omnipod DASH®

Omnipod DASH® Insulin Management System

User Guide

Welcome to Omnipod DASH®!

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

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.

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 analogues 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) 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 has a faster initial absorption than other rapid-acting U-100 insulins; always consult with your healthcare provider and refer to the insulin labelling prior to use.

PDM Model PDM-INT2-D001-MM

To access the complete *Omnipod DASH System Technical User Guide*

At any time while using Omnipod DASH, you can access or request the ***Omnipod DASH Technical 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:**
   - Call in to request one using the information on your contact card.

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 **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. Your healthcare provider can help you to coordinate and set up appropriate training.

2 **Freedom Is Yours!**

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

What's Different About the Pod? Simple.

The 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 programme your insulin delivery*. Made to be convenient and discreet, the Pod can provide up to three days of continuous insulin delivery** and can be worn almost anywhere you would give yourself an injection. Wear what you want, and do what you want. The Omnipod DASH System helps simplify insulin delivery, so you can live your life and manage diabetes around it.

Preparing to Start on the Omnipod DASH System.

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

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.

HEALTHCARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTHCARE PROVIDERS. THIS USER GUIDE IS FOR INFORMATION PURPOSES ONLY AND NOT INTENDED AS MEDICAL OR HEALTHCARE ADVICE OR RECOMMENDATIONS TO BE USED FOR DIAGNOSIS, TREATMENT OR FOR ANY OTHER INDIVIDUAL NEEDS. THIS USER GUIDE IS NOT A SUBSTITUTE FOR MEDICAL OR HEALTHCARE ADVICE, RECOMMENDATIONS AND/OR SERVICES FROM A QUALIFIED HEALTHCARE PROVIDER. THIS USER GUIDE MAY NOT BE RELIED UPON IN ANY WAY IN CONNECTION WITH YOUR PERSONAL HEALTHCARE, RELATED DECISIONS AND TREATMENT. ALL SUCH DECISIONS AND TREATMENT SHOULD BE DISCUSSED WITH A QUALIFIED HEALTHCARE 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 the tray, to ensure proper communication during priming. At least 1.5 m (5 ft) 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 an alternative way of injecting insulin
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- Ketone testing supplies
- Glucose tablets 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 the *Technical User Guide.*

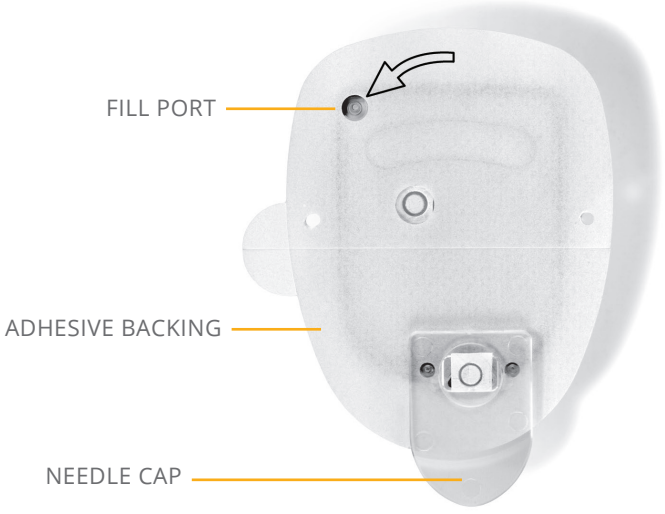
* Only Omnipod DASH System Pods can communicate with the Omnipod DASH System Personal Diabetes Manager

The Omnipod DASH System Pod

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

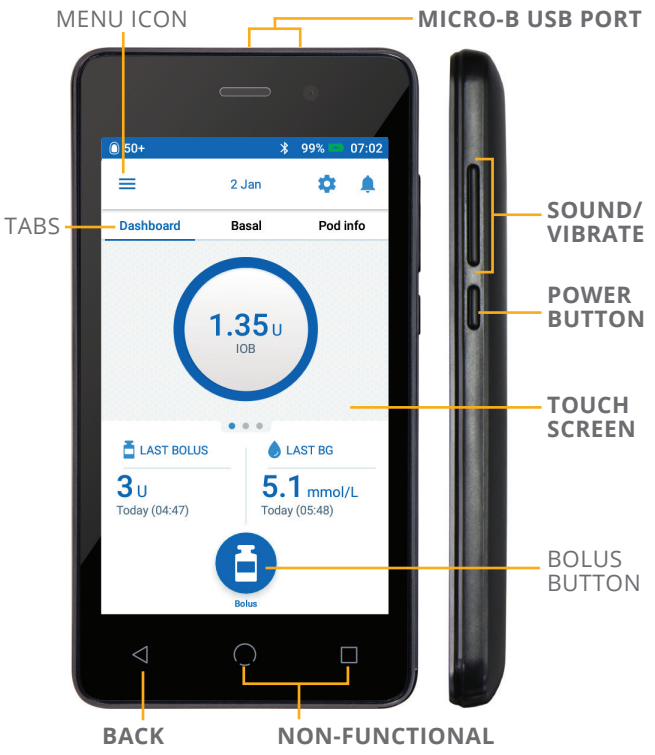
TOP

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 Programmes in the Basal view
- View details of the Pod and access Pod Change in the Pod info view
- Reference LAST BOLUS and LAST BG
- Easy access to deliver a Bolus using the 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
- View History
- Edit Settings

