OmniPod®

Insulin Management System

Welcome to OmniPod

Pre-training Guide

What's INSIDE

This guide is for PDM model UST200. The model number is on the back cover of your PDM.

Thank you for choosing the OmniPod System.

We developed the OmniPod Insulin Management System with one clear goal: to help make diabetes a smaller part of your everyday life.

That goal affects everything we do here at Insulet—from providing these pre-training materials to being available 24 hours a day to answer questions and offer support. It is also why we work hard to continually improve the OmniPod, using input from both customers and healthcare providers to evolve and optimize each feature.

We believe each OmniPod advance can enhance both your diabetes care and your personal lifestyle. Certainly, our customers tell us they do. In fact, after a year using OmniPod, a majority of our customers say that living with diabetes is easier. We hope you will join them.

Welcome to the OmniPod family.

Duane DeSisto
President & Chief Executive Officer
Insulet Corporation

When you wear the Pod, we are with you every step of the way.

At Insulet, our over-arching goal is to improve the lives of people with diabetes—both through our product and through our Customer Care and support. That support begins right now.

Soon you will work with a trained professional to learn how to use your new OmniPod System. During the following weeks, you will gradually become more familiar with pump therapy in general and the OmniPod in particular. Use this discovery period to try the Pod in different spots to find the sites that work best for you, and to become completely at ease with your therapy. Of course, if for any reason you are not completely satisfied, OmniPod offers a 45-day money-back guarantee.[1]

We know that no matter how comfortable you ultimately become with the OmniPod, sometimes you'll have questions or comments. While your healthcare provider should answer any questions about pump therapy or your diabetes care, we are ready to help with questions about your OmniPod, any way we can. **Please call on us day or night, by phoning 800.591.3455 or visiting MyOmniPod.com.**

Make your training faster and easier by first reviewing this booklet and the Pre-Training Preparation section of OmniPod's online Interactive Training Program. Together they explain the basics of pump therapy and the OmniPod System. **Please do not try to program your PDM or apply a Pod until your first training session.**

1. Reimbursement requests must be made within 45 days of the initial shipment date. Guarantee only applies to the Starter Kit and unopened Pod ten-pack boxes.

Pre-Training Checklist

1. **Make an appointment for training.**
   If you haven't already been contacted, call your healthcare provider or our Customer Care Team at 800.591.3455 to set up your appointment.
2. **Learn pump therapy basics from your healthcare provider.**
   - Basal/bolus basics
   - Blood glucose monitoring
   - Insulin delivery influencers, such as insulin-to-carbohydrate ratio, correction/sensitivity factor, duration of insulin action
   - Sick day guidelines
3. **Review pump therapy basics for the OmniPod.**
   - Read through this booklet.
   - Complete the Pre-Training Preparation section of OmniPod's online Interactive Training Program, found in the Customer Care section of MyOmniPod.com.

STUDY WITH A PRO

During your training session, your Trainer will:

- Help you set up your PDM using the settings supplied by your physician.
- Get you started with your first Pod, showing you how to fill, apply and change the Pod. **Remember: Bring two unopened Pods to your training.**
- Review the steps to check blood glucose, program a bolus and temporarily suspend insulin delivery.

DO NOT try to program your PDM or apply a Pod before your training session.

Be sure to bring two unopened Pods and this booklet to your first training session. You will use them when learning how to apply your first Pod.

The Basics of Pump Therapy with the OmniPod

A HEALTHY PANCREAS PRODUCES INSULIN AT PRECISELY THE RATE NEEDED TO KEEP BLOOD GLUCOSE LEVELS WITHIN A NORMAL RANGE. AN INSULIN PUMP IS PROGRAMMED TO MIMIC THE PANCREAS, PROVIDING A CONSTANT STEADY STREAM OF INSULIN, AS WELL AS EXTRA INSULIN IN SITUATIONS WHEN YOUR BODY NEEDS IT.

BASAL BASICS

Basal insulin is a small amount of insulin that is delivered continuously, no matter what you are doing. It is measured in units per hour (U/hr). Because the optimal delivery rate changes from person to person, you can program the OmniPod System to deliver your insulin at the basal rate that best matches your insulin needs.

