

Urgent Low Glucose

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

When your sensor glucose value is at or below 55 mg/dL, your sensor will send the value to your Pod. The Pod will sound an Advisory Alarm to let you know that your glucose is very low. You can acknowledge the alarm from your Omnipod 5 App.

If you do not have an active Pod, the Omnipod 5 App will issue the Advisory Alarm. See "21.3 Using a Libre Plus Sensor with the Omnipod 5 App" on page 337.

Note: This Alarm will occur again if another sensor glucose value of 55 mg/dL or lower is received after the initial Advisory Alarm was acknowledged. You may silence (snooze) this Advisory Alarm for 30 minutes by acknowledging the on-screen message.

Note: This Advisory Alarm will stop repeating only after a glucose value of 56 mg/dL or greater is received.

Action to Take: Use a blood glucose meter to confirm your glucose. Treat low glucose as needed.

21 About the Libre Plus Sensor

21.4 Sensor Glucose Trends and Indicators

Colors and trend arrows display on the Home Screen to show your sensor glucose value and trend. They will change depending on your Glucose Goal Range.

- 121

Trending steady

→

Sensor glucose value is within your Goal Range (in Manual Mode).
- 121

Trending steady

→

Sensor glucose value is within your Goal Range (in Automated Mode).
- 68

Rapidly falling

→

Sensor glucose value is below Goal Range.
- 258

Slowly rising

↗

Sensor glucose value is above Goal Range.

Glucose Trend Arrows

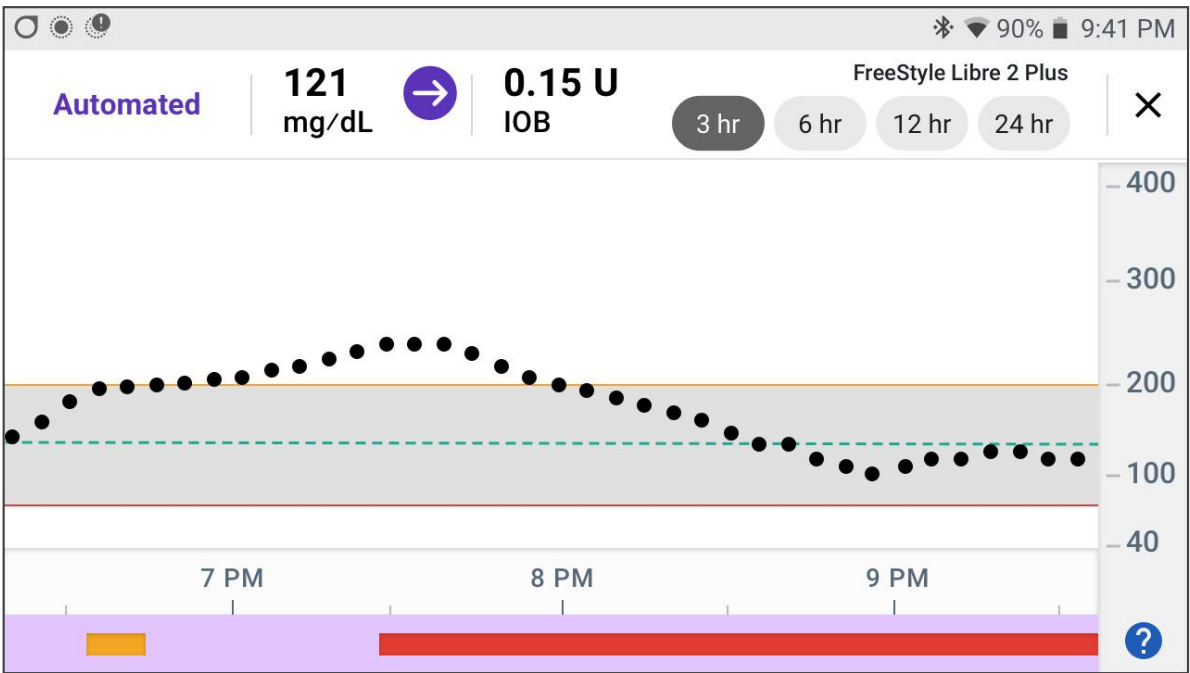
The following table describes the sensor glucose trend arrows. The trend arrows are shown in blue for example purposes only.

Trend Arrows	Description
↑	Glucose is rising quickly. (more than 2 mg/dL per minute)
↗	Glucose is rising. (between 1 and 2 mg/dL per minute)
→	Glucose is changing slowly. (less than 1 mg/dL per minute)
↘	Glucose is falling. (between 1 and 2 mg/dL per minute)
↓	Glucose is falling quickly. (more than 2 mg/dL per minute)

View Sensor Glucose Graph

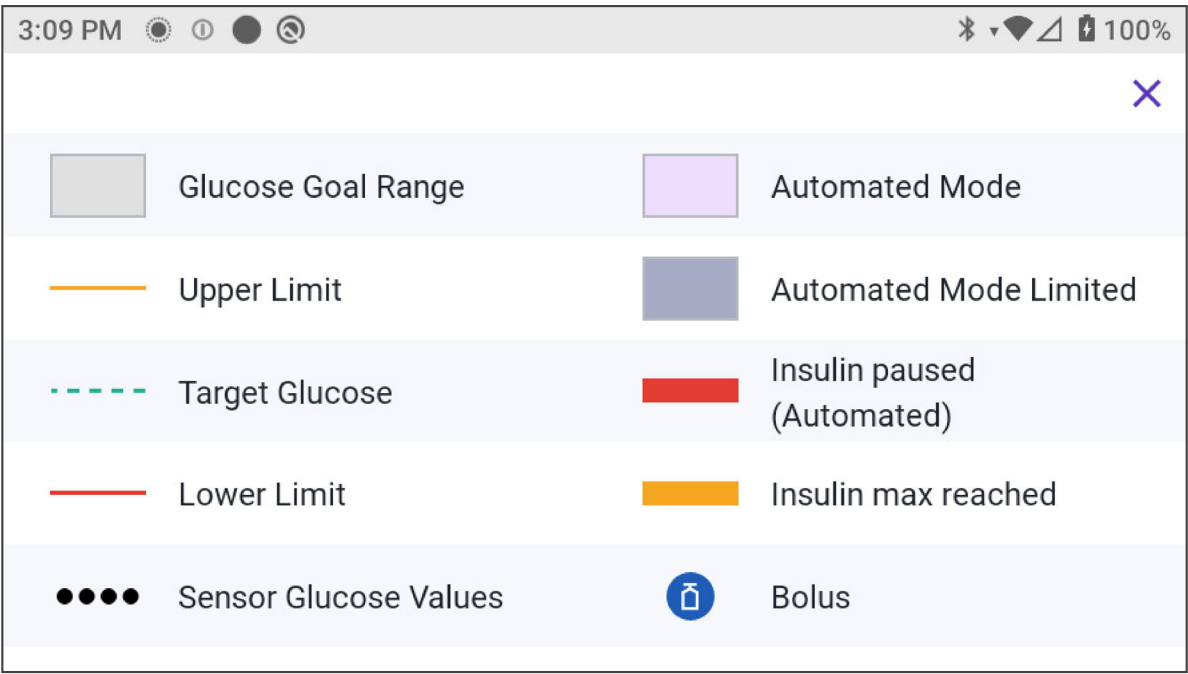
You can view the Sensor Graph from the Home Screen by tapping VIEW under the Sensor Graph icon in the lower right side of the Home screen.

When you tap **VIEW**, the Sensor Graph will display.



To display the Sensor Graph legend, tap the question mark icon in the lower right of the graph.

The Sensor Graph Legend will show:



The Sensor Graph Legend explains the colors and use of lines on the graph which show your sensor glucose values and insulin delivery over the past few hours.

21 About the Libre Plus Sensor

21.5 Libre Plus Sensor Communication and Problem Messages

Communication Messages

The following are the communication messages that show on the Dashboard of the Omnipod 5 App that are associated with the FreeStyle Libre sensors.

Communication Message	Description
CONNECTING SENSOR	Appears after you have applied and scanned a sensor and your device or Pod are connecting to the sensor.
WARMING UP SENSOR	Appears when the sensor is connected and warming up, so sensor glucose values are not available yet. No action is required within the Omnipod 5 App.
SENSOR CONNECTED	Sensor has recently completed warm-up and glucose values will be available in a few minutes.
SEARCHING FOR POD	Appears when Pod communication was not established within the most recent 5-minute update interval. Tap MORE INFORMATION for potential causes and recommended actions.

Communication Message	Description
SEARCHING FOR SENSOR	Appears when a sensor is being used with or without a Pod and the most recent sensor glucose value was not acquired within a 5-minute window. There may be no valid sensor glucose value available due to a communication issue between Pod and sensor, or it could be a temporary sensor issue that will resolve itself. Tap MORE INFORMATION for recommended action. Review Pod and sensor placement. Pod and sensor should be at least 1 inch apart and within line of sight.

21 About the Libre Plus Sensor

Problem Messages

The following is a summary of the sensor problem messages associated with the Libre Plus sensors that display on the Home screen Dashboard and indicate a problem and a need for action. These messages show with a red alarm icon and are in red text.

