

SIMPLE, NON-STOP INSULIN DELIVERY FOR PEOPLE WITH DIABETES WHO INSIST LIFE STILL COMES FIRST.







PODDERTM RESOURCE GUIDE

Omnipod[®] Insulin Management System





WELCOME

Dear Podder™,

Welcome to your new Omnipod® Insulin Management System. We are delighted to have you on board.

What's different about the Omnipod[®] System? Simple. Most insulin pumps have tubes. The Omnipod[®] System, however, is tubeless. But that's just a part of what makes the Omnipod[®] System different and makes people become dedicated Podders[™].

The Omnipod[®] System is a simple system consisting of just 2 primary parts – the tubeless Pod and the handheld Personal Diabetes Manager (PDM) – that you keep nearby to programme your insulin delivery wirelessly*.

Made to be convenient and discreet, the Pod can provide up to 3 days of non-stop insulin delivery**. It can be worn anywhere you would inject and it's waterproof***, meaning you can shower and swim as you please, wear what you want, and do what you want. The Omnipod[®] System helps simplify insulin delivery, so that you can live your life and manage diabetes around it.

Please take time to read through this Podder[™] resource guide and take it with you to your Omnipod[®] System training session, where your healthcare professional will assist you with the initial set up of your Omnipod[®] System.

It contains step-by-step instructions to help you activate, place and change Pods, guide you through the key functions and explore the advanced features on your PDM. There are also troubleshooting sections and tips and reminders to help you get the most out of your Omnipod[®] System.

If you need help or have further questions, you can contact your local Insulet Customer Care Team 24/7, or visit us at myomnipod.com.

Yours sincerely,

The Insulet Team



PDM

The Pod

*At start up, the PDM and Pod should be adjacent and touching, either in or out of tray to ensure proper communication during priming. At least 1.5 metres during normal operation. **Up to 72 hours of continuous insulin delivery. ***IPX8: 7.6 metres for up to 60 minutes for the Pod. The PDM is not waterproof.

This resource guide will help you learn more about the Omnipod[®] System and how to use it, but if you have any questions about the Omnipod[®] System, please ask your healthcare professional. This resource guide is not intended to provide you with medical advice about your condition or treatment. Your healthcare professional should provide you with medical advice about your condition and treatment. You must always ask your healthcare professional to decide the Omnipod[®] System setting which is the most suitable for you.

This Resource Guide is for PDM models ATT400, DET400, DET450, DET456, ENT450, FRT400, FRT456, ITT456 and NLT450, The PDM model number is written on

THE POD

A small, lightweight and tubeless Pod that's easy to apply and wear.



BASAL INSULIN DELIVERY

What is a basal rate?

Your body needs a small amount of insulin that's constantly delivered throughout the day, which is called basal insulin. The exact amount of insulin your body needs changes often depending on the following:

- + The things you're doing throughout the day
- + The amount of stress you have
- + Your meal timings
- + Whether you're ill



The Omnipod[®] System lets you personalise your basal rates.

When you first set up your Omnipod[®] System, your healthcare professional will assist you in programming your PDM to deliver your required basal rates. If you need to adjust your settings, you have up to 24 time intervals per basal programme. You can have up to 7 basal programmes*.

DELIVERING BOLUS INSULIN DOSES

What is a bolus dose?

A bolus is an extra dose of insulin, delivered when needed 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[®] System, you can deliver either a **normal** or an **extended** meal bolus.

- A normal meal bolus usually delivers enough 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 them 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[®] System will help to deliver your bolus doses.

Your healthcare professional will assist you in programming your PDM to deliver predetermined bolus doses when you first set up your Omnipod[®] System. As your insulin needs change, you can later adjust these settings.

Calculate bolus insulin doses.

The Omnipod[®] System also features a **Suggested Bolus Calculator**. It helps 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.