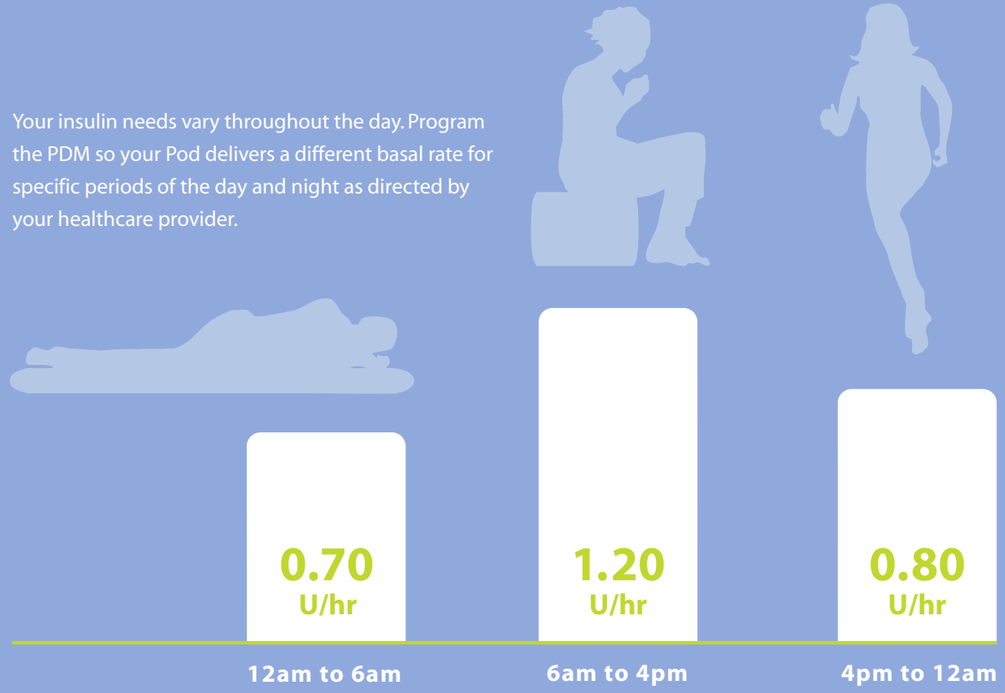
Basal Programs

Your insulin needs can vary throughout the day. For instance, many people need less insulin when they sleep.

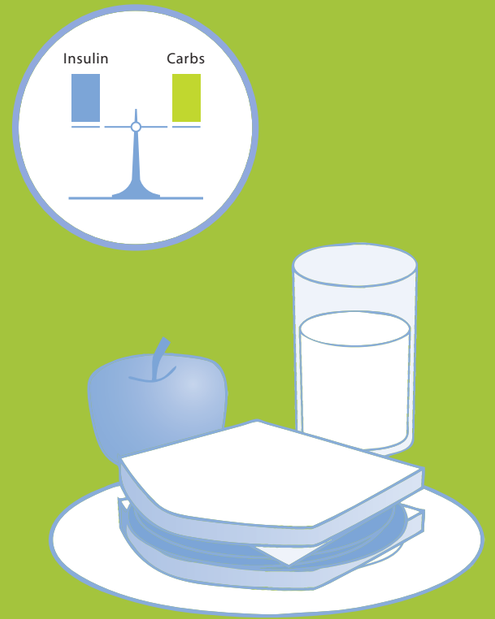
You can program the PDM so that the Pod delivers a different basal rate at specific periods, or segments, throughout a 24-hour cycle. For instance, you might choose to divide 24 hours into three time segments with a different basal rate for each segment. This sequence is called a basal program. You can create up to 7 customized basal programs with the OmniPod System—for example one for weekdays and one for weekends—specifying up to 24 segments per program.

Of course, you and your healthcare provider will decide on the basal rates that best match your lifestyle and insulin needs.

Your insulin needs vary throughout the day. Program the PDM so your Pod delivers a different basal rate for specific periods of the day and night as directed by your healthcare provider.



Values shown are for illustrative purposes only.



The OmniPod System allows you to deliver a bolus dose of insulin to match the carbohydrates in a meal or snack, or to lower your blood glucose when it gets too high.

BOLUS BASICS

The amount of insulin your body needs changes constantly, depending on factors such as your activity level, stress, when you eat and the type and amount of food you eat. You may need to deliver an extra dose of insulin, called a bolus, to match the carbohydrates in a meal or snack, or to lower your blood glucose when it gets too high. There are two basic types of boluses: meal and correction.

