Automated insulin delivery

Automated insulin delivery changes as your CGM value and trend change. The table below describes how CGM trend affects your automated insulin delivery in Automated Mode:

	Automated insulin delivery depends on your baseline adaptive basal rate. This rate is based on your past insulin usage and adapts with each Pod change.
	The System works to keep CGM values at your specified Target Glucose (110-150 mg/dL).
	Your automated insulin deliveries increase when you are predicted to be above your Target Glucose.
	Your automated insulin deliveries decrease or pause if you are predicted to be below your Target Glucose.
	The System always pauses insulin delivery when CGM values are under 60 mg/dL.

The main information that informs Automated Mode insulin delivery is your past insulin history or average total daily insulin, together with your Target Glucose. If you are very insulin sensitive, the System knows to give you less insulin than if you have higher insulin needs. While you are using Automated Mode, the main adjustable setting affecting automated insulin delivery is Target Glucose.

Target Glucose is customizable from 110-150 mg/dL (10 mg/dL increments), and you can create up to 8 different time segments per day. As you increase the Target Glucose setting value, SmartAdjust technology will deliver less automated insulin. Changing your Target Glucose throughout the day 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).
- You would like to gradually bring your CGM values down to a lower Target Glucose (For example starting the system for the first time).

Consult with your healthcare provider before making any changes in your Target Glucose. See "Omnipod 5 Clinical Studies" on page 309 for clinical study information at each Target Glucose.

SmartBolus Calculator settings can also be adjusted including 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 automated insulin delivery during Automated Mode.

21.2. About the Dexcom G6 in Automated Mode

Warning: ALWAYS be aware of your current CGM 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 CGM values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low CGM 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 *User Guide*, contact your healthcare provider.

While in Automated Mode, the Omnipod 5 System relies on your CGM values to calculate appropriate automated insulin delivery. CGM values and trends may also be used by the SmartBolus Calculator.

It is important that your Dexcom G6 is functioning properly. To ensure CGM accuracy, be aware of your CGM values. If you are experiencing symptoms that do not align with your CGM values, use a separate BG meter. Refer to your *Dexcom G6 CGM System User Guide* for details on inaccurate CGM values.

21.3. 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 "Section 3: SmartBolus Calculator" on page 225.

When delivering a bolus, it is recommended to:

- Tap USE CGM to use your CGM value in the SmartBolus Calculator. This will ensure that your CGM 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.

21.4. Pod Adaptivity

In Automated Mode, automated insulin delivery adapts to your current needs as you wear the System. As you use the Omnipod 5 System and gather delivery history, SmartAdjust technology will automatically update your next Pod with your current insulin needs.

During your first Pod wear (or if you've taken a long break between Pods), since no recent history is available, the Omnipod 5 System uses only your active Basal Program (from Manual Mode) as a starting point to adjust your insulin. After 48 hours of history is collected, which usually happens with the first Pod wear, SmartAdjust technology stops adjusting insulin against your active Basal Program and starts using the Adaptive Basal Rate for your automated insulin delivery with your next Pod change.

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

21.5. About Automated Mode: Limited

Warning: ALWAYS be aware of your current CGM 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 CGM values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low CGM 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 *User Guide*, contact your healthcare provider.

At times, your Pod and CGM may lose communication while you are in Automated Mode. There are several reasons this could happen, including the Pod and CGM not being within line of sight on your body, temporary loss of communication due to environmental interference, sensor warm-up, or required calibration. When this occurs, SmartAdjust technology can no longer fully adjust your automated insulin delivery because the Pod is not receiving updated glucose information from the CGM. After 20 minutes of the Pod not receiving CGM values, the Omnipod 5 App displays 'Limited' on the Home screen.

The System also enters Limited state after receiving the Automated Delivery Restriction Advisory alarm. For more information , see "  Automated Delivery Restriction" on page 306.

When the System enters Limited state, SmartAdjust technology never gives more than the Basal Program that would be active during Manual Mode. After an hour of missed CGM values, the Missing CGM Values advisory alarm is presented and you receive a steady rate of insulin that will not vary until CGM connection is restored.

You may also choose to switch to Manual Mode to start your Basal Program. See "22.2. Switching from Automated Mode to Manual Mode" on page 300.