ACTIVATE A NEW POD

- + Assemble the following supplies:
 - Vial of insulin at room temperature (U-100, rapid-acting). See the Omnipod[®] Insulin Management System User Guide for the insulins that are recommended for use with the Omnipod[®] System
 - One sealed Pod
 - PDM
 - Alcohol prep swab
- + Wash your hands.



1. Fill the Pod



- 1.1 + Remove the Pod from its sterile packaging.
 - + Use the alcohol prep swab to clean the top of the insulin vial.
 - + Assemble the fill syringe by twisting the needle onto the syringe.



1.2 + Remove the protective cap.



- **1.3** + Draw air into the fill syringe equal to the amount of insulin indicated in your Diabetes Management Plan.
 - + Depress air into the vial of insulin.
 - + Turn the vial and syringe upside down.
 - + Withdraw insulin from the vial and fill the syringe with the amount of insulin determined by your healthcare professional; fill it at least to the MIN line.
 - + Remove any air bubbles from the syringe.

CAUTION:

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



2.4 + Remove and discard the white paper backing from the adhesive.



- **2.5** + Apply the Pod to the selected site.
 - + Secure the adhesive using your fingers.
 - + Press Next on the PDM.
 - + To facilitate insertion, place one hand over the Pod and make a wide pinch around the skin surrounding the viewing window; this step is critical if the insertion site does not have much fatty tissue.

3. Press Start



WARNING:

+ The PDM 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 result. Verify there is no wetness or odour of insulin, which may indicate the cannula has dislodged.

Hypergroup and a standard and a stand

FEEL COMFORTABLE AND CONFIDENT

Prepping for your Pod.

Remember to stay cool and be cool (dry and not sweating) when it's time to change your Pod. Here are more potential sticking points:

Trouble with	Problem	Solutions
Oily skin	Residue from soap, lotion, shampoo or conditioner can prevent your Pod from staying secure.	Clean the area thoroughly with alcohol before applying your Pod – and be sure to let your skin air-dry.
Damp skin	Dampness gets in the way of adhesive.	Towel off and allow your skin to air-dry; do not blow on it.
Body hair	A lot of hair will prevent the Pod from sticking securely.	Clip or shave the area with a razor to create a smooth surface for your Pod to stick to. Do this 24 hours before putting on your Pod to prevent irritation.





ADDITIONAL NOTES

Prepare your lancing device in 3 easy steps.

- 1. Snap off the cap of the lancing device at an angle, and insert a new lancet firmly into the white holder cup. This action may cock the device, which is fine.
- 2. With one hand, hold the lancet in place while twisting the rounded top with your other hand. Then, replace the cap until it snaps back into place. Make sure you do not touch the exposed needle.
- **3.** Adjust the depth setting; the lancing device offers 9 different settings (including half settings). Level 1 is the shallowest depth and Level 5 is the deepest. Use a lower number to lance. Pull back the the grey slider until it clicks. (You may have already cocked the device in step 1)













You're now ready to test!

Lancing device depicted is representative only. Please follow the instructions included with your specific lancing device.

Testing your blood glucose level.

- 1. Insert your FreeStyle test strip and set the code*
 - a. Insert a new test strip into the test strip port at the bottom of the PDM until it stops. Make sure you insert only the top end of the strip.
 - To help you see the test strip port in reduced lighting, press the middle soft key labelled Light. To turn the light off, press Light again.
 - b. The PDM will display a code number once you insert the strip. This code must match the code on the side of the test strip vial to ensure test accuracy. To change this code, just press the Up/Down controller to change the numbers until they match.





<u>∕∱</u> WARNING:

The code number on the screen must match the code number on the side of your test strip vial. They must always match or your results will be inaccurate.