Meal Bolus: Normal or Extended

Generally, a normal meal bolus will cover your insulin needs for a meal or snack. Sometimes your food intake is better covered by an extended bolus, which delivers insulin over a longer period of time than a normal bolus. This feature is useful when you are eating high-fat or high-protein foods, which may take longer to digest and are possibly slower to affect blood glucose, or when you are eating over an extended period, for example, at a party or during a holiday meal.

Correction Bolus

You may also need a bolus of insulin to reduce a high blood glucose level; this correction amount is added to a meal bolus if you are eating, or delivered separately if you are not.

Bolus Calculator

The PDM's Suggested Bolus Calculator can be programmed to automatically calculate and suggest your bolus dose. You can simply accept the suggested dose, or easily adjust it by using the **Up/down controller** button.

The PDM bases calculations on several factors; some are specific to the moment:

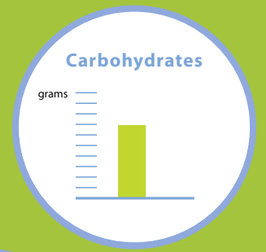
- Your current blood glucose level.
- The grams of carbohydrates you are about to eat.
- Insulin on board—the amount of insulin that is still active in your body from a previous correction bolus.

Some factors relate to the way your body uses insulin; you and your healthcare provider will determine these factors and you will enter them in your personal settings during your training session. These factors include:

- Insulin-to-carbohydrate ratio (I/C ratio): How much insulin your body needs to cover the carbohydrates you eat. For example, if your I/C ratio is 1:15, your body needs one unit of insulin for every 15 grams of carbohydrates you eat.
- Correction factor or sensitivity factor: How much one unit of insulin will lower your blood glucose level. For example, if your correction factor is 50, one unit of insulin will lower your blood glucose level by 50 mg/dL.
- Target blood glucose value: The blood glucose value that you are trying to achieve in your day-to-day diabetes management.

You should know these factors before your first training session.

The OmniPod's Suggested Bolus Calculator uses your personal settings, your blood glucose level, the amount of carbohydrates you are eating, and your insulin on board to determine a suggested bolus dose.



OmniPod Overview

THE POD

THE PDM (PERSONAL DIABETES MANAGER)

Main Menu Items

Bolus: Deliver bolus doses to cover carbohydrates or correct high blood glucose (BG) levels.

More actions:

- Change the Pod
- Add BG readings
- Assign/Edit BG tags

Temp basal: Adjust insulin delivery for exercise or illness according to your healthcare provider's recommendation. *This menu item is present only if the Temp basal option is turned on.*

My records: Review insulin delivery, blood glucose history, alarm history, carbohydrate history and personal user information.

Settings:

- Enter, edit and name basal programs
- Program temp basal, carbohydrate and bolus presets
- Customize system settings

Food library: Display reference library with carbohydrate, fiber, fat, protein and calorie counts for over 1,000 common food items.

BG history: View blood glucose history screens.

Suspend: Temporarily suspend insulin delivery.

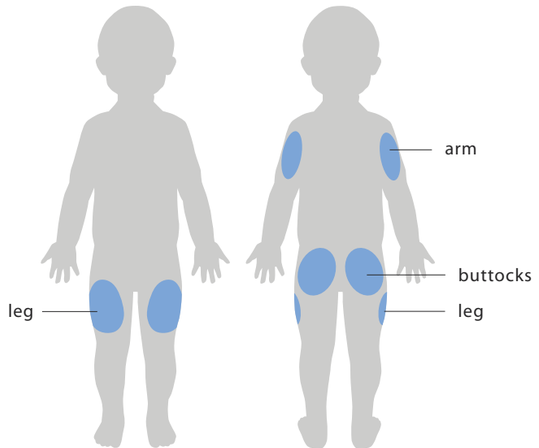
Before training, complete the Pre-Training Preparation section of OmniPod's online Interactive Training Program, found in the Customer Care section of MyOmniPod.com for an overview of the OmniPod System. Your training will be faster and easier if you familiarize yourself with the OmniPod System beforehand.

