omnipod®

INSULIN MANAGEMENT SYSTEM

Podder's handbook

3 **DAYS***
NONSTOP
INSULIN

*Up to 72 hours of insulin delivery

Contacts and Important Information

Customer Care

1-800-591-3455 — 24 hours/7 days

1-978-600-7850 when calling from outside the United States of America

Customer Care Fax: 877-467-8538

Website: www.myomnipod.com
Address: Insulet Corporation, 100 Nagog Park Acton MA, 01720, USA

Emergency Services: Dial 911 (USA only; not available in all communities)

PDM Model: UST400

Serial Number: _____

Omnipod® Insulin Management System Start Date: _____

Healthcare Provider
Name
Address
Phone
Email

Omnipod® System Trainer
Name
Address
Phone
Email

Health Insurance
Name
Address
Phone
Policy Number

Pharmacy
Name
Address
Phone
Email

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About This User Guide

Caution: This *User Guide* is intended for use only with PDM model UST400. To learn which version of the PDM you have, turn it over. On the back of the PDM, look for "UST400." If you see it, this is the correct *User Guide*. If you do not see it, please call Customer Care.

Note: Screen images shown in this *User Guide* are examples only and are not suggestions for user settings. Consult with your healthcare provider to determine the appropriate settings for you.

Health care and treatment are complex subjects requiring the services of qualified health care providers. This user guide is informational only and not intended as medical or health care 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 health care advice, recommendations and/or services from a qualified health care provider. This user guide may not be relied upon in any way in connection with your personal health care, related decisions and treatment. All such decisions and treatment should be discussed with a qualified health care provider who is familiar with your individual needs.

This *User Guide* is periodically updated. Visit the Learning Center section of *myomnipod.com* to see the most recent version and to find other helpful information.

Term	Meaning
Warning	Alerts you to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.
Caution	Alerts you to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunctions, device failure, damage to the device or damage to other property.
Note	Provides helpful information.
Tip	Offers a suggestion for successful use of the device.

Introduction

Indications and Contraindications

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

Indications for use

The Omnipod® 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 and for the quantitative measurement of glucose in fresh capillary whole blood (*in vitro*) from the finger.

The glucose measurements should not be used for the diagnosis of or screening for diabetes. The PDM glucose meter is intended for single-patient use and should not be shared.

Abbott FreeStyle test strips are used with the built-in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm.

Abbott FreeStyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

Contraindications

Insulin pump therapy is NOT recommended for people who are:

- Unable to perform at least four (4) blood glucose tests per day
- Unable to maintain contact with their healthcare provider
- Unable to use the System according to instructions

Do not use the built-in blood glucose meter for:

- Testing on neonates
- Testing arterial blood
- Diagnosing of or screening for diabetes mellitus
- Patients who are critically ill, dehydrated, or in diabetic ketoacidosis (DKA)

General Warnings and Cautions

Warnings:

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

Read all the instructions provided in this *User Guide* and practice the blood glucose testing procedures before using the System. Monitor your blood glucose with the guidance of your healthcare provider. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

Personal health considerations

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

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

Parts of the device are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

The glucose meter and lancing device are for single-patient use. Do not share the device with anyone including other family members. Do not use on multiple patients.

Warnings:

Environments to avoid

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 your Pod and put it and the PDM outside the treatment area. Check with your healthcare provider for Pod removal guidelines.

The Omnipod® System should NOT be used at low atmospheric pressure (below 696 hPA). You could encounter such low atmospheric pressures at high elevations, such as when mountain climbing or living at elevations above 10,000 feet (3,000 meters).

The Omnipod® System should NOT be used in oxygen rich environments (greater than 25% oxygen) or at high atmospheric pressure (above 1062 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.

Caution: This device is intended for self-testing by the user.

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*, call your healthcare provider.

Warning: Only use an Omnipod® Personal Diabetes Manager (PDM) to control the Pod. Use of an alternative control device can introduce unknown risks and may result in unsafe insulin dosing.

Safe Use

Pump therapy requires substantial caregiver involvement, especially with children. Work with your healthcare provider to establish diabetes management guidelines and settings that best fit your, or your child's, needs. These may include:

Insulin-to-Carbohydrate (IC) Ratio: Number of grams of carbohydrate covered by one unit of insulin. For example, if your Insulin-to-Carbohydrate Ratio is 1:15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

Correction (or Sensitivity) Factor: How much one unit of insulin lowers your blood glucose. For example, if your Correction Factor is 50, one unit of insulin lowers your blood glucose by 50 mg/dL.