*From some PDM screens, you cannot access the FreeStyle blood glucose meter. For example, you cannot use the meter while you are activating a Pod or when an alert, alarm or communication error screen is displayed. In these cases, if you insert a test strip, the PDM beeps to alert you. If you do not start the test within 2 minutes, the PDM powers off. To restart the PDM, take out the unused strip and reinsert it, or simply press and hold the **Power** button to turn on the PDM. If you need to adjust the code number after the PDM has moved to the next screen, just press **Up/Down Controller** buttons. The code screen reappears and you can adjust the number. The code number remains on the PDM screen for your reference until you have completed the BG test.

DELIVERING A BOLUS



 Wash the finger with soap and water or an alcohol wipe and dry it completely. Prick the finger with the lancing device. Press Light to illuminate the test strip in low-light situations. Apply the blood sample to the test strip.



2. When the blood glucose reading appears, press **Next** to continue.



- 3. If you are going to eat now, press Yes. OR
 - If you are not going to eat now, press No.



 If you are eating, press the Up/Down controller button to enter the correct number of carbs and then, press Enter.



7. Press Confirm to start the bolus.



 Press the User info/support button to view how the suggested bolus is calculated. Then, press Close.



8. The PDM screen will indicate when the bolus delivery has begun. If necessary, you may press **Cancel** to stop a bolus while it is being delivered. You do not need to remain near the PDM during delivery. The delivery time varies based on the size of the bolus dose. Once the bolus delivery begins, you may press and hold the **Home/Power** button to turn off the PDM screen.



6. Press Enter to accept the suggested bolus. OR

Press **Extend** and follow the on-screen instructions to deliver a portion/percentage of the bolus immediately and the rest over a set period of time. *Only use the* **Extend** *option when directed by your healthcare provider.* If extended boluses are not part of your Diabetes Management Plan, the **Extend** option will not appear on the screen.

Important PDM tips and reminders.

These tips are intended for use only with PDM models ATT400, DET400, DET450, DET456, ENT450, FRT400, FRT456, ITT456 and NLT450. The PDM model number is found on the back of the PDM next to the REF symbol.

How to view insulin records.





1. On the home screen, select My records.

2. Select Insulin delivery.



3. The PDM provides a summary of today's information including total boluses, total basal and total daily doses. Use the Up/Down controller buttons to view the summary for previous.

Important reminder



During the activation and priming of the Pod, the PDM and the Pod should be adjacent and in contact. Please refer to the Omnipod® Insulin Management System User Guide for a full set of instructions.

How to view multiple-day BG trends.





- 1. On the home screen, select My records.
- 2. Select BG history.



3. Press Trends to show the BG data for the past 7 days.



4. Continue pressing the middle soft key to show the trends for previous 14, 30, 60 and 90 days.

15:00

How to change existing basal rate.

NOTE: Insulin delivery must be suspended before changing basal rates.



1. On the home screen, select Settings.



5. Enter the basal rate for the edited segment and then, press Enter.



2. Select Basal Programs.



6. Press Save.



3. Select the basal programme to be edited. On next screen, select the segment to be edited and then, press Edit.



Enter start time for this 15:00 Back Next

4. Enter the start time and then, press Next and repeat for end time.



7. Press Save. For additional edits, repeat steps 3-8.

The values shown here are for illustrative purposes only. Actual screens may vary based on user settings and country. Consult with your healthcare professional before

OMNIPOD® SYSTEM ADVANCED FEATURES

How to use the extended bolus feature.

When to use:

WARNING:

This feature is most commonly used for high-fat and/or high-protein meals such as pizza, burgers or fried foods when the digestion of carbohydrates could be delayed.



Vhen using the extended bolus function the user should check their blood glucose levels more frequently to avoid hypoglycaemia or hyperglycaemia.

OMNIPOD® SYSTEM ADVANCED FEATURES

How to use the temp basal presets.

When to use:

It is best used for 'temporary' routine activities, such as an exercise class that occurs twice a week. The PDM can store up to 7 temporary basal presets. You will be able to access your temp basal presets when you select **Temp basal** from your home screen.



TROUBLESHOOTING

Hypoglycaemia.

