17.2. Entering Meal Information

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

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

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

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

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

3. Review the suggested meal bolus, which is shown below the grams of carbs.

4. Optional: tap CALCULATIONS to see the details of the bolus calculations.

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

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

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

Manually Enter Your Blood Glucose Reading

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

To enter a blood glucose reading:

1. Tap the Glucose field.

    If you have manually entered a blood glucose reading from a meter within the past 10 minutes, that value automatically appears in the Glucose field. If you want the SmartBolus Calculator to use that value, skip the next step.

2. Tap the box in the circle and enter the blood glucose reading. Alternatively, slide the indicator along the circle to enter the blood glucose reading.

    For the meaning of the colors displayed on the Enter Glucose screen, see "How Blood Glucose Readings are Displayed" on page 117.

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

3. Tap ADD TO CALCULATOR. The SmartBolus Calculator screen appears.

4. Review the suggested correction bolus, which is shown below the blood glucose reading. The correction bolus has been adjusted for any insulin on board (IOB) (see "SmartBolus Calculator Rules" on page 264).

Import and Use CGM Value

> **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.

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

➢   Tap USE CGM.

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

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

Tip: If you want to replace the CGM value with a blood glucose reading, tap the CGM field. See "Manually Enter Your Blood Glucose Reading" on page 242.

17.4. Insulin On Board (IOB)

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

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

• Meal IOB - from previous meal boluses.

• Correction IOB - can be from previous correction boluses or from automated insulin deliveries.

For more information, see "SmartBolus Calculator Rules" on page 264 and "SmartBolus Calculator Equations" on page 263.

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

Example: You are about to have lunch and you are unsure of how much you will eat. To avoid taking too much insulin, you deliver a meal and correction bolus based on the carbs you know you will eat and your glucose value. After delivering the bolus and eating the first portion, you decide you want to finish the remaining portion. Since you already delivered a correction with the previous bolus, and you know glucose values are on the rise, you decide to deliver a second bolus for only the remaining carbs in your meal and not enter another glucose value.

17.5. Adjustments to Your Calculation

A suggested meal bolus that is calculated using your Insulin to Carb (IC) Ratio may be further adjusted for other values entered into and used by the SmartBolus Calculator, including: blood glucose readings, CGM value and trend, and/or IOB. These adjustments can be for the following:

- Insulin on board — either meal or correction IOB

- Reverse correction, if this feature is turned ON and your glucose is below your Target Glucose

- Blood glucose reading, if manually entered

- CGM value and trend (see "19.5. CGM Trend Arrows" on page 278)

17.6. Delivering an Immediate Bolus

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

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

To review and deliver the immediate bolus:

1. Review the suggested bolus.

   a. To adjust it, tap the Total Bolus field and enter a revised bolus.

2. To review the specifics of calculations, tap CALCULATIONS. You may need to swipe up or down to see all of the calculations. Tap CLOSE when done. See "SmartBolus Calculator Equations" on page 263 for details.

3. To deliver the entire bolus immediately, tap CONFIRM.

4. Review the bolus details on the Confirm Bolus screen.

5. Optional: Set up a reminder to check your glucose:

   a. Tap CREATE BG REMINDER.

   b. Tap the Check BG in field and select the number of hours you want to be reminded in.

   c. Tap SAVE.

6.   Review the bolus details on the Confirm Bolus screen.

The total bolus includes any IOB adjustments and any adjustments you made to the calculated bolus.

Confirm Bolus screen details:

⚜ ▼ 90% ▮ 9:41 PM

← **Confirm Bolus**

🍴 Carbs   27 g ← **Grams of carbs**
🩸 BG (12:34 PM)   192 mg/dL ← **Blood glucose or CGM value**

Total Bolus   **11** U
CALCULATIONS   Adjusted for IOB of 2 U ← *Adjusted for IOB of x U* means the SmartBolus Calculator took IOB into account.

START

CREATE BG REMINDER

CANCEL

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

The Home screen tracks the delivery of an immediate or extended bolus (see "16.3. Tracking the Progress of a Bolus" on page 234).

17.7. Delivering an Extended Bolus

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

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

To review, extend and deliver the bolus:

1.   Review the suggested bolus.

    a.   To adjust it, tap the Total Bolus field and enter a revised bolus.

2.   To review the specifics of calculations, tap CALCULATIONS. You may need to swipe up or down to see all of the calculations. Tap

Extended Bolus screen:

← **Extended Bolus**

Now   **Extended**
45 %   **55** %
6 U   0 U

Duration
(0.5 to 8 hrs)
1.5 hrs

Total Bolus   **2.95** U
Meal Bolus   2.2 U
Correction Bolus   0.75 U

CANCEL   CONFIRM

CLOSE when done. See "SmartBolus Calculator Equations" on page 263 for details.

3. Tap EXTEND BOLUS.

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

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

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

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

6. Tap CONFIRM.

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

7. Review the bolus details on the Confirm Bolus screen.

The entire correction bolus is delivered immediately.

Only the meal bolus can be extended.