Target Blood Glucose (Target BG): The blood glucose level you want to achieve. For example, you may want to keep your blood glucose close to 100 mg/dL.

Duration of Insulin Action: The length of time that insulin remains active and available in your body after a correction or meal bolus.

Your healthcare provider is a valuable resource. You will rely on him or her for a lot of critical information about your Omnipod® System, especially during the first few weeks and months. When you have questions about diabetes management after starting on the Omnipod® System, do not hesitate to talk with your healthcare provider.

For technical questions about your Omnipod® System setup or operation, or to order Omnipod® System products and supplies, you can call Customer Care 24 hours a day, 7 days a week. See the front page of this *User Guide* for your Customer Care contact information.

Your healthcare provider will give you all the tools and training you need to be successful with the Omnipod® System. However, in the end, your success depends on YOU. You must become actively involved in your own diabetes management to enjoy the control, freedom and flexibility that is possible with the Omnipod® System.

Being actively involved means:

- Frequently monitoring your blood glucose levels
- Learning how to operate your Omnipod® System and practicing proper techniques
- Visiting your healthcare provider

Safety Features

The Omnipod® System's built-in safety features include:

Automatic priming, safety checks, and insertion

Every time you activate a new Pod, the Omnipod® System automatically primes and performs a safety check on the Pod, then inserts and primes the cannula. These safety checks take only a few seconds.

The Omnipod® System also performs safety checks on the PDM each time you turn on your PDM. If it detects any problems in the PDM or the Pod—or in the communication between them—it informs you with beeps and on-screen messages.

Introduction

Alarms and notifications

For your safety, the Omnipod® System provides a range of alarms and notifications to tell you that your attention is needed or to warn you of hazardous situations. For a description of the PDM's alarms and notifications, see chapter 9.

> **Warning:** You need to press **Confirm** on the ID screen before you can read the alarm or notification message.

Note: Activate your PDM periodically to confirm that there are no notifications or alarms that require a response.

> **Warning:** Do NOT attempt to use the Omnipod® System before you receive training from your Omnipod® System Trainer or healthcare provider. Inadequate training could put your health and safety at risk.

CHAPTER 1
Your Omnipod® Insulin Management System

Welcome

The Omnipod® Insulin Management System is an innovative continuous insulin delivery system that provides all the proven benefits of continuous subcutaneous insulin infusion (CSII) therapy.

Features of the Omnipod® Insulin Management System include:

No tubing: There is no tubing connecting the Pod to the Personal Diabetes manager (PDM). You can wear the Pod under your clothes and carry the PDM separately. You can swim wearing the Pod and leave the PDM on dry land. The Pod is waterproof to 25 feet (7.6 meters) for up to 60 minutes (IP28).

Bolus Calculator: If your blood glucose is high or if you are planning to eat, the PDM's Bolus Calculator can suggest a bolus dose based on your individual settings.

Built-in blood glucose meter: The PDM contains a built-in blood glucose meter. You can also manually enter blood glucose readings from any BG meter into the PDM.

Record keeping: The data storage system in the PDM displays up to 90 days of information. This includes blood glucose results, basal rates and bolus doses, carbohydrates, and alarms.

The *Getting Started* section of this book explains the basic operation and setup of the Omnipod® System. The *User Guide* section gives step-by-step instructions for using the System. The *Reference* section explains the System in detail.

Terms and conventions

Bold text	Buttons that you press, soft keys, menus, and screens are in **bold**.
Screen	Area of the PDM that displays menus, instructions, and messages.
Menu	List of options. Options allow you to perform tasks.
Icon	An image on the PDM screen that indicates a menu option or item of information (see "PDM Icons" on page 158).
Button	Physical button on the PDM, such as the **Home/Power** button.
Soft keys	Row of three buttons directly beneath the screen. The soft key's label or function appears on the screen directly above the button.
Press	Press and release a button or soft key.
Hold	Keep pressing a button until its function is complete.

The Pod and PDM

The Omnipod® System is made up of two parts: The Pod, which delivers insulin to your body, and the Personal Diabetes Manager (PDM), which allows you to control the Pod.

The Pod: The Pod is a lightweight, self-adhesive device that you fill with insulin and wear directly on your body. The Pod delivers insulin into your body through a small flexible tube called a cannula, based on instructions from the PDM.

The Pod is applied to your skin with an adhesive, similar to an adhesive bandage.