Basal and Bolus Insulin

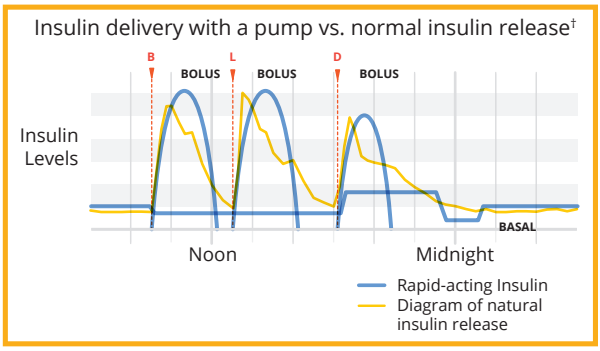
What is a Basal Rate?

Your body needs a small amount of insulin, called basal insulin, delivered constantly throughout the day. 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
- Whether you're ill

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.

The Omnipod DASH System Will Help to Calculate Your Bolus Doses.

The 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 the *Technical User Guide.*

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

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Why Carbohydrates Matter

What are Carbohydrates?

- **Starches:** Starchy vegetables like potatoes, sweetcorn and peas, dried beans and lentils, grains like oats, barley and rice, and items made from wheat flour.
- **Sugars:** Naturally occurring 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.
- **Fibre:** Can be found in fruits, vegetables, whole grains, nuts and legumes. Most dietary fibre is not digestible. Fibre contributes to digestive health, keeps you regular and helps to 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 have a slower effect on 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.

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:

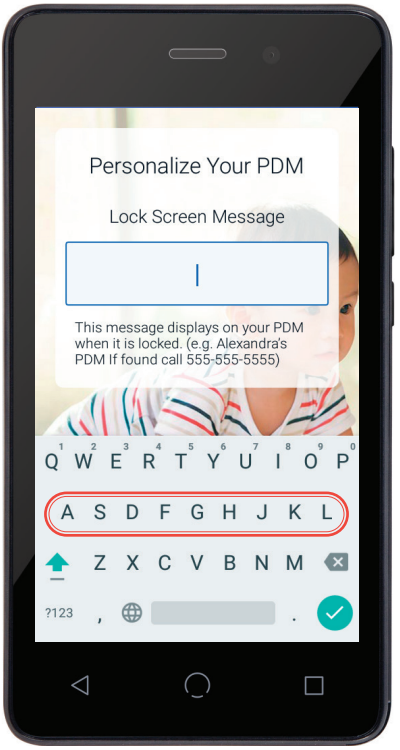
- Your PDM battery is rechargeable. Only use an Insulet-approved battery, charger and cable.
- Adjust screen time-out and brightness levels to conserve battery.
- Your Pod will continue to deliver basal insulin if your PDM powers off. You can use your PDM while it is charging.
- Develop a routine to charge your PDM at the same time every day.

Note: For more details about safe use of the PDM and PDM battery, see "Chapter 11: Taking Care of Your PDM and Pod" in your full *Omnipod DASH System Technical User Guide.*

Omnipod DASH System Initial PDM Set-up

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

- Hold down the Power button to wake up your PDM



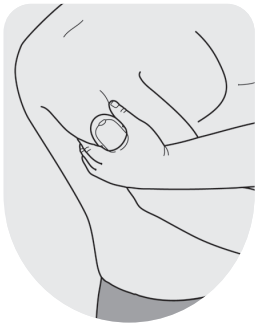
- You will begin by personalising your new PDM
- After personalisation, you will enter your insulin delivery settings
- The PDM guides you step by step. Be sure to read each screen and accurately enter each setting.
- For more information, refer to Chapter 2 “Initial PDM Set-up” in the *Omnipod DASH System Technical 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 2.5 cm (1") away from the previous one, 5 cm (2") 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.

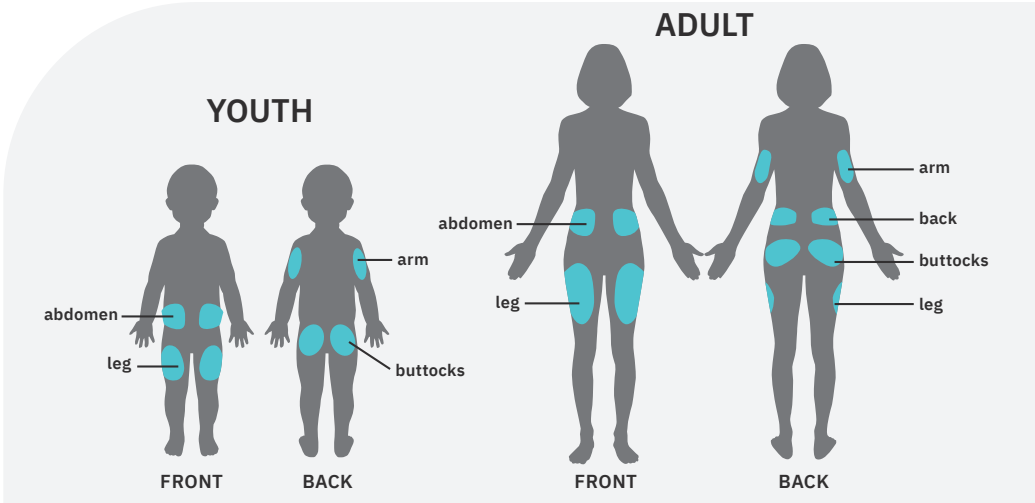


How to Place Your Pod

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.