% of **meal** bolus to be given immediately

% of **meal** bolus to be given over the extended period

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

17.8. Bolus Settings

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

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

Impacts to Suggested Bolus Calculations

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

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Carbs (grams) 0.1 – 225 g (0.1 g increments)	Enter in SmartBolus Calculator	Increase in carb amount value increases amount of suggested bolus dose. Decrease in carb amount value decreases amount of suggested bolus dose.
CGM Value (mg/dL) 40 – 400 mg/dL (1 mg/dL increments)	Select Use CGM within SmartBolus Calculator (Value comes from your connected CGM)	Increase in CGM Value increases amount of suggested bolus dose. Decrease in CGM Value decreases amount of suggested bolus dose.
Blood Glucose Reading (mg/dL) 20 – 600 mg/dL (1 mg/dL increments)	Enter in SmartBolus Calculator (Value comes from your blood glucose meter)	Increase in BG Reading increases amount of suggested bolus dose. Decrease in BG Reading decreases amount of suggested bolus dose.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Maximum Bolus 0.05 – 30 U (0.05 U increments)	Enter in Omnipod 5 App Settings or during First Time Setup	Limits amount of single bolus dose.
Extended Bolus (Manual Mode only) ON/OFF	Enter in Omnipod 5 App Settings or during First Time Setup	Allows for bolus delivery over a user-selected period of time .
Target Glucose & Correct Above Target Glucose: 110 – 150 mg/dL Correct Above: 110 – 200 mg/dL (10 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Minimum Glucose for Calculations 50 – 70 mg/dL (1 mg/dL increments)	Enter in Omnipod 5 App Settings	Disables SmartBolus Calculator when glucose is at or below setting value.
Insulin to Carb Ratio 1 – 150 g (0.1 g increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Correction Factor 1 – 400 mg/dL (1 mg/dL increments, up to 8 segments/day)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value decreases amount of suggested bolus dose. Decrease in setting value increases amount of suggested bolus dose.
Reverse Correction ON/OFF	Enter in Omnipod 5 App Settings	If "On," suggested bolus is decreased when glucose is below Target Glucose value.

Omnipod 5 Setting and Range	How to Enter the Setting	Impacts to Suggested Bolus Calculations
Duration of Insulin Action 2 – 6 hours (0.5 hour increments)	Enter in Omnipod 5 App Settings or during First Time Setup	Increase in setting value may decrease amount of suggested bolus dose for longer periods.

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

Maximum Bolus

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

To change your Maximum Bolus:

1.   Navigate to: Menu button (≡) > Settings > Bolus > Maximum Bolus.

2.   Tap the Max Bolus field and enter the new Maximum Bolus value.

3.   Tap SAVE.

Extended Bolus

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

1.   Navigate to: Menu button (≡) > Settings > Bolus.

2.   Tap the toggle next to Extended Bolus to turn ON or OFF the ability to extend a bolus.

SmartBolus Calculator Settings

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

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

Target Glucose and Correct Above

In both Automated and Manual Mode, the SmartBolus Calculator aims to bring your glucose to your Target Glucose. However, the SmartBolus Calculator only

calculates a correction bolus if your glucose is above your Correct Above setting. In Automated Mode, the Omnipod 5 System will adjust your automated insulin delivery with the goal of bringing you to your Target Glucose.

To edit Target Glucose or Correct Above values:

1. Navigate to: Menu button (☰) > Settings > Bolus > Target Glucose & Correct Above.

2. Tap NEXT.

3. To edit a segment, tap the row containing the segment you want to edit.

    a. Tap the End Time field to enter a new end time.

    b. Tap the Target Glucose field to enter a new Target Glucose.

    c. Tap the Correct Above field to enter a new Correct Above value.

    d. Tap NEXT.

4. Repeat the previous step as needed for the remaining segments.

5. After confirming that all segments are correct, tap SAVE.

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

Minimum Glucose for Calculations

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

1. Navigate to: Menu button (☰) > Settings > Bolus > Minimum Glucose for Calculations.

2. Tap the Minimum Glucose for Calculations field and enter the desired value.

3. Tap SAVE.

Insulin to Carb Ratio (IC Ratio)

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

1. Navigate to: Menu button (☰) > Settings > Bolus > Insulin to Carb Ratio.

2. Tap NEXT.

3. To edit a segment, tap the row containing the segment you want to edit.

    a. Tap the End Time field to enter a new end time.

    b. Tap the 1 Unit of Insulin Covers field and enter a new IC Ratio.

    c. Tap NEXT.

4. Repeat the previous step as needed for the remaining segments.

5. After confirming that all segments are correct, tap SAVE.

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

Correction Factor

The SmartBolus Calculator uses your Correction Factor to calculate a correction bolus when your glucose is above your Correct Above setting. See "Target Glucose and Correct Above" on page 250. To edit this value:

1. Navigate to: Menu button (≡) > Settings > Bolus > Correction Factor.

2. Tap NEXT.

3. To edit a segment, tap the row containing the segment you want to edit.

    a. Tap the End Time field to enter a new end time.

    b. Tap the 1 Unit of Insulin lowers glucose by field and enter a new Correction Factor.

    c. Tap NEXT.

