. The study population consisted of adults diagnosed with type 2 diabetes on insulin (basal-bolus, basal only, or pre-mix insulin). All participants were required to have an A1C <12.0% at screening. Those on basal insulin only also had to have an A1C ≥7%. No participants with the following conditions were enrolled:

- Use of insulin pump in automated mode in the past 3 months
- History of severe hypoglycemia (very low blood glucose event) or DKA in the past 6 months
- History of heart or blood vessel disease, heart attack, or heart surgery in the past 12 months
- Plans to receive blood transfusion during study
- Taking steroids in past 8 weeks or plans to take steroids during the study
- Pregnant or lactating, planning to become pregnant during study, or woman of childbearing potential not using birth control methods

The safety and effectiveness of the Omnipod 5 System in users with the conditions above is unknown. Please note that the study exclusion list above is a summary and does not include all criteria.

The trial was registered at clinicaltrials.gov, a national database of clinical trials in the United States, with ID number NCT05815342. Full details of the study criteria can be found there.

Demographics

Baseline characteristics, including demographics, at the start of the 3-month Omnipod 5 treatment phase are provided in the table below.

Characteristic	Adults
Number of Participants (n)	305
Age (years)	57 ± 11
Female sex	175 (57%)
Duration of diabetes (years)	17 (11, 24)
A1C at screening (%)	8.2% ± 1.4%
Insulin delivery type	
Insulin pump	17 (6%)
Injections	288 (94%)
Insulin therapy	
Basal & bolus	240 (79%)
Basal only	63 (21%)
Pre-mix	2 (<1%)
Daily insulin dose	
Units/kg/day	0.80 ± 0.46
Units/day	79.9 ± 50.0
Non-insulin diabetes medications	
GLP-1 agonists	168 (55%)
SGLT1 or SGLT2 inhibitors	135 (44%)
DPP4 inhibitors	8 (3%)
Continuous Glucose Monitor (CGM) Use	
Never	75 (25%)
In past, but not current	42 (14%)
Current	188 (62%)
Body mass index (BMI) (kg/m^2)[†]	35 ± 8
Race	

Characteristic	Adults
White	198 (65%)
Black/African American	72 (24%)
American Indian/Alaskan Native	5 (2%)
Asian	5 (2%)
More than one race	3 (<1%)
Native Hawaiian/Other Pacific Islander	2 (<1%)
Unknown/not reported	20 (7%)
Ethnicity	
Hispanic	66 (22%)
Non-Hispanic	237 (78%)
Unknown/not reported	2 (<1%)
Health Insurance	
Private	161 (53%)
Medicaid	27 (9%)
Medicare	52 (17%)
Other government	27 (9%)
No coverage	18 (6%)
No answer	20 (7%)

Plus-minus values are average ± standard deviation; results reported with one number in brackets afterwards represent number of participants (% of participants); remaining values are medians with interquartile ranges in brackets (Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

[†] *Body-mass index is the weight in kilograms divided by the square of the height in meters.*

Glycemic Results

The tables below include information on the glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System phase in adults with type 2 diabetes. The primary result of the study is average change in A1C. Participants experienced an improvement in A1C and % time in range (70–180 mg/dL, 3.9–10.0 mmol/L) after 3 months of Omnipod 5 System use. This was achieved with no increase in hypoglycemia (low blood sugar).

Some limitations to the study include: 1) single-arm design with no control group which could lead to an over-estimate of glycemic

improvement, and 2) standard therapy phase was shorter than the Omnipod 5 System phase.

Outcome	Standard Therapy†	Omnipod 5†	Change
Avg A1C% (std dev)	8.2% (1.3%)	7.4% (0.9%)	-0.8%*
Avg sensor glucose, mmol/L, mg/dL (std dev)	11.2, 202 (2.8, 50)	9.4, 170 (1.3, 24)	-1.8, -32*
Avg coefficient of variation of sensor glucose, % (std dev)	27.8% (6.3%)	27.1% (5.1%)	-0.7%
% Time glucose range			
Avg % 3.9–10 mmol/L, 70–180 mg/dL (std dev)	45% (25%)	66% (17%)	20%*
Avg % 3.9–7.8 mmol/L, 70–140 mg/dL (std dev)	21% (18%)	33% (17%)	12%*
Avg. % < 3 mmol/L, < 54 mg/dL (std dev)	0.01% (0.02%)	0.04% (0.05%)	0.01%§
Avg % < 3.9 mmol/L, < 70 mg/dL (std dev)	0.2% (0.3%)	0.2% (0.2%)	0.0%§
Avg % > 10 mmol/L, > 180 mg/dL (std dev)	54% (25%)	34% (17%)	-20%*
Avg % > 13.9 mmol/L, > 250 mg/dL (std dev)	20% (22%)	7% (8%)	-12%*
Avg % > 16.9 mmol/L, > 300 mg/dL (std dev)	7.7% (10.3%)	1.8% (2.4%)	-5.2%*

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) was 299 for all outcomes above except A1C which was 296.*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

§ *The difference in the results is non-inferior (not worse) than standard therapy.*

Glycemic Results Daytime vs Overnight

The tables below include information on the glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System phase in adults with type 2 diabetes during the day and overnight.

Outcome	Daytime (6:00 AM to < 12:00 AM)†			Overnight (12:00 AM to < 6:00 AM)†		
	Standard Therapy (n = 303)	Omnipod 5 (n = 300)	Change*	Standard Therapy (n = 300)	Omnipod 5 (n = 300)	Change*
Avg Sensor glucose, mmol/L, mg/dL (std dev)	11.3, 204 (2.8, 50)	9.6, 172 (1.3, 24)	-1.8, -32	10.9, 196 (2.9, 53)	9.2, 165 (1.5, 27)	-1.7, -31
Avg coefficient of variation of sensor glucose, % (std dev)	27.6% (6.3%)	27.3% (5.0%)	-0.3%	25.8% (7.5%)	24.6% (5.8%)	-1.1%
% Time glucose range						
Avg % 3.9–10 mmol/L, 70–180 mg/dL (std dev)	44% (25%)	64% (17%)	20%	49% (29%)	70% (20%)	20%
Avg % 3.9-7.8 mmol/L, 70-140 mg/dL (std dev)	21% (18%)	32% (16%)	11%	24% (22%)	36% (22%)	12%
Avg % < 3 mmol/L, < 54 mg/dL (std dev)	0.00% (0.00%)	0.03% (0.05%)	0.01%	0.00% (0.00%)	0.03% (0.05%)	0.01%
Avg % < 3.9 mmol/L, < 70 mg/dL (std dev)	0.16% (0.24%)	0.17% (0.21%)	0.00%	0.10% (0.14%)	0.22% (0.31%)	0.04%
Avg % > 10 mmol/L, > 180 mg/dL (std dev)	55% (25%)	36% (17%)	-20%	50% (29%)	30% (20%)	-20%

Outcome	Daytime (6:00 AM to < 12:00 AM)†			Overnight (12:00 AM to < 6:00 AM)†		
	Standard Therapy (n = 303)	Omnipod 5 (n = 300)	Change*	Standard Therapy (n = 300)	Omnipod 5 (n = 300)	Change*
Avg % > 13.9 mmol/L, > 250 mg/dL (std dev)	21.3% (22.6%)	7.9% (8.2%)	-12.7%	17.7% (22.9%)	4.8% (6.2%)	-10.9%
Avg % > 16.9 mmol/L, > 300 mg/dL (std dev)	8.2% (11.1%)	2.0% (2.7%)	-5.4%	5.8% (8.6%)	1.0% (1.4%)	-3.4%

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) was 303 for day 299 for all outcomes above except A1C which was 303.*

* *Statistical testing not done to assess significance of change between standard therapy phase and Omnipod 5 System phase.*

Change in A1C Analyzed by Baseline A1C

The table below provides information on the average change in A1C from baseline to the end of the 3 months of Omnipod 5 use grouped by what the baseline A1C was prior to starting Omnipod 5. Those with a higher baseline A1C had a greater decrease in A1C.

Subgroup Analysis of Change in Average A1C (%) by Baseline A1C

Baseline A1C	Avg A1C% Baseline *(std dev)*	Avg A1C% Omnipod 5 *(std dev)*	Change*
< 7.0% (n = 42)	6.5% (0.4%)	6.5% (0.6%)	0.0%
7.0-7.9% (n = 104)	7.5% (0.3%)	7.1% (0.6%)	-0.4%
8.0-8.9% (n = 82)	8.5% (0.3%)	7.6% (0.8%)	-0.8%
≥ 9.0% (n = 68)	10.1% (0.9%)	8.1% (0.9%)	-2.1%

Averages (avg) with standard deviation (std dev) values in brackets.

* *Statistical testing not done to assess significance of change between standard therapy phase and Omnipod 5 System phase.*

Subgroup Analysis of Average Glycemic Results by Baseline Insulin Therapy

The table below provides information on the average glycemic results during the standard therapy phase and the 3-month Omnipod 5 System phase analyzed by baseline insulin therapy in adults with type 2 diabetes. Standard therapy consisted of multiple daily injections or basal-only insulin. There were improvements in A1C and % time in range outcomes for those using multiple daily injections and for those using basal-only insulin at baseline.