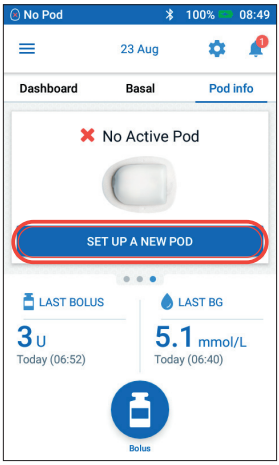
Pinching up
This step is important if your Pod location is very lean or doesn't have much fatty tissue. Place your hand over the Pod and make a wide pinch around your skin surrounding the viewing window. Then press the Start button on the Personal Diabetes Manager. You can let go when the cannula inserts.



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

Activate a New Pod

- Gather 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 Technical 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 carry out 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:
Do not use any other type of needle or filling device besides the fill syringe provided with each Pod.

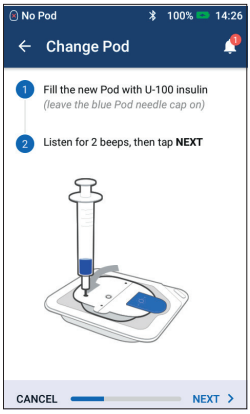
Fill the Pod

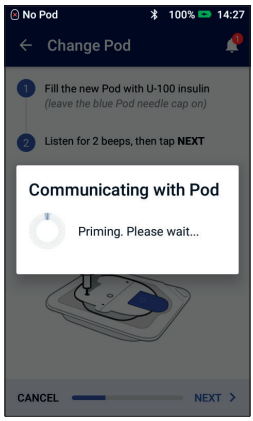
1. Remove the fill syringe and needle from its sterile packaging. Keep the Pod in its tray during set-up.
   - Use the alcohol prep swab to clean the top of the insulin vial
   - Assemble the fill syringe by twisting the needle onto the syringe

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

3. Draw air into the fill syringe equal to the amount of insulin you will use
   - Insert the 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.



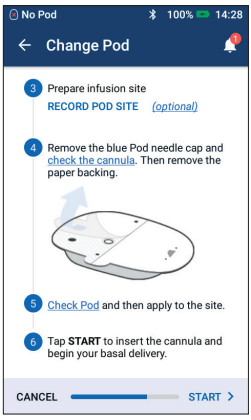


4. Leave the Pod in its plastic tray
   - Insert the needle straight down into the fill port on the underside of the Pod. To ensure proper filling, do not insert the fill syringe at an angle into the fill port.
   - Completely empty the syringe into the Pod
   - The Pod will beep twice, indicating that 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 User Guide for sites and placement tips.



Tip
Use the 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.

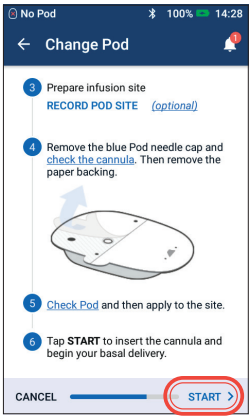
3. Remove the Pod's needle cap

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

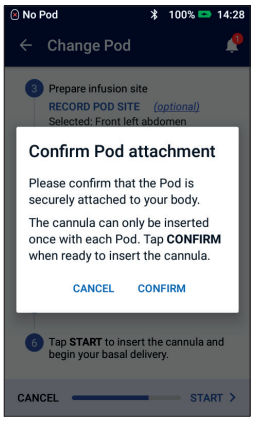
5. Apply the Pod to the selected site
   - Run your finger around the adhesive to secure it

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

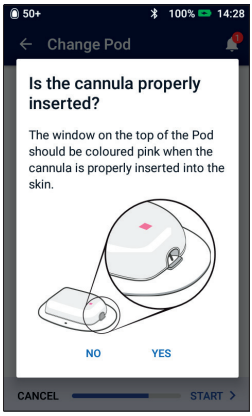
Press Start



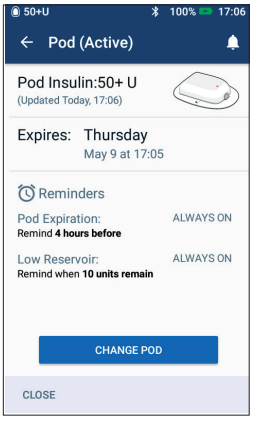
1. Tap **START**



2. Verify that the Pod is securely attached to your body, then tap **CONFIRM**
   - For the best technique, refer to the Pod Placement section of this User 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, hyperglycaemia may occur.
- Verify that there is no wetness or scent of insulin, which may indicate that the cannula has been 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 that the cannula does not extend beyond the adhesive backing once the needle cap has been removed.

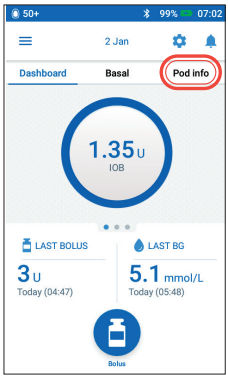
If the Personal Diabetes Manager screen times out during the process, press the Power button to continue.