4. Repeat the previous step as needed for the remaining segments.

5. After confirming that all segments are correct, tap SAVE.

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

Reverse Correction

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

To turn Reverse Correction ON or OFF:

1. Navigate to: Menu button (≡) > Settings > Bolus.

2. Tap the toggle on the Reverse Correction line to turn it ON or OFF.

Duration of Insulin Action

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

1. Navigate to:
    Menu button (≡) > Settings > Bolus > Duration of Insulin Action

2. Tap the Duration of Insulin Action field and enter the new value.

3. Tap SAVE.

Note: While in Automated Mode, SmartAdjust technology does not use this Duration of Insulin Action setting to calculate automated basal insulin delivery. See "17.4. Insulin On Board (IOB)" on page 244.

CHAPTER 18
Understanding SmartBolus Calculator Calculations

Contents

18.1. The SmartBolus Calculator

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

SmartBolus Calculator Boluses

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

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

Extended boluses

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

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

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

→ Extend   = 3 units (3 units meal bolus)

Maximum Bolus

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

Controlling the bolus amount

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

When the SmartBolus Calculator Does Not Work

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

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

Factors Used in the SmartBolus Calculator Calculations

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

- Your current glucose (manually entered or from CGM), CGM trend (if CGM value is used), Target Glucose, Correct Above threshold, and Correction Factor.

- The carbs you are about to eat or drink and your IC Ratio.

- Your Duration of Insulin Action and insulin on board (IOB).

- Your Minimum Glucose for Calculations.

- Reverse Correction, if it is enabled.

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

CGM trend

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

Target Glucose

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

Correct Above threshold

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

Insulin on board

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

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

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

Duration of Insulin Action

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

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

Minimum Glucose for Calculations

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

Reverse Correction

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

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

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

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

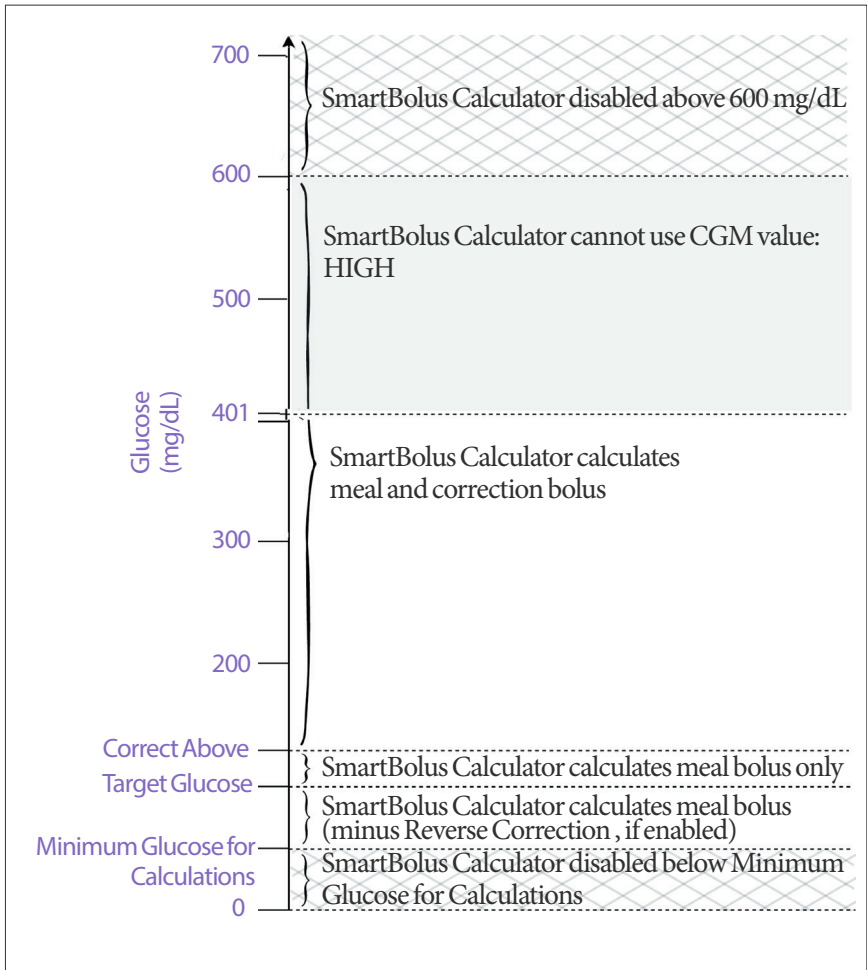|	Accepted Value	How does the SmartBolus Calculator use this value?
Using Omnipod 5 System with an FDA-Cleared Blood Glucose Meter		
Blood Glucose Reading from a BG Meter	20-600 mg/dL	To calculate total bolus volume. You can enter a blood glucose reading directly into the SmartBolus Calculator. If 5 or more minutes have passed since entering the reading, it will expire. Reading saved to the Omnipod 5 System history may be used for up to 10 minutes after entry.
Omnipod 5 Insulin Pump		
Minimum Glucose for Calculations	50-70 mg/dL	Disables bolus delivery when glucose is below this value. You can adjust this value in your Omnipod 5 System settings.
Correction Factor	1-400 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates how much one unit of insulin will lower your blood glucose.
Correct Above	110-200 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates the minimum glucose at which a Correction Bolus will be included in the total bolus volume.
Carbohydrates	0.1-225 grams	To calculate total bolus volume. You can enter your Carbohydrates value directly into the calculator to inform the Meal Bolus.