Outcome	Multiple Daily Injections (n = 219)			Basal-Only Insulin (n = 62)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg A1C% (std dev)	8.2% (1.4%)	7.4% (0.9%)	-0.8%*	8.6% (1.2%)	7.5% (0.8%)	-1.2%*
Avg % Time in range 3.9–10 mmol/L, 70–180 mg/dL (std dev)	45% (25%)	66% (17%)	20%*	40% (25%)	64% (17%)	23%*
Avg % Time < 3.9 mmol/L, < 70 mg/dL (std dev)	0.28% (0.41%)	0.21% (0.25%)	-0.04%	0.07% (0.10%)	0.13% (0.15%)	0.05% (0.11%)

Averages (avg) with standard deviation (std dev) values in brackets.

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Glycemic outcomes were analyzed by other baseline demographics, and it was found that the improvements in glycemic outcomes for all groups were similar to those of the full study population, with the exception of race/ethnicity. Those who are Latino/Hispanic or listed as "other" experienced a greater decrease in A1C with Omnipod 5 than other race/ethnicity groups, although all race/ethnicity groups saw benefit. Note that the study was not designed to determine differences in benefit or risk from each subgroup.

Percent of Participants Meeting Recommended Glucose Targets

The table below provides information on the % of participants who met recommended glucose targets for A1C and % time in range (3.9–10 mmol/L, 70–180 mg/dL). A high % of participants achieved an A1C <8%.

Glucose Target	Standard Therapy†	Omnipod 5
% achieving A1C < 7%	15%	37%
% achieving A1C< 8%	50%	76%
% achieving time in range, 3.9–10 mmol/L, 70–180 mg/dL, > 70%	19%	42%

Statistical testing not done to assess change between standard therapy phase and Omnipod 5 System phase.

† *Number of participants (n) for A1C outcomes was 305 for Standard Therapy phase and 296 for Omnipod 5 phase. Number of participants (n) for % time in range outcomes was 299 for both phases.*

Quality of Life

The table below provides information on the results of surveys assessing diabetes distress, sleep, and hypoglycemia confidence during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes. Participants on Omnipod 5 reported experiencing less diabetes distress.

Outcome†	Standard Therapy†	Omnipod 5	Change
Avg Type 2 Diabetes Distress Assessment System (T2-DDAS) survey score	2.5 (1.0)	2.2 (0.9)	-0.3*
% of participants with high diabetes distress (T2-DDAS ≥ 2.0%)	66%	55%*	
Avg Pittsburgh Sleep Quality Index (PSQI) survey score (std dev)	7.3 (4.0)	7.0 (4.1)	-0.4§
% of participants with poor sleep (PSQI > 5.0)	63%	59%§	

Outcome†	Standard Therapy†	Omnipod 5	Change
Avg Hypoglycemia Confidence Scale (HCS) survey score (std dev)	3.2 (0.6)	3.3 (0.6)	0.1
% of participants with low hypoglycemia confidence (HCS < 3.0)	32%	25%	

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) for T2-DDAS outcomes was 305 for Standard Therapy phase and 301 for Omnipod 5 phase. Number of participants (n) for PSQI outcomes was 304 for Standard Therapy phase and 294 for Omnipod 5 phase. Number of participants (n) for HCS outcomes was 305 for Standard Therapy phase and 300 for Omnipod 5 phase.*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant and clinically meaningful.*

§ *Change in total score between standard therapy phase and Omnipod 5 phase was statistically significant, but the change was not clinically meaningful. As a result, participants on Omnipod 5 did not experience improved sleep.*

Insulin Requirements

The table below provides information on the average insulin requirements during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes.

	Standard Therapy†	Omnipod 5†	Change
Avg total daily insulin, U/kg/day (std dev)	0.80 (0.46)	0.57 (0.29)	-0.23*
Avg total daily insulin, U/day (std dev)	79.9 (50.0)	57.3 (33.0)	-22.7

Averages (avg) with standard deviation (std dev) values in brackets.

† *Number of participants (n) for U/kg/day outcomes was 305 for Standard Therapy phase and 300 for Omnipod 5 phase. Number of participants (n) for U/day outcomes was 305 for Standard Therapy phase and 304 for Omnipod 5 phase.*

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Body Mass Index

The table below provides information on body mass index (BMI), which is a measure of weight adjusted for height, during the standard therapy phase and the 3-month Omnipod 5 System phase in adults with type 2 diabetes.

	Standard Therapy (n = 305)	Omnipod 5 (n = 300)	Change
Avg BMI	34.9 (7.5)	35.1 (7.6)	0.3*

Averages (avg) with standard deviation (std dev) values in brackets.

* *Change between standard therapy phase and Omnipod 5 System phase was statistically significant.*

Omnipod 5 System Use

The table below provides information on the median % of time study participants used the Omnipod 5 System in Automated Mode.

	Omnipod 5 (n = 305)
% Time in Automated Mode	93% (87%, 97%)

Value is median with interquartile ranges in brackets (Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

Adverse Events

The table below provides a list of the glycemic adverse events per participant that occurred during the 3-month Omnipod 5 System treatment phase. Severe hypoglycemia was the only severe adverse event that occurred that was related to glycemia. Thirteen non-glycemic serious adverse events were reported during the Omnipod 5 phase. All 13 of those events were not related to Omnipod 5 and resulted in a full recovery except one event of stomach pain due to ascites.

Glycemic Adverse Events during the Omnipod 5 System Phase

Adverse Event Per Participant	Omnipod 5 (n = 305)
Severe hypoglycemia	1
DKA	0
Hyperosmolar hyperglycemic syndrome (HHS)	0

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ADDITIONAL INFORMATION

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CHAPTER 27

Frequently Asked Questions and Troubleshooting

Contents

27.1 Omnipod 5 Pump FAQs

The following topics have been frequently asked during the use of Omnipod 5, and the main causes and recommended actions are listed below.

Pod Issues

Issue	Possible Cause	What you can do
During Pod activation, did not hear the 2 beep confirmation after filling the Pod with insulin	Pod not filled with at least 85 units of insulin	Make sure the Pod is filled with at least 85 units of insulin. If you have filled the Pod with at least 85 units and you still do not hear 2 beeps, you will need to discard the Pod and start a new one.
The adhesive around the Pod keeps lifting from the skin	It is important that the Pod stays on the body to ensure that the cannula stays under the skin to deliver insulin. If the area where you apply the Pod is not cleaned and dry, the adhesive may not stick well.	Make sure that the skin is cleaned and dry before applying the Pod. Avoid the use of moisturizers, oils, conditioners, sunscreen, or insect repellent around the site. If there is a lot of body hair, you may need to clip or shave the area 24 hours prior to Pod change. Be sure to remove old adhesive residue from the skin. Insulet has produced a special tape called PodPals™ that can help keep the Pod on for longer.

Issue	Possible Cause	What you can do
Pod alarm sounding	Because the delivery of insulin is so critical to your health, it is important to know if the Pod stops working. The Pod may stop working for many reasons, for example, a blockage (occlusion) is detected, electrostatic discharge affects the circuit, or some interference is detected.	This continuous loud noise is intended to alert you to remove the Pod and replace it with a new one. You can try to deactivate the Pod with your Omnipod 5 App. Occasionally, the app will not be able to communicate with the Pod and you will have to discard the Pod. In this case, you will need to remove the Pod and disable the alarm switch. See page page 215 for guidance.

Finding Out How Much Insulin Was Delivered

Issue	What you can do
Where to see how much insulin is delivered while in Automated Mode	The Sensor Graph will show you the latest sensor glucose value received by the Pod and what mode of insulin delivery the system is in. (To see the graph, tap **VIEW** from the lower right part of the Home screen.) The graph will also show when your last boluses were delivered. You can see on the legend for the graph that insulin suspension is shown as the red bar, and maximum delivery during Automated Mode is shown as the orange bar. To know the exact amount of insulin delivered in Automated Mode, go to: **Menu button (☰) > History Detail > AUTO EVENTS** This will show you the time, sensor glucose value, and corresponding amount of insulin delivered at each 5-minute interval.
Where to find history of insulin deliveries	The Omnipod 5 App maintains the history for previous insulin deliveries. You can check here: **Menu button (☰) > History Detail > Summary**. Scroll down and look for previous insulin deliveries. If you tap the entry, you will see how the calculations for the bolus were made if the SmartBolus Calculator was used.

Controller Issues

Issue	Possible Cause	What you can do
Controller unable to power on or screen is unreadable	Device error	Try restarting the Controller by holding down the Power button for 10 seconds. The Controller should restart and regain communication successfully. If the issue does not resolve, call Insulet Customer Care at 1-800-591-3455. It is important to keep your settings recorded or written down in a safe place so that you can start a replacement system without delay. Insulet does not keep your insulin delivery settings.
Screen turns black (times out) too soon	Screen Time-Out setting needs adjustment.	You can change the screen setting so that the screen stays on for longer. On your Controller, go to: **Menu button** (☰) > **General.** This can be set to 30 seconds, 1 minute, or 2 minutes.
Controller unable to power on and/or not displaying a state of charge while charging	Battery is discharged (dead) due to either prolonged storage or typical use (draining capacity to ~0%) without charging for an extended period.	Charge (or continue to charge) the Controller for 30 minutes. The Controller should display a state of charge and be able to power on. If the issue does not resolve, call Insulet Customer Care at 1-800-591-3455.

Issue	Possible Cause	What you can do
Controller is charging slowly	Using a charging cable or adapter that did not come with the starter kit.	Use ONLY the USB charging cable 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.

