omnipod DASH®

Omnipod DASH® Insulin Management System

Quick Start Guide

Welcome to Omnipod DASH®!

This guide provides you with step-by-step instructions for getting started with your new Omnipod DASH System.

The Omnipod DASH Insulin Management System is intended for subcutaneous delivery of insulin at set variable rates for the management of diabetes mellitus in persons requiring insulin.

INDICATIONS FOR USE

The Omnipod DASH Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

Additionally, the Omnipod DASH System is interoperable with a compatible blood glucose meter to receive and display blood glucose measurements.

CONTRAINDICATIONS

Insulin pump therapy is NOT recommended for people who are:

- Unable to monitor blood glucose levels as recommended by their healthcare provider
- Unable to maintain contact with their healthcare provider
- Unable to use the Omnipod DASH System according to instructions

COMPATIBLE INSULINS

The Omnipod DASH System is designed to use rapid-acting U-100 insulin. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: NovoLog® (insulin aspart), Fiasp® (insulin aspart), Humalog® (insulin lispro), Admelog® (insulin lispro), Lyumjev™ (insulin lispro-aabc), and Apidra® (insulin glulisine). NovoLog, Fiasp, Humalog, and Admelog are compatible with the Omnipod DASH System for use up to 72 hours (3 days). Apidra is compatible with the Omnipod DASH System for use up to 48 hours (2 days).

If you have questions about using other insulins, contact your healthcare provider. Fiasp and Lyumjev have a faster initial absorption than other rapid-acting U-100 insulins; always consult with your healthcare provider and refer to the insulin labeling prior to use.

To access the complete Omnipod DASH System User Guide

At any time while using Omnipod DASH, you can access or request the ***Omnipod DASH User Guide***.

1. **Download or print a digital copy:**
   - Scan this QR code with your smartphone
   - Visit omnipod.com/guides
2. **Request to receive a free printed copy:**
   - Online request form at omnipod.com/guides
   - Call in to request: 800-591-3455

Contents

New Omnipod User

You must follow the steps below BEFORE you can get started.

Before you begin, be sure to follow the appropriate instructions outlined here.

1 Call or Sign Up

To start your training on the Omnipod DASH Insulin Management System with an Omnipod Certified Pod Trainer (CPT), fill out the form on **omnipod.com/training.** Your local CPT will call you back with desired training options. You may also call your prescribing physician to assist you.

2 Receive Training

Learning how to use your Omnipod DASH System the correct way is important for safe and effective use. Different training methods are available based on your and your healthcare provider's preferences.

3 Freedom Is Yours!

You'll then be ready to enjoy the benefits and flexibility of your new Omnipod DASH System.

Any questions, call: **800-591-3455**

Existing Omnipod User

You can get started right away!

1. Using this Quick Start Guide and User Guide as references, complete the DASH online training at **omnipod.com/training.**
2. To set up your new Omnipod DASH System Personal Diabetes Manager (PDM), you need your settings from your current PDM. If you currently use the previous generation PDM, the instructions on Page 42 of this Quick Start Guide will help you find your current settings.

⚠ **For your safety, DO NOT attempt to create your own Omnipod DASH System PDM settings.**

What's Different About the Pod? Simple.

Omnipod DASH System is a simple system consisting of just 2 parts—the tubeless Pod and the handheld Personal Diabetes Manager (PDM) that you use to wirelessly program your insulin delivery*. Made to be convenient and discreet, the Pod can provide up to 3 days of continuous insulin delivery** and can be worn almost anywhere you would give yourself a shot. Wear what you want, and do what you want. Omnipod DASH System helps simplify insulin delivery, so you can live your life and manage diabetes around it. That's just part of what makes so many people passionate Podders®.

Preparing to Start on Omnipod DASH System.

This Quick Start Guide will lead you through some of the key functions you may need to perform with the Omnipod DASH System.

24/7 Customer Care: 1-800-591-3455
From Outside the US: 1-978-600-7850
Omnipod.com

In an emergency, you should call your healthcare provider as well as an emergency contact.

Healthcare provider name
Healthcare provider number

Emergency contact name
Emergency contact number

Always consult with your healthcare provider to determine the appropriate settings for you.

HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS. THIS QUICK START GUIDE IS INFORMATIONAL AND NOT INTENDED AS MEDICAL OR HEALTH CARE ADVICE OR RECOMMENDATIONS TO BE USED FOR DIAGNOSIS, TREATMENT OR FOR ANY OTHER INDIVIDUAL NEEDS. THIS QUICK START GUIDE IS NOT A SUBSTITUTE FOR MEDICAL OR HEALTH CARE ADVICE, RECOMMENDATIONS AND/OR SERVICES FROM A QUALIFIED HEALTH CARE PROVIDER. THIS QUICK START GUIDE MAY NOT BE RELIED UPON IN ANY WAY IN CONNECTION WITH YOUR PERSONAL HEALTH CARE, RELATED DECISIONS AND TREATMENT. ALL SUCH DECISIONS AND TREATMENT SHOULD BE DISCUSSED WITH A QUALIFIED HEALTH CARE PROVIDER WHO IS FAMILIAR WITH YOUR INDIVIDUAL NEEDS.

* At start up the Personal Diabetes Manager and Pod should be adjacent and touching, either in or out of tray to ensure proper communication during priming. At least 5 feet (1.5 meters) during normal operation

** Up to 72 hours of insulin delivery

Emergency Kit

You Should Have the Following Supplies on Hand at All Times:

- Omnipod DASH PDM
- Several new, sealed Omnipod DASH Pods
- Vial of rapid-acting U-100 insulin
- Blood Glucose (BG) meter
- BG test strips
- Lancing device & lancets
- Alcohol swabs
- Syringes or pens/needles for alternative way of injecting insulin
- Instructions from your healthcare provider about how much insulin to inject if delivery from Pod is interrupted
- Ketone testing supplies
- Glucose tabs or another fast-acting source of carbohydrate
- Glucagon emergency kit and written instructions for giving an injection if you are unconscious
- Phone numbers for your healthcare provider in case of an emergency

⚠ Caution: Consult User Guide.

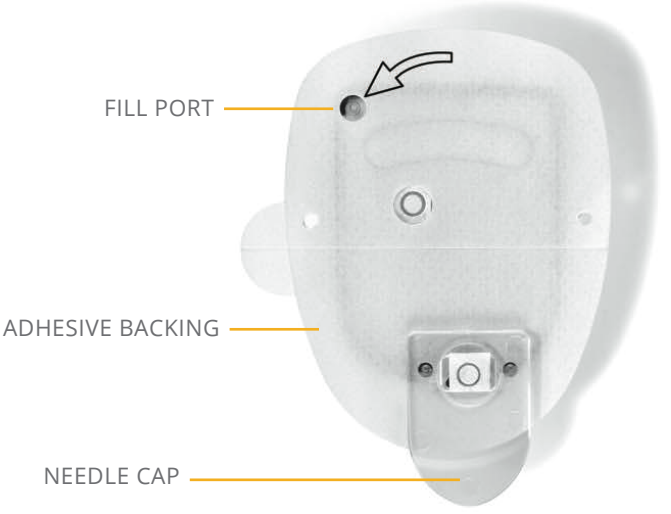
* Only Omnipod DASH System Pods can communicate with the Omnipod DASH System Personal Diabetes Manager

The Omnipod DASH System Pod

A Bluetooth®-Enabled Pod that Delivers both Basal and Bolus Insulin.

TOP

BOTTOM



The Omnipod DASH System Personal Diabetes Manager

A Bluetooth®-Enabled Personal Diabetes Manager (PDM) that Controls All Pod Functions.

Home Screen View

- View current Pod and Personal Diabetes Manager Status
- Access more system options in the Menu icon
- View Notifications and Alarms
- Access IOB in the Dashboard view
- Review and edit Basal Programs in Basal view
- View details of the Pod and access Pod Change in Pod info view
- Reference LAST BOLUS and LAST BG
- Easy access to deliver a Bolus via Bolus Button

Tip

You can find the following items when you tap on the Menu icon:

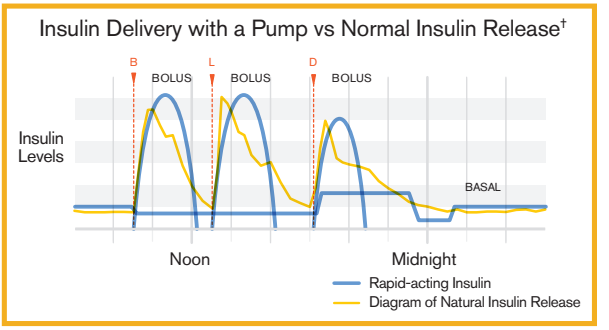
- Alternate access to Basal and Pod Info
- Set Temp Basal
- Enter BG
- Suspend Insulin
- Manage Temp and Bolus Preset
- Access Food Library
- View History
- Edit Settings

Basal and Bolus Insulin

What is a Basal Rate?

Your body needs a small amount of insulin constantly delivered throughout the day, called basal insulin. Basal rates are specified in units per hour (U/hr). The exact amount of basal insulin your body needs changes often depending on:

- What you're doing throughout the day
- How stressed you are
- When you're sick



What is a Bolus?

A bolus is a dose of insulin, delivered to match the carbohydrates in a meal or snack and/or to lower your blood glucose when it gets too high. There are two types of bolus doses:

- Meal bolus
  - With the Omnipod DASH System, you can deliver either an immediate or an extended meal bolus
  - An immediate meal bolus delivers insulin for a meal or snack you are about to eat
  - An extended meal bolus delivers insulin over a longer period of time. When you eat foods high in fat and/or protein or are eating over a long period of time, such as at a party, you might need an extended meal bolus.
- Correction bolus
  - A correction bolus can be delivered with or without a meal bolus if you need to lower your blood glucose level

Omnipod DASH System Will Help to Calculate Your Bolus Doses.

Omnipod DASH System also features a Bolus Calculator to help you deliver an accurate bolus dose. The calculator uses your current blood glucose, carbs entered, and your insulin on board (IOB) to determine a suggested bolus dose.

⚠ **CAUTION:** Consult User Guide.