Insulin to Carb Ratio	1-150 grams	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates the grams of carbohydrate covered by one unit of insulin.
Duration of Insulin Action	2-6 hours	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. The value indicates how long insulin remains in effect after the bolus has delivered.
Meal IOB Portion	0-X Units	To calculate total bolus volume. The value is known by the Omnipod 5 System and used by the Calculator to indicate any previously delivered Meal Boluses that may still be in effect.
Target Glucose	110-150 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. In Automated Mode, basal insulin delivery will be adjusted automatically to bring you towards your Target Glucose. The value informs the Correction Bolus volume.
SmartAdjust™ technology (Automated Mode)		
Target Glucose	110-150 mg/dL	To calculate total bolus volume. You can adjust this value in your Omnipod 5 System settings. In Automated Mode, basal insulin delivery will be adjusted automatically to bring you towards your Target Glucose. The value informs the Correction Bolus volume.
Correction IOB Portion	0-X Units	To calculate total bolus volume. This value is known by the Omnipod 5 System and used by the Bolus Calculator to indicate any previously delivered Correction Boluses that may still be in effect.
Using Omnipod 5 with a compatible iCGM		
Glucose Reading CGM	40-400 mg/dL	To calculate total bolus volume. If you elect to use a CGM, you can select Use CGM directly in the Bolus Calculator. As a safety constraint, the Calculator will only accept CGM values that are on trend with previous CGM values.

Boundaries of the SmartBolus Calculator suggestions

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

- When your glucose is between your Target Glucose and your Correct Above the SmartBolus Calculator calculates a meal bolus only

- When your CGM value is over 400 mg/dL the value is recorded as "HIGH" and cannot be used for bolusing.

- When your blood glucose reading is above 600 mg/dL the reading is recorded as "HI" and the SmartBolus calculator is disabled.

Considerations about SmartBolus Calculator Recommendations

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

- The SmartBolus Calculator uses your SmartBolus Calculator settings for the time you are requesting a bolus (See "SmartBolus Calculator Settings" on page 250).

- The SmartBolus Calculator refreshes values every 5 minutes. If you do not start your bolus within 5 minutes of entering the SmartBolus Calculator, the Omnipod 5 System will need to clear the screen so that it has the latest IOB and CGM information.

- When changing time zones, always check your IC Ratio and Correction Factor settings for the new time to ensure it still meets your body's true insulin needs.

- The SmartBolus Calculator will suggest doses depending on the carbs you enter and the glucose at that time. Check the nutritional content of your meals to ensure the carbs entered is as accurate as possible. Only enter BG readings that have been obtained with the last 10 minutes or use CGM. These factors will make sure that the SmartBolus Calculator suggests a bolus dose that is suitable for you.

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

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

Delivery Limitations	Description
Maximum Bolus Setting	The SmartBolus Calculator will not deliver boluses that exceed the Maximum Bolus Setting you entered (0.05 - 30 U). For example, if you rarely deliver more than 5 U boluses, and you set the Maximum Bolus Setting at 5 U, the system will prevent you from delivering anything greater than this amount.
Blood Glucose Reading Time Out	The SmartBolus Calculator will not calculate a suggested bolus dose using a blood glucose reading you entered from the Main Menu (≡) that is older than 10 minutes. You will need to enter a more recent blood glucose reading within the SmartBolus Calculator.

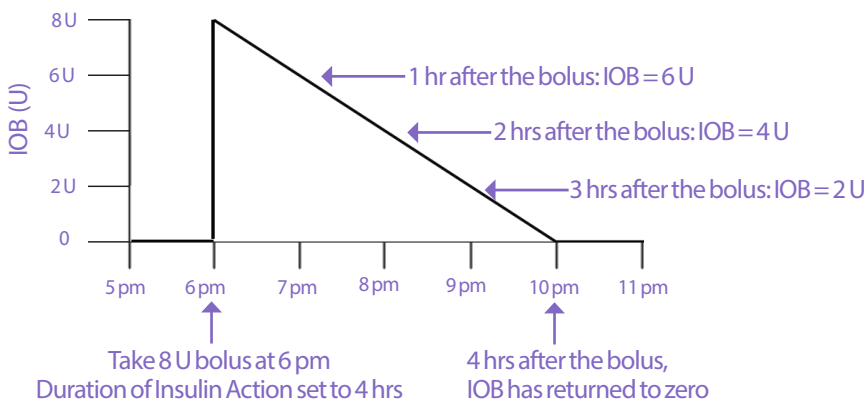|	
SmartBolus Calculator Time Out	The SmartBolus Calculator considers the values you input for a given bolus calculation valid for up to 5 minutes from initial entry of the value into the SmartBolus Calculator. If 5 minutes or more have elapsed, you will be notified that you must refresh the SmartBolus Calculator and input the values again.
Time Zones	The SmartBolus Calculator relies on accurate, updated insulin delivery history and data logging from your Omnipod 5 System. If a time zone change is detected by the Controller or smartphone, the system will notify you. Update time zones on your Omnipod 5 App according to your healthcare provider's guidance.