Omnipod 5 App Issues

Warning: DO NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that is not deactivated properly can continue to deliver insulin as programmed, putting you at risk of over-delivery of insulin, which can lead to hypoglycemia.

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

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

Issue	Possible Cause	What you can do
Omnipod 5 App does not work on the smartphone	Using a smartphone that is not compatible.	If you are not using a compatible smartphone, you will not be able to use the Omnipod 5 App. To find out if your smartphone is compatible, go to: *https://www.omnipod.com/compatibility*
	Controller or smartphone operating system is not compatible.	If your operating system is not compatible, you will not be able to use the Omnipod 5 App until your operating system is updated. Update your operating system when an update becomes available.
	Omnipod 5 App is not compatible.	If your Omnipod 5 App is not compatible, you will not be able to use the Omnipod 5 App until it is updated. Update your Omnipod 5 App when an update becomes available.
Received a "New Device Detected" message when signing into Omnipod 5 App	You are currently signed into another device, either the Controller or another smartphone, with your Omnipod ID.	**Note:** If you are wearing an active Pod when signing into a new device, your current Pod will still be delivering insulin, but you will not be able to manage it on the new device. 1. Remove the current Pod in order to stop receiving insulin. 2. After removing the current Pod, you will need to go through the setup process again, including pairing a new Pod and re-entering your Sensor information.

Issue	Possible Cause	What you can do
Received an "Omnipod 5 failed to start" message when opening the Omnipod 5 App	Your Omnipod 5 App encountered into a problem starting up.	1. Close the Omnipod 5 App and reopen the app. 2. If the problem continues contact Customer Care.
Not receiving important updates about insulin therapy	You force stopped the Omnipod 5 App. Force stopping is not the same as locking your screen or putting your App to sleep. It means stopping the app from running in the background. The App must be running in order to notify you of important updates regarding your insulin therapy.	Open the app so you can receive important updates. **Note:** Even if you did force stop the Omnipod 5 App, your Pod is still delivering insulin according to the last instruction it received.

Issue	Possible Cause	What you can do
Opening the Omnipod 5 App restarts the setup process	You cleared App data for the Omnipod 5 App. This causes you to lose all your settings and insulin history.	If you clear data for the Omnipod 5 App, your current Pod will still be delivering insulin, but you won't be able to manage it with your Omnipod 5 App. 1. Remove the current Pod in order to stop receiving insulin. 2. After removing the current Pod, you will need to go through the setup process again, including pairing a new Pod and re-entering your Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number. **Tip:** You can get your Dexcom G6 Transmitter SN from the Dexcom G6 App. You can get your Dexcom G7 pairing code and serial number from the Dexcom G7 applicator. If you do not have a record of your settings, contact your healthcare provider for assistance. **Note:** It may take the Sensor or Transmitter and Pod up to 20 minutes to connect.
Manage Sensor options list does not show the Sensor I want to use	The FreeStyle Libre 2 Plus Sensor is compatible only with the Insulet-provided Controller.	If you want to use the FreeStyle Libre 2 Plus Sensor, you will need to use the Omnipod 5 App on the provided Controller. If you want to use a compatible smartphone, you will need to select a Sensor that is currently compatible with your smartphone.

27.2 SmartBolus Calculator FAQs

Issue	Possible Cause	What you can do
With carbs entered and sensor glucose value available, the SmartBolus Calculator recommends no bolus or 0 insulin	You have already received a lot of insulin (your IOB is high), and your sensor glucose trend is falling.	You can remove the sensor glucose value so that the calculator only suggests a bolus amount for the carbs entered. Alternatively, you can decide on a different amount and enter this directly into the Total Bolus field at the bottom of the screen. Check your Calculations screen before you deliver a bolus to see how the calculator determines the suggested bolus. Always confirm the bolus amount before you deliver it to make sure the system delivers what you want.

Issue	What you can do
I'm having a second serving of an item at a meal. How should I handle delivering a bolus?	After meals, it is common for glucose to rise. If you have already bolused for carbohydrates and entered a sensor glucose value or blood glucose reading at the start of a meal, you can just enter carbohydrates for the second serving. The SmartBolus Calculator will suggest a bolus amount for the carbohydrates only.
I typically deliver the bolus following the meal as it is difficult to predict how many carbs my child will eat. What is the best way to use the SmartBolus Calculator in this case?	It is difficult, especially for young children, to predict how much will be eaten at each meal. In this case,you may choose to use the SmartBolus Calculator to deliver the correction bolus by tapping USE SENSOR or entering the blood glucose reading to deliver some insulin prior to the meal. After you are comfortable, you can separately enter the carbohydrates into the SmartBolus Calculator to deliver the full meal bolus.

27.3 Sensor FAQs

Dexcom G6 and Dexcom G7

Dexcom Issue	Possible Cause	What you can do
Activated a Pod and cannot see sensor glucose values in the Omnipod 5 App	Problem with the Sensor or Transmitter.	Check your Dexcom App and if you do not see sensor glucose values, then follow instructions there
	Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number not entered into the Omnipod 5 App.	Go to: **Menu button** (☰)> **Manage Sensor.** Make sure important Dexcom numbers are entered and entered correctly. If you have just connected, it can take up to 20 minutes for values to appear in the Omnipod 5 App.
	You are using the Dexcom receiver.	Use the Dexcom App on your smartphone. The Omnipod 5 System is not compatible with the Dexcom receiver. Then, turn off the Dexcom receiver.
	You selected Dexcom G7 as your Sensor, but you are using a Pod that is not compatible with Dexcom G7.	If your Pod and Sensor are not compatible, you will not be able to connect them to use the Sensor with Omnipod 5 . Deactivate the incompatible Pod and use a Pod that shows Dexcom G7 on the Pod tray lid and outer packaging.

Dexcom Issue	Possible Cause	What you can do
Sensor glucose values no longer show up in the Omnipod 5 App. Instead, there are dashed lines. The Dexcom App does not show a problem.	The most likely reason for this to happen is an interruption in communication between the Sensor or Transmitter and the Pod.	To minimize the risk of interruption, make sure your Sensor and Pod are worn on the same side of the body. Wireless communications do not travel well through the body. For example, if your Sensor is worn on the abdomen and the Pod is on the back of the arm, the signal may be interrupted. Try to keep the Pod and Sensor on the same side of the body to maximize your time in Automated Mode. You can also try deleting the Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number and re-entering it. ➢ Go to: **Menu button** (☰)> **Manage Sensor.** This resets the communication between the Sensor or Transmitter and the Pod.
Sensor glucose values on the Dexcom App look different from those on the Omnipod 5 App	The Dexcom App receives sensor glucose values directly from the Sensor. The Omnipod 5 App receives sensor glucose values from the Pod. Occasionally, there is a slight delay before the value is updated on the Omnipod 5 App.	The difference should be minor. To bring the value up to date, bring the Controller or smartphone close to the Pod.

FreeStyle Libre 2 Plus Sensor

FreeStyle Libre 2 Plus Sensor Issue	Possible Cause	What you can do
Activated a Pod and cannot see FreeStyle Libre 2 Plus sensor glucose values in the Omnipod 5 App. Problem with the Sensor.	FreeStyle Libre 2 Plus is not selected as Sensor in the Omnipod 5 App.	Check your Omnipod 5 App. If you do not see sensor glucose values, then follow instructions there. ➢ Go to: **Menu button** (☰)> **Manage Sensor.** Make sure FreeStyle Libre 2 Plus is selected. If you have just connected, it can take up to 20 minutes for values to appear in the Omnipod 5 App.
	You selected FreeStyle Libre 2 Plus as your Sensor, but you are using a Pod that is not compatible with FreeStyle Libre 2 Plus.	If your Pod and Sensor are not compatible, you will not be able to connect them to use the Sensor with Omnipod 5 . Deactivate the incompatible Pod and use a Pod that shows FreeStyle Libre 2 on the Pod tray lid and outer packaging.
FreeStyle Libre 2 Plus sensor glucose values no longer show up in the Omnipod 5 App. Instead, there are dashed lines.	There may be an interruption in communication between the FreeStyle Libre 2 Plus Sensor and the Pod.	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. For example, if your FreeStyle Libre 2 Plus Sensor is worn on the back of the right arm and the Pod is on the left side of the abdomen, the signal may be interrupted. Try to keep the Pod and Sensor on the same side of the body to maximize your time in Automated Mode.

High Glucose Issues

Issue	Possible Cause	What you can do
After using the system for a couple of weeks, sensor glucose values are running high after breakfast. The Insulin-to-Carb ratio is the same.	One of the benefits of automated insulin delivery is the greater ability to stay closer to your Target Glucose overnight. What this often means is that prior to breakfast, there is less insulin in your body compared to Manual Mode.	It is common to need changes to your Insulin-to-Carb ratio, generally a lowering of the ratio to receive more insulin before meals (for example, lowering the carbohydrate value covered by 1U of insulin). Another setting that you can change is Reverse Correction. When the toggle for this is ON (blue), it means the calculator will recommend less insulin when your sensor glucose values or blood glucose reading is below your Target Glucose. Discuss with your healthcare provider what settings are best for you. Your SmartBolus Calculator settings are available under: **Menu button** (☰) > **Settings > Bolus.**

Issue	Possible Cause	What you can do
After using the system in Automated Mode for a few weeks, sensor glucose values have been running high	Your Target Glucose may need to be adjusted. In Automated Mode, Target Glucose is the main setting that you can control to adjust automated insulin delivery.	Check your Target Glucose here: **Menu button** (☰)> **Settings > Bolus** The Target Glucose can be set between 110-150 mg/ dL. If you're running high, you can try reducing the Target Glucose around the period that you're running higher than desired.
	Other SmartBolus Calculator settings may need to be adjusted.	Think about your SmartBolus Calculator settings: In particular, your Insulin-to-Carb ratio, Correction Factor and, Target Glucose might need to be adjusted. For example, if these high periods are after lunch, you might need more insulin around lunchtime to reduce the likelihood of running high in the afternoon. Changing your Basal Programs or Max Basal setting will not make a difference for the Automated Mode function. This only works for Manual Mode. Discuss with your healthcare provider what settings are best for you.