For more information about the Suggested Bolus Calculator, refer to your Omnipod DASH Insulin Management System User Guide.

† ©2002 by the American Diabetes Association®. Smart pumping for people with diabetes. Reprinted with permission from the American Diabetes Association®.

Why Carbohydrates Matter

What are Carbohydrates?

- **Starches:** Starchy vegetables like potatoes, corn and peas, dried beans and lentils, grains like oats, barley, rice and items made from wheat flour
- **Sugars:** Naturally occur in milk and fruit, or added during cooking or processing. Common names for sugar are table sugar, brown sugar, molasses, honey, cane sugar, maple syrup, high fructose corn syrup and agave nectar.
- **Fiber:** Can be found in fruits, vegetables, whole grains, nuts and legumes. Most dietary fiber is not digestible. Fiber contributes to digestive health, keeps you regular and helps make you feel full and satisfied after eating.

Impact on Blood Glucose

Carbohydrates (carbs) are important because they provide us with energy and essential vitamins and minerals. Proteins and fats also contain calories, vitamins, and minerals, but do not contain carbohydrates unless the food is a mixed item like a casserole. Carbohydrates are the primary foods that affect blood glucose levels.

Proteins and fats take longer to digest and are slower to affect your blood glucose. Higher consumption of protein or fat at meals can delay glucose absorption and create higher blood glucose levels later. The section "Omnipod DASH System Advanced Features" will teach you more about bolusing for certain meals with the Omnipod DASH Insulin Management System.

How Do I Figure Out the Amount of Carbohydrates in My Meal?

Check the Label

The two key pieces of information on the nutrition facts label for carb counting are the serving size and total carbohydrates.

Use the PDM Food Library to Search

Your PDM is equipped with CalorieKing®! Simply browse by category or enter a keyword in search. Carbohydrate amounts can be seamlessly added to the bolus calculator.

NUTRITION LABEL

Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

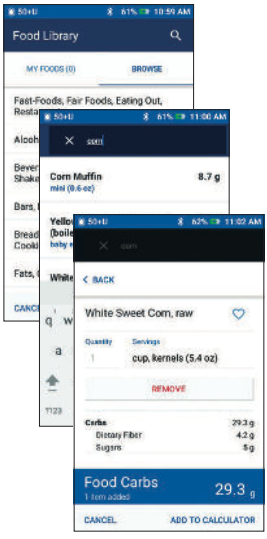
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0 mg	**0%**
Sodium 160 mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice

Source: US Food and Drug Administration Website

FOOD LIBRARY



Beaser RS. Joslin's Diabetes Deskbook: A guide for primary care providers. 3rd ed. Boston, MA. Joslin Diabetes Center; 2014

The PDM Battery

- Use the pull-tab to remove the back cover
- Insert the battery into the PDM
- Remove the pull-tab and replace the back cover

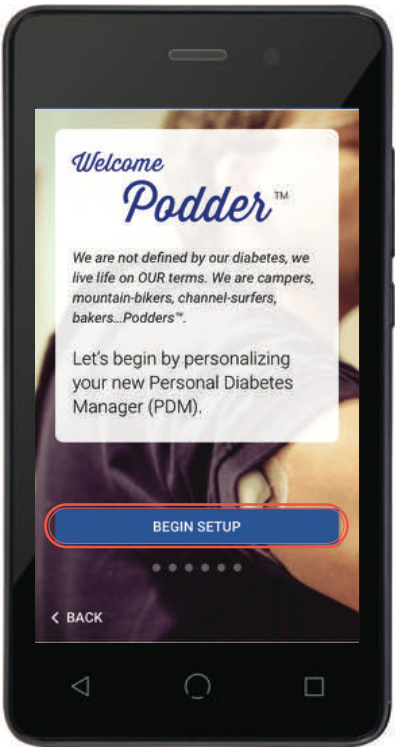
Battery Tips:

- Your PDM battery is rechargeable. Use only an Insulet-approved battery, charger, and cable.
- Adjust screen time-out and brightness levels to conserve battery.
- Your Pod will continue to deliver basal insulin if your PDM powers off. You can use your PDM while it is charging.
- Develop a routine to charge your PDM at the same time each day.
- Consider keeping more than one charger for home, office, school, etc.

Omnipod DASH System Initial PDM Setup

Your initial pump therapy settings are needed to setup your new PDM. These settings are provided to you by your healthcare provider.

- Hold down the Power button to wake your PDM



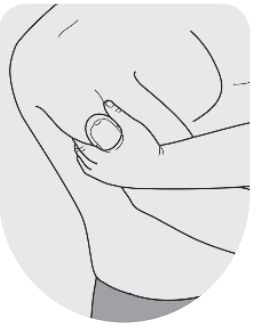
- You will begin by personalizing your new PDM
- After personalization, you will enter your insulin delivery settings
- The PDM guides you step-by-step. Be sure to read each screen, and accurately enter each setting.
- For more information, refer to Chapter 2 “Initial PDM Setup” in the Omnipod DASH System User Guide

Feel Comfortable and Confident With Your Omnipod DASH Pod

It's easy to find a place for your Pod. And your Pod is tubeless and lightweight, so you can wear it with freedom.

Where to Wear Your Pod

It's important to choose a new area every time when placing your Pod to avoid site overuse, which could result in variable absorption. The new area should be at least 1 inch away from the previous one, 2 inches away from the navel and not over a mole, scar, or tattoo, where insulin absorption may be reduced. Be sure to put your Pod somewhere you'll be comfortable—avoid sites where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the Pod.

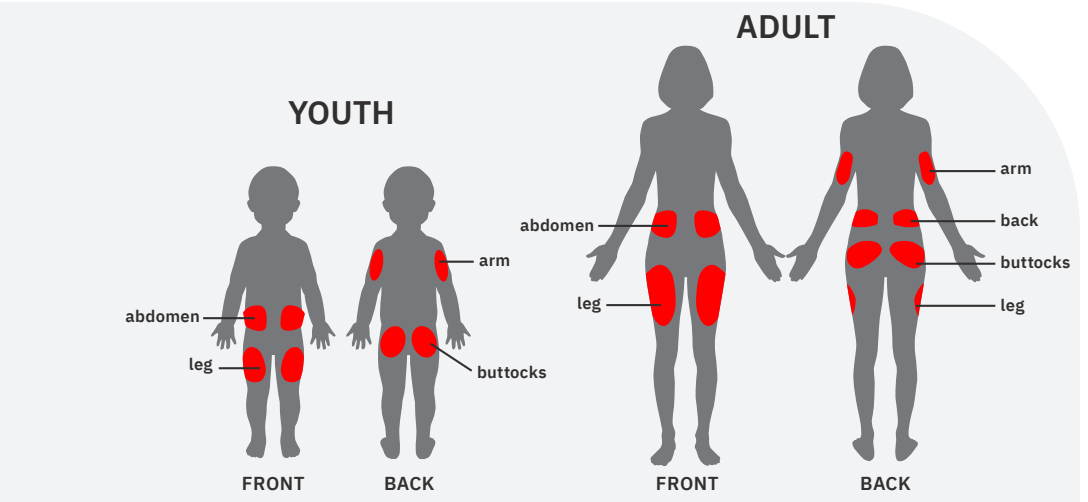


How to Place Your Pod

Arm and leg
Position the Pod vertically or at a slight angle.

Back, abdomen, and buttocks
Position the Pod horizontally or at a slight angle.

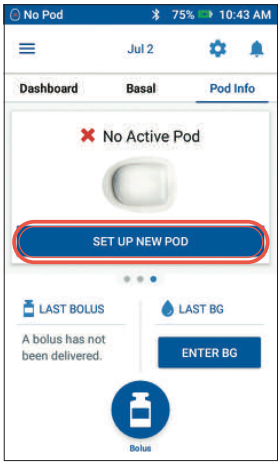
Pinching up
This step is important if your Pod location is very lean or doesn't have much fatty tissue. Place your hand over the Pod and make a wide pinch around your skin surrounding the viewing window. Then press the Start button on the Personal Diabetes Manager. You can let go when the cannula inserts.



WARNING:
Occlusions may result in lean areas if you do not use this technique.

Activate a New Pod

- Assemble the following supplies:
  - DASH Personal Diabetes Manager (PDM)
  - Sealed DASH Pod
  - Vial of U-100, rapid acting insulin at room temperature. (See the Omnipod DASH System User Guide for insulins tested and found to be safe with the Omnipod DASH Insulin Management System.)
  - Alcohol prep swab
- Wash your hands



1. To set up a new Pod, Tap **SET UP NEW POD**
2. Read and perform each instruction carefully

WARNING:
- NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.
- NEVER use a Pod if you hear a crackling noise or feel resistance when you depress the plunger.

These conditions can result in interrupted insulin delivery caution:

CAUTION:
Do not use any other type of needle or filling device besides the fill syringe provided with each Pod.

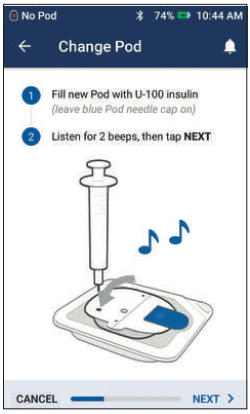
Fill the Pod

1. Remove the fill syringe and needle from its sterile packaging. Keep the Pod in its tray during set up.
   - Use the alcohol prep swab to clean the top of the insulin vial
   - Assemble the fill syringe by twisting the needle onto the syringe

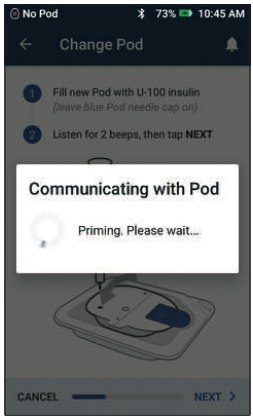
2. Pull outward to remove the syringe's protective cap

3. Draw air into the fill syringe equal to the amount of insulin you will use
   - Insert needle into the vial of insulin and inject air
   - Turn the vial and syringe upside down
   - Slowly withdraw insulin from the vial and fill the syringe with the amount of insulin you will use; fill at least to the MIN line
   - Tap or flick the syringe to remove any air bubbles

If the Personal Diabetes Manager screen times out during the process, press the Power button to continue.