Check your Dexcom G6 app to see if there are any CGM actions you need to take to re-establish communication. See your *Dexcom G6 CGM System User Guide*.

Note: Automated Mode: Limited state can occur due to a loss of communication between the CGM and Pod. It is possible that your Dexcom G6 app is still receiving CGM values. Open your Dexcom G6 app to check.

CHAPTER 22

Switching Between Manual Mode and Automated Mode

Contents

22.1. Switching from Manual Mode to Automated Mode

Warning: ALWAYS be aware of your current CGM 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 CGM values do not match your symptoms, ALWAYS check your blood glucose using a BG meter, consider treatment and/or CGM sensor calibration if necessary. ALWAYS switch to Manual Mode if you feel you are receiving inaccurate CGM values.

- Erroneously high CGM values can cause excessive insulin delivery, leading to severe hypoglycemia, seizure, loss of consciousness or death.
- Erroneously low CGM 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 *User Guide*, contact your healthcare provider.

Before you begin

First, make sure you have an active Pod and connected CGM. See "Activating and Changing Your Pod" on page 79 and "Connecting CGM to the Pod" on page 281.

Do the following, if necessary:

- Cancel your temp basal or extended bolus, if either is running. See "7.3. Canceling a Temp Basal or Temp Basal Preset" on page 107 or "16.4. Canceling a Bolus in Progress" on page 235.
- Start insulin, if it is paused. See "9.3. Starting Insulin Delivery" on page 122.

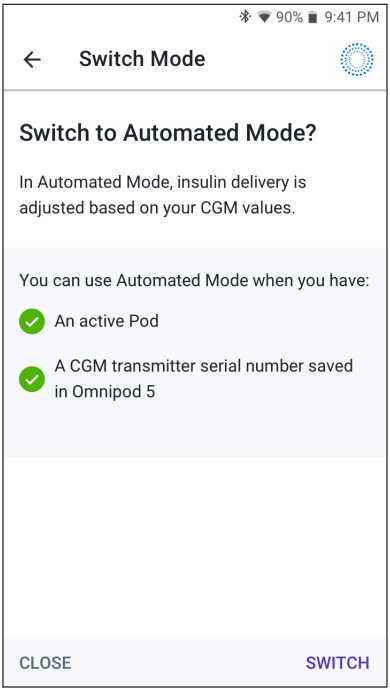
To switch to Automated Mode

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.



22.2. 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 the CGM System 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:

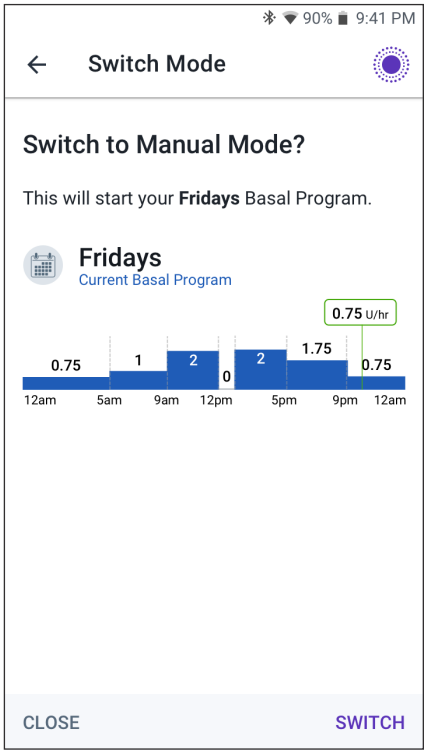
- Cancel the Activity feature, if it is enabled. See "23.3. Canceling the Activity Feature" on page 303.