How to Change the Pod

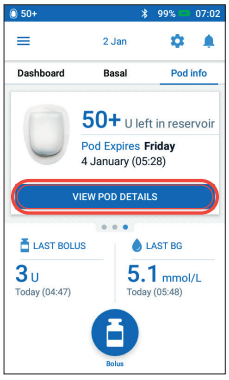
You May Need to Change the Pod:

- When the reservoir is low or empty, or the Pod is nearing expiry or expired
- In response to an alarm
- If the Pod/cannula has become dislodged
- If you have a blood glucose reading of 13.9 mmol/L or more and ketones are present
- If you experience unexpected high blood glucose levels
- As directed by your healthcare provider
- If the Pod fails to beep during activation

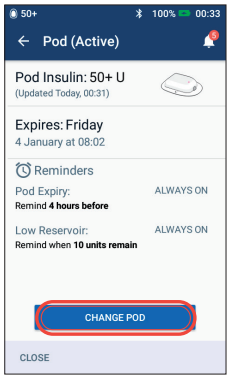
Deactivate an Old Pod



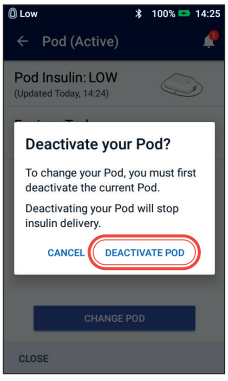
1. Tap **Pod Info** on the Home screen



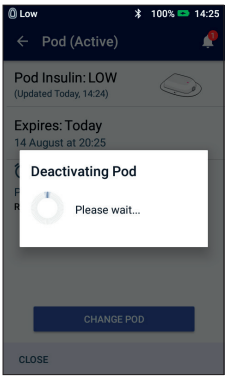
2. Tap **VIEW POD DETAILS**



3. Tap **CHANGE POD**



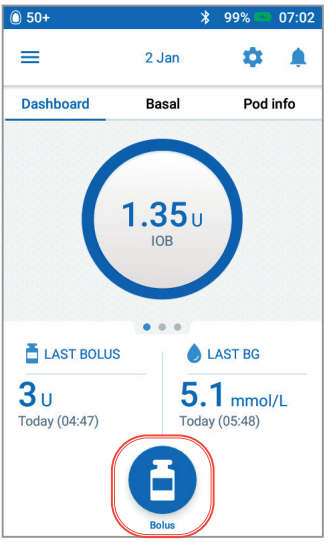
4. Confirm and tap **DEACTIVATE POD**



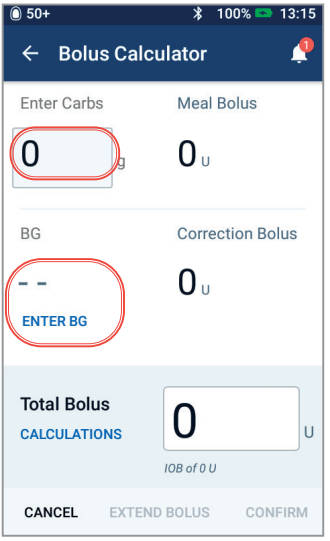
5. The Pod will take a moment to deactivate
6. Follow the steps on the preceding pages to activate, fill, apply and start a new Pod.

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

Deliver a Bolus

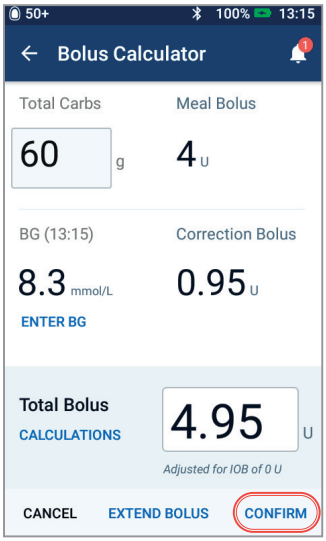


1. Tap the Bolus button on the Home screen

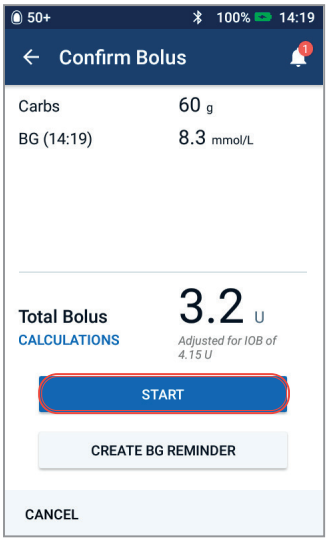


2. Tap the **Enter Carbs** entry box to input grams of carbs. Sync or enter your BG manually by tapping the **ENTER BG** entry box.