POD PLACEMENT OPTIONS

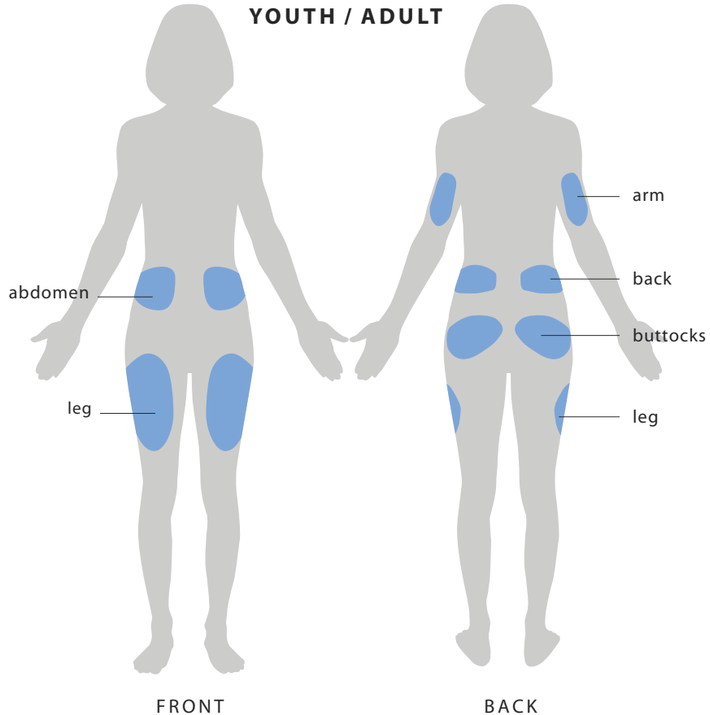
You can wear the Pod comfortably anywhere you would give yourself a shot. Please note the recommended positioning for each body area.

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.

TODDLER



YOUTH / ADULT



PLACEMENT TECHNIQUES FOR BEST RESULTS

Pod Positioning

Arm and Leg: Position the Pod *vertically* or at a slight angle.

Abdomen, Back and Buttocks: Position the Pod *horizontally* or at a slight angle.

Site Selection

Change your site location each time you apply a new Pod; improper site rotation can reduce insulin absorption. Your new site should be at least 1 inch away from the previous site, 2 inches away from the navel, and not over a mole or scar.

STARTING INSULIN DELIVERY

Activate a New Pod

- Assemble the following supplies:
  - Vial of insulin at room temperature (U-100, rapid-acting). *See User Guide for insulins approved for use with the OmniPod System.*
  - One sealed Pod
  - PDM
  - Alcohol prep swab
- Wash your hands.

Step One: Fill the Pod

- 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, then remove the protective cap.

CAUTION

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

- Fill the syringe with up to 200 units of insulin; fill at least to the MIN line. Remove any air bubbles from the syringe.

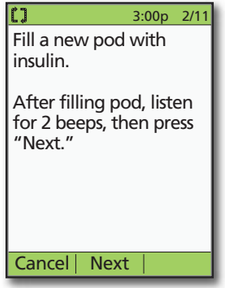
- Insert the needle straight down into the fill port on the underside of the Pod. To ensure proper fill, do not insert fill syringe at an angle into the Pod.
- Completely empty the syringe into the Pod.
- The Pod will beep twice, indicating that the System is ready to proceed.

WARNING

WARNING: NEVER use a Pod if you hear a crackling noise or feel resistance when you depress the plunger. These conditions can result in underdelivery of insulin.

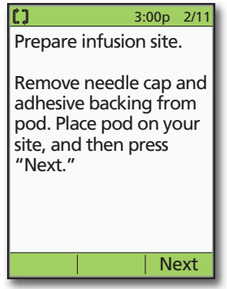
WARNING

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



- Return to the PDM. If the PDM screen times out, press and hold the **Home/power** button to turn it back on.
- Press **Next**.
- The PDM establishes a one-to-one relationship with the Pod, which will not allow it to communicate with any other Pod while this Pod is active. Once the Pod successfully completes its priming and safety checks, the PDM will beep.

This symbol will remind you to refer to the OmniPod System User Guide for complete information on how to use the System, and for all related warnings and cautions.