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 23

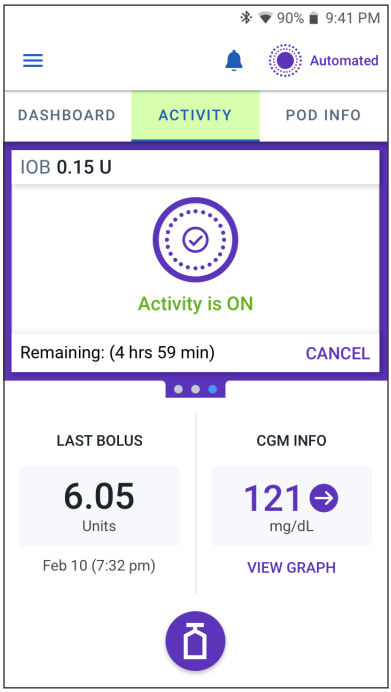
Activity Feature

Contents

23.1. About the Activity Feature

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

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



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

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

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

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

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

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

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

23.2. Starting the Activity Feature

Before you begin, do the following:

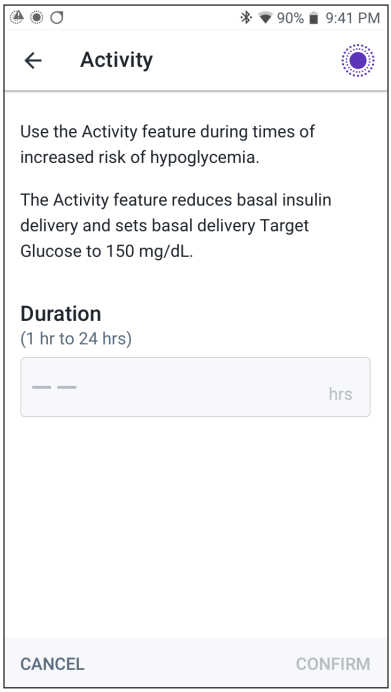
➢ Switch to Automated Mode if currently using Manual Mode. See "22.1. Switching from Manual Mode to Automated Mode" on page 298.

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.



23.3. 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.

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CHAPTER 24

Automated Mode Alarms

Contents

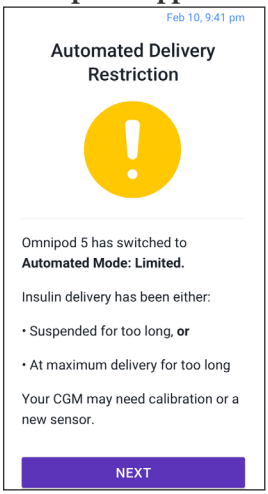
24.1. Advisory Alarm List

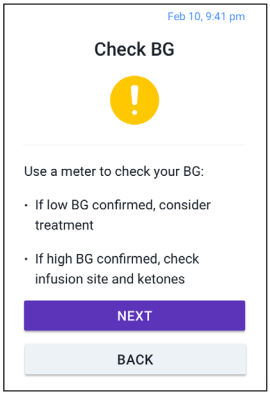
Advisory alarms inform you of a situation that needs your attention in the near future.

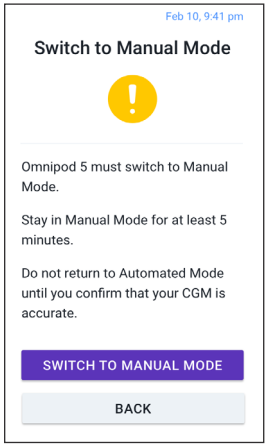
Automated Delivery Restriction

Only occurs in Automated Mode.

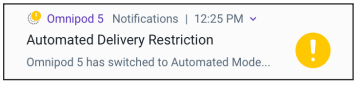
Omnipod 5 App Screens:







Lock Screen:



Cause	Insulin was either paused for too long or at maximum delivery for too long while the Omnipod 5 System was in Automated Mode.
Tone (Pod)	• 6 beep tone, repeats once every minute for 3 minutes • Pattern repeats every 15 minutes
Vibration/Tone (Controller or smartphone)	• 3 second tone • 3 second vibration • Vibration and tone repeat every 15 minutes until acknowledged

What to do	1. Tap NEXT to see the next screen. 2. Use a BG meter to confirm your blood glucose. • If low confirmed, consider treatment. • If high confirmed, check infusion (Pod) site and ketones. • If your CGM value is not what you expected, you may need to calibrate or replace your Dexcom G6 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.