Problem Message	Description	Action to Take
Sensor Too Cold	Your sensor is too cold to provide a glucose value.	Move to a warmer location and try again in a few minutes.
Sensor Too Hot	Your sensor is too hot to provide a glucose value.	Move to a cooler location and try again in a few minutes.
Temporary Sensor Problem	Your sensor is temporarily unable to send sensor glucose values to the Pod or Omnipod 5 App.	Check again in 10 minutes.
Sensor Error	Sensor glucose value is unavailable. Occurs early in sensor wear when values might be less accurate.	Tap Need Help to see when to check back for sensor glucose values.
Sensor Ended	Your sensor has ended. Your Omnipod 5 Pod and App will receive no further information from this sensor.	Remove your current sensor, and add a new sensor. For detailed instructions, see "22.2 Connecting a Libre 2 Plus or Libre 3 Plus Sensor" on page 351.
No Sensor	No sensor is detected.	Add a new sensor. For detailed instructions, see "22.2 Connecting a Libre 2 Plus or Libre 3 Plus Sensor" on page 351.

Problem Message	Description	Action to Take
Replace Sensor	The System has detected a problem with your sensor that cannot be fixed. Your Omnipod 5 Pod and App will receive no further information from this sensor.	Remove your current sensor, and add a new sensor. For detailed instructions, see "22.2 Connecting a Libre 2 Plus or Libre 3 Plus Sensor" on page 351.
Failed to Connect	Your Pod and sensor were not able to connect.	Try connecting again. If the problem continues, reboot your Controller or smartphone, or replace the recently applied Pod or sensor. Keep your Pod and sensor close to each other on your body.

How to respond to Problem Messages

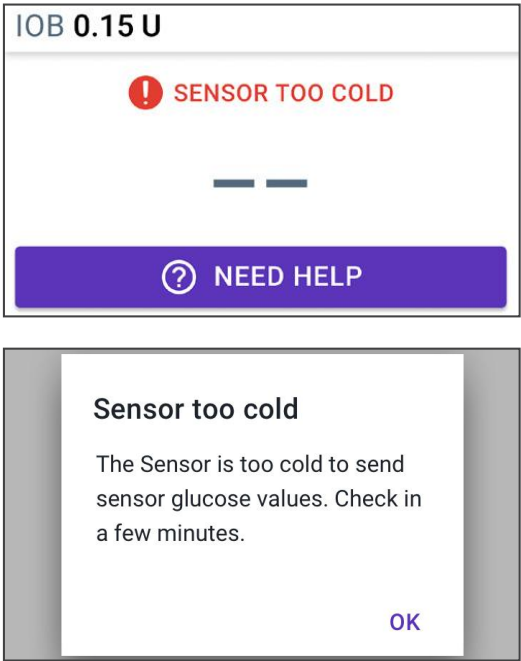
Respond to these problems as soon as possible.

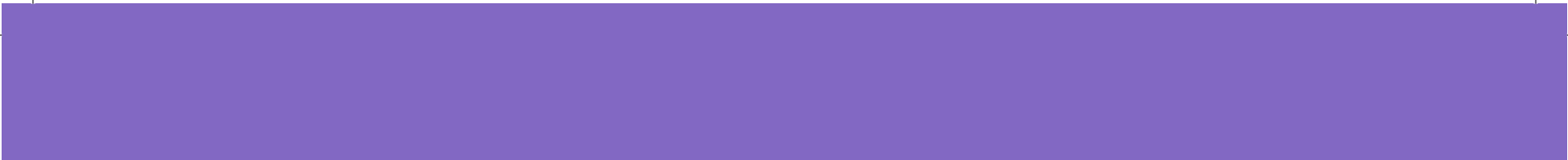
- 1. When a message displays, follow the on-screen instructions.

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.





This page intentionally left blank.

CHAPTER 22

Connecting a Libre Plus Sensor

Contents

22.1 About Connecting a Libre Plus Sensor to the Pod 350

22.2 Connecting a Libre 2 Plus or Libre 3 Plus Sensor . . . 351

 Apply and scan a Libre 2 Plus Sensor 351

 Apply and scan a Libre 3 Plus Sensor 354

 Using Sensor Glucose Values in the First 12 Hours 356

22.3 Edit Sensor Settings 357

22.4 Disconnect a Libre Plus Sensor 359

 Removing a Sensor 359

 Sensor Ending 359

 Disconnecting a Sensor 359

22.5 Switching to a Libre Plus Sensor from Another Sensor 361

 Automated: Limited State 363

22 Connecting a Libre Plus Sensor

22.1 About Connecting a Libre Plus Sensor to the Pod

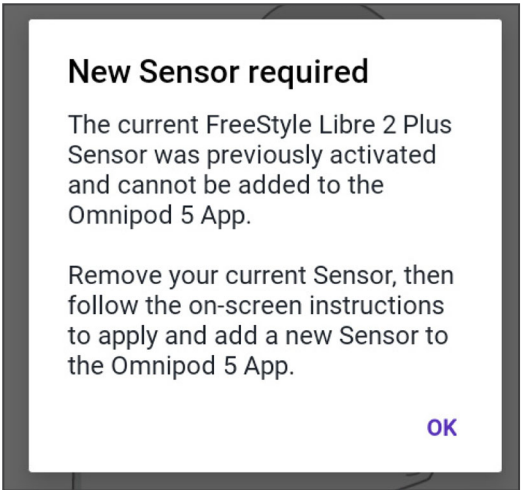
The Omnipod 5 System is designed to work with the FreeStyle Libre 2 Plus or FreeStyle Libre 3 Plus sensors. To use a Libre Plus sensor with the Omnipod 5 System, you will need to obtain a Libre 2 Plus or Libre 3 Plus sensor and the corresponding *Libre Plus Sensor Instructions for Use*.

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 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 sensor if you started the sensor using another device. You must start the sensor with the Omnipod 5 App.
- 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 sensor.
- Always confirm that you are using a Pod that is compatible with a Libre 2 Plus or Libre 3 Plus sensor. The Pod tray lid and Pod box will show compatibility with a Libre 2 Plus or Libre 3 Plus sensor.



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

22.2 Connecting a Libre 2 Plus or Libre 3 Plus Sensor

If you had previously connected a sensor and your sensor has expired, you must connect a new sensor to continue using sensor glucose values for Automated Mode or bolus calculations.

Note: Always confirm that the Pod you are wearing or activating is compatible with the Libre 2 Plus or Libre 3 Plus sensor. The Pod tray lid and Pod box will show compatibility with a Libre 2 Plus or Libre 3 Plus sensor.

To connect a Libre 2 Plus or Libre 3 Plus sensor:

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

Note: If you are starting the Omnipod 5 System for the first time, you will be prompted to apply and scan your sensor during first-time setup.

2. Tap **ADD SENSOR**.

If you are not in Manual Mode, you will be prompted to switch to Manual Mode.

Follow the on-screen instructions or the instructions in the next sections to apply, scan, and connect your sensor.

Apply and scan a Libre 2 Plus Sensor

1. Clean, disinfect, and dry the intended site.
 - a. Select a site on the back of your upper arm that stays flat during normal activity. See "21.2 Libre Plus Sensor Placement" on page 335 for more information.
 - b. Clean the skin with plain soap and water.
 - c. Use an alcohol wipe to disinfect the skin and let it air dry before proceeding.
 - d. Choose a site that is in line of sight to and at least 1 inch (2.5 cm) away from your Pod.

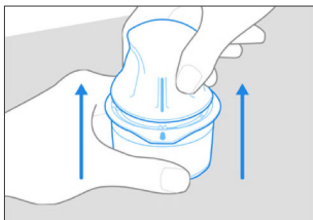
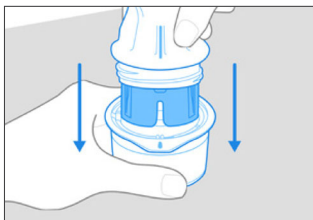
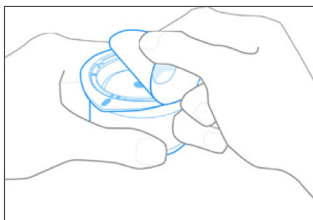


Note: Line of sight means that the Pod and sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.

22 Connecting a Libre Plus Sensor

Note: Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

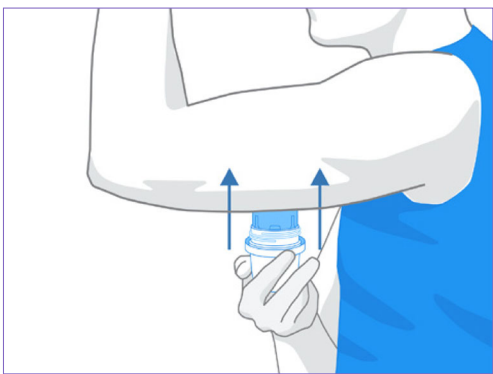
2. Prepare the applicator.
 - a. Open the sensor Pack by peeling back the lid.
 - b. Unscrew the cap from the bottom of the sensor applicator.
 - c. Line up the marks on the sensor applicator as you insert it into the Sensor Pack.
 - d. Press down firmly on the applicator on a hard surface until it comes to a stop. Then lift the applicator.