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



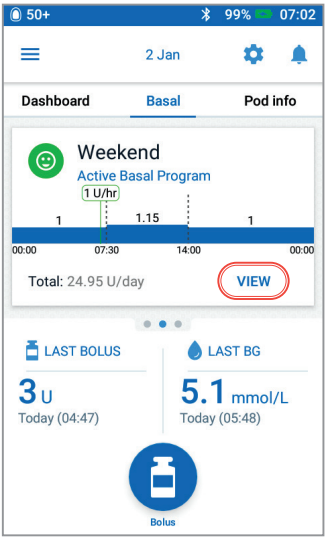
3. Review your values, then tap **CONFIRM**



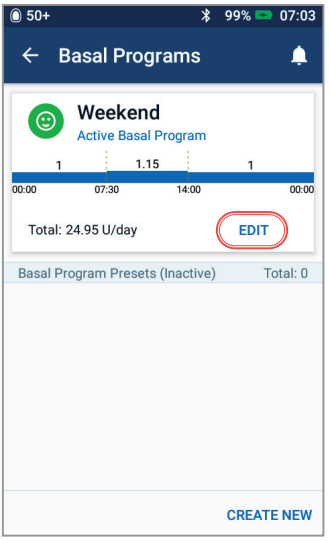
4. Tap **START** to begin bolus delivery

Edit an Active Basal Programme

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

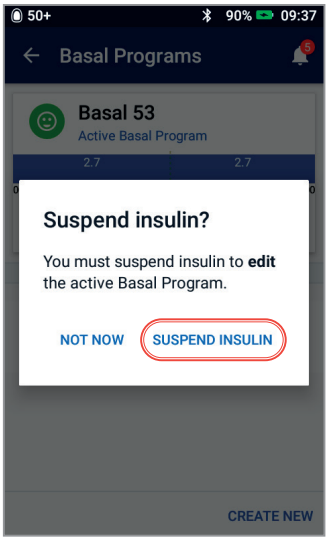


1. Tap the Basal tab on the Home screen. Tap **VIEW**

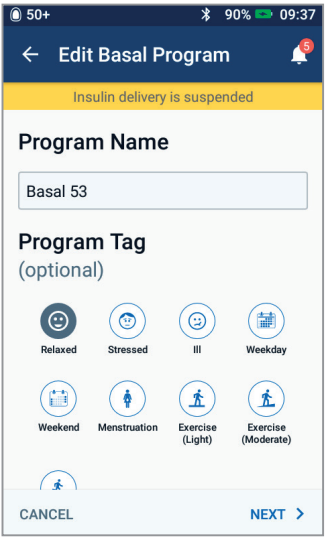


2. Tap **EDIT**

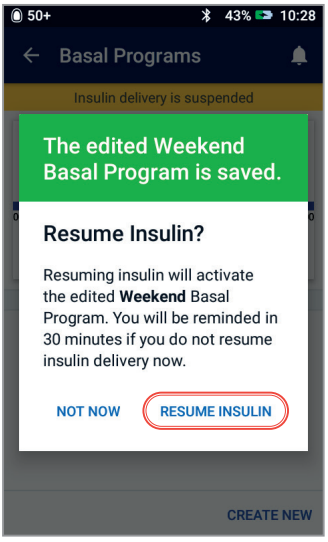
Disclaimer: These screens are for demonstration purposes only. The values shown are educational and may not reflect real-life scenarios.



3. Tap **SUSPEND INSULIN**

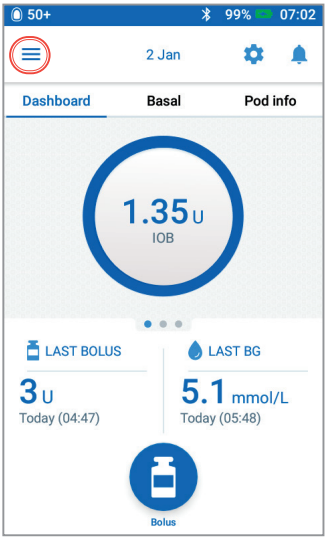


4. Tap to edit the programme name and tag or tap **NEXT** to edit the basal time segments and rates

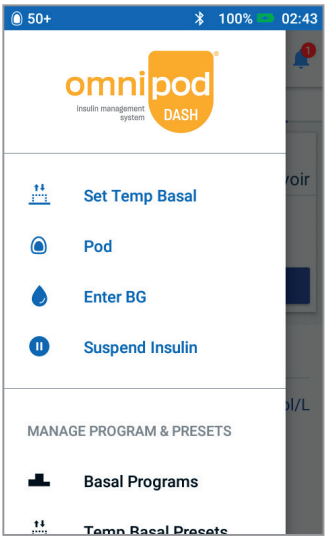


5. Once you are finished editing, tap **RESUME INSULIN**

Suspend Insulin Delivery



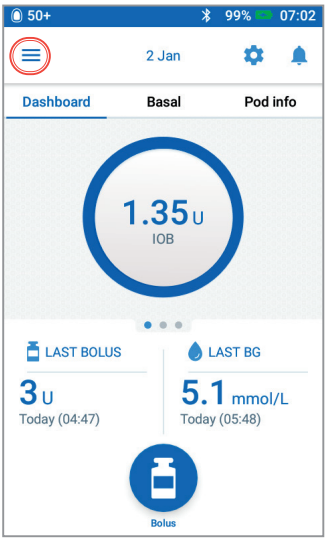
1. Tap the Menu icon on the Home screen



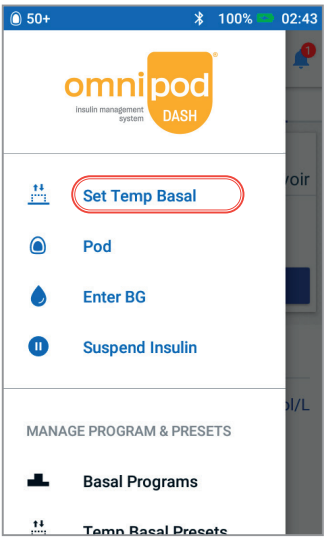
2. Tap **Suspend Insulin** and follow the on-screen instructions