Step Two: Apply the Pod

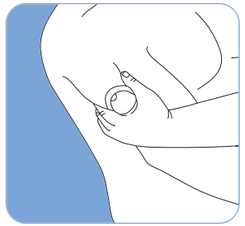
- Select your infusion site, being careful to avoid areas where the Pod will be affected by folds of skin. Refer to the figures on pages 12 and 13 for recommended sites and placement tips.

- 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.

- Remove the needle cap.

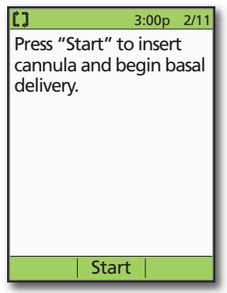
- Remove and discard the white paper backing from the adhesive.

- Apply the Pod to the selected site.
- Run your finger around the adhesive to secure it.
- Press **Next** on the PDM.

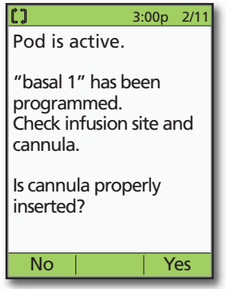


Step Three: Press Start

- To facilitate insertion, place one hand over the Pod, pinching up the skin near the cannula; this step is critical if the insertion site does not have much fatty tissue. Release the skin after the cannula inserts.



- Press **Start**. The Pod automatically inserts the cannula and delivers a prime bolus to fill the cannula with insulin. It takes a few seconds to complete this process.

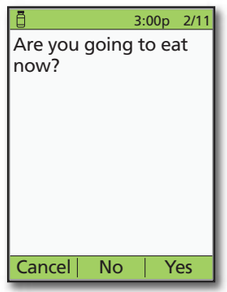


- Once complete, the PDM indicates that the Pod is active and asks you to check the infusion site.
- Look through the Pod's viewing window to check that the cannula is properly inserted, then press **Yes**.

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.

DELIVERING A BOLUS WITH THE SUGGESTED BOLUS CALCULATOR

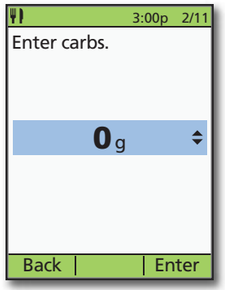
You may need to deliver an extra dose of insulin—a bolus—to match the carbohydrates in a meal or snack, or to lower your blood glucose when it gets too high.



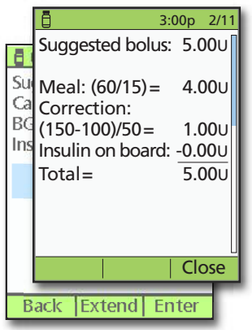
- After you check your BG, the screen shown at left will appear.
- If eating now, press **Yes**.

OR

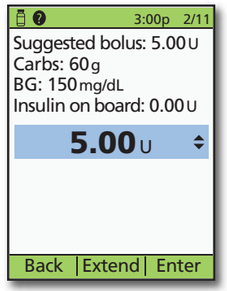
- If not eating, press **No**.



- If eating, press the **Up/down controller** button to enter the correct number of carbs. Then press **Enter**.



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

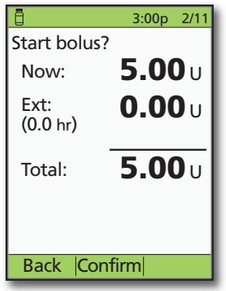


- Press **Enter** to deliver the bolus immediately.

OR

- Press **Extend** and follow 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 recommended by your healthcare provider.*

Please check with your healthcare provider before using the suggested bolus calculator. See your User Guide for a detailed explanation of how suggested bolus amounts and IOB are calculated. PDM imagery shown in this guide is for illustrative purposes only and should not be considered suggestions for user settings.



- Press **Confirm** to deliver.
- The PDM screen will indicate when 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. Delivery times vary depending on the size of the bolus.
- Once bolus delivery begins, you may press and hold the **Home/power** button to turn off the PDM screen.

DATA MANAGEMENT

Using the USB cable included in your Starter Kit, your PDM can download insulin delivery, BG and carbohydrate records to the CoPilot® Health Management System from Abbott Diabetes Care. Use the data to create customized reports, charts and graphs of your results quickly and easily. You can also track changes to your personal settings with the OmniPod PDM Settings Report.

For the minimum system requirements and for additional help installing your free data management software visit the Customer Care section of MyOmniPod.com.