The sensor applicator is now ready to apply the sensor.

Caution: The sensor applicator contains a needle. Do not touch the inside of the sensor applicator or put it back into the Sensor Pack.

3. Apply the sensor.
 - a. Place the sensor applicator over the selected site on the back of your upper arm and press firmly to apply.
 - b. Gently pull the sensor applicator away from your body.
 - c. Make sure the sensor is secure by pressing down on the sensor and running your finger along the sensor adhesive.



Caution: Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.

4. Tap **CONTINUE** in the App.

Connecting a Libre Plus Sensor 22

5. Scan the Libre 2 Plus sensor by holding the bottom third of your Controller up to the sensor.

Hold the Controller near the sensor, and do not move it until the Controller vibrates to show that the scan is complete.

Note: It can scan through your clothes.

6. When you place the Controller up to the sensor, it will activate the scan.

When the scan successfully completes, a message shows that you will not need to scan again until you start a new sensor.

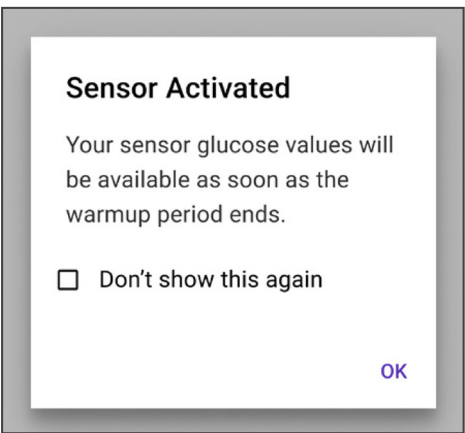
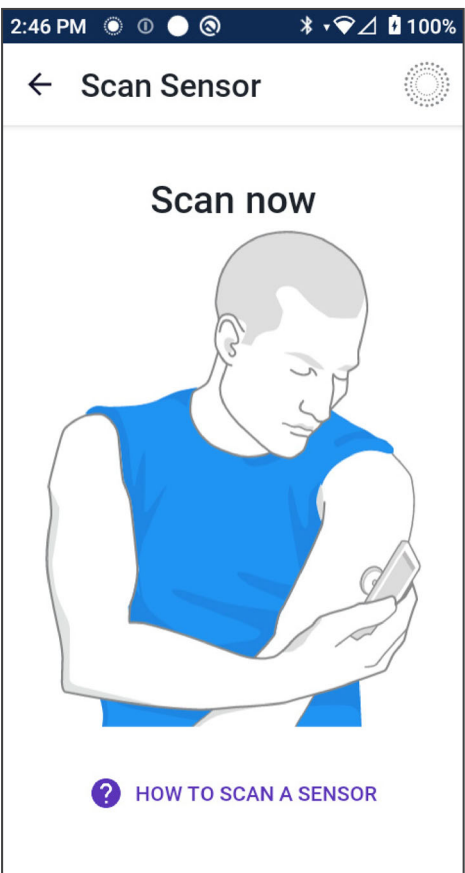
7. Tap **OK**.

Note: The Pod receives an updated sensor glucose value and trend every 5 minutes. You will not need to scan the sensor for a new value. If you do not have an active Pod, the Omnipod 5 App will update its displayed glucose value from the sensor.

8. The sensor will begin its 1-hour warm-up.

You can watch the progress of the warm-up on the Omnipod 5 App Home screen.

At the end of the warm-up period, your sensor glucose values are available to view in the app and for use in Automated Mode to adjust your insulin delivery.



22 Connecting a Libre Plus Sensor

Apply and scan a Libre 3 Plus Sensor

1. Clean, disinfect, and dry the intended site.

- Select a site on the back of your upper arm that stays flat during normal activity. See "21.2 Libre Plus Sensor Placement" on page 335 for more information.
- Clean the skin with plain soap and water.
- Use an alcohol wipe to disinfect the skin and let it air dry before proceeding.
- Choose a site that is in line of sight to and at least 1 inch (2.5 cm) away from your Pod.



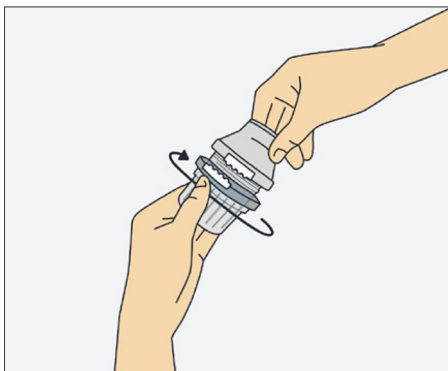
Note: Line of sight means that the Pod and sensor are worn on the same side of the body in a way that the two devices can "see" one another without your body blocking their communication.

Note: Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

2. Prepare the applicator:

- Remove the assembled applicator from the box.
- Unscrew the cap.

The sensor applicator is now ready to apply the sensor.



Caution: The sensor applicator contains a needle. Do not touch the inside of the sensor applicator or put it back into the Sensor Pack.

3. Apply the sensor.

- Place the sensor applicator over the selected site on the back of your upper arm and press firmly to apply.
- Gently pull the sensor applicator away from your body.
- Make sure the sensor is secure by pressing down on the sensor and running your finger along the sensor adhesive.



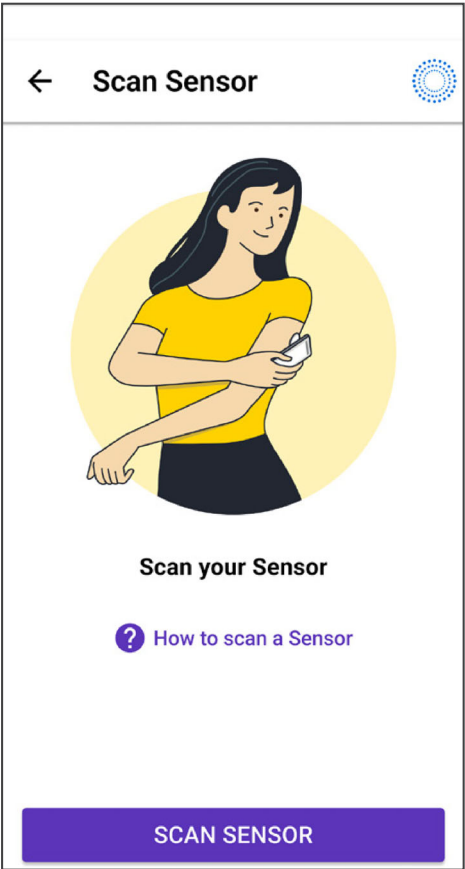
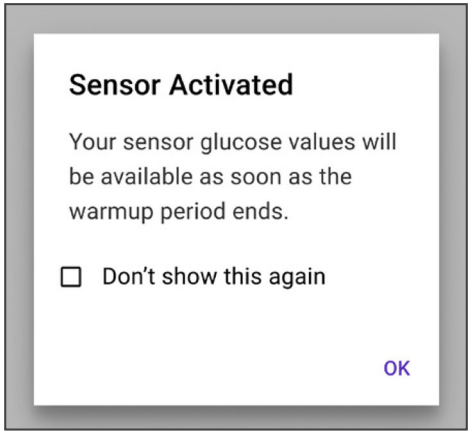
Connecting a Libre Plus Sensor 22

Caution: Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.

- 4. Tap **NEXT** in the App.
- 5. Tap **SCAN SENSOR**.
- 6. Hold the back of your Controller or smartphone near the sensor.

Do not move the device until it vibrates to show that the scan is complete.

A confirmation message also shows when the scan is successful.



- 7. Tap **OK**.

Note: The Pod receives an updated sensor glucose value and trend every 5 minutes. You will not need to scan the sensor for a new value. If you do not have an active Pod, the Omnipod 5 App will update its displayed glucose value from the sensor.

- 8. The sensor will begin its 1-hour warm-up.

You can watch the progress of the warm-up on the Omnipod 5 App Home screen.

At the end of the warm-up period, your sensor glucose values are available to view in the app and for use in Automated Mode to adjust your insulin delivery.

22 Connecting a Libre Plus Sensor

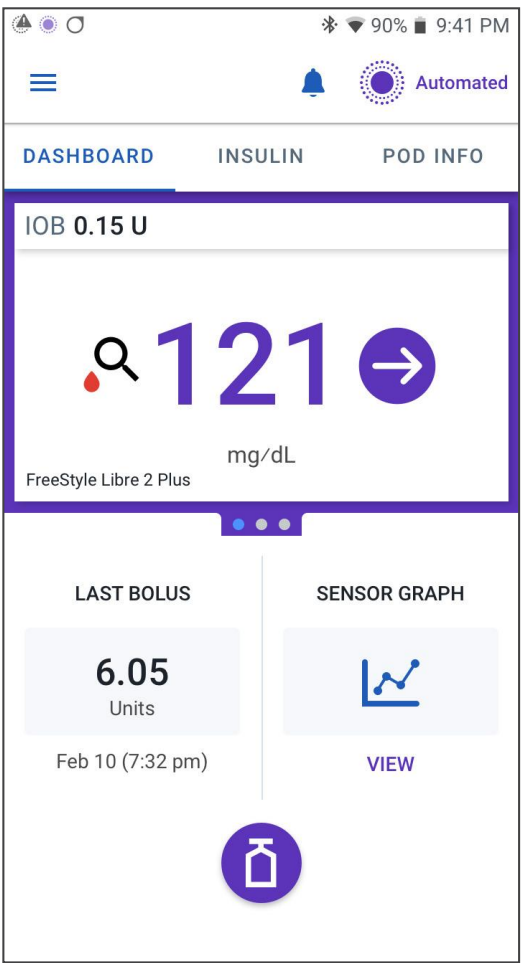
Using Sensor Glucose Values in the First 12 Hours

Caution: During the first 12 hours of use of a Libre 2 Plus or Libre 3 Plus sensor, use a fingerstick reading from a BG meter before making treatment decisions. After the first 12 hours, you can tap "Use Sensor" to use the value and trend in the SmartBolus Calculator.