4. Leave Pod in its plastic tray
   - Insert the needle straight down into the fill port on the underside of the Pod. To ensure proper fill, do not insert fill syringe at an angle into the fill port.
   - Completely empty the syringe into the Pod
   - The Pod will beep twice, indicating that the Omnipod DASH System is ready to proceed
   - Return to the PDM. If the PDM screen times out, press the Power button to turn it back on. Place the PDM next to the Pod so they are touching.
   - Tap **NEXT**

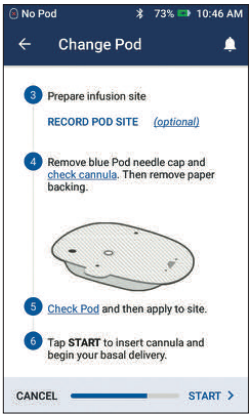


5. The PDM establishes a one-to-one relationship with the Pod, which will prevent it from communicating with any other Pod while this Pod is active. Once the Pod successfully completes its priming and safety checks, the PDM will beep.

Reminder
During activation and priming the PDM and Pod should be next to each other and touching.

Apply the Pod

1. Select the infusion site, being careful to avoid areas where the Pod will be affected by folds of skin. Refer to the Pod Placement section of this Quick Start Guide for sites and placement tips.



Tip
Use Pod site map to help you track your current and recent Pod site locations. This feature can be turned on in Settings.

If the Personal Diabetes Manager screen times out during the process, press the Power button to continue.

Apply the Pod (continued)

2. For optimal adhesion, always clean the site thoroughly with an alcohol swab to remove all body oils and lotions, which may loosen the Pod's adhesive. Let the site air-dry completely; do not blow on the site to dry it.

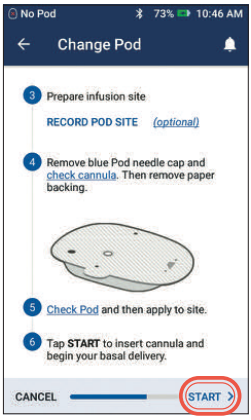
3. Remove Pod's needle cap

4. Carefully remove white paper backing from the adhesive, ensuring the adhesive is clean and intact

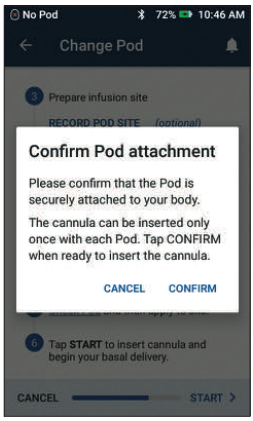
5. Apply the Pod to the selected site
   - Run your finger around the adhesive to secure it

If the Personal Diabetes Manager screen times out during the process, press the Power button to continue.

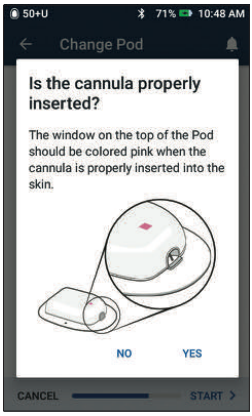
Press Start



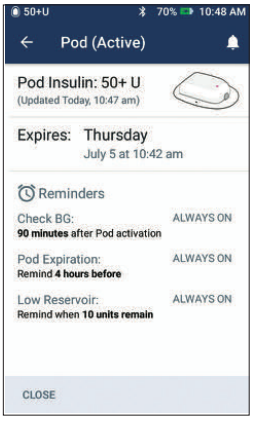
1. Tap **START**



2. Verify that the Pod is securely attached to your body, then tap **CONFIRM**
   - For best technique refer to the Pod Placement section of this Quick Start Guide for sites and placement tips



3. The Pod automatically inserts the cannula and delivers a prime bolus to fill the cannula with insulin. Once the cannula has inserted, verify proper insertion by checking that the pink slide insert is visible in the faint window on the top of the Pod



4. Your Pod is now active!
   - The PDM will generate an automatic reminder to check your blood glucose 1.5 hours after each Pod change

⚠ WARNING:
- The Personal Diabetes Manager will generate an automatic reminder to check your blood glucose 1.5 hours after each Pod change. If the cannula is not properly inserted, hyperglycemia may result.
- Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.
- NEVER inject insulin (or anything else) into the fill port while the Pod is on your body. Doing so may result in unintended or interrupted insulin delivery.
- Verify cannula does not extend beyond adhesive backing once needle cap is removed.

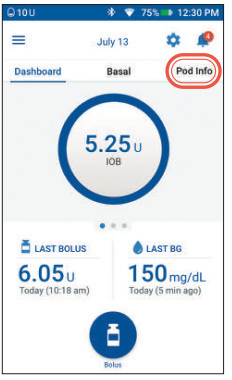
If the Personal Diabetes Manager screen times out during the process, press the Power button to continue.

How to Change the Pod

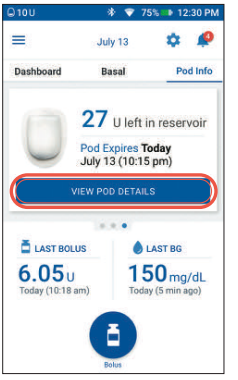
You May Need to Change the Pod:

- When the reservoir is low or empty, or the Pod is nearing expiration or expired
- In response to an alarm
- If the Pod/cannula has become dislodged
- If you have a blood glucose reading of 250 mg/dL or more and ketones are present
- If you experience unexpected elevated blood glucose levels
- As directed by your healthcare provider
- If during activation the Pod fails to beep

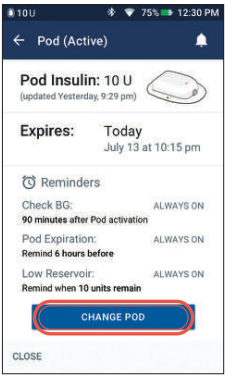
Deactivate an Old Pod



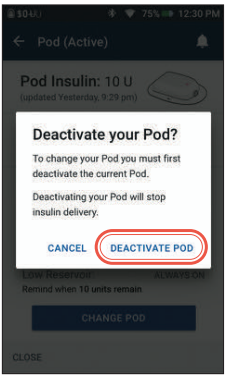
1. Tap **Pod Info** on the Home screen



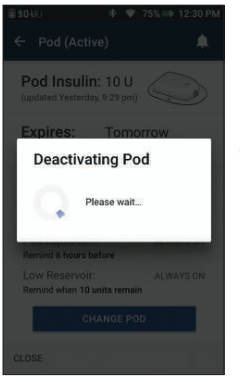
2. Tap **VIEW POD DETAILS**



3. Tap **CHANGE POD**



4. Confirm and tap **DEACTIVATE POD**



5. The Pod will take a moment to deactivate
6. Follow the steps on the preceding pages to activate, fill, apply, and start a new Pod.

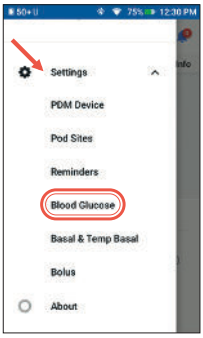
If the Personal Diabetes Manager screen times out during the process, press the Power button to continue.

CONTOUR®NEXT ONE

Blood Glucose Meter Pairing (Optional)

With Omnipod DASH, you can choose the BG meter that works for you (and is covered by your health plan) and enter your BG readings taken from that meter.

If you choose to use the optional CONTOUR® NEXT ONE BG meter that can connect directly to Omnipod DASH, follow these steps to connect your meter and PDM.

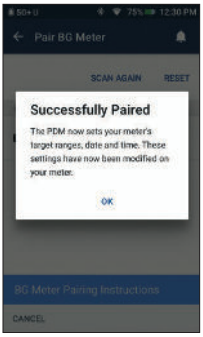


1. Tap Menu icon on the Home screen
2. Under "Settings" tap **Blood Glucose**

3. Tap **Pair BG Meter**

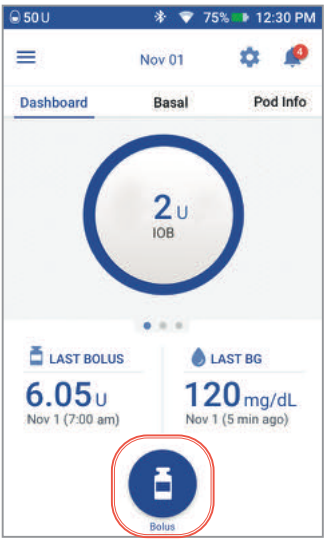
   NOTE Your BG meter must be in pairing mode before tapping **Pair BG Meter**

4. Your PDM will search for available CONTOUR®NEXT ONE BG Meter(s)
   - Select the appropriate meter that matches the serial number on the back of your BG meter
   - Tap **PAIR**
   - If needed tap **BG Meter Pairing Instructions** for additional instructions

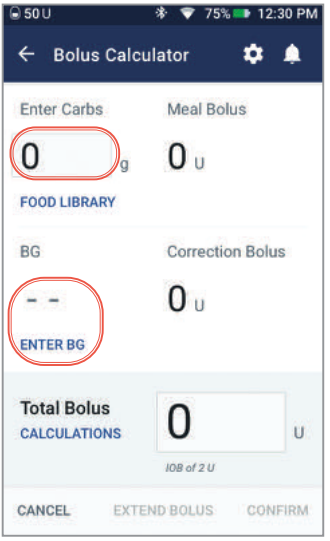


5. Your PDM will indicate it's connecting to the BG Meter
   - Your PDM is now paired with your CONTOUR®NEXT ONE BG meter

Deliver a Bolus

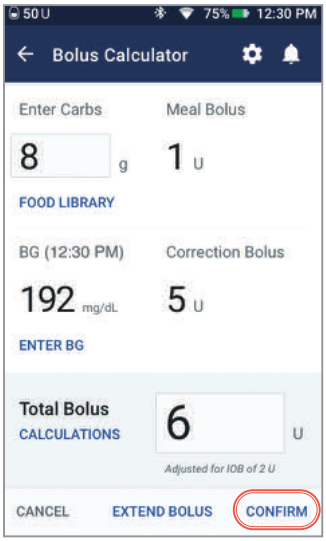


1. Tap the Bolus button on the Home screen

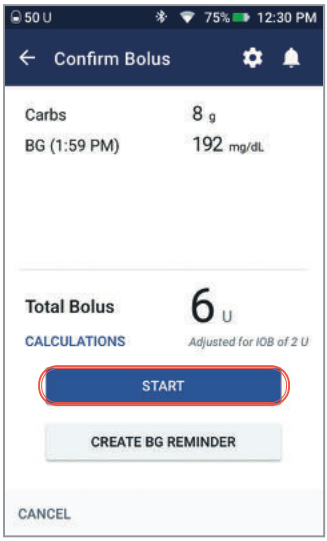


2. Tap the **Enter Carbs** entry box to input grams of carbs. Sync or enter your BG manually by tapping the **ENTER BG** entry box.