Top **Bottom**

Adhesive backing
Fill port
Housing vent
Paper cover for adhesive backing
Viewing window
Pod needle cap
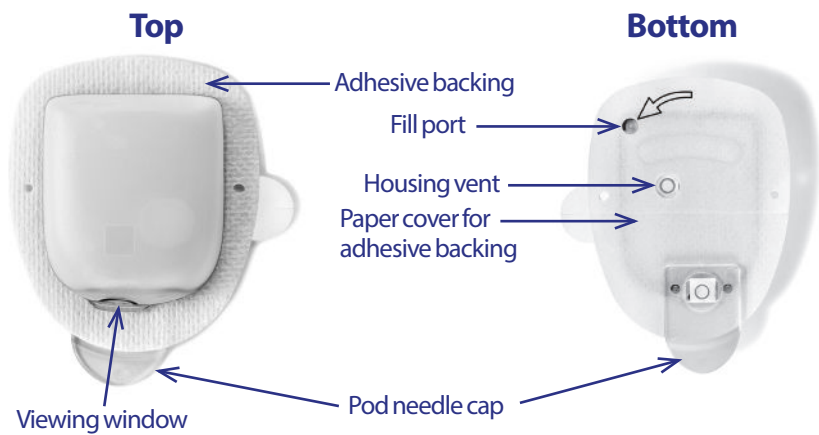
The PDM: The PDM is a handheld device that:

- Wirelessly programs the Pod with your personalized insulin-delivery instructions
- Wirelessly monitors the Pod's operation
- Includes a built-in blood glucose meter

USB port

Header bar

Home Screen

Soft key label

Soft key

Home/Power button

Info button

Test strip port

Up/Down button

Screen Navigation

The PDM communicates with you by displaying images on its screen. You communicate with the PDM by pressing buttons and soft keys.

The Home/Power button

Press and hold the **Home/Power button** to turn the PDM on or off.

When the PDM is on, briefly press this button to return to the **Home** screen from any other screen.

The Up/Down button

The **Up/Down** button is used in the following ways:

- Press and release to increase or decrease a number. Holding the button down changes the number more rapidly.

- Press and release to scroll through a list of available menu options. Holding the button down scrolls faster.

- Some screens have text that continues below what is visible on the screen. Use the **Up/Down** button to scroll down to view any off-screen text.

Press the Up arrow (the upper part of the **Up/Down** button) to increase a number or to move up on a screen. Press the Down arrow (the lower part of the **Up/Down** button) to decrease a number or move down on a screen.

Soft keys and soft key labels

Soft key labels appear on the screen directly above the soft key buttons. The soft key labels differ on different PDM screens. Press a soft key to select an action or to navigate between screens. For example, on the **Home** screen shown on the previous page, the two soft key labels are "Status" and "Select."

- Press the right-hand soft key, directly below the "Select" soft key label, to select the highlighted "Bolus" menu item. The **Bolus** screen appears.

- Press the left-hand soft key, beneath the word "Status," to bring up the **Status** screen.

Tip: *Pressing a soft key that has no soft key label above it prevents the PDM from going to sleep but has no other action.*

The Info button

Some screens have a "more info" ? icon in the header bar (see page 7) or displayed to the right of an item in a list. When the "more info" icon is present, press the **Info** button to display a screen with additional details.

Screen with ? icon	Pressing the Info button displays
Home screen	Username, other personalized entries (if any), Insulet Corporation contact information, device serial number
Status screen	Insulin on board (IOB) details
Suggested bolus screen	Bolus calculation details
History screen	Details about a tagged event

Screen brightness

The **Info** button can also be used to make your PDM screen brighter or less bright. Press and hold the **Info** button for two seconds to toggle the "bright mode" on or off. To control the dimming of the screen, see "Backlight time-out" on page 61.

Navigation shorthand

The *User Guide* uses the ">" symbol to indicate navigating from one screen to another. For example, the following notation:

Home > Settings > Presets > Carb presets

tells you to:

1. Turn on the PDM and confirm your ID, if necessary.

2. Press the **Home/Power** button.

3. Use the **Up/Down** button to highlight the **Settings** option, then press the soft key under **Select** to bring up the Settings menu.

4. Use the **Up/Down** button to highlight the **Presets** option, then press the soft key under **Select** to bring up the Presets menu.

5. Use the **Up/Down** button to highlight the **Carb presets** option, then press the soft key under **Select** to bring up the Carb presets menu.

Data Entry

This section explains how to enter numbers or text into the PDM. Refer back to this section as needed while you are learning to use your PDM.