Your sensor glucose values can be used by the Omnipod 5 System in Automated Mode to adjust your insulin as soon as the 1-hour warm-up is complete, but your sensor glucose values and trend cannot be used with the SmartBolus Calculator for the first 12 hours of sensor wear.

During the first 12 hours after connecting a sensor, you cannot tap **USE SENSOR** to import your sensor glucose value and trend into the SmartBolus Calculator.

You can manually enter a blood glucose reading from a meter during the first 12 hours of sensor use and whenever you see the Verify Sensor Values icon on the Home screen.



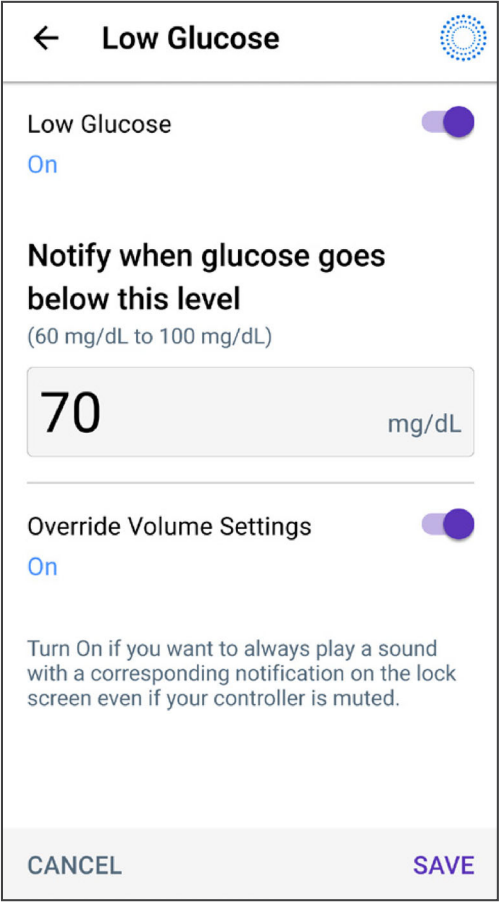
22.3 Edit Sensor Settings

There are 3 optional, adjustable sensor alarms to alert you to out-of-range glucose. For more information about each notification, see "21.4 Sensor Glucose Trends and Indicators" on page 342

During first-time setup, you reviewed these settings, but you can edit them at any time.

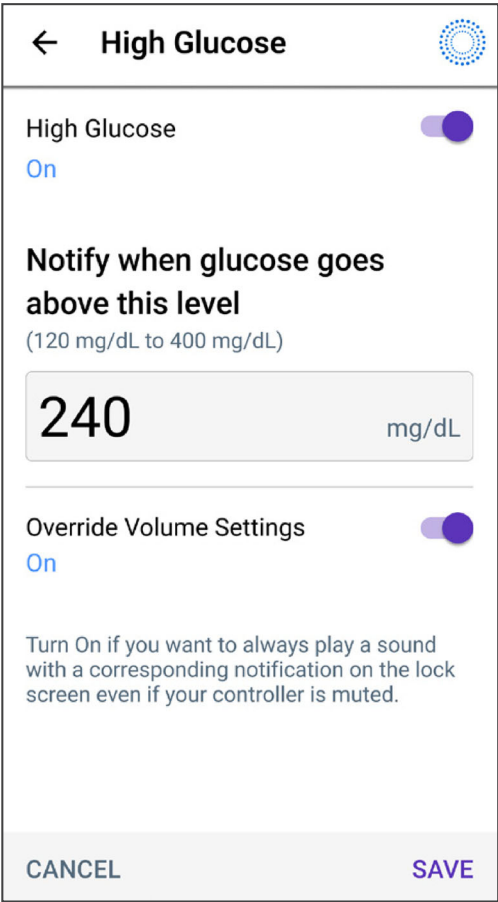
To edit these alarm settings:

- 1. From the Home screen, tap **Menu button** () > **Manage Sensor**.
- 2. Tap **SENSOR SETTINGS**.
- 3. Tap one of the alarms to update the settings:
 - Low Glucose
 - High Glucose
 - Missing Sensor Values
- 4. For Low Glucose:
 - a. The notifications are **On** by default. Tap the toggle to turn **Off**.
 - b. To change the Low Glucose Setting, tap the glucose field to access a scroll wheel.
 - c. Select a Low Glucose value, and then tap **DONE** to save your selection.
 - d. Select your alarm volume preferences.



22 Connecting a Libre Plus Sensor

- 5. For High Glucose:
 - a. The notifications are **On** by default. Tap the toggle to turn **Off**.
 - b. To change the Low Glucose Setting, tap the glucose field to access a scroll wheel.
 - c. Select a High Glucose value, and then tap **DONE** to save your selection.
 - d. Select your alarm volume preferences.



- 6. For Missing Sensor Values:
 - a. The notifications are **On** by default. Tap the toggle to turn **Off**.
 - b. Select your alarm volume preferences.
- 7. Tap **SAVE**.
Your sensor settings are saved.

22.4 Disconnect a Libre Plus Sensor

Removing a Sensor

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 *Libre 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 Libre Plus Sensor Communication and Problem Messages" on page 344.

Disconnecting a Sensor

To stop the Pod or App from communicating with the sensor, delete the sensor from the App. If you delete the sensor, you will no longer be able to enter Automated Mode until you add a new sensor.

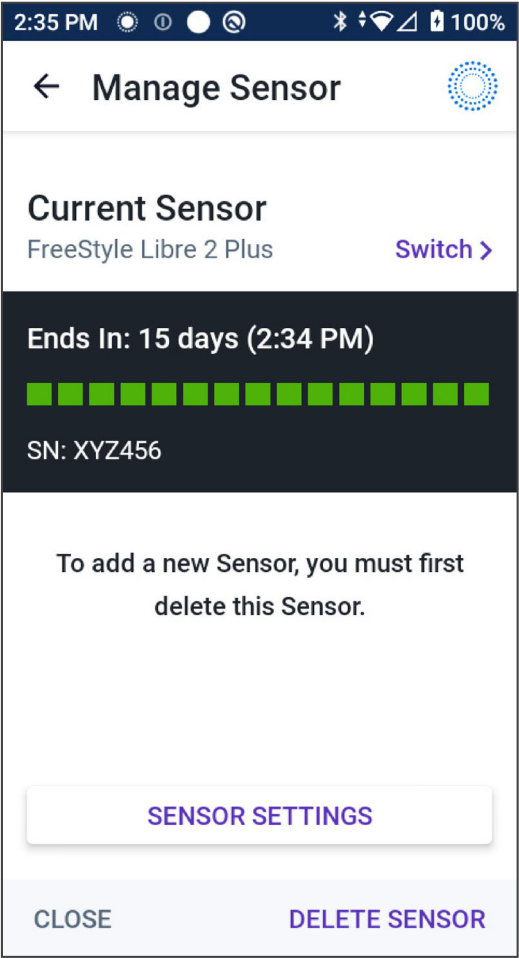
You do not need to delete a sensor that lasts the full wear duration.

To delete a sensor from the Omnipod 5 App:

- 1. From the Home screen, tap **Menu button** (≡) > **Manage Sensor**.
- 2. 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.