Disclaimer: These screens are for demonstration purposes only. The values shown are educational and may not reflect real life scenarios.



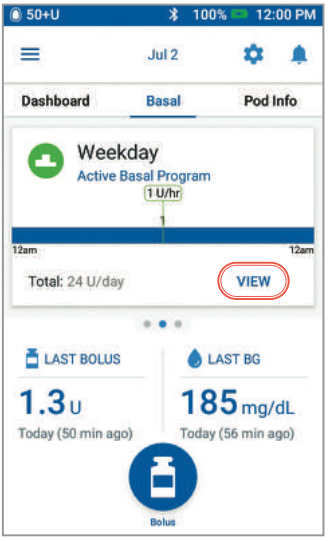
3. Review your values, then tap **CONFIRM**



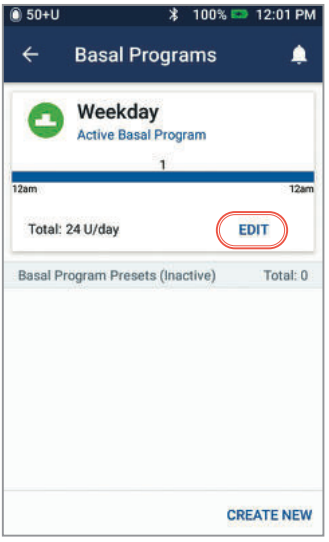
4. Tap **START** to begin bolus delivery

Edit an Active Basal Program

NOTE: You must suspend insulin before editing the active Basal Program.

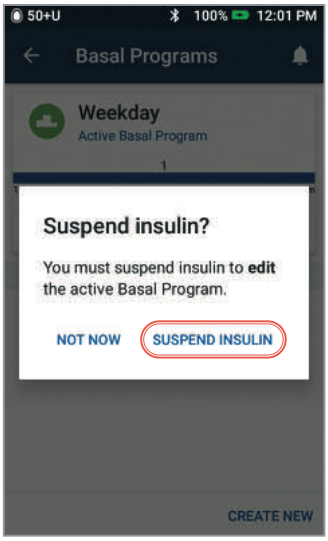


1. Tap Basal tab on the Home screen. Tap **VIEW**

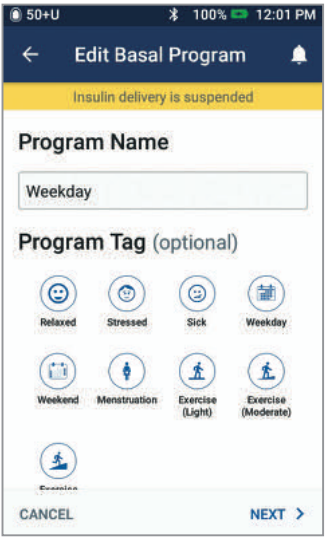


2. Tap **EDIT**

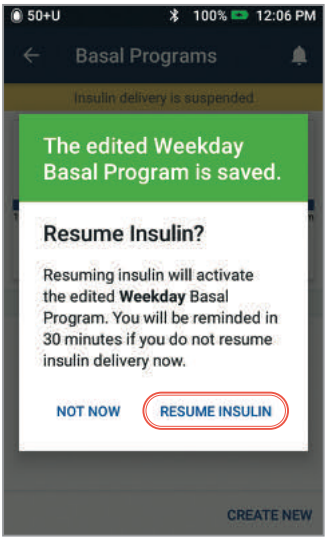
Disclaimer: These screens are for demonstration purposes only. The values shown are educational and may not reflect real life scenarios.



3. Tap **SUSPEND INSULIN**

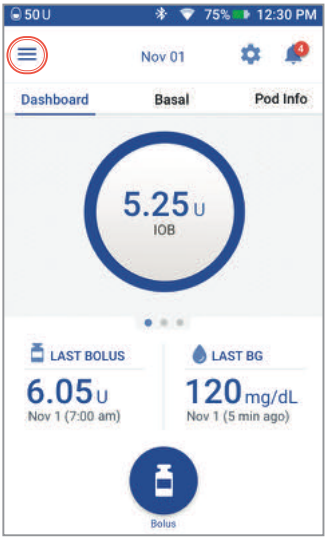


4. Tap to edit program name and tag or tap **NEXT** to edit basal time segments and rates

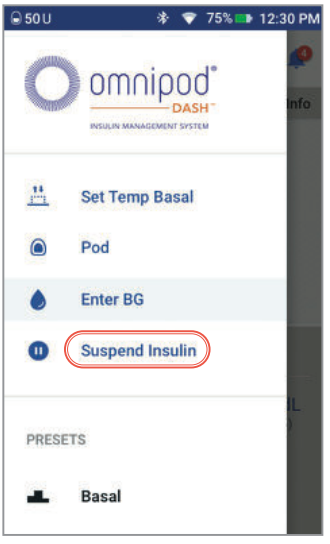


5. Once you are finished editing, tap **RESUME INSULIN**

Suspend Insulin Delivery



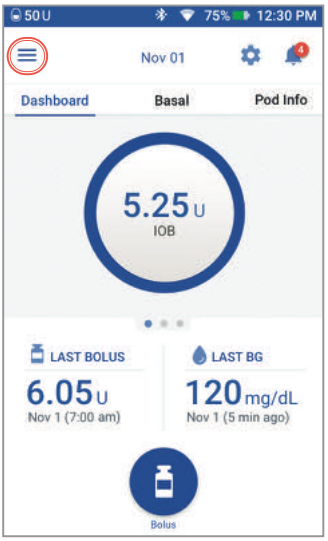
1. Tap Menu icon on the Home screen



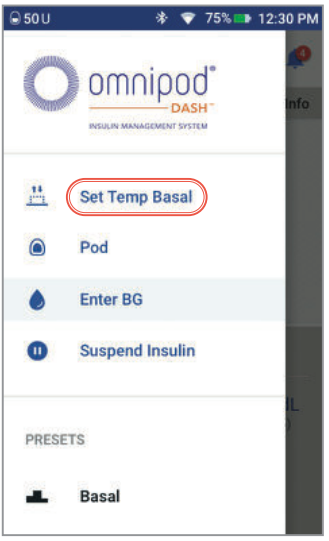
2. Tap **Suspend Insulin** and follow the on-screen instructions

Disclaimer: These screens are for demonstration purposes only. The values shown are educational and may not reflect real life scenarios.

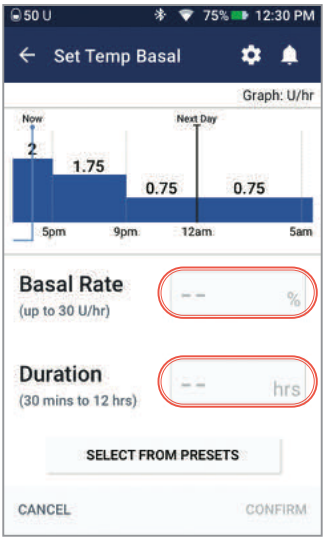
Set a Temporary Basal Rate



1. Tap Menu icon on the Home screen



2. Tap **Set Temp Basal**



3. Tap **Basal Rate** entry box and select your % change. Tap **Duration** entry box and select your time duration. Tap **CONFIRM**.

Advanced Insulin Delivery Features

- **Extended Bolus**
  Allows you to deliver a bolus over a longer period of time. It's most commonly used for high-fat and/or high-protein meals, such as pizza, cheeseburgers, or fried chicken when the digestion of carbohydrates could be delayed
- **Temp Basal Presets**
  Allows you to create a save a frequently used temp basal rate, such as for a weekly exercise class, that you can quickly activate it
- **Additional Basal Programs**
  Allows you to create and save more than one basal program if they have days where your routine changes, such as weekends vs workdays
- **CalorieKing® Food Library***
  Allows you to look up carbohydrate amounts for various foods.
- **Custom Foods**
  Allows you to create and save entries for your favorite food items, snacks, and meals in your Food Library
- **Bolus Presets**
  Allows you to create and save a frequently used bolus amount. It's most commonly used for people who are prescribed a set bolus amount at meals.

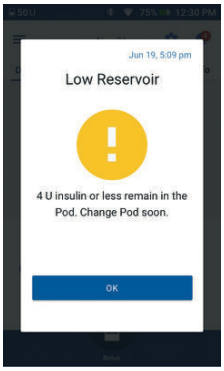
For information on how to set up and use these advanced features, see the full Omnipod DASH System User Guide.

*CalorieKing® Food Library only available in English.

Omnipod DASH Notifications and Alarms

Advisory Alarms

An **advisory alarm** can be adjusted based on your needs. There are several different kinds of advisory alarms on your Omnipod DASH System:



- **Pod expired alarm**
  When your Pod will stop delivering insulin soon, you'll hear 2 sets of beeps every minute for 3 minutes. This pattern will repeat every 15 minutes until you press OK on your PDM.
- **Low reservoir advisory alarm**
  So you can plan ahead to change your Pod and make sure you have enough insulin, your Pod will inform you when your insulin reaches a certain level.
- **Auto-off advisory alarm**
  This advises you if you have had no interaction with your PDM in your chosen timeframe. It informs you that you need to wake up your PDM to avoid having your Pod deactivate due to inactivity.

Advisory alarms beep intermittently to let you know about a condition that requires your attention.