Entering numbers

Use the **Up/Down** button to increase or decrease a number.

Initial settings for numerical values are often "---." Press the **Up/Down** button once, either up or down, to display the default value. Continue to press the **Up** button or the **Down** button to increase or decrease the number.

Entering text

During setup, you will enter a username for your PDM's **ID** screen and, optionally, a name for your first Basal Program. Later on, you can add names for other settings or edit existing names.

To enter text:

1. Use the **Up/Down** button to scroll through the alphabet and other characters. A blank character or space precedes the "a" and follows the "Z" of the alphabet. Numbers and a few other characters, such as - and @, are found following the alphabet and the space character.

2. Press the middle soft key (labeled with the right arrow) to move the underscore to the next character.

3. Enter each character one at a time. An up-and-down-arrow symbol on the screen indicates the character you are currently changing.

For example, to enter a username of "MKC 2-5-10", use the **Up/Down** button and the middle soft key to enter M. K. C, [space], 2, -, 5, -, 1, 0.

The PDM considers capital and lowercase letters to be the same. In other words, the PDM considers "myFavoriteFood" and "myfavoritefood" to be the same name, and it will not allow you to use both of them as the name of two different presets.

Note: Many settings provide a default naming system consisting of a generic description of the item being named followed by a number. Each subsequent item ends with the next higher number. For example, the default naming system for custom reminders is reminder 1, reminder 2, reminder 3, and reminder 4.

The Header Bar

A screen's header bar gives useful information that is not found anywhere else. The information on the header bar varies according to each screen's purpose.
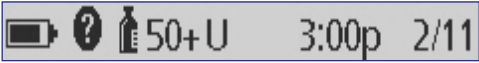
PDM battery level indicator

The batteries in your PDM should last about three weeks. The header bar on the **Status** screen displays the amount of battery life left as follows:

| Full | 3/4 full | Half full | 1/4 full | Empty |

See "Replacing the PDM's batteries" on page 110 for more information.

More info indicator

The "more info" indicator is found on the header bar of some screens (see "The Info button" on page 5).

Insulin level indicator

The insulin level indicator is found on the **Status** screen's header bar only. The header bar displays the amount of insulin remaining as follows:

Display in header bar	Units of insulin remaining
50+U	Any amount above a 50 unit threshold
50U (to 5U)	Number displayed (counts down 1 unit at a time between 50 units to 5 units)
LOW	Less than 5 units

Time and date

The time and date appear in the header bar of all screens.

The PDM's Top-level Screens

This section introduces you to the PDM's top-level screens:

- The **ID** screen identifies the PDM as being yours.

- The **Home** screen and the **More actions** screen are the main menus. They provide the entry point to the PDM's functions.

- The **Status** screen shows the Pod and PDM's status, lists current or recent basal, bolus and blood glucose information, and displays messages.

- The **IOB** screen gives details about how much insulin is active in your body.

ID screen

The **ID** screen performs a very important function: It allows you to identify the PDM as yours.

To confirm that the PDM is yours:

1. Press the **Home/Power** button to turn on your PDM. The **ID** screen appears. Verify that the username is yours.

2. Press **Confirm**. The **Status** screen appears.

In the remainder of this *User Guide*, instructions to "turn on the PDM" indicate both pressing the **Home/Power** button and confirming the **ID** screen.
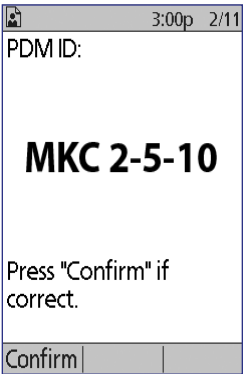
> **Warning:** Always identify the PDM as yours before using it.

Home screen and More actions screen

The menu items on the **Home** screen and its **More actions** submenu give you access to the Omnipod® System's features.

The **Home** screen can be accessed from most screens by pressing the **Home/ Power** button. Select **More actions** on the **Home** screen to see other useful menu choices.