Install the Software

- Assemble the following:
  - PDM
  - Personal computer
  - Internet connection to download the CoPilot and OmniPod Extension installation files
  - USB cable (USB A to USB mini-B)

Step One: Install the CoPilot® Health Management System Software

- Be sure to install CoPilot **before** installing the OmniPod Extension.
- Visit the Customer Care section of MyOmniPod.com for download instructions and a link to obtain CoPilot.

Step Two: Install the OmniPod Extension Software

- Download the OmniPod Extension installation file from the Customer Care section of MyOmniPod.com; then double-click the file (**OmniPod.exe**).
- Installation will begin automatically, and may take a few minutes. A series of screens will guide you through the process. Navigate through the installation screens, adjusting installation settings as necessary. Click <**Next**> to proceed to the next screen, or <**Cancel**> to quit installation. At the end, you may have to restart your computer.

Download Your PDM Data

Step One: Connect Your PDM

- Connect the large end of the USB cable (USB A) to a USB port on your computer, and connect the small end of the USB cable (USB mini-B) to your PDM. Wait for the PDM to display "USB device ready" to indicate that it has finished preparing the data file for download.

CAUTION

When you connect a USB cable to the PDM, only use a cable that is less than or equal to 9 feet (2.7 meters) in length.

WARNING

Only connect a USB cable to your PDM when downloading data to a computer. Other PDM functions are disabled while a USB cable is connected, and the PDM cannot communicate with the Pod.

WARNING

Never attempt to test your blood glucose while your PDM is connected via USB cable to a computer. Doing so could result in electric shock.

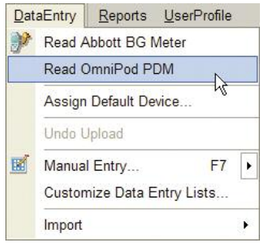
WARNING

The PDM is compatible only with Windows®-based operating systems. Do not connect a USB cable from the PDM or attempt to download data to a computer using a non-Windows-based operating system, as the PDM may alarm and require a reset.

Step Two: View Your Data

To view your insulin, glucose and carb data in CoPilot

- Start the CoPilot System.
- Start the download by choosing <**DataEntry**>, <**Read OmniPod PDM**> from the CoPilot home page.



If this is the first time you are downloading your PDM to CoPilot, you will see the New Device/Data Source message. Select the user to associate to this PDM. If you have not set up your user profile in CoPilot, choose **Add a new user**.

To associate the PDM with a user who already has a profile in CoPilot, choose <**Cancel**>, then choose the person to assign the PDM to in the **Select User** or **Select Patient box**. Then restart the download.

- The CoPilot System displays a status report with a summary of all event types and the number of records transferred.

Your glucose, insulin and other event data are now ready to be viewed in CoPilot reports.

To view your PDM settings in the OmniPod PDM Settings Report

- While the PDM is connected to the computer, choose <**OmniPod**>, <**OmniPod PDM Settings Report**> or click the toolbar icon <>.

Your PDM settings data are now ready to be viewed in the OmniPod PDM Settings Report. Verify the serial number displayed on the PDM Settings Report matches the serial number of your PDM.

To Access Help

- For help with the OmniPod Extension or the OmniPod PDM Settings Report: Choose <**OmniPod**>, <**OmniPod Extension Help**>.
- For help with CoPilot and details on using the reports: Choose <**Help**>, <**Contents**>, or press the <**F1**> key from any page in CoPilot for topic specific help.

Check with your healthcare provider on which reports are appropriate for you and then get into a routine of downloading and reviewing them often.

Notes:

Ordering OmniPod Supplies

Ensure plenty of time for delivery by restocking your supplies when you open your last box of Pods. Our Auto-Ship Program keeps it easy, automatically mailing you a three-month supply of Pods each quarter.

To join the Auto-Ship Program or to simply order new Pods call: 800.591.3455 (from outside the United States, 781.457.5098)

Monday-Friday, 8:30 am–8 pm Eastern Time

FreeStyle® test strips, alcohol swabs and other diabetes supplies are available through pharmacies nationwide.

OmniPod®

Insulin Management System

Insulet Corporation
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Bedford, MA 01730 USA
800.591.3455 / 781.457.5098

MyOmniPod.com

Model: **UST200**

13579-AW Rev B