Issue	Possible Cause	What you can do
Sensor glucose values have been running high over several days.	Although the system is able to automate insulin delivery, your body's insulin needs can change daily. This means that every day with diabetes is different.	Think about diet, exercise, Pod insertion site, and change in your body's needs and how they are affecting your glucose. The system will adapt with every new Pod to give you just the right amount of insulin to get you to the Target Glucose. As the system detects higher insulin needs, it will adapt to adjust insulin dosing accordingly.

Low Glucose Issues

Issue	Possible Cause	What you can do
Sensor glucose values are running low in the late evening; needing hypoglycemia treatment before going to bed.	Your Target Glucose may need to be adjusted for the period to avoid the low.	Check your Target Glucose here: **Menu button** (☰)> **Settings > Bolus**
	If lows are happening soon after the dinner bolus, you might need adjustment of your SmartBolus Calculator settings to receive less insulin for the dinner bolus. Another option is to check how long it has been since the last bolus.	Discuss with your healthcare provider what settings are best for you. Your SmartBolus Calculator settings are available here: **Menu button** (☰)> **Settings > Bolus**

Following afternoon exercise, sensor glucose values are going low.	During exercise, your body is often prone to low glucose.	To reduce the risk of this low, you can use the Activity feature. With this feature, the system delivers less insulin and also drives insulin delivery to a target of 150 mg/dL. It is recommended that you turn this setting ON at least 30–60 minutes before exercise. Exercise with diabetes requires trial and error. Keep a record of activity, carbohydrates consumed, and insulin delivery to work out the best method for you. Your healthcare provider can help provide different ways to confidently manage your diabetes with exercise.

27.4 Automated Mode FAQs

Issue	Possible Cause	What you can do
Activated a Pod and unable to switch to Automated Mode (Dexcom)	Your Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number are not entered into the Omnipod 5 App.	Go to: **Menu button** (☰)> **Manage Sensor.** **Tip:** Always check that the numbers entered into the Omnipod 5 App is the same as the numbers on the Dexcom Sensor or Transmitter you are wearing.
Activated a Pod and unable to switch to Automated Mode (with a FreeStyle Libre 2 Plus Sensor)	Your Sensor is not the one that you started and paired with the Omnipod 5 App on your Controller.	Activate a new FreeStyle Libre 2 Plus Sensor and pair it with the Pod with the Omnipod 5 App on your Controller.

Issue	Possible Cause	What you can do
Screen shows Automated Mode: Limited	Interruption in communication between the Sensor and the Pod.	To minimize the risk of interruption, make sure your Pod and Sensor are worn on the same side of the body. Wireless communications do not travel well through the body. For example, if your Sensor is worn on the abdomen and the Pod is on the back of the arm, the signal may be interrupted.
	Problem with the Sensor or Transmitter.	Check your Dexcom App and if you don't see sensor glucose values, then follow instructions there. If you use a Dexcom Sensor, check your Dexcom App to see if there are sensor glucose values present or if the cause of the loss of communication is related to the Sensor. If you use a FreeStyle Libre 2 Plus Sensor, check your Notifications and Manage Sensor screens in your Omnipod 5 App for any details about a problem with your Sensor. You may decide to switch to Manual Mode or wait for a sensor glucose value to be received.
	Automated Mode may have reached the limits of insulin delivery, either the maximum or the minimum.	Follow the instructions on the screen to check your glucose. After 5 minutes in Manual Mode and you are confident that your Pod and Sensor are working well, you can switch back to Automated Mode. See page 383.

27.5 Pod Communication Issues – "Try Again"

Warning: DO NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that is not deactivated properly can continue to deliver insulin as programmed, putting you at risk of over-delivery of insulin, which can lead to hypoglycemia.

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. Make sure to check your glucose frequently.

No Pod Communication

There may be times while wearing an active Pod when the Pod and the Omnipod 5 App are unable to communicate. You will see the message "No Pod Communication" in the Pod Info tab when this occurs. Your Dashboard will also show "**Searching for Pod**".

If your App is attempting to send an instruction to your Pod (e.g., a bolus), an error will appear on your screen and the app will beep every 10 seconds until the message is acknowledged.

What should you do?

- Bring your Controller or compatible smartphone within five feet of your active Pod to try to restore connection.
- Ensure that no other Pods that have been previously discarded are near your Controller or compatible smartphone.
- If there is an error displayed in your App, tap Try Again (or Check Status) and follow the on-screen instructions to resolve the issue.
- Toggle Bluetooth on and off, if using a compatible smartphone, and remove other devices that may be connected to Bluetooth.

If the above steps do not resolve the communication issue, attempt the options below.

Additional Troubleshooting Options

Reboot the Omnipod 5 App

Controller: Hold down the Power button for approximately 10 seconds, then tap "**POWER OFF**". Let your device turn off completely, then turn back on. This process may last approximately 20 seconds.

Compatible Smartphone: Restart your compatible smartphone. When the phone restarts, open the Omnipod 5 App and tap Try Again (or Check Status) and communication should be restored.

Discard Pod and Activate a New Pod

This option should only be used when the above troubleshooting steps have not resolved the communication issue in your Omnipod 5 App.

- Select DISCARD POD.

  Note: Discarding the Pod will end communication between the Pod and your Omnipod 5 App. The Pod is not deactivated and can still deliver insulin.

- Remove the Pod and ensure it is outside of the communication range of the App.

  - If you previously connected your discarded Pod to your Sensor, you will need to move it out of range of the Sensor to allow the new Pod and Sensor to establish communication.

- Activate and apply your new Pod.

Tip: When there is a communication issue, the Omnipod 5 App offers you options to help you resolve it. It is in your best interest to leave any options to **DISCARD** or **DEACTIVATE POD** as the last choice after trying the other option(s).

Error when sending insulin instructions to the Pod

A communication error may occur when the Omnipod 5 App attempts to send insulin delivery instructions to the Pod. If a communication error occurs when the Omnipod 5 App attempts to send an insulin delivery instruction, the Omnipod 5 App offers you different options.

If the Omnipod 5 App has sent the Pod the instruction and hasn't received confirmation that it was carried out, the Omnipod 5 App offers these options:

- **CHECK STATUS**: Move to a new location, then select this option to recheck for confirmation that the instruction was carried out.

- **DEACTIVATE POD**: This should not be your first choice. When you select this option, you can follow the instructions for replacing your Pod.

If the Omnipod 5 App has not sent the Pod the instruction, the Omnipod 5 App tells you to move to a new location, and tap **TRY AGAIN** to reattempt communication. After you tap **TRY AGAIN** if the next communication attempt fails, the Omnipod 5 App offers these options:

- **CANCEL**: Select this option to cancel sending the instruction. In this case, the Pod continues with its prior insulin delivery mode. You can try to send the instruction later.
- **TRY AGAIN**: Move to a new location, then select this option to tell the Omnipod 5 App to reattempt to send the instruction to the Pod.
- **DEACTIVATE POD**: This should not be your first choice. When you select this option, you can follow the instructions for replacing your Pod.

Error when canceling a bolus

If you are trying to cancel a bolus when a communication error occurs, the following options become available:

- **CANCEL**: Select this option to stop attempting to cancel the bolus. The Pod continues to deliver the bolus.

  Note: If the 'cancel bolus' instruction has already been sent, this CANCEL option is not available.
- **TRY AGAIN**: Move to a new location, then select this option to tell the Omnipod 5 App to continue attempting to communicate with the Pod.
- **DEACTIVATE POD**: This should not be your first choice. When you select this option, you can follow the instructions for replacing your Pod.

If the 'cancel bolus' instruction has already been sent from the Omnipod 5 App when a communication error occurs, the Omnipod 5 App offers these options:

- **CHECK STATUS:** Select this option to attempt to re-establish communication with the Pod and obtain the current status of the 'cancel bolus' command.
- **DEACTIVATE POD:** This should not be your first choice. Select this option to deactivate the Pod when **CHECK STATUS** is unsuccessful.

Error when activating a Pod

If a communication error occurs during Pod activation, the following options become available:

- **DISCARD POD**: This should not be your first choice. Select this option to stop attempting to use this Pod.
- **TRY AGAIN**: Select this option to attempt to re-establish communication.

Error when deactivating a Pod

If a communication error occurs during Pod deactivation, the following options become available:

- **DISCARD POD**: Select this option if the **TRY AGAIN** option has not resolved the problem. This will tell your Omnipod 5 System to unpair from that Pod. The Omnipod 5 App instructs you to remove your Pod and tap **CONTINUE.**
- **TRY AGAIN**: Select this option to attempt to re-establish communication.