22 Connecting a Libre Plus Sensor

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

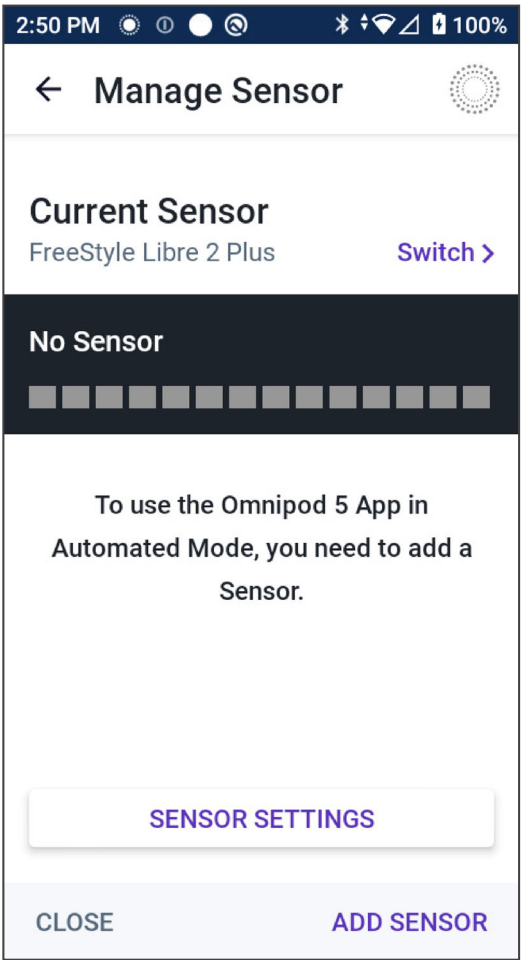
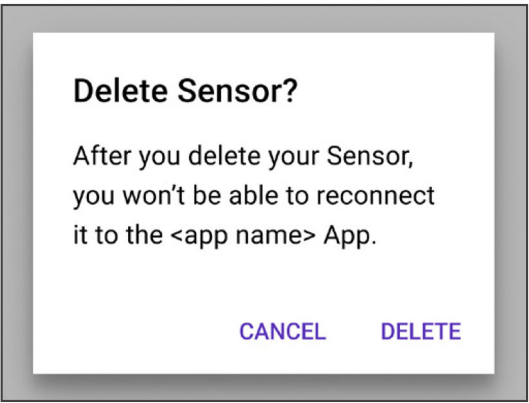
If you do not want to delete the sensor, tap **CANCEL**.

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, scan, and connect the Omnipod 5 System with the new sensor.



22.5 Switching to a Libre 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 Libre 2 Plus or Libre 3 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.

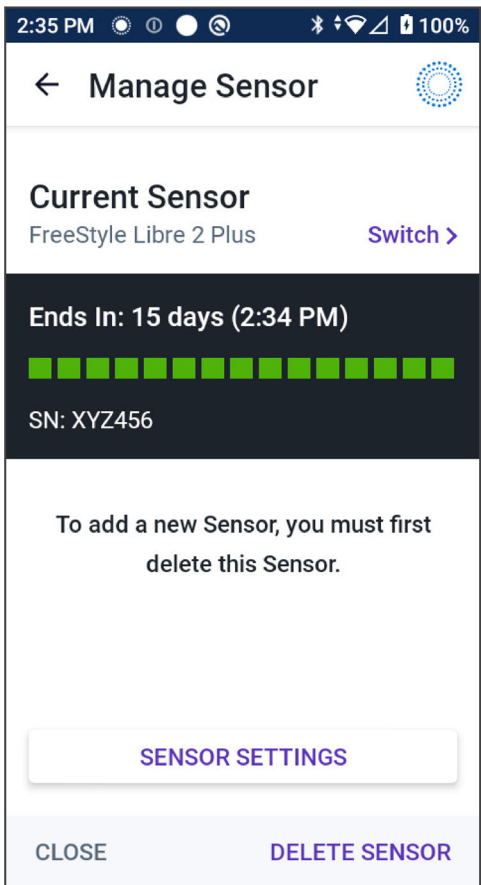
To switch to a Libre 2 Plus or Libre 3 Plus sensor from another sensor:

1. Navigate to **Menu button (≡) > Manage Sensor.**

The Omnipod 5 App shows your current sensor.

For example, you may have been using a Libre 2 Plus sensor and would like to switch to using a Libre 3 Plus sensor.

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



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

22 Connecting a Libre Plus Sensor

3. To switch to the Libre 3 Plus sensor with the Omnipod 5 system, select FreeStyle Libre 3 Plus.

 **Sensor Selection** 

Select your Sensor:

☐

Dexcom G6

☐

Dexcom G7

☐

FreeStyle Libre 2 Plus

☒

FreeStyle Libre 3 Plus

☐

No Sensor

CANCEL

SAVE

Tap **SAVE**.

4. Confirm that your Pod is compatible with the sensor you selected.

Tap **CONTINUE**.

5. 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 more information about the sensor settings, see "22.3 Edit Sensor Settings" on page 357.

The Omnipod 5 App will ask if you want to add a sensor now.

6. Tap **ADD** to add your sensor.

Note: Tap **NOT NOW** to add the sensor to the Omnipod 5 App later.

7. Follow the on-screen prompts to apply, scan, and connect the Omnipod 5 System with a new sensor.

Note: For more information about applying and scanning a sensor, see "22.2 Connecting a Libre 2 Plus or Libre 3 Plus Sensor" on page 351.

8. Follow the on-screen prompts to activate a new Pod and wait for the sensor warm-up to complete.

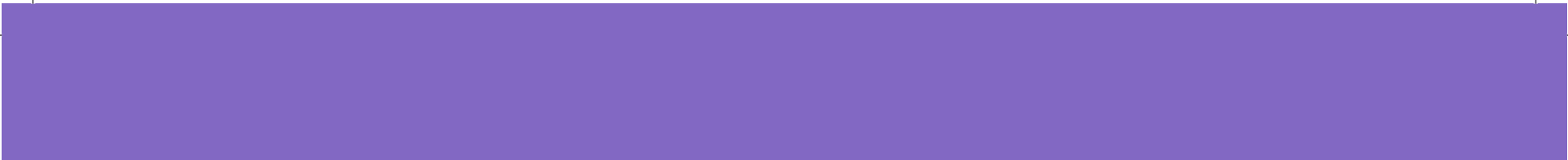
You will then be able to enter Automated Mode.

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.



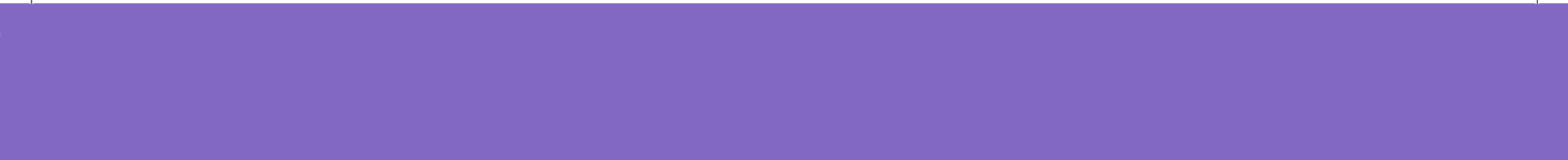
This page intentionally left blank.

AUTOMATED MODE

Automated Mode Important
Saftey Information

- 23 About Automated Mode
- 24 Switching Between Manual Mode
and Automated Mode
- 25 Activity Feature
- 26 Automated Mode Alarms
- 27 Omnipod 5 System Clinical Studies





This page intentionally left blank.

Automated Mode Important Safety Information

Automated Mode Warnings

Warning: The Omnipod 5 algorithm should NOT be used by anyone under the age of 2 years old. The Omnipod 5 algorithm 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 the Omnipod 5 algorithm in pregnant women, critically ill patients, and those on dialysis. The safety of the Omnipod 5 algorithm has not been evaluated in these populations. Consult with your healthcare provider if any of these conditions apply to you before using the Omnipod 5 algorithm.

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.

Important Safety Information

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

Warning: 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 Libre 2 Plus or Libre 3 Plus sensor if you are taking ascorbic acid (Vitamin C), a substance found in supplements like multivitamins 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 23

About Automated Mode

Contents

23.1 About Automated Mode 370

 How insulin is calculated and delivered during Automated Mode371

 Increasing Insulin Delivery371

 Decreasing and Pausing Insulin Delivery.....371

 Viewing Automated Insulin Delivery372

 Adjusting settings for Automated Insulin Delivery...372

23.2 About the Sensor in Automated Mode 374

23.3 Bolus Settings and Importance of a Bolus 375

23.4 Pod Adaptivity 376

 The First Pod376

 Ongoing Use377

23.5 About Automated Mode: Limited..... 377

23.6 Check blood glucose Advisory Alarm..... 379

 Low Glucose379

 High Glucose.....380

 Switch to Manual Mode for Automated Delivery Restriction Alarm380

23 About Automated Mode

23.1 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, the Omnipod 5 algorithm predicts where your glucose will be 60 minutes into the future. The algorithm technology uses this information, along with your current sensor glucose value and trend, to automatically adjust insulin delivery. Every 5 minutes, the System makes a decision about your insulin. It pauses or decreases insulin to protect against hypoglycemia or corrects for hyperglycemia. The System's goal is to help you bring your glucose to your defined Target Glucose.

The Omnipod 5 algorithm 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 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 rate changing with each new Pod to better match your true insulin needs.

Using this adaptive 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 autocorrects 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.

23 About Automated Mode

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 154.

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 166.

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 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, the Omnipod 5 algorithm 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 100 –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, the Omnipod 5 algorithm will deliver less automated insulin.

Note: The 100 mg/dL Target Glucose setting is available only when using a Pod with a software version of 12.0 or greater.

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 "Clinical Studies in Children, Adolescents, and Adults with Type 1 Diabetes" on page 400 for 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 the Omnipod 5 algorithm.

23.2 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, 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.

23 About Automated Mode

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 "23.5 About Automated Mode: Limited" on page 377.

If you experience frequent connectivity loss between the Pod and sensor, see "28.3 Sensor FAQs" on page 451.