When you hear an advisory alarm, check your PDM. A message will appear describing the alarm and telling you what to do next.

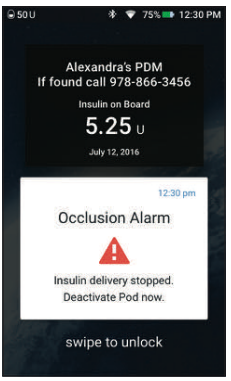
It's important to resolve an advisory alarm as quickly as possible. If you wait too long to address the alarm, it can escalate to a hazard alarm. You can customize your reminders and advisory alarms in settings.

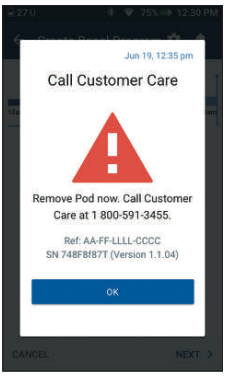
For more information about advisory alarms, see Chapter 10, "Alarms, Notifications, and Communication Errors" in your Omnipod DASH Insulin Management User Guide

WARNING:

- The Low reservoir advisory alarm will escalate to an Empty reservoir hazard alarm when insulin is depleted. Be sure to respond to alert when it first occurs.
- The Auto-off advisory alarm will escalate to a hazard alarm if ignored, and will result in the deactivation of your active Pod. Be sure to respond to the alert when it occurs.

Hazard Alarms





A hazard alarm is a notification to make you aware of serious, or possibly serious, conditions.

Hazard alarms sound a continuous tone to let you know when an issue with the Pod is becoming urgent or something is wrong with the PDM.

When a hazard alarm goes off, all insulin delivery stops and the Pod must be changed. To avoid hyperglycemia, follow the instructions on your PDM to resolve the issue quickly.

Reminders

A **reminder** is a notification you can turn on or off at any time and customize to fit your needs. Your Omnipod DASH System has a number of different reminders:

- **Blood glucose (BG) reminders**
  Your PDM can remind you to check your BG every time you deliver a bolus.
- **Bolus reminders**
  Your PDM can remind you if you haven't delivered a meal bolus within a specific time frame.
- **Program reminders**
  Your Pod will automatically beep to let you know that a temporary basal and/or extended bolus program is in progress.
- **Confidence reminders**
  You can choose to hear a beep so you can know when certain programs have started and finished, including:
  - Bolus delivery
  - Extended bolus
  - Temporary basal
- **Custom reminders**
  Enter text reminders into your PDM to be delivered when you choose.

⚠ **CAUTION**: Consult User Guide.

To learn more about alarms and how to handle them, see Chapter 10, Alarms, Notifications and Communication Errors, in your Omnipod DASH Insulin Management System User Guide.

Hypoglycemia (Low Glucose)

Blood Glucose (BG) < 70 mg/dL or ≤ 80 mg/dL with Symptoms

Hypoglycemia Symptoms

- Shakiness
- Fatigue
- Hunger
- Sweating
- Cold, clammy skin
- Weakness
- Blurred vision
- Headache
- Rapid heartbeat
- Confusion
- Tingling
- Anxiety
- Drowsiness
- Dizziness
- Personality change

If you have symptoms of low glucose, check your blood glucose. Depending on the results, do one of the following:	
If your glucose is less than 50 mg/dL:	**If your glucose is less than 70 mg/dL:**
1. Treat with 30 grams of fast-acting carbohydrate. 2. Wait 15–20 minutes	1. Treat with 15 grams of fast-acting carbohydrate. 2. Wait 15 minutes
Recheck your blood glucose. Depending on the results, do one of the following:	
If your glucose is less than 80 mg/dL:	**If your glucose is greater than 80 mg/dL:**
1. Treat with 30 grams of fast-acting carbohydrate. 2. Wait 15–20 minutes, then recheck your blood glucose. 3. If your glucose remains low after repeated treatments, notify your healthcare provider immediately and/or go to the nearest emergency room.	1. Follow with your next scheduled meal or a snack. Depending on how long you have to wait for that meal or snack, do one of the following: • If your next meal/snack is 30 mins away, take an additional 15 grams of fast-acting carbohydrate. • If your next meal/snack is 60 mins away, take an additional 30 grams of fast-acting carbohydrate. 2. If your glucose remains low after repeated treatments, notify your healthcare provider immediately and/or go to the nearest emergency room.
Important Notes: • Make sure your blood glucose is at least 100mg/dL before driving or working with dangerous machinery or equipment. • Even if you cannot check your blood glucose, do not wait to treat symptoms of hypoglycemia. • If you have hypoglycemia unawareness, check your blood glucose more frequently.	

Action Plan

Never ignore the signs of low blood glucose, no matter how mild. If left untreated, severe hypoglycemia may cause seizures or lead to unconsciousness. If loss of consciousness, inability to swallow glucose treatment or seizures are experienced or observed take the following action immediately:

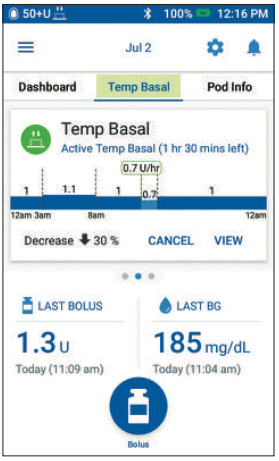
- Give glucagon as instructed by healthcare provider
- Call 911
- Notify healthcare provider
- Suspend insulin delivery

Troubleshooting Frequent Hypoglycemia

Check Personal Diabetes Manager Settings

- Is the correct basal program active?
- Is the PDM time set correctly?
- Is the temp basal (if active) correct?
- Are target blood glucose levels correct?
- Is the insulin correction factor set correctly?
- Is the insulin-to-carb ratio correct?

Consult your healthcare provider for guidance about adjusting settings on your PDM and their suggestions for treating hypoglycemia.



Review Recent Activity

Physical activity

- Has your exercise been unusually long or strenuous?
- Have you been unusually physically active? (e.g., extra walking, housework, heavy or repetitive tasks, lifting or carrying?)
- Did you use a decreased temp basal during this activity?
- Did you consume carbs before, during and/or after activity?

Meals/Snacks

- Did you count the carbs correctly—including subtracting significant fiber?
- Did you bolus with food?
- Did you consume alcohol?

Consult your Omnipod DASH Insulin Management System User Guide for additional information.

CAUTION: Consult User Guide.

The above general guidelines are drawn from Joslin Diabetes Center. For further guidance please consult with your healthcare provider for individualized advice.

Hyperglycemia (High Glucose)

Blood Glucose (BG) Reading ≥ 250 mg/dL

Hyperglycemia Symptoms

- Fatigue
- Blurred vision
- Unusual thirst or hunger
- Unexplained weight loss
- Frequent urination (i.e. at night)
- Slow healing of cuts or sores

If you're experiencing symptoms of high glucose:

1. Verify and check your BG reading.
2. If your BG reading is over 250 mg/dL, check your urine or blood ketone level and refer to the table below for next steps.

If your ketone level is:	**Trace or Negative**	**Small (urine) 0.6–0.9 mmol/L (blood)**	**Moderate to Large (urine) 1.0 or higher mmol/L (blood)**
Insulin	Take a correction bolus with the PDM.	Take a correction bolus with a syringe or pen. Change your Pod.	Take a correction bolus with a syringe or pen. Change your Pod.
BG	Recheck in 2 hours. If BG has lowered, return to normal dosing schedule, and monitor BG.	Recheck in 2 hours. If BG has lowered, return to normal dosing schedule, and monitor BG.	Recheck in 2 hours. If BG has lowered, return to normal dosing schedule, and monitor BG.
Ketones	Recheck ketones if your BG at the 2-hour BG check is unchanged or higher.	Recheck blood ketones in 1 hour or urine ketones in 2 hours.	Recheck blood ketones in 1 hour or urine ketones in 2 hours.
Food and Drink	Usual meal plan with extra water or sugar-free fluids.	Usual meal plan with extra water or sugar-free fluids.	Usual meal plan with extra water or sugar-free fluids.
Additional Steps		If BG and ketones remain high after 2 or more treatments with syringe or pen, contact your healthcare provider.	Contact your healthcare provider.

Troubleshooting Frequent Hyperglycemia

Check Personal Diabetes Manager Settings

Check status screen

- Last bolus: was the bolus too small?
  - Was the bolus timing correct?
  - Did you account for high-protein or high-fat meal?
- Basal program: Is the proper basal program running?
- Temp basal: Do you have a temp basal running that you should have turned off?

Check my Records

- Alarm history: Did you ignore or not hear alarms that should have been addressed?

Action Plan

There are several factors that can cause hyperglycemia. Common causes include illness, stress, infection, and missed insulin doses. Only rapid-acting insulin is used in your Pod, so you have no long-acting insulin in your body. If an occlusion or other interruption of insulin delivery occurs, your blood glucose may rise rapidly. Do not ignore the signs and symptoms of hyperglycemia.

Check Pod

Check your cannula through the viewing window

- Did the cannula slip out from under your skin?
- Is there blood in the cannula?
- Is there redness, drainage, or other signs of infection around the cannula?

If YES, change your Pod. If you suspect an infection, then call your healthcare provider.

Check Your Infusion Site

- Is there redness or swelling around the Pod and adhesive?
- Is insulin leaking from your infusion site or is there odor of insulin?

If YES, change your Pod. If you suspect an infection, then call your healthcare provider.

Check Your Adhesive Dressing

- Is the adhesive dressing coming loose from your skin?
- Is the Pod becoming detached from the adhesive dressing?

If YES, and if cannula is still inserted properly, you may tape down the Pod or adhesive to prevent further detachment.

If cannula is no longer under your skin, change your Pod.

Check Your Insulin

- Is the insulin used expired?
- Has the insulin used been exposed to extreme temperatures?

If YES, change Pod using a new vial of insulin.

Reminder

If you are experiencing persistent nausea and/or vomiting, or have diarrhea over two hours, contact your healthcare provider immediately.

WARNING:
Hyperglycemia symptoms can be confusing. Always check your BG before treating your hyperglycemia. Consult with your healthcare provider.