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

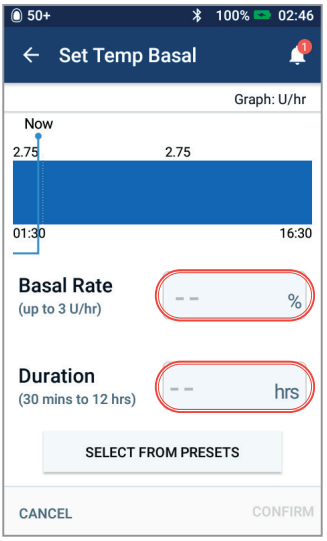
Set a Temporary Basal Rate



1. Tap the Menu icon on the Home screen



2. Tap **Set Temp Basal**



3. Tap the **Basal Rate** entry box and select your % change. Tap the **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 and save a frequently used temp basal rate, such as for a weekly exercise class, that you can quickly activate

- **Additional Basal Programmes**
  Allows you to create and save more than one basal programme if you have days when your routine changes, such as weekends vs workdays

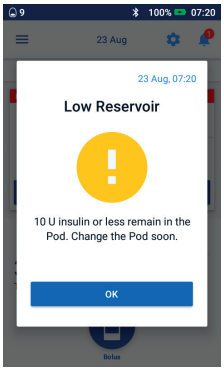
- **Bolus Presets**
  Allows you to create and save a frequently used bolus amount. It's most commonly used for people who are prescribed a set bolus amount at meals.

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

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.

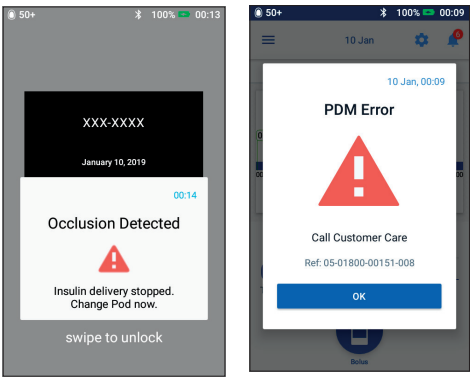
It's important to resolve an advisory alarm as quickly as possible. If you wait too long to address the alarm, it can escalate to a hazard alarm. You can customise your reminders and advisory alarms in settings.

⚠ For more information about advisory alarms, see Chapter 10, "Alarms, Notifications and Communication Errors" in your Omnipod DASH Insulin Management *Technical 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 an 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 conditions that are serious or possibly serious.

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 hyperglycaemia, 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 customise 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.
- **Programme reminders**
  Your Pod will automatically beep to let you know that a temporary basal and/or extended bolus programme is in progress.
- **Confidence reminders**
  You can choose to hear a beep so you can know when certain programmes 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 the *Technical 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 *Technical User Guide*.

Hypoglycaemia (Low Glucose)

Blood Glucose (BG) < 3.9 mmol/L or ≤ 4.4 mmol/L with Symptoms

Hypoglycaemia 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 2.8 mmol/L:	**If your glucose is less than 3.9 mmol/L:**
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 lower than 4.4 mmol/L:	**If your glucose is higher than 4.4 mmol/L:**
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 department.	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 department.
Important Notes: • Make sure your blood glucose is at least 5.6 mmol/L before driving or working with dangerous machinery or equipment. • Even if you cannot check your blood glucose, do not wait to treat symptoms of hypoglycaemia. • If you have hypoglycaemia 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 hypoglycaemia 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:

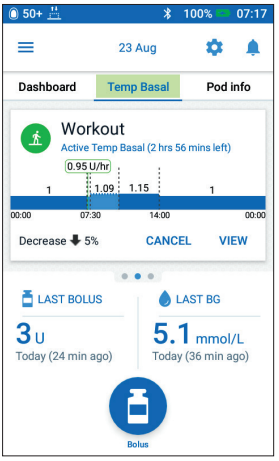
- Give glucagon as instructed by your healthcare provider
- Call the Emergency Services
- Notify your healthcare provider
- Suspend insulin delivery

Troubleshooting Frequent Hypoglycaemia

Check the Personal Diabetes Manager Settings

- Is the correct basal programme active?
- Is the PDM time set correctly?
- Is the temp basal correct (if active)?
- 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 hypoglycaemia.



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 fibre?
- Did you bolus with food?
- Did you consume alcohol?

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

CAUTION: Consult the *Technical User Guide*.

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

Hyperglycaemia (High Glucose)

Blood Glucose (BG) Reading ≥ 13.9 mmol/L

Hyperglycaemia 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 13.9 mmol/L, check your urine or blood ketone level and refer to the table below for what steps to take next.

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 your BG has dropped, return to your normal dosing schedule and monitor BG.	Recheck in 2 hours. If your BG has dropped, return to your normal dosing schedule and monitor BG.	Recheck in 2 hours. If your BG has dropped, return to your normal dosing schedule and monitor BG.
Ketones	Recheck ketones if your BG is unchanged or higher at the 2-hour BG check.	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 a syringe or pen, contact your healthcare provider.	Contact your healthcare provider.