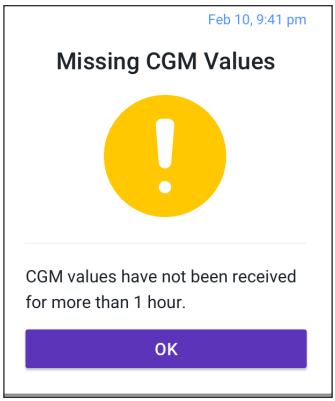
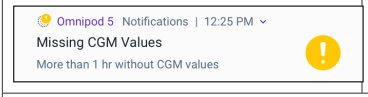
While in Manual Mode, you can check your CGM graph to find out whether your insulin has been paused or has been at a maximum for a long time.

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

For more information about Automated Mode: Limited state, see "21.5. About Automated Mode: Limited" on page 295.

Missing CGM Values

Only occurs in Automated Mode.

Screen Alert	Description
Omnipod 5 App: 	**Why it occurs:** The Pod has not received CGM values for more than one hour. The system will continue to operate in Automated Mode: Limited state until CGM 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 CGM 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 295.

Check your Dexcom G6 app to see if there are CGM values present or if the cause of the loss of communication is related to the sensor/transmitter. Examples to look for within the Dexcom G6 app include sensor error/expiration, transmitter error/expiration, sensor warm-up, or signal loss alert.

If the Dexcom G6 app is receiving CGM values, there may be a temporary communication issue between your Pod and the Dexcom G6. You may decide to switch to Manual Mode or wait for a CGM value to be received while in Automated Mode: Limited state. If this is frequently occurring, check to see if the Pod and CGM are located on your body at least 3 inches (7.62 cm) apart and within line of sight. If not, when you remove one, position the new one so that your Pod and CGM are within line of sight to one another.

Note: For information about your Dexcom G6 app, refer to your *Dexcom G6 CGM System User Guide*.

CHAPTER 25

Omnipod 5 Clinical Studies

The goal of the pivotal study of the Omnipod 5 System was to assess the safety and efficacy 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. 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 subjects 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 subjects were required to have a A1C < 10.0% at screening. Subjects < 18 years had to be living with a parent or legal guardian. No subjects 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 subjects > 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 subjects 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 subjects (% of subjects).

[§] 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 subjects. Groups are not mutually exclusive .

Glycemic Results

The tables below include information on the primary and secondary glycemic results from the standard therapy phase compared to the 3-month Omnipod 5 System treatment phase. The primary results of the study included change in average A1C% and % time in range (70-180mg/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 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 70-180mg/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 % <54mg/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 % <70mg/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 % >180mg/dL (std dev)	45.3% (16.7%)	30.2% (8.7%)	-15.1%*	32.4% (17.3%)	24.7% (11.2%)	-7.7%*
Avg % ≥250mg/dL (std dev)	19.1% (13.1%)	9.6% (5.4%)	-9.4%*	10.1% (10.5%)	5.8% (5.5%)	-4.3%*
Avg % ≥300mg/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 < 70mg/dL and < 54mg/dL is reported as medians with interquartile ranges in brackets(Q1,Q3). The median is the middle number in an ascending list of numbers and the interquartile range represents the middle 50% of values.

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

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

Characteristic	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70 years) (n=128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg % time 70-180mg/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 % <54mg/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 % <70mg/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 % >180mg/dL (std dev)	42.2% (20.0%)	20.7% (10.8%)	-21.5%*	32.1% (20.2%)	20.7% (14.1%)	-11.3%*
Avg % ≥250mg/dL (std dev)	16.3% (15.0%)	5.4% (5.1%)	-10.9%*	10.6% (12.7%)	4.8% (7.0%)	-5.7%*
Avg % ≥300mg/dL (std dev)	6.7% (9.1%)	1.8 (2.5%)	-4.8%*	4.2% (8.0%)	1.5% (3.1%)	-2.7%*

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

Change in A1C Analyzed by Baseline A1C

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

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

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

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

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

Glycemic Results by Baseline Treatment

The table below provides information on the average glycemic results at baseline (or during standard therapy phase) and the 3-month Omnipod 5 System treatment phase analyzed by baseline treatment (standard therapy). Standard therapy consisted of multiple daily insulin injections (MDI) or insulin pump use. Time in range (70-180 mg/dL) and A1C were improved after 3 months of Omnipod 5 System use regardless of baseline treatment type. After 3 months of Omnipod 5 System use, time <70mg/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 70-180mg/dL	52%	69%*	53%	68%*
% Time <70mg/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 <70mg/dL are medians, the remaining values in the table are averages .