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 (for Standard Dexcom G7 sensors) or display device (for Dexcom G7 15 Day sensors) and the pairing code and serial number from your Dexcom G7 applicator. When using a Dexcom G7 15 Day sensor, you can use either a Dexcom receiver or smartphone as a display device to use the Dexcom G7 app.
- If using a Libre 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.

23.3 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 251.

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.

23.4 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, the Omnipod 5 algorithm will automatically update your next Pod with information from your last few Pods about your recent total daily insulin (TDI).

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

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

23 About Automated Mode

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).The Omnipod 5 algorithm sets a starting baseline adaptive 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, the algorithm will start using your insulin delivery history instead of its original estimate to update the adaptive 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 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.

23.5 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, 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, the Omnipod 5 algorithm 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.

23 About Automated Mode

When the System enters Automated: Limited state, the Omnipod 5 algorithm bases its insulin delivery on the following:

- It looks at your basal rate in Manual Mode at this time of day and your adaptive rate for this Pod and chooses the lower of the two values every 5 minutes. In this way, the algorithm never gives more than the Basal Program that would be active during Manual Mode.
- If the Omnipod 5 algorithm 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 rate 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 you receive the Check blood glucose or Automated Delivery Restriction Advisory Alarms. For more information about these alarms, see "23.6 Check blood glucose Advisory Alarm" on page 378.

You may also choose to switch to Manual Mode to start your Basal Program. See page 382.

If you use Dexcom as your sensor, check your Dexcom display device. See your *Dexcom CGM System Instructions for Use*.

If you use Libre Plus as your sensor, check for notifications related to Libre 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 display device is still receiving sensor glucose values. Open your Dexcom display device to check.

23.6 Check blood glucose Advisory Alarm

Note: This alarm is called the Automated Delivery Restriction Advisory alarm if you are using a Pod with a software version older than 12.0.

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.

Low Glucose

If your glucose has been trending low, the Omnipod 5 algorithm may have paused insulin. A red bar will show on your Sensor Graph for "Insulin paused."

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.

You will see either the Check blood glucose or Automated Delivery Restriction alarm in the App, depending on your Pod software version. If you have a newer Pod, the Check blood glucose alarm will also switch the System to Automated: Limited state until you acknowledge the alarm.

This alarm 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, the Omnipod 5 algorithm may have delivered the highest amount of insulin microboluses allowed by the System.

You'll see an orange bar on your Sensor Graph for "Insulin max reached".

Note: This insulin max value is different than your Max Basal setting in Manual Mode. Adjusting your Max Basal setting in Manual Mode will not impact the amount that the algorithm 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.

23 About Automated Mode

You will see the Check blood glucose alarm in the App to 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.

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.

Switch to Manual Mode for Automated Delivery Restriction Alarm

For Pods with a software version older than 12.0, the System will ask you to switch to Manual Mode for 5 minutes or longer when the Automated Delivery Restriction alarm appears. 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 the **Menu button** () > **Switch Modes**.

CHAPTER 24

Switching Between Manual Mode and Automated Mode

Contents

24.1 Switching from Manual Mode to Automated Mode 382

 Before you begin382

 To switch to Automated Mode383

24.2 Switching from Automated Mode to Manual Mode..... 384

 Before you begin, do the following:.....384

 To switch to Manual Mode384

24 Switching Between Manual Mode and Automated Mode

24.1 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 97 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 127 or "16.4 Canceling a Bolus in Progress" on page 260.
- Start insulin, if it is paused. See "9.3 Starting Insulin Delivery" on page 141.

Switching Between Manual Mode and Automated Mode 24

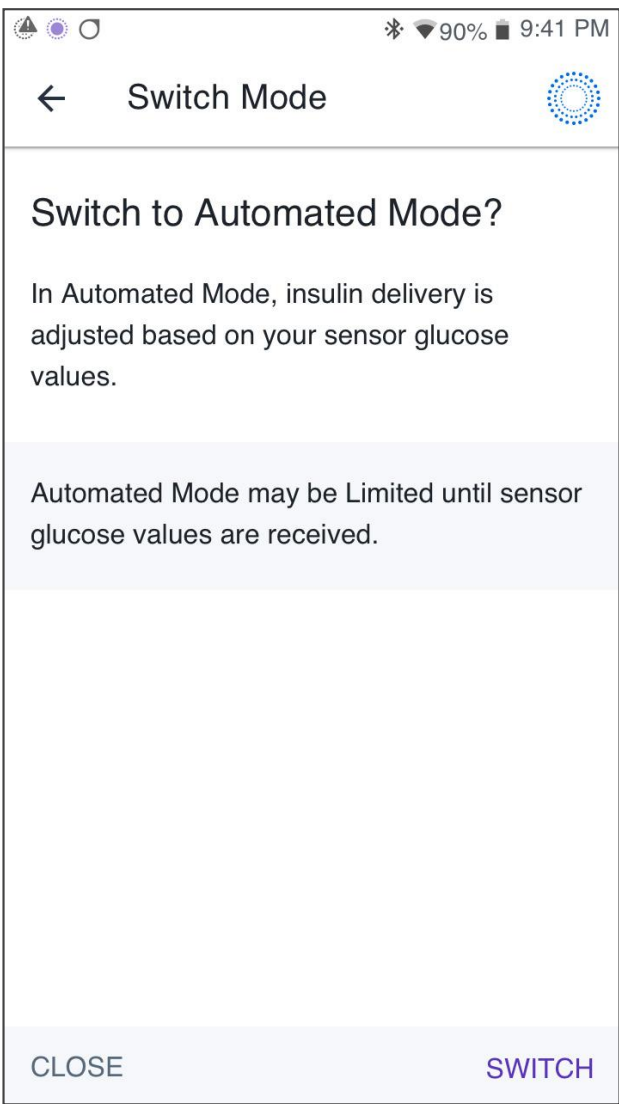
To switch to Automated Mode

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**.



24 Switching Between Manual Mode and Automated Mode

24.2 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 "25.3 Canceling the Activity Feature" on page 388

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 25

Activity Feature

Contents

25.1 About the Activity Feature386

25.2 Starting the Activity Feature 387

25.3 Canceling the Activity Feature 388

25 Activity Feature

25.1 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 setting.

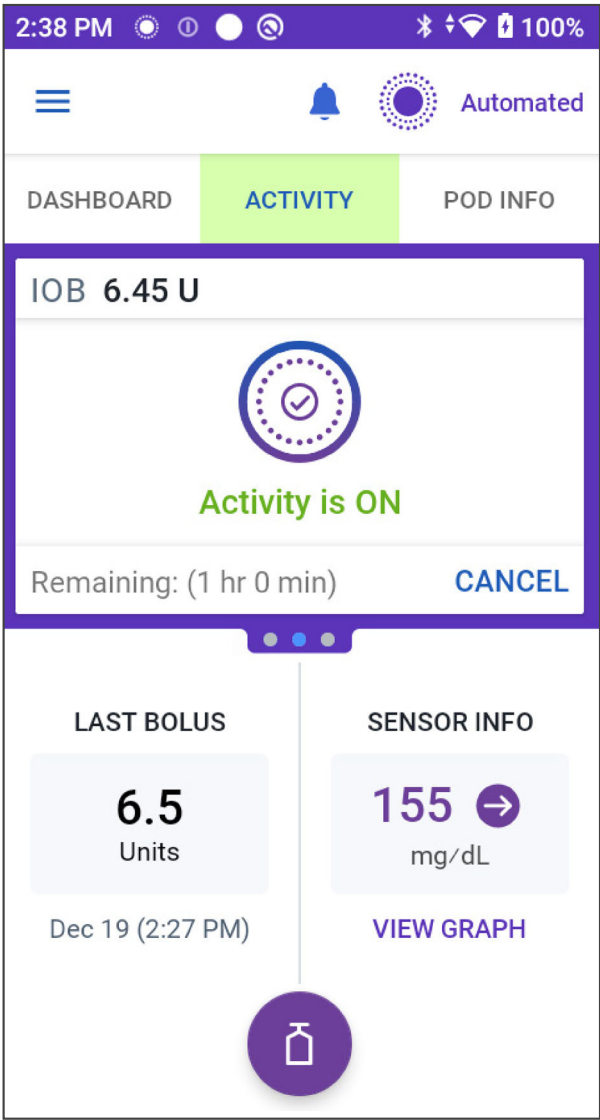
With Activity enabled, you can still deliver a bolus as you normally would.

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 the Omnipod 5 algorithm 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.