Insulin on Board (IOB)

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

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

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

Bolus IOB depletion

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

Take 8 U bolus at 6 pm
Duration of Insulin Action set to 4 hrs

4 hrs after the bolus,
IOB has returned to zero

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

Insulin on board (IOB) calculations

$$\frac{\text{Duration of Insulin Action} - \text{time since previous bolus}}{\text{Duration of Insulin Action}} \times \text{previous bolus}$$

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

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

Correction IOB example

Duration of Insulin Action: 3 hours
Time since previous correction bolus: 1 hour
Previous correction bolus: 3 U

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

Final IOB shown to you:

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

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

Correction Meal IOB example

Duration of Insulin Action: 3 hours
Time since previous meal bolus: 2 hours
Previous meal bolus: 4.5 U

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

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

SmartBolus Calculator Equations

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

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

Preliminary correction bolus $= \dfrac{\text{Current BG or CGM - Target Glucose}}{\text{Correction Factor}}$

> **Example**: Current BG or CGM: 200 mg/dL, Target Glucose: 150 mg/dL
> Correction Factor (CF): 50
>
> $\dfrac{200 \text{ mg/dL} - 150 \text{ mg/dL}}{50} = 1$ U prelim. correction bolus

Preliminary meal bolus $= \dfrac{\text{Carb intake}}{\text{Insulin-to-Carb (IC) ratio}}$

> **Example**: Carb intake: 45 grams of carb, IC ratio: 15
>
> $\dfrac{45}{15} = 3$ U prelim. meal bolus

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

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

Meal bolus = prelim. meal bolus - remaining correction IOB

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

Calculated bolus = correction bolus + meal bolus

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

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

> **Example**: Current BG or CGM: 75 mg/dL, Target Glucose: 150 mg/dL
> Correction Factor: 50, Preliminary meal bolus: 2.5 U
>
> $\dfrac{75 \text{ mg/dL} - 150 \text{ mg/dL}}{50} = -1.5$ U Reverse Correction
>
> - 1.5 U (Reverse Correction) + 2.5 U (prelim meal bolus) = 1.0 U meal bolus
>
> A Reverse Correction is only applied to the meal bolus. In this example, the meal bolus is reduced by 1.5 units, resulting in a meal bolus of 1.0 U.

SmartBolus Calculator Rules

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

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

Overview of the Bolus Calculations Screen

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

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

Current CGM Value

Calculated correction and adjusted for CGM trend

📶 🔽 90% 🔋 9:41 PM

← Bolus Calculations

Correction Bolus   0 ᵤ

CGM = 99, Target Glucose = 110
Correction Factor = 50
Calculated correction ≈ 0 U
Adjusted for CGM: Rapidly rising

Meal IOB adjustment
Meal IOB = 0.6 U
N/A: Correction bolus is <= 0 U

Correction IOB adjustment
Correction IOB = 0.45 U
N/A: Correction bolus is <= 0 U

Meal Bolus   7.05 ᵤ

Carbs = 75 g, IC Ratio = 10 g/U
7.5 / 10 ≅ 7.5 U

Correction IOB adjustment
Remaining correction IOB = 0.45 U
7.5 U − 0.45 U = 7.05 U

Calculated Bolus   7.05 ᵤ

Total Bolus   =   **4.1** ᵤ

18.2. SmartBolus Calculator Examples

Example 1

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

Correction Bolus	**-- U**

BG = N/A, Target Glucose = N/A
Correction Factor = N/A

Meal IOB adjustment
Meal IOB = 0.6 U
N/A: No BG reading

← The SmartBolus Calculator does not adjust your correction bolus by the meal IOB since there is no glucose information.

Correction IOB adjustment
Correction IOB = 0.5 U
N/A: No BG reading

← The SmartBolus Calculator also does not adjust your correction bolus by the correction IOB since there is no glucose information.

Meal Bolus	**5 U**

Carbs = 50 g, IC Ratio = 10 g/U
50 / 10 = 5 U

← You are eating 50 g carbs. With your IC ratio at 10, you will need a 5 U meal bolus.

Correction IOB adjustment
IOB is subtracted from a bolus only when BG is known.

← Your meal bolus is not adjusted by your IOB when there is no blood glucose reading or CGM value.

Calculated Bolus	**5 U**

← The calculated bolus is just the meal bolus since there is no correction bolus.

Your Adjustment Meal bolus + 2 U	2 U

← You can make manual adjustments to your bolus by tapping on the Total Bolus field at the bottom of the SmartBolus Calculator screen.

Total Bolus	**=**	**7 U**

← The Total Bolus is the sum of the calculated bolus and any adjustments you made.

Example 2

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

Correction Bolus	**1.2 U**

CGM = 180, Target Glucose = 130
Correction Factor = 50
(180-130) / 50 = 1 U

← Your glucose is 180 mg/dL which is 50 mg/dL over your target. Because your correction factor is 50, the initial correction bolus is 1 U.

Meal IOB adjustment
Meal IOB = 0 U
1 U – 0 U = 1 U

← The SmartBolus Calculator does not adjust your correction bolus by the meal IOB since there is no meal IOB.