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

Characteristic	MDI (n=20)		Insulin Pump (n=105)	
	Standard Therapy	Omnipod 5	Standard Therapy	Omnipod 5
% Time in range 70-180mg/dL	60%	72%*	66%	74%*
% Time <70mg/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 70mg/dL are medians, the remaining values in the table are averages.

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

Insulin Requirements

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

Characteristic	Children (6 to 13.9 years) (n=112)			Adolescents & Adults (14 to 70 years) (n=128)		
	Standard Therapy	Omnipod 5	Change	Standard Therapy	Omnipod 5	Change
Avg total daily insulin, U/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/m^2 (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 subjects used the Omnipod 5 System in Automated Mode.

Percent Time Spent in Automated Mode

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

Adverse Events

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

Adverse Events during the Omnipod 5 System Phase

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

Results reported as number oif 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 ≥300mg/dL and ketones >1.0mmol/L*

Glycemic Results at Target Glucose Settings in Pivotal Study

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

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

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

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

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

**Results for the 140 mg/dL and 150 mg/dL (with the Activity feature OFF) Target Glucose settings in adults are not shown due to too few subjects 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. 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	110mg/dL Target Glucose (n=11)	120mg/dL Target Glucose (n=3)	130mg/dL Target Glucose (n=18)[a]	140mg/dL Target Glucose (n=18)	150mg/dL Target Glucose (n=18)[b]
Avg % time 70-180 mg/dL (std dev)	**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 subjects 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 subjects felt their insulin needs were reduced.*

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

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

[a] *All subjects 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 subjects felt their insulin needs were reduced.*

CGM-Informed SmartBolus Calculator Clinical Study

A study was conducted on 25 participants with type 1 diabetes aged 6-70 years to assess the Omnipod 5 CGM-informed SmartBolus Calculator. During Phase 1, participants used the Omnipod 5 system in Manual Mode for the first 7 days without a connected CGM (standard SmartBolus Calculator). In Phase 2, participants used the Omnipod 5 system in Manual Mode with a connected CGM (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 CGM 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 CGM 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 CGM between the two study phases. The results indicate that the use of the CGM-informed SmartBolus Calculator was associated with less time in hypoglycemia within 4 hours of bolusing.

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 CGM	Standard Smart-Bolus Calculator	CGM-Informed SmartBolus Calcu-lator	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.

ADDITIONAL INFORMATION

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CHAPTER 26

Frequently Asked Questions and Troubleshooting

Contents

26.1. Omnipod 5 Pump FAQs

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

Pod Issues

Issue	Possible Cause	What you can do
During Pod activation, did not hear the 2 beep confirmation after filling the Pod with insulin	Pod not filled with at least 85 units of insulin.	Make sure the Pod is filled with at least 85 units of insulin. If you have filled the Pod with at least 85 units and you still do not hear 2 beeps, you will need to discard the Pod and start a new one.
The adhesive around the Pod keeps lifting from the skin	It is important that the Pod stays on the body to ensure that the cannula stays under the skin to deliver insulin. If the area where you apply the Pod is not cleaned and dry, the adhesive may not stick well.	Make sure that the skin is cleaned and dry before applying the Pod. Avoid the use of moisturizers, oils, conditioners, sunscreen, or insect repellent around the site. If there is a lot of body hair, you may need to clip or shave the area 24 hours prior to Pod change. Be sure to remove old adhesive residue from the skin. Insulet has produced a special tape called PodPals™ that can help keep the Pod on for longer.
Pod alarm sounding	Because the delivery of insulin is so critical to your health, it is important to know if the Pod stops working. The Pod may stop working for many reasons, for example, a blockage (occlusion) is detected, electrostatic discharge affects the circuit, or some interference is detected.	This continuous loud noise is intended to alert you to remove the Pod and replace it with a new one. You can try to deactivate the Pod with your Omnipod 5 App. Occasionally, the App will not be able to communicate with the Pod and you will have to discard the Pod. In this case, you will need to remove the Pod and disable the alarm switch. See page 197 for guidance.