Note: After selecting the discard option, you can prevent future alarms from the discarded Pod by following the instructions in "13.8 Silencing Unresolved Alarms" on page 215.

Note: If there is an unconfirmed bolus when you discard a Pod, the Omnipod 5 System does not know how much of the bolus was delivered. Therefore, the Omnipod 5 System temporarily disables the SmartBolus Calculator for a period equal to your Duration of Insulin Action setting. If you tap the Bolus button while the SmartBolus Calculator is disabled, the Omnipod 5 App displays a message that says "SmartBolus Calculator temporarily disabled." You can deliver a manual bolus when the SmartBolus Calculator is disabled.

27.6 About Keeping Your Omnipod 5 Controller and/or Smartphone Nearby

You will use your Controller or smartphone to activate a new Pod every 2–3 days. After you activate a Pod, you will start receiving insulin based on your active Basal Program in Manual Mode, whether or not your Controller or smartphone is nearby. You will need to access the app, however, to resolve any alerts or alarms that may originate from your Pod, to deliver a bolus, or check the status of your System and glucose.

Dexcom G6 and Dexcom G7: After you have entered either the Dexcom G6 Transmitter serial number (SN) or Dexcom G7 pairing code and serial number into the Omnipod 5 App and used the Dexcom App on your smartphone to activate your Sensor, you can switch from Manual Mode to Automated Mode.

FreeStyle Libre 2 Plus Sensor: After you have started a FreeStyle Libre 2 Plus Sensor with the Omnipod 5 App, you can switch from Manual Mode to Automated Mode.

In Automated Mode, the Pod will directly receive sensor glucose values wirelessly and automate insulin delivery depending on your needs.

The System is designed to continue delivering insulin in the absence of your Controller or smartphone, so you will not be alerted that the Pod and display device are out of range of one another if you choose to leave your Controller and/or smartphone behind.

Although your Omnipod 5 System does not require the Controller to be nearby to continue your insulin delivery in Manual Mode or Automated Mode, the Controller and/or smartphone provide(s) you with important information about recent insulin delivery, alerts, and alarms that come from your Pod, and allows you to deliver a bolus.

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.

27.7 Deleting the Omnipod 5 App

If you delete the Omnipod 5 App from your smartphone, all your settings and insulin history will be removed. If you choose to download the Omnipod 5 App later, you will have to go through the setup process again, entering all your insulin therapy settings.

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

Before you begin

- Use the pages at the end of this *Technical User Guide* to write down all of your settings, in case you need them later. If you use a smartphone, you may wish to take screenshots or photos of your Omnipod 5 App settings to keep for future reference.
- If you wish to stop receiving insulin, remove your Pod.

To delete the Omnipod 5 App:

1. Open Google Play.
2. Tap **MENU**.
3. Tap **MY APPS & GAMES**.
4. Tap on the app or game.
5. Tap **UNINSTALL**.

27.8 Device Complaints

If you have a problem with your System, contact Customer Care at 1-800-591-3455. You may be asked to share device data.

To share device data:

1. Ensure a working Wi-Fi connection.
2. Go to: **Menu button** (☰) **> About.**
3. Tap **SEND FILES TO CUSTOMER CARE.**
4. Enter the PIN provided by Customer Care.

If you see an exclamation mark (!) icon, alert your Customer Care representative. Navigate to the Home Screen to clear the (!) icon. If the icon persists, restart your controller.

If this occurs: Data upload is pending.

If this occurs: Data upload is full.

27.9 Factory Mode and Boot Mode

Factory Mode

Factory Mode may appear when you are holding down the Volume DOWN button while pressing the Power Button. This typically happens when powering up the Controller.

Since the touch screen will not work in this mode, you will need to navigate through the options using the Volume buttons. Use the Power Button is to select the highlighted option.

In the Factory Mode menu, the options are "Version" and "Reboot." Your selection is highlighted with a blue background and yellow colored text.

1. Press Volume Down button to move the highlighted bar to "Reboot" option.
2. Press the Power button to select "Reboot" option.

   Note: If you select the Version option by mistake, press the Volume Down button until Back is highlighted on the bottom right corner of the screen. Press the Power button to return to the Factory Mode screen.
3. The Controller will reboot and start normally after selecting Reboot.

Boot Mode

Boot Mode may appear when you are holding down the Volume UP button while pressing the Power Button. This typically happens when powering up the Controller.

Since the touch screen will not work in this mode, you will need to navigate through the options using the Volume buttons. Use the Power Button is to select the highlighted option.

In the Boot Mode menu, the options are "Recovery Mode," "Fastboot Mode," and “Normal Mode.” Your selection is highlighted with <<== pointed to the option.

1. Press the Volume Up Button on the Controller until the <<== is pointing to the Normal Boot option.
2. Press the Volume Down Button on the Controller to make the selection.
3. The Controller will reboot and start normally after selecting Normal.

   Note: If you select “Recovery” or “Fastboot” by mistake, you will need to do a Hard Reset. To Hard Reset the Controller, press and hold down the Power button for 7 to 10 seconds until the screen turns off and restarts.

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Appendix

Summary of Settings and Options

The options for the various Omnipod 5 Automated Insulin Delivery System settings are:

Time format	12-hour
Time zone	GMT-11:00 to GMT+13.00
Daylight Savings Time	ON or OFF. Default based on date and time zone.
Date format	MM/DD/YYYY
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9
Dexcom G6 Transmitter serial number (SN)	6 characters
Dexcom G7 pairing code	4 characters
Dexcom G7 serial number	12 characters
Maximum Basal Rate	Select one value between 0.05-30 U/hr in 0.05 U/hr increments. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12
Basal rate segments	24 per Basal Program
Activity feature	Range: 1 to 24 hrs In increments of 1 hour
Temp basal	%, units/hr, or OFF. Default is OFF. Duration: 30 min to 12 hrs in 30-min increments
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr
Glucose Goal Range (for blood glucose history)	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments

BG reminder	ON or OFF. Default is OFF. Maximum of 4 active at one time. A reminder can occur between 30 min and 4 hrs after a bolus is started. Set in 30-minute increments.
Target Glucose value	Maximum of 8 segments; 110 to 150 mg/dL in 10 mg/dL increments
Correct Above threshold	Maximum of 8 segments; Target Glucose to 200 mg/dL in 1 mg/dL increments
Minimum Glucose for Calculations	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL
Reverse Correction	ON or OFF. Default is ON
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Bolus size	Range: 0.05-30 U in 0.05 U increments
Extended bolus	%, Units, or OFF. Default is OFF. 30 minutes to 8 hours in 30-minute increments.
Pause insulin	30 minutes to 2 hours
Low Pod Insulin advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Pod Shut-Off timer	OFF, or 1 to 24 hours in 1-hour increments. Default is OFF.
History screen display	Rolling 90-day period
Language	English, Spanish. Default is English.

Pod Specifications

Size: 1.53" wide x 2.05" long x 0.57" high (3.9cm x 5.2cm x 1.45cm)

Weight (without insulin): 0.92 oz (26 grams)

Operating temperature range: Pod operating environment of 41°F to 104°F (5°C to 40°C).

Startup temperature: above 50°F (10°C)

Storage temperature range: 32°F to 86°F (0°C to 30°C)

Warm-up time (0°C to 20°C): 7 minutes

Cooldown time: No time is required for cooldown from maximum storage temperature (30°C) to operating temperature.

Reservoir volume (deliverable): 200 units

Cannula insertion depth: 0.16–0.28 in (4 to 7 mm)

Depth of insulin infusion: ≥ 0.16 in (4 mm)

IP (Ingress Protection) rating for moisture and dust: IP28 (protected from touch by fingers and objects 12.5 millimeters or larger; protected from water to a depth of up to 25 feet (7.6 meters) for up to 60 minutes)

Insulin concentration: U-100

Sterilizing agent: Sterilized using ethylene oxide

Alarm type: Audible. Output: ≥ 45 db(A) at 1 meter

Operating relative humidity range: 20 to 85%, non-condensing

Storage relative humidity range: 20 to 85%, non-condensing

Operating atmospheric pressure: 700 hPa to 1060 hPa

Storage atmospheric pressure: 700 hPa to 1060 hPa

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.05 U

Flow Capability:

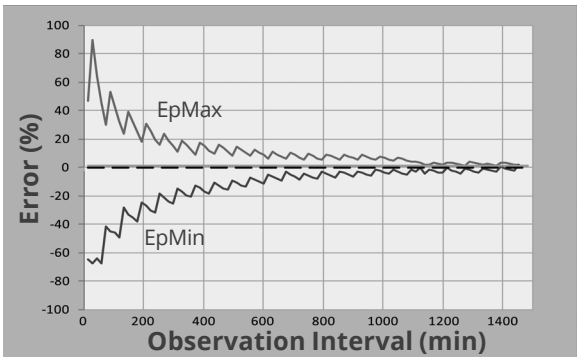
Prime rate: 0.05 unit per second.
Basal: Programmable by the user in 0.05 U increments up to 30.0 U per hour
Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

Delivery accuracy (tested per IEC 60601-2-24):

Basal: ± 5% at rates ≥ 0.05 U/hr
Bolus: ± 5% for amounts ≥ 1.0 unit
± 0.05 units for amounts < 1.0 unit

Note: You should consider bolus dose accuracy when setting a bolus dose. When using the lowest bolus dose allowable (0.05 units), the actual bolus delivered may be as low as 0.00 units or as high as 0.10 units.