Correction IOB adjustment
Correction IOB = 0 U
1 U - 0 U = 1 U

← The SmartBolus Calculator also does not adjust your correction bolus by the correction IOB since there is no correction IOB.

Adjusted correction bolus = 1.2 U
Adjusted for CGM: Rising

← The correction bolus is increased to account for your rising CGM trend.

Meal Bolus	**3.6 U**

Carbs = 30 g, IC Ratio = 10 g/U
30 / 10 = 3 U

← You are eating 30 g carbs. With your IC ratio at 10, you will need a 3 U meal bolus. The SmartBolus Calculator does not adjust your meal bolus by the correction IOB since there is no correction IOB.

Correction IOB adjustment
Remaining correction IOB = 0 U
3 U – 0 U = 3 U

← The SmartBolus Calculator does not adjust your meal bolus by the correction IOB since there is no correction IOB.

Adjusted meal bolus = 3.6 U
Adjusted for CGM: Rising

← The meal bolus is increased to account for your rising CGM trend.

Calculated Bolus	**4.8 U**

← The calculated bolus is the sum of your correction bolus and meal bolus that has been adjusted for rising CGM value.

Total Bolus	**4.8 U**

← The total bolus is the sum of the calculated bolus and any adjustment you made.

Example 3

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

Correction Bolus	0 U

CGM = 180,
Target Glucose = 130
Correction Factor = 50
(180 - 130) / 50 = 1 U

Your glucose is 180 mg/dL, which is 50 mg/dL over target. Because your correction factor is 50, the initial correction bolus is 1 U.

Meal IOB adjustment
Meal IOB = 0.8 U
1 U - 0.8 U = 0.2 U

Since you have 0.8 U of meal IOB remaining from a previous meal bolus, this is subtracted from the initial correction bolus of 1 U, and you have 0.2 U of correction bolus remaining.

Correction IOB adjustment
Correction IOB = 0.5 U
0.2 U - 0.5 U < = 0 U

You also have 0.5 U of correction IOB from previous insulin action. This is subtracted from the remaining correction bolus of 0.2 U, driving the final calculated correction bolus to 0 U. Note that 0.3 U of correction IOB still remains after driving correction bolus to 0 U, and this is used in the meal bolus calculations.

Meal Bolus	0 U

Carbs = 0 g, IC Ratio = 10 g/U
0/10 = 0 U

You did not enter any carbs, so you do not receive any calculated meal bolus dose.

Correction IOB adjustment

Remaining correction
IOB = 0.3 U
0 U - 0.3 U < = 0 U

Although there is a remaining correction IOB of 0.3 U, your initial meal bolus is already at 0 U, so it is not adjusted further, and your meal bolus remains at 0 U.

Calculated Bolus	0 U

Even though your glucose is above target, you have enough IOB. As a result, the SmartBolus Calculator recommends that you do not deliver any additional insulin.

Total Bolus	0 U

USING A CGM WITH OMNIPOD 5

CGM Important Safety Information

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CGM Important Safety Information

CGM Warnings

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.

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

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

Warning: Device components including the Pod, CGM transmitter, and CGM sensor may be affected by strong radiation or magnetic fields. Device components must be removed (and the Pod and CGM sensor should be disposed of) before X-ray, Magnetic Resonance Imaging (MRI), or Computed Tomography (CT) scan (or any similar test or procedure). In addition, the Controller and smartphone should be placed outside

of the procedure room. Exposure to X-ray, MRI, or CT, treatment can damage these components. Check with your healthcare provider on Pod removal guidelines.

Warning: DO NOT use Omnipod 5 System if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom G6 CGM values may be falsely elevated and result in over-delivery of insulin that can result in severe hypoglycemia.

CGM Precautions

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

About the Dexcom G6

Contents

19.1. CGM Overview

> **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.

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

Read and follow all Dexcom G6 product instructions, including Safety Statements, in the *Dexcom G6 CGM System User Guide*.

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

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

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

• Always check the Dexcom G6 expiration dates for the sensor and transmitter. Only use a sensor and transmitter that are within their use-by date.

• Adhere to Dexcom's approved site placements for Dexcom G6 wear.

• All Dexcom G6 alerts are configured and driven by your Dexcom G6 app. Set your Low and High alerts, as well as any other alerts in your Dexcom G6 app before using the Omnipod 5 System.