Finding Out How Much Insulin Was Delivered

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

Controller Issues

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

Omnipod 5 App Issues

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

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

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

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

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

Issue	Possible Cause	What you can do
Opening the Omnipod 5 App restarts the setup process	You cleared App data for the Omnipod 5 App. This causes you to lose all your settings and insulin history.	If you clear data for the Omnipod 5 App, your current Pod will still be delivering insulin, but you won't be able to manage it with your Omnipod 5 App. 1. Remove the current Pod in order to stop receiving insulin. 2. After removing the current Pod, you will need to go through the setup process again, including pairing a new Pod and re-entering your CGM transmitter serial number. **Tip:** You can get your CGM transmitter serial number from the Dexcom G6 app. If you do not have a record of your settings, contact your healthcare provider for assistance. **Note:** It may take the CGM and Pod up to 20 minutes to connect.

26.2. SmartBolus Calculator FAQs

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

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

26.3. CGM FAQs

Issue	Possible Cause	What you can do
Activated a Pod and cannot see CGM values in the Omnipod 5 App	Problem with the CGM.	Check your Dexcom G6 app and if you do not see CGM values, then follow instructions there.
	CGM transmitter serial number is not entered into the Omnipod 5 App.	1. Go to: Menu button (☰) > Settings > CGM Transmitter. 2. Make sure the serial number is entered and entered correctly. If you have just connected, it can take up to 20 minutes for values to appear in the Omnipod 5 App.
	You are using the Dexcom G6 receiver.	1. Use the Dexcom G6 app on your smartphone. The Omnipod 5 System is not compatible with the Dexcom G6 receiver. 2. Then, turn off the Dexcom G6 receiver.

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

High Glucose Issues

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

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

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

Low Glucose Issues

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

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

26.4. Automated Mode FAQs

Issue	Possible Cause	What you can do
Activated a Pod and unable to switch to Automated Mode	Your CGM transmitter serial number is not entered into the Omnipod 5 App.	Go to: Menu button (☰) > Settings > CGM Transmitter. **Tip:** Always check that the serial number entered into the App is the same as the number on the transmitter you are wearing.

Screen shows Automated Mode: Limited	Interruption in communication between the CGM and the Pod.	To minimize the risk of interruption, make sure your Pod and CGM are worn on the same side of the body. Wireless communications do not travel well through the body. For example, if your sensor is worn on the abdomen and the Pod is on the back of the arm, the signal may be interrupted.
	Problem with the CGM	Check your Dexcom G6 app and if you don't see CGM values, then follow instructions there.
	Automated Mode may have reached the limits of insulin delivery, either the maximum or the minimum.	Follow the instructions on the screen to check your glucose. After 5 minutes in Manual Mode and you are confident that your Pod and CGM are working well, you can switch back to Automated Mode. See page 298.

26.5. Pod Communication Issues – "Try Again"

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

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

If a Pod communication issue occurs, you will see a "No Pod communication" message on the POD INFO tab. Follow the on-screen instructions to resolve the issue. Your Controller will also beep every 10 seconds when there is an unacknowledged communication issue due to an instruction being unable to be sent to the Pod.

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

Error when sending insulin instructions to the Pod

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

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

- CHECK STATUS: Move to a new location, then select this option to recheck for confirmation that the instruction was carried out.
- DEACTIVATE POD: This should not be your first choice. When you select this option, you can follow the instructions for replacing your Pod.

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

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

Error when canceling a bolus

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

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

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

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

- CHECK STATUS: Select this option to attempt to re-establish communication with the Pod and obtain the current status of the 'cancel bolus' command

- DEACTIVATE POD: This should not be your first choice. Select this option to deactivate the Pod when CHECK STATUS is unsuccessful.

Error when activating a Pod

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

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

Error when deactivating a Pod

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

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

Note: After selecting the discard option, you can prevent future alarms from the discarded Pod by following the instructions in "13.9. Silencing Unresolved Alarms" on page 197.

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

26.6. About Keeping Your Omnipod 5 Controller and/or Smartphone Nearby

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

After you enter the CGM transmitter serial number into the Omnipod 5 App and use the Dexcom G6 app on your smartphone to activate your sensor, you can switch from Manual Mode to Automated Mode. In Automated Mode, the