25.2 Starting the Activity Feature

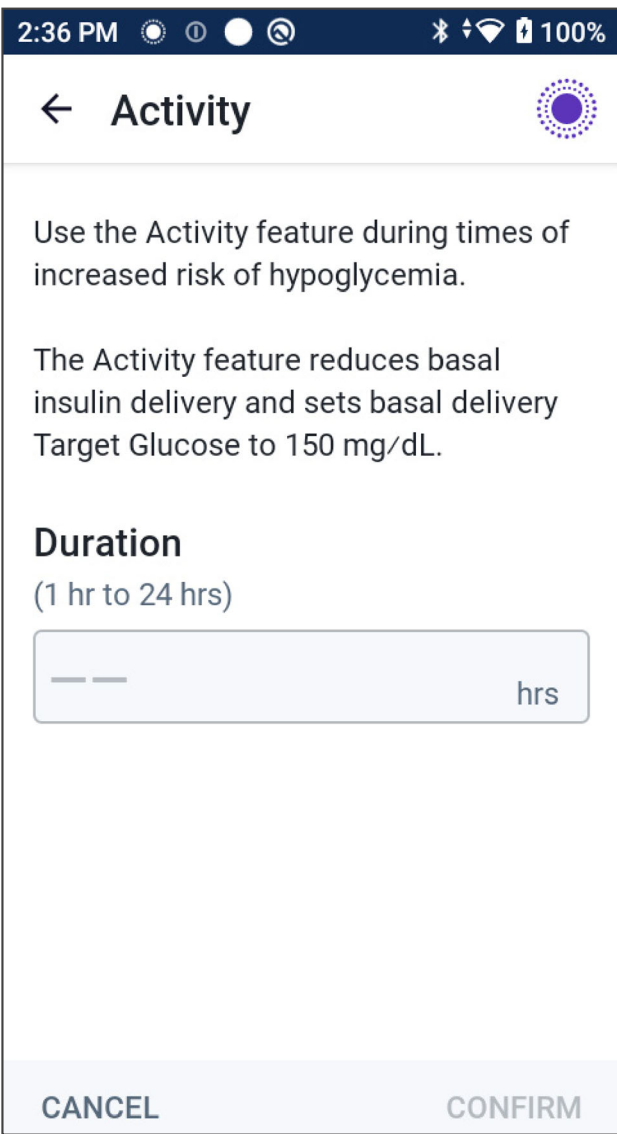
Before you begin, do the following:

- Switch to Automated Mode if currently using Manual Mode. See page 382.

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.



25 Activity Feature

25.3 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 26

Automated Mode Alarms

Contents

26.1	Advisory Alarm List.	390
	! Check blood glucose (low)	390
	! Check blood glucose (High)	391
26.2	Advisory Alarm List.	392
	! Missing Sensor Glucose Values	394

26 Automated Mode Alarms

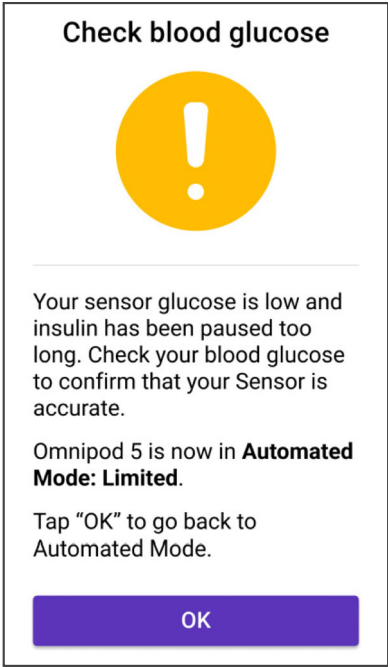
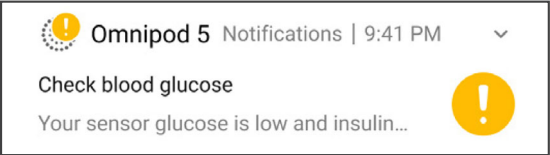
26.1 Advisory Alarm List

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

Check blood glucose (low)

Note: You will see this alarm only when using a Pod with a software version of 12.0 or greater. For Pods with an older software version, you will see the Automated Delivery Restriction alarm.

Occurs only in Automated Mode.

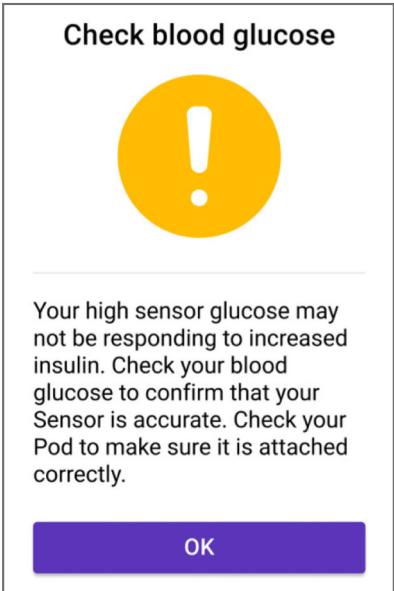
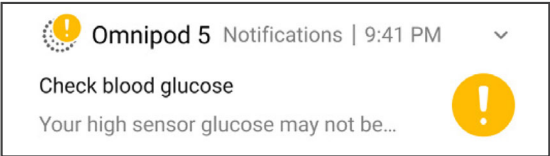
Screen Alert	Description
Omnipod 5 App Screen: 	Why it occurs: Insulin was paused for too long while the Omnipod 5 System was in Automated Mode. Pod sound: • 6 beep tone, repeats once every minute for. • Pattern repeats every 15 minutes. Controller/Smartphone sound and vibration: • 3 second tone • 3 second vibration • Vibration and tone repeat every 15 minutes until acknowledged.
Lock Screen: 	What to do: 1. Use a BG meter to confirm your blood glucose. - If low confirmed, consider treatment. - If your sensor glucose value is not what you expected, you may need to replace your sensor. 2. Tap OK after you confirm your blood glucose to go back to Automated Mode from Automated Mode: Limited state.

For more information about Automated Mode: Limited state, see "23.5 About Automated Mode: Limited" on page 377.

 Check blood glucose (High)

Note: You will see this alarm only when using a Pod with a software version of 12.0 or greater. For Pods with an older software version, you will see the Automated Delivery Restriction alarm.

Occurs only in Automated Mode.

Screen Alert	Description
Omnipod 5 App Screen: 	Why it occurs: Insulin was delivering at insulin max for too long while the Omnipod 5 System was in Automated Mode.
	Pod sound: • 6 beep tone, repeats once every minute for 3 minutes. • Pattern repeats every 15 minutes.
	Controller/Smartphone sound and vibration: • 3 second tone • 3 second vibration • Vibration and tone repeat every 15 minutes until acknowledged.
Lock Screen: 	1. Use a BG meter to confirm your blood glucose. - 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. - Check your Pod to make sure it is attached correctly. 2. Tap OK after you confirm your blood glucose.

26 Automated Mode Alarms

26.2 Advisory Alarm List

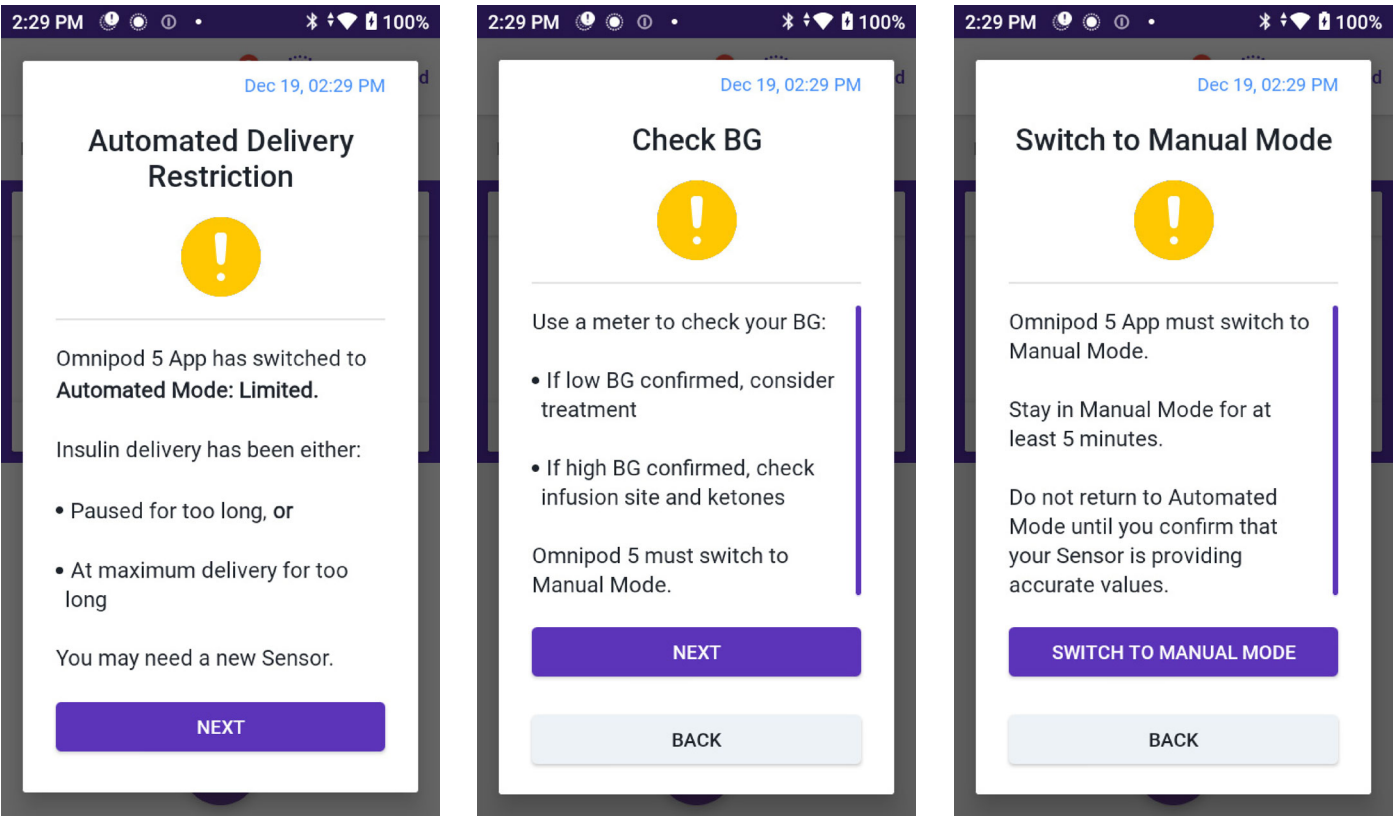
You will see this alarm only when using a Pod with an older software version. For Pods with a software version of 12.0 or greater, you will see the Check blood glucose alarms.