Accuracy test results: The following graph shows the flow accuracy of the Pod against given time periods. The measurements were made using a Pod with a basal rate of 0.5 µl/h (which delivers 0.05 U/h of U-100 insulin) at a high operating temperature. The overall mean percentage flow error was 1.40%.



Controller Specifications

Size: 5.67" high x 2.66" wide x 0.49" deep
(143.92 mm x 67.57 mm x 12.33 mm)

Weight: 5.82 oz (165 grams)

Screen active area: 2.21" wide x 4.75" high (56.16 mm x 120.58 mm)

Operating temperature range: 41°F to 104°F (5°C to 40°C)

Storage temperature range: 32°F to 86°F (0°C to 30°C)

Operating relative humidity range: 20% to 90%, non-condensing

Storage relative humidity range: 20% to 90%, non-condensing

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The Controller and Pod should be:

- At startup: Adjacent and touching, with the Pod either in or out of tray, to ensure proper communication during priming
- During normal operation: Within 5 feet (1.5 m) of each other. Depending on the location, the communication distance may handle separations up to 50 feet (15 meters) away

Alarm type: Audible. Output: ≥ 45 db(A) at 1 meter

IP (Ingress Protection) rating for moisture and dust: IP22 (protected from touch by fingers and objects 12.5 millimeters or larger; not well-protected from water–avoid liquid)

Notification type: Audible and vibratory

Battery: Rechargeable Li-ion battery, 3.8V, 2800 mAh

Battery Operational Life: Full charge covers approximately 36 hours with typical use

Controller Service Life: 2 approximately 2 years (based on 300-500 charge cycles) with typical use

Shelf Life (Starter Kit): 18 months

Battery charger operating line voltage: 100 to 240 VAC, 50/60 Hz

Only use the Noetic approved power adapter (Insulet PN PT-000428) with the Controller.

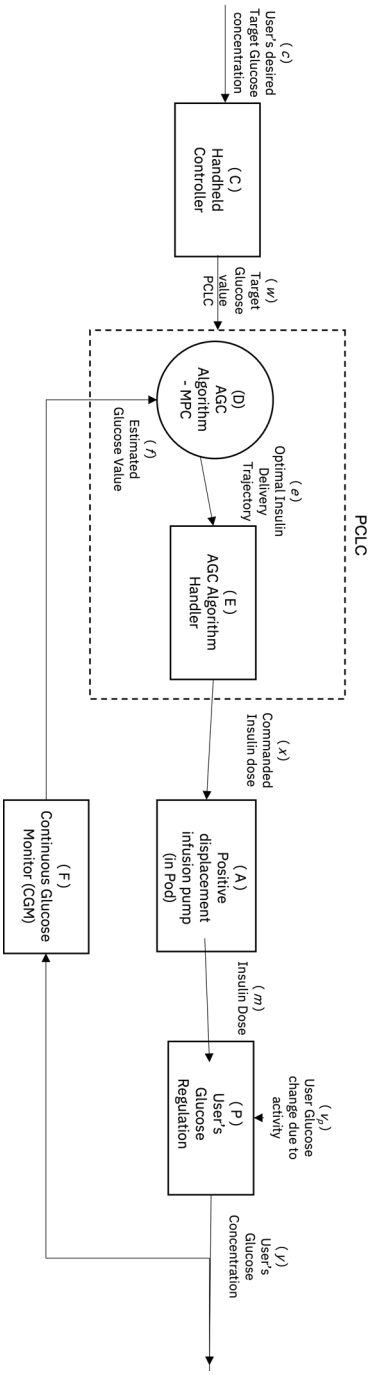
Dexcom Specifications

For information about Dexcom operating specifications, see the *Dexcom CGM System Instructions for Use.*

FreeStyle Libre 2 Plus Sensor Specifications

For information about FreeStyle Libre 2 Plus Sensor operating specifications, see the *FreeStyle Libre 2 Plus Sensor Instructions for Use.*

Theory of Operation for Physiologic Closed Loop Control System



Protection from Over-Infusion or Under-Infusion

The Pod software monitors the infusion rate. If an error that would result in over-infusion or under-infusion is detected and cannot be corrected, insulin delivery stops, and an alarm sounds.

Blockage (occlusion) detection

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).

Caution: ALWAYS check your glucose frequently when you use very low basal rates. Checking your glucose frequently can alert you to the presence of a blockage (occlusion). Blockages can result in hyperglycemia.

A blockage (occlusion) is an interruption in insulin delivery from the Pod. If the Omnipod 5 System detects a blockage, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

A blockage hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts blockage detection for three different situations when using U-100 insulin. For example, if the Pod's cannula becomes blocked when delivering a 5 U bolus, 35 minutes may pass before the Pod sounds a hazard alarm.

	Time between blockage and Pod alarm	
	Typical time	**Maximum time**
5.00 U bolus	33 minutes	35 minutes
1.00 U/hr basal	3.0 hr	5.5hr
0.05 U/hr basal	51 hr	80 hr (Pod expiration)

If a blockage spontaneously clears up, a volume of insulin could be released. That volume would not exceed the volume of the programmed insulin intended for delivery.

If your Omnipod 5 System detects a potential blockage to your insulin delivery, it will set a blockage alarm to sound. If a blockage alarm is set to alarm while an immediate bolus is in progress, the alarm is delayed until completion of the bolus.

Performance Characteristics

The Omnipod 5 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Insulet.

Delivery performance characterization

Basal Delivery: In order to assess basal delivery accuracy, 12 Pods were tested by delivering at low, medium, and high basal rates (0.05, 1.00, and 30.0 U/hr). Water was used as a substitute for insulin. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for the low, medium, and high basal rate settings for all pumps tested with no warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.05 U/hr)			
Basal Duration (Number of units requested)	**1 hour (0.05 U)**	**6 hours (0.30 U)**	**12 hours (0.60 U)**
Amount Delivered	0.049 U	0.30 U	0.59 U
[min, max]	[0.00, 0.12]	[0.13, 0.57]	[0.34, 0.99]

Medium Basal Rate Delivery Performance (1.00 U/hr)			
Basal Duration (Number of units requested)	**1 hour (1.00 U)**	**6 hours (6.00 U)**	**12 hours (12.00 U)**
Amount Delivered	0.99 U	5.97 U	11.88 U
[min, max]	[0.65, 1.55]	[5.06, 6.87]	[10.53, 13.26]

High Basal Rate Delivery Performance (30.00 U/hr)		
Basal Duration (Number of units requested)	**1 hour (30.00 U)**	**6 hours (180.00 U)**
Amount Delivered	29.82 U	179.33 U
[min, max]	[28.85, 31.39]	[177.49, 181.15]

Note: A measurement at the 12-hour period with a 30.0 U/hr basal rate is not applicable to the Omnipod 5 System as the reservoir will empty at approximately 6 ⅔ hours at this rate.

Bolus Delivery: In order to assess bolus delivery accuracy, 12 Pods were tested by delivering a minimum, intermediate, and maximum bolus amount (0.05, 5.00, and 30.0 Units). Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid delivered was used to assess pumping accuracy.

The following table summarizes the typical bolus performance observed for the requested minimum, intermediate, and maximum size bolus for all pumps tested. For each individual target bolus size, the number of boluses observed is shown along with the average (mean), minimum, and maximum units delivered as measured by a scale.

Individual Bolus Accuracy Performance	Target Bolus Size (Units)	Mean Bolus Size (Units)	Min Bolus Size (Units)	Max Bolus Size (Units)
Min Bolus Delivery Performance (n = 5987 boluses)	0.05 U	0.050 U	0.00 U	0.119 U
Intermediate Bolus Delivery Performance (n = 300 boluses)	5.00 U	5.01 U	4.49 U	5.37 U
Max Bolus Delivery Performance (n = 72 boluses)	30.00 U	30.05 U	29.56 U	30.62 U

The tables below show for each requested bolus size, the range of amount of insulin that was observed delivered compared to the requested amount. Each table provides the number and percent of delivered bolus sizes observed within the specified range.