Note: The Omnipod 5 System also alerts you when your CGM values are at or below 55 mg/dL.
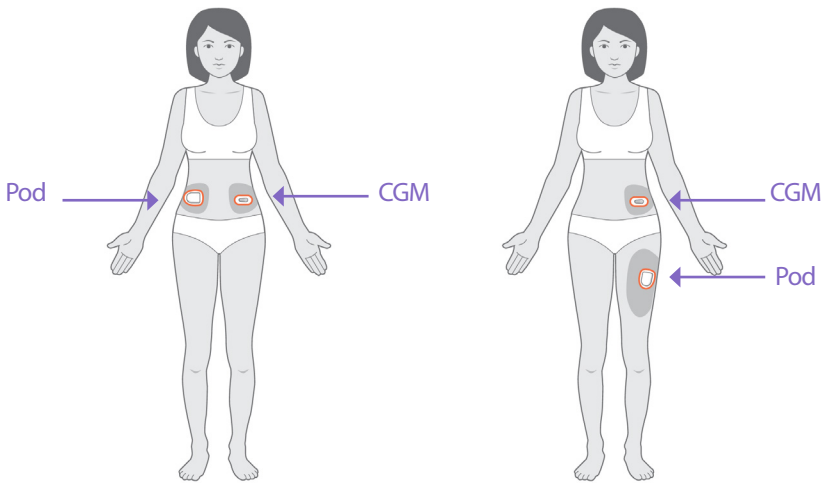
•   Always ensure the transmitter serial number entered in the Dexcom G6 and Omnipod 5 Apps match the transmitter on your body.
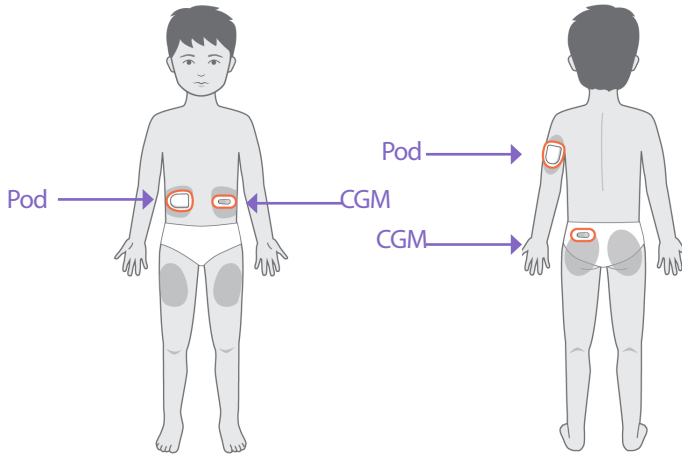
19.2. CGM Placement

The Bluetooth connection between the CGM and the Pod is optimal when the signal does not pass through the body. Keeping both devices at least 3 inches (7.62 cm) apart and within line of sight allows for consistent CGM communication with the Pod.

Note: Line of sight means that the Pod and CGM 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.

Adult placement examples

Pediatric placement examples

Note: Consult the *Dexcom G6 CGM System User Guide* for more information on approved CGM placement locations.

19.3. Using the Dexcom G6 with Omnipod 5

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

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

19.4. CGM Values

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

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

High and Low CGM Values

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

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

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

Urgent Low Glucose

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

When your CGM value is at or below 55 mg/dL, your Dexcom G6 will send the value to your Pod. The Pod will sound an Advisory alarm to let you know that your glucose is very low. You can acknowledge the alarm from your Controller or smartphone. See "13.7. Advisory Alarm List" on page 171

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

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

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

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

19.5. CGM Trend Arrows

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

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

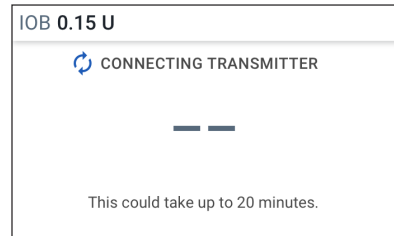| CGM Value Color	Description
Purple	CGM value is within Glucose Goal Range (Automated Mode)
Blue	CGM value is within Glucose Goal Range (Manual Mode)
Red	CGM value is below Glucose Goal Range
Orange	CGM value is above Glucose Goal Range

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

CGM Trend Arrows	Description
→	Steady; decreasing/increasing less than 1 mg/dL per minute
↘ ↗	Slowly falling/rising; glucose could decrease/increase 30-60 mg/dL in 30 minutes
↓ ↑	Falling/rising; glucose could decrease/increase 60-90 mg/dL in 30 minutes
↓↓ ↑↑	Rapidly falling/rising; glucose could decrease/increase more than 90 mg/dL in 30 minutes

19.6. Communication Messages

The DASHBOARD displays the following communication messages:

- CONNECTING TRANSMITTER: Occurs after you have entered a transmitter serial number and the Pod is attempting to connect with the transmitter.

IOB **0.15 U**

↻ CONNECTING TRANSMITTER

— —

This could take up to 20 minutes.

- WAITING FOR DEXCOM SETUP: When the transmitter is connected but CGM values are unavailable because the Dexcom G6 is in sensor warm-up or requires calibration. See the Dexcom G6 app for details. No action is required within the Omnipod 5 App.

- SEARCHING FOR POD: When Pod communication was not established within the most recent 5-minute update interval. Tap MORE INFORMATION for potential causes and recommended actions.

- SEARCHING FOR CGM: When the CGM is active and connected to the Omnipod 5 Pod but the most recent CGM value was not acquired within the 5-minute window. There may be no valid CGM value available due to a Pod/CGM communication issue or a temporary CGM sensor issue (recoverable without any user action). Tap MORE INFORMATION for recommended action. Review Pod and CGM placement. Pod and CGM should be at least 3 inches (7.62 cm) apart and within line of sight.

- DEXCOM ISSUE DETECTED: When CGM values are not available due to a sensor error (including sensor expiration). See the Dexcom G6 app for details. No action is required within the Omnipod 5 App

IOB **0.15 U**

🔴 DEXCOM ISSUE DETECTED

DEXCOM G6

See Dexcom app for details.