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

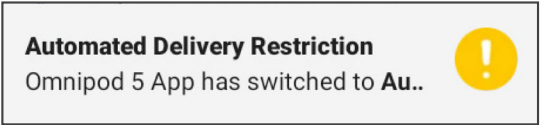
! Automated Delivery Restriction

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.

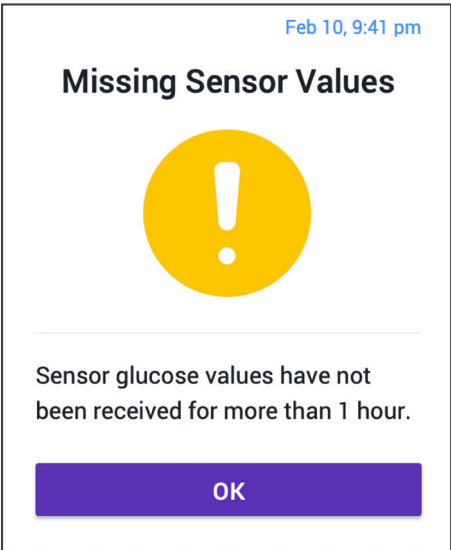
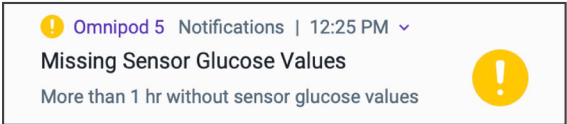
After at least 5 minutes of Manual Mode, you can return to Automated Mode after you have confirmed your sensor glucose values are accurate.

For more information about Automated Mode: Limited state, see "23.5 About Automated Mode: Limited" on page 377.

26 Automated Mode Alarms

! Missing Sensor Glucose Values

Only occurs in Automated Mode.

Screen Alert	Description
Omnipod 5 App: 	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.
	Pod sound: • 3 beep tone • Repeats every 60 minutes.
	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.
Lock Screen: 	What to do: ➤ Tap OK to acknowledge the alert.

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 display device 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 display device include sensor error/expiration, Transmitter error/expiration, sensor warm-up, or signal loss alert.

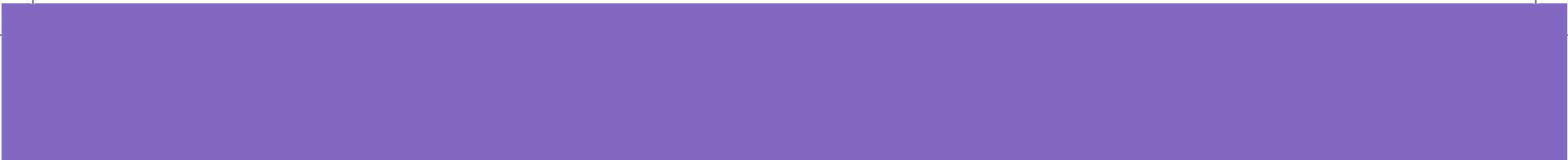
If the Dexcom display device is receiving sensor glucose values, there may be a temporary communication issue between your Pod and the Dexcom sensor. You may decide to switch to Manual Mode or wait for a sensor glucose values to be received while in Automated Mode: Limited state. If this is happening 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 Libre 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 Libre 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 Libre Plus sensor, refer to your *Libre Plus Sensor Instructions for Use*.



This page intentionally left blank.

CHAPTER 27

Evidence for Omnipod 5

Contents

27.1 Clinical Studies in Children, Adolescents, and Adults with Type 1 Diabetes400

 Omnipod 5 Pivotal Study in Children, Adolescents, and Adults (6–70 years).....400

 Demographics.....401

 Baseline Characteristics at Omnipod 5 Treatment Phase Start (n = 240)401

 Glycemic Results.....402

 Glycemic Results Overall (24 hours)403

 Glycemic Results Overnight (12:00AM to 6:00AM) ..404

 Change in A1C Analyzed by Baseline A1C405

 Subgroup Analysis of Change in Average A1C (%) by Baseline A1C (%)405

 Glycemic Results by Baseline Treatment406

 Subgroup Analysis of Average Glycemic Results by Baseline Treatment in Children (6 to 13.9 years) ...406

 Subgroup Analysis of Average Glycemic Results by Baseline Treatment in Adolescents and Adults (14 to 70 years).....407

 Insulin Requirements.....408

 Body Mass Index Results.....409

 Omnipod 5 System Use409

 Percent Time Spent in Automated Mode409

 Adverse Events410

 Adverse Events during the Omnipod 5 System Phase.....410

 Glycemic Results at Target Glucose Settings in Pivotal Study411

 Overall (24 hours) Glycemic Results at Target Glucose Settings in Children (6 to 13.9 years) from Pivotal Study411

 Overall (24 hours) Glycemic Results at Target Glucose Settings in Adolescents and Adults (14 to 70 years) from Pivotal Study412

 Omnipod 5 System Pre-Pivotal Glycemic Results at Target

27 Evidence for Omnipod 5

Glucose Settings412

 Glycemic Results at Target Glucose Settings in
 Pre-Pivotal Study412

 Overall (24 hours) Glycemic Results at Target Glucose
 Settings in Adolescents and Adults (14 to 70 years)
 from Pre-Pivotal Study.....414

CGM-Informed SmartBolus Calculator Clinical Study in
Children, Adolescents, and Adults415

 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).....415

**27.2 Clinical Studies in Very Young Children with
Type 1 Diabetes 416**

 Omnipod 5 Clinical Study in Very Young Children416

 Demographics417

 Baseline Characteristics at Omnipod 5 Treatment
 Phase Start417

 Glycemic Results418

 Glycemic Results Overall (24 hours)418

 Glycemic Results Overnight (12:00AM to 6:00AM) ..419

 Change in A1C Analyzed by Baseline A1C420

 Subgroup Analysis of Change in Average A1C (%) by
 Baseline A1C (%)420

 Glycemic Results by Baseline Treatment420

 Subgroup Analysis of Average Glycemic Results by
 Baseline Treatment420

 Insulin Requirements421

 Body Mass Index Results.....421

 Omnipod 5 System Use421

 Adverse Events422

 Adverse Events during the Omnipod 5
 System Phase422

 Glycemic Results at Target Glucose Settings.....423

 Overall (24 hours) Glycemic Results at Target
 Glucose Settings.....423

 CGM-Informed SmartBolus Calculator Clinical Study
 in Very Young Children.....424

27.3 Clinical Studies in Adults with Type 2 Diabetes. 426

 Omnipod 5 Pivotal Study in Adults with
 Type 2 Diabetes (18–75 years)426

Demographics.....427

Glycemic Results428

Glycemic Results Daytime vs Overnight430

Change in A1C Analyzed by Baseline A1C431

 Subgroup Analysis of Change in Average A1C (%) by
 Baseline A1C431

Subgroup Analysis of Average Glycemic Results
by Baseline Insulin Therapy432

Percent of Participants Meeting Recommended
Glucose Targets433

Quality of Life433

Insulin Requirements434

Omnipod 5 System Use435

Adverse Events435

 Glycemic Adverse Events during the Omnipod 5
 System Phase436

27.4 Virtual Performance Evaluation..... 436

 Glycemic Results:436

 Safety:437

27 Evidence for Omnipod 5

27.1 Clinical 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.

27 Evidence for Omnipod 5

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.

27 Evidence for Omnipod 5

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.

27 Evidence for Omnipod 5

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 Baseline Treatment 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.

27 Evidence for Omnipod 5

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%)

27 Evidence for Omnipod 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. 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

	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)
Characteristic					
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

27 Evidence for Omnipod 5

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.

27 Evidence for Omnipod 5

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

	110mg/dL	120mg/dL	130mg/dL	140mg/dL	150mg/dL
	Target Glucose	Target Glucose	Target Glucose	Target Glucose	Target Glucose
Characteristic	(n = 12)	(n = 7)	(n = 18) ^a	(n = 18)	(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.

27 Evidence for Omnipod 5

27.2 Clinical 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.

27 Evidence for Omnipod 5

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.

27 Evidence for Omnipod 5

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).