Blood glucose (BG) reading of less than 70 mg/dL / 3.9 mmol/L or \leq 80 mg/dL / 4.5 mmol/L with symptoms.

Always follow your healthcare professional's recommendations on how to manage hypoglycaemia, including how to best manage your sick days and emergency situations.

Never leave a person who is hypoglycaemic unattended!

Tips for troubleshooting.

Check PDM settings.

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



Consult your healthcare professional for guidance regarding adjusting settings on your PDM.

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[®] System User Guide for additional information.

IMPORTANT NOTES:

Make sure your blood glucose is at least 100mg/dL / 5.5 mmol/L before driving or working with dangerous machinery or equipment. Even if you cannot check BG, do not wait to treat symptoms of hypoglycaemia. Avoid hypoglycaemia unawareness by checking your BG more frequently.

CUSTOMISING REMINDERS AND ALERTS

Get to know your Omnipod[®] System reminders.

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

+ Blood glucose (BG) reminders

Programme your Personal Diabetes Manager (PDM) to remind you to check your blood sugar levels every time you deliver a bolus dose.

+ 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 process.

+ Confidence reminders

Your PDM is preset to beep and therefore, 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 want them.

Get to know your Omnipod[®] System alerts.

An *alert* is a notification you can adjust based on your needs. There are 4 different kinds of alerts on your Omnipod[®] System:

+ Pod expiration alerts

When your Pod is about to expire (nearing the 72 hour expiration time), 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 alerts

So you can plan ahead to change your Pod and make sure you have enough insulin; your Pod will alert you when your insulin reaches a certain level.

+ Auto-off alerts

Programme your PDM to alert you if it hasn't received a Pod status within 1 to 24 hours.

+ Blood glucose meter alerts

If there is an error with your blood glucose meter, test strip, sample or results, your PDM will beep and display an error message number. To learn more about addressing specific error messages, Alerts and Alarms, refer to your Omnipod[®] System User Guide.

Area of the second seco

WARNING:

The Low reservoir alert 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 alert 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.

MAKING THE MOST OF YOUR PDM

What happens if ...?

You already know that your PDM enables you to live a tubeless life, delivering basal and bolus insulin doses remotely and wirelessly* to your Pod. However, from time to time, you may find yourself asking the question 'Why does my PDM do that?'.

The Insulet Customer Care Team has heard it all, and we've compiled the top 3 areas our Podders[™] ask or comment about the most. Read on to understand how to use your PDM to its maximum potential.

Your PDM battery.

The PDM requires two AAA alkaline batteries to perform at the optimal level. If you are using another type of battery, your battery life could suffer and ultimately damage the PDM. AAA alkaline batteries are readily available at most pharmacies, supermarkets or electrical shops.





Your PDM automatically takes steps to maximise the battery life when running low. You'll first see the Low PDM battery alert and then, your PDM will:

- + Turn off your vibration alert (if set)
- + Disable the bright mode
- + Disable the test strip port light

Once you replace your battery, these functions resume.

PDM communication.

One of the key benefits of the Omnipod[®] System is the wireless^{*}, tubeless communication between the PDM and the Pod. This means that you don't have to keep your PDM next to you all the time. However, there are a few actions that require your PDM and Pod to be in close proximity to communicate.

Here are a few ways you can help that 'conversation':

- + When you deactivate a Pod, it can take a few moments for the Pod to fully deactivate. Often you'll see the 'Please Wait' screen while your Pod and PDM communicate. Make sure you wait until the Pod is fully deactivated before you attempt to activate a new Pod.
- + If you are helping deliver a bolus to someone in your care (or changing the basal rate), remember that the PDM and Pod need to keep communicating until the Bolus is confirmed. Make sure you keep both the Pod and the PDM in close proximity to each other within 1.5 metres until you see the confirmation screen.



*At start up the PDM and Pod should be adjacent and touching, either in or out of tray to ensure proper communication during priming. At least1.5 metres during normal operation.