Amount of Insulin Delivery for a Minimum (0.05 U) Bolus Request

Amount (Units) **(% of settings)**	<0.0125 (< 25%)	0.0125–0.0375 (25-75%)	0.0375–0.045 (75-90%)	0.045–0.0475 (90-95%)	0.0475–0.0525 (95-105%)
Number and percent of boluses within range	61/5987 (1%)	639/5987 (10.7%)	1284/5987 (21.4%)	504/5987 (8.4%)	1100/5987 (18.4%)
Amount (Units) (% of settings)	0.0525–0.055 (105-110%)	0.055–0.0625 (110-125%)	0.0625–0.0875 (125-175%)	0.0875–0.125 (175-250%)	>0.125 (>250%)
Number and percent of boluses within range	504/5987 (8.4%)	1192/5987 (19.9%)	582/5987 (9.7%)	121/5987 (2%)	0/5987 (0%)

Amount of Insulin Delivery for an Intermediate (5.00 U) Bolus Request

Amount (Units) (% of settings)	< 1.25 (< 25%)	1.25-3.75 (25–75%)	3.75-4.50 (75–90%)	4.50-4.75 (90–95%)	4.75-5.25 (95–105%)
Number and percent of boluses within range	0/300 (0%)	0/300 (0%)	1/300 (0.3%)	4/300 (1.3%)	287/300 (95.7%)
Amount (Units) (% of settings)	5.25–5.50 (105–110%)	5.50–6.25 (110–125%)	6.25–8.75 (125–175%)	8.75–12.50 (175–250%)	>12.50 (>250%)
Number and percent of boluses within range	8/300 (2.7%)	0/300 (0%)	0/300 (0%)	0/300 (0%)	0/300 (0%)

Amount of Insulin Delivery for a Maximum (30.0 U) Bolus Request

Amount (Units) (% of settings)	< 7.5 (< 25%)	7.5–22.5 (25–75%)	22.5–27.0 (75–90%)	27.0–28.5 (90–95%)	28.5–31.5 (95–105%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	72/72 (100%)
Amount (Units) (% of settings)	31.5–33.0 (105-110%)	33.0–37.5 (110-125%)	37.5–52.5 (125-175%)	52.5–75.0 (175-250%)	>75.0 (>250%)
Number and percent of boluses within range	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)	0/72 (0%)

Omnipod 5 System Label Symbols Glossary

The following symbols appear on the Omnipod 5 System or its packaging:

Symbol	Meaning	Symbol	Meaning
	Do not re-use		MR unsafe
	Refer to instruction manual / booklet		Do not use if package is damaged and consult instructions for use
	Sterilized using ethylene oxide		Type BF applied part
	Date of manufacture		Manufacturer
	Country of Manufacture – United States of America		Country of Manufacture – Malaysia
	Country of Manufacture – China		Compatible with
	Batch code		Keep dry
	Use-by date		Temperature limit
	Catalogue number		Humidity limitation
	Serial number		Atmospheric pressure limitation
	UK Conformity Assessed		Australian Regulatory Compliance Mark
	Marking of conformity		Importer
IP28	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; Submersible: Waterproof to 7.6 meters (25 feet) for up to 60 minutes	**IP22**	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; avoid liquid

Symbol	Meaning	Symbol	Meaning
	Non-pyrogenic fluid path	MD	Medical device
	Discard electrical and electronic equipment separately from standard waste.	automated insulin delivery system	Automated Insulin Delivery System
	Single sterile barrier system		Single patient multiple use
	Email address		Toll free number
	Local number		Recycling
U100 INSULIN	Compatible with U-100 Insulin Only		Consult instructions for use or consult electronic instructions for use
FCC ID:	Federal Communication Commission Identifier with number	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
IC:	Complies with ISED Canada Radio Standards Specifications	HVIN:	Hardware version identification number
CH REP	Switzerland Authorized Representative	EC REP	Authorized representative in the European Community/ European Union
	(France) The Triman indicates that the product must be sorted or returned to a collection point.	ETL CLASSIFIED Intertek	Intertek Authorized Product Certification Mark
	(France) This product must be separated from conventional perforating DASTRI for recycling.		(France) This pictogram means that the product contains a piercing object.

Symbol	Meaning	Symbol	Meaning
	(France) Electronic perforating waste must be stored in the secure DASTRI purple box. These purple boxes are distributed free of charge in pharmacies.		(France) All pharmacies distribute and collect DASTRI needle boxes free of charge from self-treatment patients.
	(France) Packaging intended for recycling		(France) The puncture waste must be placed in a DASTRI needle box. These needle boxes are distributed by pharmacies.
	Charging cable		Charging adapter
	Fill Syringe and Needle Assembly		Pod
	Controller skin		Omnipod 5 Controller

Omnipod 5 System Notice Concerning Interference

Caution: DO NOT make changes or modifications to any component of the Omnipod 5 System that has not been authorized by Insulet Corporation. Unauthorized tampering with the System can revoke your right to operate it.

The Omnipod 5 Automated Insulin Delivery System is designed to comply with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with the instructions may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If the equipment does cause harmful interference to radio and television reception, the user is encouraged to try to correct the interference by one of the following measures:

- Move or relocate the Omnipod 5 System
- Increase the separation between the Omnipod 5 System and the other device that is emitting or receiving interference
- Consult the dealer or an experienced radio/TV technician for help

Quality of Service

The Omnipod 5 System includes two wireless transmission pathways. Insulet defines the quality of service of the Omnipod 5 System for each of the two pathways:

Omnipod 5 App to Pod wireless communication definition

Successful transfer of commands, data, and alarms between the Controller or smartphone running the Omnipod 5 App and Pod when in communication range (within 5 ft during normal

operation). The Omnipod 5 App informs the user when transfer of commands, data, and alarms is unsuccessful. For Insulin Delivery commands, the system performance requirements state that communication between the Pod and the Controller or smartphone running the Omnipod 5 App occurs within 8 seconds at a reliability rate of 95%. The Omnipod 5 App will inform the user when there are communication errors between the Pod and the Controller or smartphone. When such an error occurs, the Omnipod 5 App will beep once every 10 seconds and the communication failure will continue to be indicated within the Omnipod 5 App until the communication error is resolved.

Pod to Sensor wireless communication definition

The percentage of sensor glucose values successfully received by the Pod when the Sensor and Pod attempt to communicate every 5 minutes. The System performance requirements state that at least 80% of sensor glucose values will be successfully received by the Pod when the Sensor is worn within line of sight of the Pod. The System informs the user of missing sensor glucose values in real time by the dashes on the home screen or by missed dots on the Sensor Graph.

To maintain quality of service when other devices operating in the 2.4 GHz band are around, the Omnipod 5 System uses the coexistence features provided by Bluetooth® wireless technology.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod 5 System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

The Omnipod 5 System has been tested and found to have acceptable immunity to emissions from RFID and EAS systems.

The Omnipod 5 System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and

put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod 5 System fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

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.

Care should be taken if the Omnipod 5 System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod 5 System should be observed to verify normal operation in this setting.

The Omnipod 5 System communicates by low-level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod 5 System communicates with the following characteristics:

Frequency: 2.402-2.480 GHz, digitally modulated, with an effective Isotropic radiated power of 1.14mW

The Omnipod 5 System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

Caution: DO NOT use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 12 inches (30 cm) to any part of the Omnipod 5 System, as it may impact the communication between your smartphone or Controller and your Pod.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should ensure that is used in such an environment.		
Emissions	**Compliance according to**	**Electromagnetic environment**
RF Emissions (CISPR11)	Group 1	The Pod, Controller, Dexcom G6 Transmitter, Dexcom G7 Sensor, and FreeStyle Libre 2 Plus Sensor emit low-level electromagnetic energy (RF) in order tocommunicate. Although unlikely, nearbyelectronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments, including domestic establishments.
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations/ Flicker Emissions (IEC 61000-3-3)	Pst ≤ 1.0 Plt ≤ 0.65 dc ≤ 3% dmax ≤ 4% d(t) ≥ 200 ms during a voltage change should be ≤ 3%	

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this device)**	**Electromagnetic environment**
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Electrical Fast Transient/ burst (IEC 61000-4-4)	± 2 kV power supply lines ± 2 kV Input DC Power Port ± 1 kV input/ output lines	± 2 kV power supply lines ± 2 kV Input DC Power Port ± 1 kV input/ output lines	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Conducted Disturbances induced by RF fields (IEC 61000-4-6)	3V 150 KHz-80 MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MHz	3V 150 KHz-80 MHz 6V in ISM and amateur radio bands between 150 KHz and 80 MH	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

Electromagnetic Immunity			
Voltage Dips, Short Interruptions, Voltage Variations on Power Supply input lines (IEC 61000-4-11)	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% UT (100% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user requires continued operation during power mains interruptional, it may be necessary to use an uninterruptible power supply or a battery.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod 5 System.

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communication equipment. The frequencies and services listed in the table are representative examples in various locations where the System may be used.

Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380–390	TETRA 400	Pulse modulation b)18Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulatio n b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800. ODEM 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	G GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2450-2570	Bluetooth WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	0.2	0.3	9
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.

This table lists the immunity levels at specific test frequencies for Proximity Magnetic Fields Range of 9 kHz to 13.56 MHz.

Test Frequency	Modulation	Immunity Test Level (A/m)
30kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1 kHz	65 c)
13.56 MHz	Pulse modulation b)	7.5 c)
a) This test is applicable only to ME equipment and ME systems intended in a HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) RMS before modulation is applied.		

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

Field strengths from fixed Transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. In order to assess the electromagnetic environment due to fixed RF Transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Customer's Bill of Rights

Mission Statement

Insulet Corporation is dedicated to designing, developing, and distributing products that provide superior treatment options and lifelong health benefits for people with diabetes.

Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod 5 Automated Insulin Delivery System.

The Omnipod 5 System consists of the Pod and the handheld, wireless Controller or compatible smartphone running the Omnipod 5 App, which programs the Pod with insulin delivery instructions.

Compliance

The Omnipod 5 Automated Insulin Delivery System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

Inquiries

Representatives are available to answer product-related inquiries 24 hours per day at our toll-free number, 1-800-591-3455 (from outside the United States, 1-978-600-7850). For all other questions, concerns, or complaints, please contact us between the hours of 8:30 am and 6:00 pm Eastern Time, Monday through Friday, at 1-800-591-3455 (from outside the United States, 1-978-600-7850). We will respond immediately whenever possible; some issues may take up to 14 days to resolve.

CHAP Accredited

Insulet Corporation has been accredited by the Community Health Accreditation Program (CHAP) since 2007. To learn more about CHAP or to communicate concerns that you have been unable to resolve directly with the company, please visit www.chapinc.org or call CHAP at 1-800-656-9656.