CAUTION: Consult User Guide.

Sick Day Management

Action Plan

Discuss Sick Day Management with your healthcare provider. The below guidelines are recommendations and may differ from your own healthcare provider's guidelines.

Emergency situations

- For BG of 250 mg/dL or more see: Hyperglycemia Action Plan
- For BG of 70 mg/dL or less (and/or symptoms) see: Hypoglycemia Action Plan

Throughout an illness

If you have a cold, stomach virus, toothache or other minor illness:

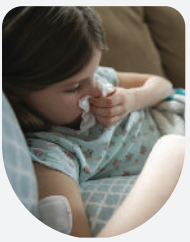
- Check blood glucose more often (every 2-4 hours or at least 4 times a day)
- Check ketones—any time BG is 250 mg/dL or more
- Use temp basal as directed by your healthcare provider
- Stay hydrated
- Monitor urine output
- Keep a record of information (BG, ketone checks, fluids, and time/amount of urine, vomiting, diarrhea, temperature)

Call your healthcare provider immediately if you have:

- Persistent nausea and/or if you are vomiting or have diarrhea over two hours
- Difficulty breathing
- Unusual behavior (such as confusion, slurred speech, double vision, inability to move, jerking movements)
- Persistent high BG and/or positive ketones after treating with extra insulin and drinking fluids
- Persistent low BG that is not responsive to decreasing insulin and drinking carbohydrate-containing fluids
- A fever above 100.5°F
- Moderate to large urine ketones or ≥ 1.0 mmol/L blood ketones

Reminder

The symptoms of DKA (diabetic ketoacidosis) are much like those of the flu. Before assuming you have the flu, check your BG to rule out DKA. Consult your healthcare provider for further information.



The below guidelines are recommendations and may differ from your own healthcare provider's guidelines. For further guidance please consult with your healthcare provider for individualized advice.

Omnipod iPhone Widgets

A remote view of insulin delivery and blood glucose data on a single screen. Set up new Omnipod DISPLAY® and Omnipod VIEW® widgets next to your Dexcom widget for a quick glance of your PDM and CGM data together on your own iPhone.

- Download the **Omnipod DISPLAY** and **Omnipod VIEW** apps to access the Omnipod widgets

Omnipod DISPLAY App

Allows convenient and discreet access to Omnipod DASH System status.

Download on the App Store

Benefits

- "Find My PDM" app feature allows you to quickly locate your PDM**
- Omnipod DASH System notifications and alarms on your iPhone for added discretion
- Invite friends and family to use the Omnipod VIEW app to help you stay informed
- Available Omnipod DISPLAY widget allows access to combined view of Omnipod DASH System and a CGM status

** Omnipod DASH PDM must be within 30 ft.

Omnipod VIEW App

Allows caregivers to remotely view Podder insulin delivery data.

Download on the App Store

Benefits

- Remote therapy status monitoring to help manage diabetes
- Provides Omnipod DASH System notifications to stay informed of the Podder's status
- Ability to monitor up to 12 Podders
- Available Omnipod VIEW widget for access to the Podder's Omnipod DASH System info

*iPhone widgets are mobile application shortcuts that are visible after swiping right from the home screen to the iPhone's Today View. Omnipod DISPLAY and Omnipod VIEW widgets are available for Omnipod DISPLAY, Omnipod VIEW, Dexcom G5 and Dexcom G6. Dexcom System does not have integrated functionality with the Omnipod DASH System. The Omnipod DISPLAY and Omnipod VIEW apps are supported on any iPhone model that runs iOS 11.3 or greater. Tablets and laptop computer(s) are not supported. Android compatibility coming soon.

Insulet Provided Glooko®

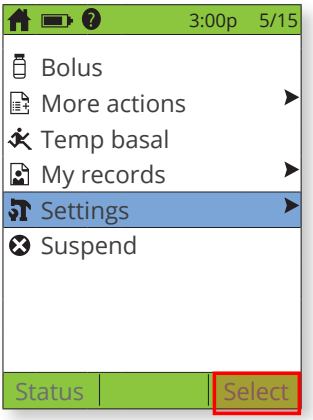
We want to make sure you have all the tools you need to succeed – that's why we provide a free Glooko account to all of our Omnipod users.

Glooko is a diabetes management system that is used by healthcare providers and patients to help track progress over time and identify trends within your data.

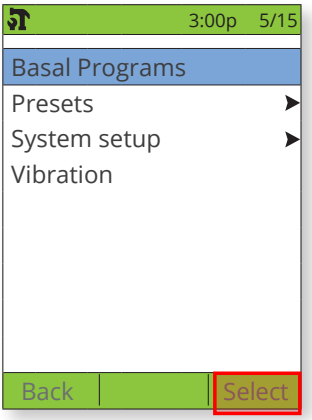
With your Glooko account, you'll be able to upload data from home and share directly with your care team. You can also view your trends and patterns directly from your phone on the Glooko Mobile App.

Find Your Current Omnipod System PDM Settings

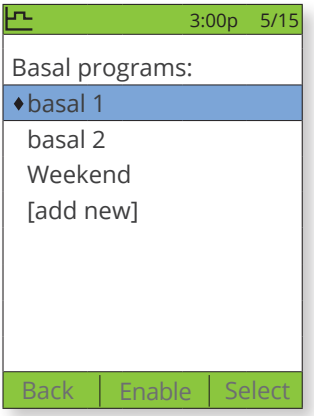
How to Find and Transfer Your Basal Program Settings if Coming from Original Omnipod Insulin Management System



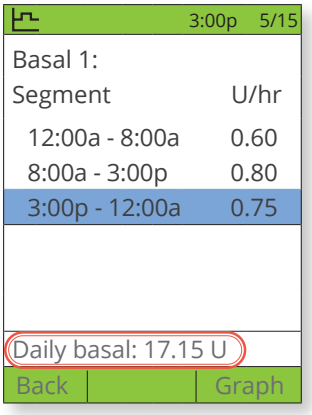
1. On home screen select **Settings**



2. Select **Basal Programs**

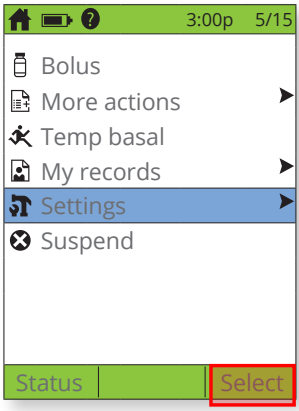


3. Select the basal program to review. On the next screen, select **View.**

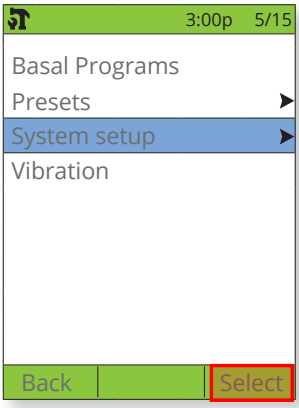


4. You will first see the graph, press **List** to view your basal segments as shown
5. Take note of your Total Daily Basal

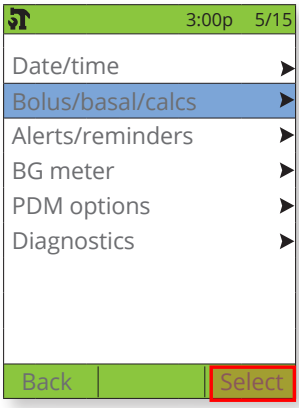
How to Find and Transfer Your Bolus Calculator Settings if Coming from Original Omnipod Insulin Management System



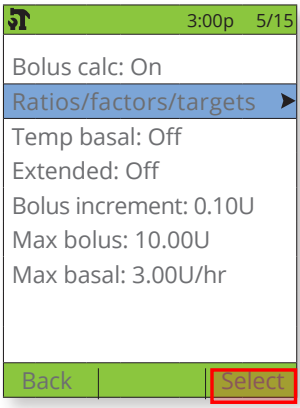
1. On home screen select **Settings**



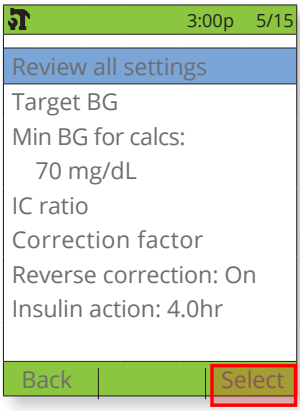
2. Select **System setup**



3. Select **Bolus/basal/calcs**



4. Select **Ratios/factors/ targets.** NOTE: Bolus calcs must be "On."



5. Select **Review all settings**

My PDM Settings

You may use the following worksheet to write down your PDM settings from your current PDM (model UST400).

Maximum Basal Rate	_____U/H		
Basal 1	12am to _____ _____ to _____ _____ to _____ _____ to _____	_____U/hr _____U/hr _____U/hr _____U/hr	Total Daily Basal _____U
Temporary Basal Rate	On	Off	(Select "On" if model UST400 is set to % or U/Hr. "On" is in %)
BG Goal Limits	Lower Limit _____mg/dL	Upper Limit _____mg/dL	Find in model UST400: Settings>System Setup> BG Meter>BG Goal
Suggested Bolus Calculator	On	Off	
Target BG	12am to _____ _____ to _____ _____ to _____ _____ to _____	Target_____ mg/dL Target_____ mg/dL Target_____ mg/dL Target_____ mg/dL	Correct Above_____mg/dL Correct Above_____mg/dL Correct Above_____mg/dL Correct Above_____mg/dL
Min BG – for bolus calculations	_____mg/dL		
Insulin-to-Carbohydrate (IC) Ratio	12am to _____ _____ to _____ _____ to _____ _____ to _____	_____g/carb _____g/carb _____g/carb _____g/carb	
Correction Factor	12am to _____ _____ to _____ _____ to _____ _____ to _____	_____mg/dL (1 unit of insulin decreases BG by) _____mg/dL (1 unit of insulin decreases BG by) _____mg/dL (1 unit of insulin decreases BG by) _____mg/dL (1 unit of insulin decreases BG by)	
Reverse Correction	On	Off	
Duration of Insulin Action	_____hours		
Maximum Bolus	_____U		
Extended Bolus	On	Off	(Select "On" if model UST400 is set to % or U/Hr. "On" is in %)

Summary of Settings and Options

The options for the various Omnipod DASH Insulin Management System settings are:

Time format	12-hour or 24-hour clock.
Time zones	GMT-11:00 to GMT+13.00.
Date format	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9.
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
Temp basal	%, units/hr, or Off. Default is Off. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Temp basal presets	Maximum of 12.
BG Goal Range for blood glucose history	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments.
BG reminder	On or Off. Default is Off. Maximum of 4 active at one time. Reminder can occur between 30 min to 4 hrs after bolus is started. Set in 30-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, Off.
Bolus Calculator	On or Off. Default is On.