The values shown here are for illustrative purposes only. Actual screens may vary based on user settings and country. Consult with your healthcare professional before

TRAVELLING WITH YOUR OMNIPOD® SYSTEM

Going on a holiday with your Omnipod[®] System is easy. The following information will help you plan your trip.

Holiday Checklist.

Medical supplies and equipment

- □ Sealed Pods enough to cover your whole holiday, including spares, just in case
- □ Insulin vials as above (remember to place in a clear plastic bag if you are carrying in your hand luggage)
- D PDM
- □ Extra, new PDM batteries (AAA alkaline)
- □ Spare PDM
- □ Plenty of alcohol prep swabs
- □ Back-up insulin pens (for long and short-acting insulin)
- □ Insulin cartridges/vials for your back-up insulin pens
- □ Spare syringes or pens/needles
- □ Back-up blood glucose meter (in addition to the one integrated into the PDM)
- □ Blood glucose test strips, for both meters
- □ Ketone testing devise and strips
- □ Lancing device and lancets
- □ Glucose tablets or another fast-acting source of carbohydrate
- Glucagon emergency kit and written instructions for administering an injection if you are unconscious

Documentation

- □ Travel letter from your healthcare professional (see example below) covering the medical supplies and equipment you are required to travel with
- □ Prescriptions for all the medical supplies that you are carrying
- □ List of your latest Omnipod[®] System settings basal rates/target BG/ratios
- □ Travel insurance
- □ Emergency contact details

Other

□ If traveling to a different time zone, ensure you have adjusted your basal rate profile accordingly – ask your doctor for guidance

Further travel advice.

Your Pod is waterproof*, so you are free to go swimming and even to dive without disrupting your insulin delivery. Remember to rinse your Pod with fresh water afterwards and gently pat dry. You should check regularly that the Pod is still firmly attached and in place.

It is important to protect your insulin from extreme temperatures that can impact its effectiveness. Remember to keep your Pod out of direct sunlight and avoid saunas, steam rooms and jacuzzis.

OMINPOD® SUPPORT PROGRAMME



The Omnipod[®] Support Programme has been designed to make your transition to the Omnipod[®] System as **simple as possible**. The programme offers a range of **value added services** to help you make the most of what the Omnipod[®] System has to offer.

For more information about the individual services and their availability in your country, please visit myomnipod.com or give your local Insulet Customer Care Team a call.

- + Pod Sample Kit A free, non-functioning* sample Pod for people that want to try it out.
- + Omnipod[®] System Training Available to all new Podders[™] – speak to your healthcare professional.
- + Educational and Training Resources How-to videos, resource guides, troubleshooting and tips, lots of educational and training support always available on myomnipod.com.
- + PDM Holiday Loaner Programme Supporting you wherever you are in the world. Contact your local Insulet Customer Care Team for more information.
- + Reordering consumables** For guidance on how to reorder Pods and other consumable items in your country, please contact your local Insulet Customer Care Team.

+ Insulet Pod Disposal Programme

Insulet's Pod Disposal Programme provides Podders[™] with an alternative way to dispose of used Pods. Please contact your local Insulet Customer Care Team or current Omnipod[®] System provider for more information.

 Insulet partnering with Glooko[®] + diasend[®]
 With Glooko + diasend[®], you and your healthcare professional have access to all of your diabetes information in one easy-to-



use platform. Glooko + diasend[®] allows you to review your blood glucose patterns on your smartphone or personal computer, understand the impact of your activities on your blood glucose and easily share your diabetes data with your healthcare professional.

Important reminders:

Always talk to your healthcare professional about what insulin pump options are best suited for you and your needs.





Perse F. Dadabae Nice 2013



YS^{**}

Insulet International Ltd. 1 King Street, 5th Floor, Hammersmith, W6 9HR Phone: 0800 011 6132

myomnipod.com