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.
2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.
3. Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice later in this section.
4. Receive a timely response to your request for service.
5. Receive continued service.
6. Select the medical equipment supplier of your choice.
7. Make informed decisions regarding your care planning.
8. Understand what services will be provided to you.
9. Obtain an explanation of charges, including policy for payment.
10. Agree to or refuse any part of the plan of service or plan of care.
11. Voice complaints without fear of termination of service or other reprisals.
12. Have your communication needs met.

You have the responsibility to:

1. Ask questions about any part of the plan of service or plan of care that you do not understand.
2. Use the equipment for the purpose for which it was prescribed, following instructions provided for use, handling care, safety and cleaning.
3. Supply Insulet Corporation with insurance information necessary to obtain payment for services.
4. Be accountable for charges not covered by your insurance. You are responsible for settlement in full of your account.
5. Notify us immediately of:
    a. Equipment failure, damage, or need of supplies.
    b. Any change in your prescription or physician.
    c. Any change or loss in insurance coverage.
    d. Any change of address or telephone number, whether permanent or temporary.

Limited Express Warranty, Disclaimer, and Limitation of Remedies for the Controller and Pods

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE OMNIPOD 5 AUTOMATED INSULIN DELIVERY SYSTEM HANDHELD CONTROLLER AND PODS (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Handheld Controller

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Insulet Corporation ("Insulet") warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System ("Omnipod 5 System"), that, if Insulet determines, during the period of four (4) years from the date of purchase, that the Omnipod 5 System handheld hardware Controller ("Controller") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will either repair or replace, at its sole option, the Controller. This four-year (4) warranty period applies only to new Controllers and, in the event the Controller is repaired or replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Controller under this Limited Express Warranty, the warranty coverage for the replacement Controller shall expire four (4) years from the date of purchase of the original Controller.

Limited Warranty Coverage for the Omnipod 5 Automated Insulin Delivery System Pods

Subject to this Limited Express Warranty, Insulet warrants to you, the original purchaser of the Omnipod 5 Automated Insulin Delivery System, that, if Insulet determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod 5 Automated Insulin Delivery System Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e., occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet of the claim).

This eighteen (18) month and seventy-two (72) hour warranty period apply only to new Pods and, in the event a Pod is replaced, the warranty period shall not be extended or reset. Thus, if Insulet replaces a Pod under this Limited Express Warranty, the warranty coverage for the replacement Pod shall expire either eighteen (18) months from the manufacture date of the original Pod or seventy-two (72) hours from the time of activation of the original Pod, whichever occurs first.

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Insulet of the claimed defect with the Controller or the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). For a claim involving the Controller, you must provide the Controller serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the Controller and/or the Pod, the manufacture date of the Pod and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet elects to repair the Controller (which may include, but is not limited to, a repair kit or replacement part(s) Insulet provides) or refers you to a third party, you must obtain a prior authorization and return the Controller or the Pod to Insulet. The Controller or Pod must be properly packaged and returned to Insulet according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a prior authorization, Insulet will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the Controller or Pod to Insulet under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet, except those performed or provided by third parties to which you were explicitly referred by Insulet.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, Insulet may require that you provide a valid proof of purchase, manufacture or activation. Your failure to provide a valid proof of purchase, manufacture or activation, as determined by Insulet, may result in the denial of coverage under this Limited Express Warranty.

Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental or other transfer of the Controller or of the Pod to any other person or entity.

This Limited Express Warranty will apply only if the Controller or the Pod at issue has been used in accordance with the Omnipod 5 Automated Insulin Delivery System *Technical User Guide* and/or other written instructions provided by Insulet. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE Controller OR THE POD HAVE BEEN:

- Altered, changed or modified by any person or entity other than Insulet
- Opened, serviced or repaired by any person or entity other than Insulet
- Damaged by an act of God or other “force majeure” like event
- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage

- Damaged by wear and tear, causes unrelated to defective materials or workmanship
- or other circumstances outside of the reasonable control of Insulet

This Limited Express Warranty does not apply to test strips, batteries that are not provided by Insulet, other accessories, or related products provided by third parties (e.g., data management tools, Sensors).

This Limited Express Warranty does not extend to design defects (i.e. claims that the Controller or the Pod should have been designed in a different way).

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

REPAIR OR REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE CONTROLLER OR THE POD IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF INSULET. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE SO LONG AS INSULET IS WILLING AND ABLE TO REPAIR OR REPLACE A CONTROLLER OR A POD WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER PRESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN THE CONTROLLER OR A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

Important Additional Provisions

Insulet Corporation does not warrant the suitability of the Controller or the Pod or the Omnipod 5 Automated Insulin Delivery System for any specific person as health care and treatment are complex subjects requiring the services of qualified health care providers.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction. The above Limited Express Warranty applies only to Controllers and the Pods that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. Insulet Corporation's liability in such jurisdictions shall be limited to the maximum extent permitted by law. Such limitations shall include but are not limited to the following: any implied warranties that cannot be disclaimed under the law of a particular jurisdiction are limited, to the extent allowed by law, to the time period covered by the above limited express warranty, or to the applicable time period provided by law, whichever period is shorter.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System. No employee, agent or other representative of Insulet or any other party is authorized to make any product warranty or agreement applicable to a Controller, a Pod, or an Omnipod 5 Automated Insulin Delivery System in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod 5 Automated Insulin Delivery System, please return any Omnipod 5 Automated Insulin Delivery System products (including any Controller and Pods) to Insulet in exchange for a full refund. Failure to return such Omnipod 5 Automated Insulin Delivery System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Rev: January 2021

HIPAA Privacy Notice

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

This notice of privacy practices (the "HIPAA Privacy Notice") describes how we may use and disclose your Medical Information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act, and all regulations issued thereunder ("HIPAA"). It also describes your rights to access and control your Medical Information. As used herein, "Medical Information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. Most uses or disclosures of your Medical Information constituting psychotherapy notes will be made only after receiving your written authorization. We will not use or disclose your Medical Information for purposes of marketing, except as permitted

by law and/or outlined in this HIPAA Privacy Notice. We will not sell your Medical Information, without first obtaining your written authorization. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations where we may use or disclose your Medical Information without your prior written authorization, as described further below:

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided By Us

Treatment, Payment and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

Family, Friends and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or

disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities, or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.

Inmates: We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and good order of the correctional institution.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Non-identifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical

Information is still maintained in our records. If you would like to make a request to review your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment, payment or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. Except as otherwise provided in this HIPAA Privacy Notice, we are not required to agree to a restriction that you may request. We are required to agree to your request to restrict disclosure of your Medical Information to a health plan if (i) the disclosure is to carry out payment or healthcare operations and is not otherwise required by law; and (ii) your Medical Information pertains solely to a healthcare item or service for which you or someone (other than the health plan) on your behalf, has paid us in full. If we agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications From Us By Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer at

https://www.omnipod.com/privacyrequest

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, for notification purposes, for national security or intelligence purposes, to correctional institutions or law enforcement officials, or as part of a limited data set. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under

applicable law. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please submit a request at

https://www.omnipod.com/privacyrequest

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

You Have The Right to Obtain a Copy of this HIPAA Privacy Notice: You have the right to obtain a paper copy of this HIPAA Privacy Notice from us, upon request, even if you have agreed to accept this notice electronically. If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request at

https://www.omnipod.com/privacyrequest

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our legal duties and privacy practices with respect to Medical Information, and to notify you if there is a breach resulting in disclosure of your unsecured Medical Information.

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our website at

https://www.omnipod.com

If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request at

https://www.omnipod.com/privacyrequest

What To Do If You Have a Problem or Question

If you are unable to use the online privacy request form, you may obtain assistance by calling our toll-free number: 1-800-591-3455.

If you have any further questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us in writing or by phone at:

Insulet Corporation
Attn: Privacy Officer
Email: privacy@insulet.com

(866) 941-0155

Our mailing address is:

100 Nagog Park
Acton, MA 01720

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling (877) 696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

Revision Dates: April 1, 2009, September 20, 2013, April 22, 2014, September 2, 2014, and September 15, 2022.

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Use these pages to keep track of your important settings. Remember to update your information if you change or add settings.

Basal Program 1

Name_____ Basal rate

midnight	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr

Basal Program 2

Name_____ Basal rate

midnight	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr

Basal Program 3

Name_____ Basal rate

midnight	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr

Basal Program 4

Name_____ Basal rate

midnight	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr
_____	to	_____	_____U/hr

Target Glucose

Time segment			Target Glucose: Bolus Calculator aims for this value	Correct Above: Suggest correction if glucose is above
midnight	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL
_____	to	_____	_____mg/dL	_____mg/dL

Correction Factor

Correction Factor for each time segment	1 unit of insulin lowers glucose by
midnight to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL
_____ to _____	_____ mg/dL

Insulin-to-Carbohydrate Ratio (IC Ratio)

IC Ratio for each time segment	1 unit of insulin lowers glucose by
midnight to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb
_____ to _____	_____ g carb

Duration of Insulin Action

Time that insulin remains "active" in the body after a bolus _____ hrs

Favorite Foods

Name	Grams of carbohydrates
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

Max Basal Rate

Upper limit for basal rates in a Basal Program or temp basal _____U/hr

Max Bolus

Maximum amount of insulin that you can request in a single bolus _____U/hr