Target BG value	Maximum of 8 segments; 70 to 200 mg/dL in 1 mg/dL increments.
Correct Above threshold	Maximum of 8 segments; Target BG to 200 mg/dL in 1 mg/dL increments.
Minimum BG for Calcs	50 to 70 mg/dL in 1 mg/dL increments. Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.
Reverse Correction	On or Off. Default is On.
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Maximum Bolus size	0.05-30 U.
Extended bolus	%, Units, or Off. Default is Off. 30 minutes to 8 hours in 30-minute increments.
Bolus preset	Maximum of 7. Cannot exceed the Maximum Bolus.
MY FOODS list	Maximum of 50 items.
Custom foods	Range: 0-225 g carbohydrates.
Suspend	30 minutes to 2 hours.
Low reservoir volume advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Auto-off timer	Off, or 1 to 24 hours in 1-hour increments. Default is Off.
History screen display	Rolling 90-day period.
Language	English, Spanish. Default is English.

Pod Specifications

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

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

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

The Pod temperature equilibrates from 73°F to 98.6°F (23°C to 37°C) when worn on the body.

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

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

Warm-up time (0°C to 20°C): 7 minutes

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

Reservoir volume (deliverable): 200 units

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

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

Waterproof rating: IP28 (25 feet (7.6 meters) for up to 60 minutes)

Insulin concentration: U-100

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

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

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

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.5 U

Flow Capability:

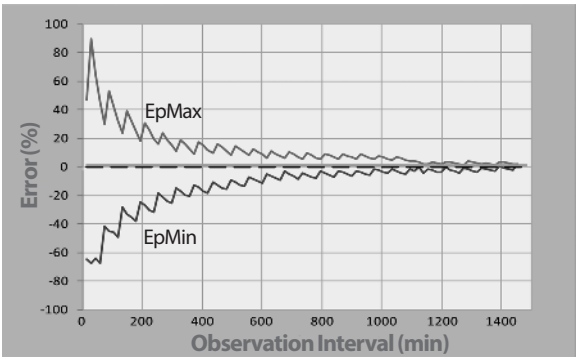
Prime rate: 0.05 unit per second
Basal: Programmable by the user in 0.05U increments up to 30.0 U per hour
Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

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

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

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

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



PDM Specifications

Size: 6.4cm wide x 12.2cm long x 1.0cm high (2.52" x 4.79" x 0.39")

Weight: 3.74 oz (106 grams)

Screen active area: 4.0" diagonal ± 5% (10.2 cm ± 5%)

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

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

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

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

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The PDM and Pod should be

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

Waterproof rating: IP22 when used with outer case (avoid liquid)

Note: The IP22 rating applies ONLY when your PDM is used with the provided outer case (gel skin). The risk of water ingress into the PDM is greater without the outer case. Contact Customer Care about purchasing additional outer cases, if needed.

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

Notification type: Audible and vibratory

PDM Service Life: 5 years

Battery: Rechargeable Li-ion battery, 3.7V, 1300 mAh

Only use the NUU mobile Li-Ion battery Model NUBA1 (Insulet PN 18363) with the PDM.

Battery life: Full charge covers approximately 2 days of typical use after 2 years of typical use

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

Use only the Insulet-provided charger to charge your PDM. Using unapproved chargers can cause the battery to explode or damage the PDM and may void the warranty.

Battery charger service life: 10,000 operating hours

Protection from Over-infusion or Under-infusion

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

Occlusion detection

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

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

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

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

If an occlusion is detected during an immediate bolus, the Pod sounds a hazard alarm at the conclusion of the immediate bolus.

Warning: At very low basal flow rates, checking your blood glucose frequently may give you an early indication of an occlusion. Occlusions can result in hyperglycemia.

Omnipod DASH System Label Symbols

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

Symbol	Meaning	Symbol	Meaning
	Single use only		MR unsafe
	Consult accompanying documents		Do not use if package is damaged
	Sterilized using ethylene oxide		Type BF applied part
	Date of manufacture		Manufacturer
	Batch code		Keep dry
	Use by date		Storage temperature, Operational temperature
	Reference number		Storage relative humidity, Operational relative humidity
	Serial number		Storage atmospheric pressure, Operational atmospheric pressure
IP28	Submersible: Waterproof to 25 feet (7.6 meters) for up to 60 minutes		Non-pyrogenic fluid path
IP22	Avoid liquid	**Rx ONLY**	Prescription only
	Do not dispose with household waste	**RoHS**	RoHS compliant
	Importer		Pod
	Medical Device		UK Conformity Assessed
	Switzerland Authorized Representative		

Staying Safe while Using the Omnipod DASH System

General Warnings

Warning: Do NOT attempt to use the Omnipod DASH System before you receive training. Inadequate training could put your health and safety at risk.

Warning: Read all the instructions provided in this User Guide before using the Omnipod DASH System. Monitor your blood glucose with the guidance of your healthcare provider. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

Warning: Not recommended for individuals with hearing loss. Always verify your ability to hear Pod/PDM alarms and notifications.

Warning: If you are unable to use the Omnipod DASH System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the Omnipod DASH System properly.

Warning: The Omnipod DASH System should NOT be used at low atmospheric pressure (below 700 hPA). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 10,000 feet (3,000 meters).

Warning: The Omnipod DASH System should NOT be used in oxygen rich environments (greater than 25% oxygen) or at high atmospheric pressure (above 1060 hPA), both of which can be found in a hyperbaric chamber. Hyperbaric, or high pressure, chambers are sometimes used to promote healing of diabetic ulcers, or to treat carbon monoxide poisoning, certain bone and tissue infections, and decompression sickness.

Warning: When using the extended bolus function, check your blood glucose levels more frequently to avoid hypoglycemia or hyperglycemia. Warning: Insulin delivery does not automatically resume at the end of the suspension period. You must tap RESUME INSULIN to resume insulin delivery. If you do not resume insulin delivery, you could develop hyperglycemia.

Warning: The Bolus Calculator displays a suggested bolus dose based on the personalized settings you have programmed into the PDM. Check with your healthcare provider before adjusting your Bolus Calculator settings. Giving too much insulin can cause hypoglycemia.

Warning: If you are unable to use the Omnipod DASH System according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have concerns about using the Omnipod DASH System.

Warning: Keep an emergency kit with you at all times to quickly respond to any diabetes emergency.

Warning: The atmospheric pressure in an airplane cabin can change during flight, which may affect the Pod's insulin delivery. Check your blood glucose frequently while flying. If needed, follow your healthcare provider's treatment instructions.

Warning: An occlusion may result from a blockage, Pod malfunction, or from using old or inactive insulin (see "Occlusion detection" on page 192). If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.

Warning: The Pod and PDM may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove and dispose of your Pod and place your PDM outside the treatment area. Check with your healthcare provider on Pod removal guidelines.

Warning: At very low basal flow rates, checking your blood glucose frequently may give you an early indication of an occlusion. Occlusions can result in hyperglycemia.

Insulin Warnings

Warning: Rapid-acting U-100 insulin: The Omnipod DASH System is designed to use rapid-acting U-100 insulin. The following U-100 rapid-acting insulin analogs have been tested and found to be safe for use in the Pod: NovoLog® (insulin aspart), Fiasp® (insulin aspart), Humalog® (insulin lispro), Admelog® (insulin lispro), Lyumjev™ (insulin lispro-aabc), and Apidra® (insulin glulisine). NovoLog, Fiasp, Humalog, and Admelog are compatible with the Omnipod DASH System for use up to 72 hours (3 days). Apidra is compatible with the Omnipod DASH System for use up to 48 hours (2 days).If you have questions about using other insulins, contact your healthcare provider. Fiasp and Lyumjev have a faster initial absorption than other rapid-acting U-100 insulins; always consult with your healthcare provider and refer to the insulin labeling prior to use.

Warning: Because the Pod uses only rapid-acting U-100 insulin, you are at increased risk for developing hyperglycemia if insulin delivery is interrupted. Severe hyperglycemia can quickly lead to diabetic ketoacidosis (DKA). DKA can cause symptoms such as abdominal pain, nausea, vomiting, breathing difficulties, shock, coma, or death. If insulin delivery is interrupted for any reason, you may need to replace the missing insulin. Ask your healthcare provider for instructions for handling interrupted insulin delivery, which may include an injection of rapid-acting insulin.

Warning: NEVER use insulin that is cloudy; it may be old or inactive. Always follow the insulin manufacturer's instructions for use. Failure to use rapid-acting U-100 insulin, or using insulin that has expired or is inactive, could put your health at risk.

Glucose Warnings

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

Warning: Follow the guidance of your healthcare provider for proper blood glucose monitoring.

Warning: Blood glucose readings below 70 mg/dL may indicate hypoglycemia (low blood glucose). Blood glucose readings above 250 mg/dL may indicate hyperglycemia (high blood glucose). Follow your healthcare provider's suggestions for treatment.

Warning: If you get a "Treat your low BG!" message and feel symptoms such as weakness, sweating, nervousness, headache, irritability, or confusion, follow your healthcare provider's recommendation to treat hypoglycemia.

Warning: If you get a "Treat your high BG! If it remains high, seek medical advice" reading message and feel symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your healthcare provider's recommendation to treat hyperglycemia.

Warning: "LO" or "HI" blood glucose readings can indicate potentially serious conditions requiring immediate medical attention. If left untreated, these situations can quickly lead to diabetic ketoacidosis (DKA), shock, coma, or death.