Troubleshooting Frequent Hyperglycaemia

Check the Personal Diabetes Manager Settings

Check status screen

- Last bolus: was the bolus too small?
  - Was the bolus timing correct?
  - Did you account for a high-protein or high-fat meal?
- Basal programme: Is the proper basal programme 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 hyperglycaemia. 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 hyperglycaemia.

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, 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 an odour of insulin?

If YES, change your Pod. If you suspect an infection, 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 the cannula is no longer under your skin, change your Pod.

Check Your Insulin

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

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

Reminder

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

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

CAUTION: Consult the *Technical 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 13.9 mmol/L or more see: Hyperglycaemia Action Plan
- For BG of 3.9 mmol/L or less (and/or symptoms) see: Hypoglycaemia Action Plan

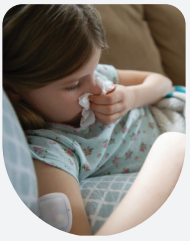
Throughout an illness

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 13.9 mmol/L 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, diarrhoea, temperature)

Call your healthcare provider immediately if you have:

- Persistent nausea and/or if you are vomiting or have diarrhoea for over two hours
- Difficulty breathing
- Unusual behaviour (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 38°C (100.5°F)
- Moderate to large urine ketones or ≥ 1.0 mmol/L blood ketones



Reminder

The symptoms of DKA (diabetic ketoacidosis) are very similar to 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 personalised advice.

My PDM Settings

You may use the following worksheet to write down your PDM settings from your current PDM.

Maximum Basal Rate	_____U/H		
Basal 1	00:00 to _____ _____ to _____ _____ to _____ _____ to _____	_____U/hr _____U/hr _____U/hr _____U/hr	Total Daily Basal _____U
Temporary Basal Rate	On	Off	(Select "On" if set to % or U/Hr. "On" is in %)
BG Goal Limits	Lower Limit _____mmol/L	Upper Limit _____mmol/L	
Suggested Bolus Calculator	On	Off	
Target BG	00:00 to _____ _____ to _____ _____ to _____ _____ to _____	Target_____ mmol/L Target_____ mmol/L Target_____ mmol/L Target_____ mmol/L	Correct Above_____mmol/L Correct Above_____mmol/L Correct Above_____mmol/L Correct Above_____mmol/L
Min BG – for bolus calculations	_____ mmol/L		
Insulin to Carbohydrate (IC) Ratio	00:00 to _____ _____ to _____ _____ to _____ _____ to _____	_____g/carb _____g/carb _____g/carb _____g/carb	
Correction Factor	00:00 to _____ _____ to _____ _____ to _____ _____ to _____	_____mmol/L (1 unit of insulin decreases BG by) _____mmol/L (1 unit of insulin decreases BG by) _____mmol/L (1 unit of insulin decreases BG by) _____mmol/L (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 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 to 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 Programmes	Maximum of 12.
Basal rate segments	24 per Basal Programme.
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 the Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Temp basal presets	Maximum of 12.
BG Goal Range for blood glucose history	Lower and upper limits: 3.9 to 11.1 mmol/L in 0.1 mmol/L 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, Once only, Off.
Bolus Calculator	On or Off. Default is On.
Target BG value	Maximum of 8 segments; 3.9 to 11.1 mmol/L in 0.1 mmol/L increments.
Correct Above threshold	Maximum of 8 segments; Target BG to 3.9 to 11.1 mmol/L in 0.1 mmol/L increments.

Minimum BG for Calcs	2.8 to 3.9 mmol/L in 0.1 mmol/L increments. Default is 3.9 mmol/L.
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; 0.1 to 22.2 mmol/L in 0.1 mmol/L increments. Default is 2.8 mmol/L.
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 to 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.
Suspend	30 minutes to 2 hours.
Low reservoir volume advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiry 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	Multiple languages.

Pod Specifications

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

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

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

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

Start-up temperature: Above 10°C (50°F)

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

Warm-up time (0°C to 20°C): 7 minutes

Cool-down time: No time is required for cool-down from maximum storage temperature (30°C) to operating temperature.

Reservoir volume (deliverable): 200 units

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

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

Waterproof rating: IP28 (7.6 m (25 ft) for up to 60 minutes)

Insulin concentration: U-100

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

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

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

Operating atmospheric pressure: 700 hPA to 1,060 hPA

Storage atmospheric pressure: 700 hPA to 1,060 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:

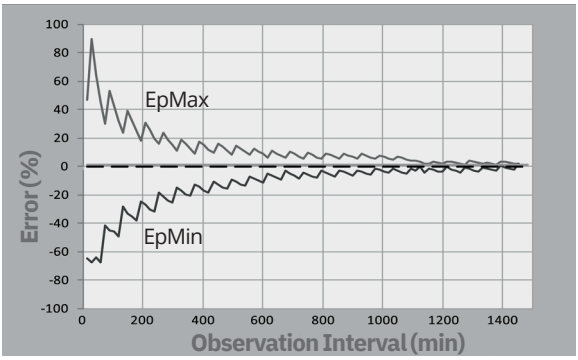
Prime rate: 0.05 units per second
Basal: Programmable by the user in 0.05 U increments up to 30.0 U per hour
Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

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

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

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

Weight: 106 grams (3.74 oz)

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

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

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

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

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

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

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

Operating atmospheric pressure: 700 hPA to 1,060 hPA

Storage atmospheric pressure: 700 hPA to 1,060 hPA

Communication distance: The PDM and Pod should be

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

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

Note: The IP22 rating applies ONLY when your PDM is used with the outer case (gel skin) provided. 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 m

Notification type: Audible and vibratory

PDM service life: 5 years

Battery: Rechargeable Li-ion battery, 3.7 V, 1,300 mAh

Use ONLY the rechargeable battery that came with your 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 expiry)

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 hyperglycaemia.