- TRANSMITTER ERROR: When the transmitter connected with the Omnipod 5 System has expired or experienced a non-recoverable error. Tap NEED HELP for potential causes and recommended actions. To set up a new transmitter, see "20.3. Connecting the Transmitter" on page 283.

- TRANSMITTER NOT FOUND: When the Pod tried to connect with a transmitter but after 20 minutes was unable to do so. Tap NEED HELP for potential causes and recommended actions. See "26.3. CGM FAQs" on page 332 for additional information.

Note: For all CGM related issues, refer to your *Dexcom G6 CGM System User Guide*

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Connecting Dexcom G6 CGM to the Pod

Contents

20.1. About Connecting Dexcom G6 to the Pod

The Omnipod 5 System is designed to work with the Dexcom G6 CGM. To use the Dexcom G6 CGM with the Omnipod 5 System, you will need to obtain the Dexcom G6 sensor and transmitter, *Dexcom G6 User Guide*, and download the Dexcom G6 app on your personal smartphone.

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

Note: The Dexcom G6 sensor must be started in the Dexcom app in order to use CGM values and trends in the Omnipod 5 System.

Before you begin, do the following:

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

20.2. Connecting the Dexcom G6 during Initial Pod Setup

To connect the CGM transmitter during initial Pod setup:

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

   Note: If you tap NOT NOW after activating your Pod during initial setup, you can connect the CGM at a later time. See "Connecting the Dexcom G6 Transmitter" below.

2. Go to step 3 of "Connecting the Dexcom G6 Transmitter" below.

20.3. Connecting the Dexcom G6 Transmitter

> **Warning:** ALWAYS confirm the Dexcom G6 Transmitter serial number you save in the Omnipod 5 App matches the one you are wearing. In cases where more than one person in the household uses the Dexcom G6 CGM, mismatching transmitter serial numbers could result in over-delivery or under-delivery of insulin, which can lead to hypoglycemia and hyperglycemia.

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

To connect the Dexcom G6 transmitter:

1. From the Home screen, tap Menu button (≡) > Settings > CGM Transmitter.

    The CGM Transmitter screen displays the saved serial number .

    Note: If the transmitter serial number was previously deleted, the serial number field is empty. (See "20.4. Disconnecting the CGM from the Pod" on page 284).
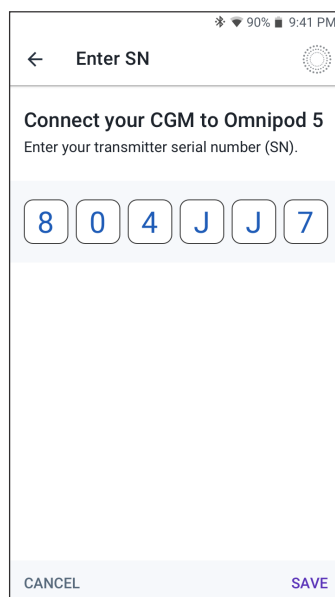
2. Tap ENTER NEW.

3. Tap the serial number field to display the alphanumeric keypad.

4. Enter the serial number printed on the back of your transmitter or on the transmitter box, then tap Done.

5. Tap SAVE.

    Note: If you tap CANCEL or exit the current screen (by pressing the back arrow), the serial number is not saved. Tap CONFIRM to start connecting your CGM transmitter to your Pod. The connection process can take up to 20 minutes.

6. Tap CONFIRM to start connecting your transmitter to your Pod. The connection process can take up to 20 minutes.

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

If the Pod is unable to connect with the CGM transmitter within 20 minutes, the message "Transmitter Not Found" displays. Tap NEED HELP for more information. See "26.3. CGM FAQs" on page 332 for additional information.

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

20.4. Disconnecting the CGM from the Pod

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

To delete the serial number:

1.   From the Home screen, tap Menu button (≡) > Settings > CGM Transmitter.

The CGM Transmitter screen displays the saved serial number.

2.   Tap DELETE.

3.   Tap OK, DELETE to confirm.

AUTOMATED MODE

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Automated Mode Important Safety Information

Automated Mode Warnings

Warning: SmartAdjust technology should NOT be used by anyone under the age of 6 years old. SmartAdjust technology should also NOT be used in people who require less than 6 units of insulin per day as the safety of the technology has not been evaluated in this population.

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

Warning: ALWAYS be aware of your current 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 can 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.

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 if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. Your Dexcom G6 CGM readings could be falsely elevated and could result in over-delivery of insulin which can lead to severe hypoglycemia.

CHAPTER 21
About Automated Mode

Contents

21.1. 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 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.

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 system automatically adjusts your insulin delivery every 5 minutes, based on the current CGM value and trend, with the goal of bringing your glucose to your defined Target Glucose.

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

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

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

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

The Pod contains SmartAdjust technology, which adjusts your adaptive basal rate. You will stay in Automated Mode when 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 CGM value and trend.

The automated insulin delivery amount given every 5 minutes while in Automated Mode can be seen in the Auto Events tab of the History Detail screen. See "Automated Events (Auto Events)" on page 146.

The CGM 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 CGM Graph" on page 134.

Note: The Controller or smartphone running the Omnipod 5 App must be in Pod communication range to receive the most up-to-date information.