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

Warning: If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

Warning: If left untreated, DKA can cause breathing difficulties, shock, coma, and eventually death.

Pod Warnings

Warning: After use, parts of the device are considered biohazardous and can potentially transmit infectious diseases.

Warning: Do NOT use a Pod if you are sensitive to or have allergies to acrylic adhesives, or have fragile or easily damaged skin.

Warning: The Pod and its accessories, including the needle cap, contain small parts that may be dangerous if swallowed. Be careful to keep these small parts away from young children.

Warning: Do NOT apply a new Pod until you have deactivated and removed the old Pod. A Pod that has not been deactivated properly can continue to deliver insulin as programmed, putting you at risk of over infusion and possible hypoglycemia.

Warning: Do NOT apply or use a Pod if the sterile packaging is open or damaged, or if the Pod has been dropped after removal from the package, as this may increase the risk of infection. Pods are sterile unless the packaging has been opened or damaged.

Warning: Do NOT apply or use a Pod that is damaged in any way. A damaged Pod may not work properly.

Warning: Do NOT use a Pod if it is past the expiration date on the package. To minimize the possibility of site infection, do NOT apply a Pod without first using aseptic technique.

This means to:

- Wash your hands.
- Clean the insulin vial with an alcohol prep swab.
- Clean the infusion site with soap and water or an alcohol prep swab.
- Keep sterile materials away from any possible germs.

Warning: Make sure there are no air bubbles or pockets of air in the fill syringe before filling a Pod with insulin. Air transferred from the fill syringe into the Pod may result in interrupted insulin delivery.

Warning: Before filling a Pod, ensure that no other Pods are being activated within 5 feet (1.5 m) of your PDM.

Warning: NEVER use a Pod if you feel resistance when you depress the plunger. This condition can result in interrupted insulin delivery.

Warning: NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

Warning: Verify that the cannula does not extend beyond the adhesive backing once the Pod's needle cap is removed.

Warning: If you are applying a Pod in a place that does not have a lot of fatty tissue, squeeze the skin around the Pod throughout the next step. Occlusions may result if you do not use this technique for lean areas.

Warning: Check the infusion site after insertion to ensure that the cannula was properly inserted. If the cannula is not properly inserted, hyperglycemia may result.

Warning: Never inject insulin (or anything else) into the fill port while the Pod is on your body. Doing so may result in unintended or interrupted insulin delivery.

Warning: Check often to make sure the Pod and soft cannula are securely attached and in place. A loose or dislodged cannula may interrupt insulin delivery. Verify that there is no wetness or scent of insulin, which may indicate that the cannula has dislodged.

Warning: If an infusion site shows signs of infection:

- Immediately remove the Pod and apply a new Pod at a different infusion site.
- Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

Warning: Store all Omnipod DASH System products and supplies, including unopened Pods, in a cool, dry place. Products or supplies that have been exposed to extreme temperatures may not function properly.

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

Warning: Do NOT expose your Pod to water at depths greater than 25 feet (7.6 meters) or for longer than 60 minutes.

Warning: If you are unable to deactivate a Pod, it continues to pump insulin. Be sure to remove the old Pod before activating a new Pod. Giving too much insulin can cause hypoglycemia.

PDM Warnings

Warning: Always identify the PDM as yours before using it. Using someone else's PDM can result in incorrect insulin delivery for both of you.

Warning: Follow your healthcare provider's instructions for initializing the PDM. Improper setup could put your health and safety at risk.

Warning: If the PDM fails to beep, call Customer Care immediately. If an activated Pod fails to beep, change the Pod immediately. Continuing to use the Omnipod DASH System in these situations may put your health and safety at risk.

Warning: The software update process will take a few minutes. Please refrain from excessive operations during the update and make sure your device is plugged into a power source or has more than a 30% charge before starting the installation process.

Warning: You must use the PDM within 15 minutes of the onset of the Auto-off advisory alarm. If you do not, the PDM and Pod sound a hazard alarm and your Pod stops delivering insulin.

Warning: If your PDM is damaged or not working as expected, call Customer Care for assistance. Be sure to check your blood glucose frequently. Remove your Pod and contact your healthcare provider for treatment guidelines.

Warning: Do not expose your battery to high heat. Do not puncture, crush, or apply pressure to your battery. Failure to follow these instructions could result in an explosion, fire, electric shock, damage to the PDM or battery, or battery leakage.

Warning: Do not incinerate a battery. Dispose of an old battery in accordance with local waste disposal regulations.

Warning: If the battery power becomes critically low, the PDM turns itself off to preserve the data in memory. At this point, you cannot use the PDM until you have plugged in the charger.

Alarm Warnings

Warning: Respond to hazard alarms as soon as possible. Pod hazard alarms indicate that insulin delivery has stopped. Failure to respond to a hazard alarm can result in hyperglycemia.

Warning: If you need to return the PDM for replacement, contact your healthcare provider for instructions about using injections to ensure appropriate insulin delivery.

Warning: Three advisory alarms (Pod Expired, Low Reservoir, and Auto-off) become hazard alarms and result in a stoppage of insulin delivery if ignored. Be sure to respond to all advisory alarms when they occur.

General Precautions

Caution: This Quick Start Guide is intended for use only with Personal Diabetes Manager (PDM) model PDM-USA1-D001-MG-USA1. To learn which version of the PDM you have, turn it over. If you see "PDM-USA1-D001-MG-USA1" on the back of the PDM, this is the correct Quick Start Guide. If you do not see it, call Customer Care.

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

Caution: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the Omnipod DASH System. Otherwise, degradation of the performance of this equipment could result.

Glucose Precautions

Caution: Always measure your blood glucose prior to delivering a bolus.

Pod Precautions

Caution: Be sure to insert the fill syringe into the fill port and not any other location on the Pod. Do not insert the fill syringe more than once into the fill port. Only use the fill syringe and needle that came with your Pod. The fill syringe is intended for single use only and should only be used with the Omnipod DASH System.

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

Caution: Hold the Pod securely and take care while cleaning it, so the cannula does not kink and the Pod does not detach from your skin.

PDM Precautions

Caution: Only press the Power button briefly. If the PDM asks if you would like to "Power off," tap outside the message to cancel the instruction. Once you begin using your PDM, do not turn the power off. The PDM can sound an alarm only when powered on.

Caution: Only use the micro-USB charger that came with the PDM.

Caution: Only use the rechargeable battery that came with your PDM or an Insulet authorized replacement. Contact Customer Care if you have questions.

Caution: Do not turn off the PDM power. The PDM must be ON in order to sound an alarm. If you press the Power button for too long, the PDM will display a menu with a Power Off option. Do NOT tap Power Off. Tap outside the menu to dismiss it and to keep the PDM on.

Caution: Check that you have set the time correctly. The time setting affects the operation of several Omnipod DASH System features and can impact your insulin delivery.

Caution: The upper right corner of the Wi-Fi screen has an Options icon ( ). The options in this Options menu have not been integrated into the Omnipod DASH System. Do not change any of the options found in this Options menu.

Caution: Be careful to set the time correctly. The time setting affects the operation of several Omnipod DASH System features.

Caution: Resetting the PDM resets your IOB to zero; however, the Bolus Calculator is not disabled.

Caution: Be sure to connect to Wi-Fi periodically to check for software updates.

Caution: Do not attempt to install other software or alter the software in any way.

Caution: Do not turn your PDM off or remove its battery during the software installation.

Caution: Be sure your PDM battery level icon is green before removing the battery. Do not turn your PDM off for more than six months at a time.

Caution: Do not store or leave the PDM where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the PDM to malfunction.

Caution: Never use a blow dryer or hot air to dry the PDM. Extreme heat can damage the electronics.

Caution: The PDM is not waterproof. Do NOT place it in or near water.

Caution: Only connect a USB cable to your PDM when charging the battery or transferring data to a computer or another device. Never connect a USB cable to the PDM for any other reason.

Caution: When you connect a USB cable to the PDM, only use a cable that is less than or equal to 4 feet (1.2 meters) in length.

Caution: Do not use solvents to clean your PDM. Do not immerse your PDM in water.

Caution: While cleaning, do NOT allow debris or liquid to get into the USB port, speaker, earphone jack socket, Sound/vibrate button, or Power button.

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

Caution: Only use the rechargeable battery that came with your PDM or an Insulet authorized replacement. Contact Customer Care if you have questions.

Caution: Do not remove the label from the battery.

Caution: Be careful not to damage any of the small metal parts inside the battery compartment.

Caution: Do not select the [Fastboot Mode] because it will stop the PDM from responding. If the PDM stops responding, remove the battery, reinsert it, and restart the PDM to return to normal operation.

Caution: Changes or modifications not expressly approved by Insulet Corporation could void the user's authority to operate the equipment.

Caution: Cables and accessories not specified within the instructions for use are not authorized. Using other cables or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Alarm Precautions

Caution: Be sure to check the alarm function at every Pod change (see "Check alarms" on page 105).

Caution: There is no hazard alarm when the battery completely runs out. Plug in the charger as soon as possible after seeing the low battery message.

Settings Precautions

Caution: Check with your healthcare provider before adjusting Basal, Bolus, and BG Goal Range settings.

Caution: Resetting the PDM deletes your Basal Programs, temp basal presets, bolus presets, and all Bolus Calculator settings. Before using this feature, check with your healthcare provider and be sure you have a written record of your current information so that you can reprogram your PDM. You will also need to activate a new Pod after resetting your PDM.

BG Meter Precautions

Caution: After pairing, the PDM controls the date, time and BG goal/target range on your paired BG meter. To avoid mislabeling of history records, make all changes to date and time on your PDM, not on your BG meter.

Caution: The REMOVE METER option makes the CONTOUR® NEXT ONE BG meter unpairable to any other PDM.

Caution: Do not let anyone else use your BG meter. Even if you unpair your BG meter from your PDM, the BG meter still contains all of your past blood glucose readings.

omnipod® DASH®

Insulet Corporation
100 Nagog Park
Acton, MA 01720
1-800-591-3455 | 1-978-600-7850
omnipod.com

For more information:

Please refer to your Omnipod DASH System User Guide.
Download the Omnipod Mobile Apps.

Download on the App Store