Omnipod DASH System Label Symbols

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

Symbol	Meaning
	Single use only
	Consult the accompanying documents
STERILE EO	Sterilised using ethylene oxide
	Date of manufacture
LOT	Batch code
	Use-by date
REF	Reference number
SN	Serial number
IP28	Submersible: Waterproof to 7.6 m (25 ft) for up to 60 minutes
IP22	Avoid liquid
	Do not dispose of with household waste
	DASH® PDM

Symbol	Meaning
	MR unsafe
	Do not use if the package is damaged
	Type BF applied part
	Manufacturer
	Keep dry
	Storage temperature, Operational temperature
	Storage relative humidity, Operational relative humidity
	Storage atmospheric pressure, Operational atmospheric pressure
	Non-pyrogenic fluid path
EC REP	Authorised Representative in the European Community
RoHS	RoHS-compliant
CE	Marking of conformity

	Omnipod® carry case
	User Guide/ Technical User Guide
	Charging cable
	PDM battery
	Medical device
	UK Conformity Assessed
	Australian Regulatory Compliance Mark

	PDM skin
	Pod
	Charging adapter
	Importer
	Switzerland Authorised Representative
	Product is intended for recycling and should not be placed in the normal bin

Medical Device Directive

This device complies with Medical Device Directive 93/42/EEC.

EU General Data Protection Regulation (GDPR)

Insulet complies with the EU 2016/679 General Data Protection Regulation.

EU Authorised Representative details

Contact Person: The Complaints Officer

Address: Insulet Netherlands B.V., WTC Utrecht Stadsplateau 7, Suite 7.06,
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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 hyperglycaemia or hypoglycaemia can develop 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 the 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 3,000 m (10,000 ft).

Warning: The Omnipod DASH System should NOT be used in oxygen-rich environments (greater than 25% oxygen) or at high atmospheric pressure (above 1,060 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 hypoglycaemia or hyperglycaemia.

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 hyperglycaemia.

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

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

Warning: The atmospheric pressure in an aeroplane 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.
If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycaemia 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 hyperglycaemia.

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 analogues 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) 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 has a faster initial absorption than other rapid-acting U-100 insulins; always consult with your healthcare provider and refer to the insulin labelling prior to use.

Warning: Because the Pod uses only rapid-acting U-100 insulin, you are at increased risk for developing hyperglycaemia if insulin delivery is interrupted. Severe hyperglycaemia 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 3.9 mmol/L may indicate hypoglycaemia (low blood glucose). Blood glucose readings above 13.9 mmol/L may indicate hyperglycaemia (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 hypoglycaemia.

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 hyperglycaemia.

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 department 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 hypoglycaemia.

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 expiry date on the package. To minimise the possibility of site infection, do NOT apply a Pod without first using the 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 1.5 m (5 ft) 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 has been 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 develop 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, hyperglycaemia may occur.

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 become 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 7.6 m (25 ft) 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 hypoglycaemia.

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 initialising the PDM. Improper set-up could put your health and safety at risk.

Warning: If the PDM fails to beep, contact 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: 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, contact 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 or the back of the PDM. If you see that the back of the PDM is curved or will not stay in place, contact Customer Care. 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: Do not remove the battery from the PDM after first-time insertion of the battery. If you see any battery performance issues, contact Customer Care.

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 hyperglycaemia.

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 User Guide is intended for use only with Personal Diabetes Manager (PDM) model PDM-INT2-D001-MM. To learn which version of the PDM you have, turn it over. If you see "PDM-INT2-D001-MM" on the back of the PDM, this is the correct User Guide. If you do not see it, contact Customer Care.

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

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

Caution: Only use the rechargeable battery that came with your PDM. 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: 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: Do not attempt to install other software or alter the software in any way.

Caution: Do not turn your PDM off for more than six months at a time.

Caution: Do not store, charge 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. See the PDM Specifications for appropriate operating, charging and storage temperature ranges. For specific operating temperatures, see the PDM Specifications in these Instructions for Use.

Caution: Never use a hair 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 1.2 m (4 ft) 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: 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, contact Customer Care.

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 authorised. 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.

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 Programmes, 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 reprogramme your PDM. You will also need to activate a new Pod after resetting your PDM.

Device Complaints

If a serious incident has occurred during the use of this device or as a result of its use, please report it to the manufacturer and/or its authorised representative and to your national authority.

Contact details for the manufacturer can be found on the back cover of this document. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/health/md_sector/contact_en

If you have a problem with your System, contact Customer Care using the information on the Contact Card provided.

omnipod® DASH

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For more information:

Please refer to your *Omnipod DASH System Technical User Guide*.

MD UK CA 0086 CE 2797

PT-001390

Reference number: PDM-INT2-D001-MM PT-001390-AW Rev. 02 01/24