The Home screen   *The More actions screen*
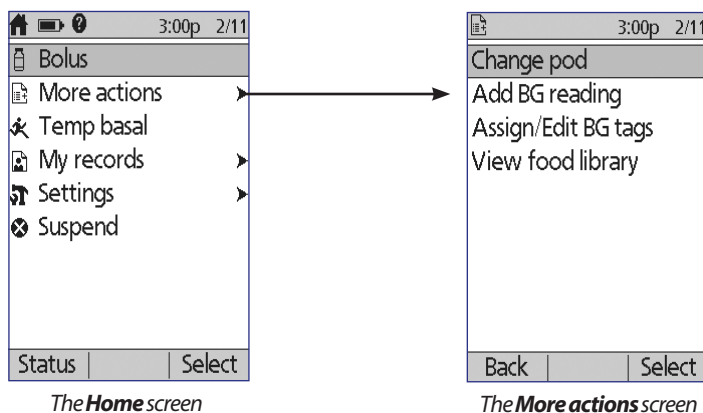
Menu item	Allows you to ...	See ...
Bolus	Deliver boluses	page 45
More actions	Bring up the More actions screen	page 9
Temp basal	Define a temporary basal rate (this menu item does not appear if the temp basal feature is turned off, see "Temp basal configuration" on page 66)	page 53
My records	View history of insulin delivery, blood glucose readings, carbs eaten, and alarms	page 83
Settings	Create and edit Basal Programs and presets, and customize your settings, including sound or vibration	page 59
Suspend	Suspend, cancel, or resume insulin delivery	page 57
Change pod	Deactivate and activate a Pod	page 23
Add BG reading	Enter a BG reading taken with a separate BG meter	page 43
Assign/Edit BG tags	Label a BG reading for future reference	page 44
View food library	Look up amount of carbs in a food	page 51

Status screen

The **Status** screen is an important screen. Navigating to the **Status** screen causes the PDM to ask the Pod about its (the Pod's) current state. For details, see "Status checks: How the PDM checks Pod function" on page 130.

You can navigate to the **Status** screen in two ways:

- Turn on your PDM by pressing-and-holding the **Home/Power** button. The **Status** screen appears after you confirm your ID.

- If the PDM is on, briefly press the **Home/Power** button and then press **Status**.

Tip: *Visit your* **Status** *screen often to make sure the Pod is working properly. If the* **Status** *screen says it is unable to communicate with the Pod, see "Failure to receive a Pod status" on page 100.*

The **Status** screen shows:

The header bar (see "The Header Bar" on page 7).

Your most recent BG reading and the time and date it was recorded.

Your most recent bolus and the time and date delivery began.

Your insulin on board, or IOB (insulin from boluses still active in your body), if the Bolus Calculator is on (see "Turn the Bolus Calculator on or off" on page 68).

Message about the Pod's current activity. This area usually shows the active Basal Program and the current basal rate. However, a different message appears if insulin delivery is suspended, a temp basal or extended bolus is running, you have no active Pod, or if the PDM cannot communicate with the Pod.

The time and date that your Pod will expire. If the Pod has already expired, "Pod exp: change Pod" appears instead.

IOB screen

For details about your insulin on board (IOB), navigate to the **Status** screen and press the **Info** button.

The **IOB** screen shows you how much of your total IOB is from a meal IOB and how much is from a correction IOB.

For more information about the IOB calculation and how the Bolus Calculator uses IOB, see page 141.

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CHAPTER 2
Initial PDM Setup

The Starter Kit

Your initial shipment contains the Starter Kit and other items needed to begin using the Omnipod® Insulin Management System.

After you unpack the Starter Kit, use the "Contents" label on the side of the box to make sure you have everything. Then complete and return the warranty card.

The Starter Kit contains:

- 1 PDM & 2 AAA alkaline batteries
- 1 USB cable
- 1 User Guide
- 1 carrying case
- 1 Diabetes Troubleshooting Guide
- 1 warranty registration card

You can obtain Pods by contacting Customer Care (see "Contacts and Important Information" on the front page of this *User Guide*). You can obtain test strips, control solution, and a lancing device at many pharmacies.

Preparing for Your Training

If you are a first-time Omnipod® System user, you need to meet with your Omnipod® System Trainer to set up your Personal Device Manager (PDM) and first Pod.

To get a head start on learning about the Omnipod® System, review this *User Guide* prior to meeting with your Omnipod® System trainer, including the "Introduction" on page ix, "Your Omnipod® Insulin Management System" on page 1, and "Taking Care of Your PDM and Pod" on page 107.

> **Warning:** Do NOT use the Omnipod® System until you have been trained by your Omnipod System Trainer. He or she will help you initialize the PDM based on your individual needs. Inadequate training or improper setup could put your health and safety at risk.

Note: Keep an emergency kit with you at all times to quickly respond to a diabetes emergency.

Items to bring to the meeting with your Omnipod® System trainer

- Your PDM

- Two Pods

- FreeStyle Test Strips and Control Solution, and a lancing device (available from many pharmacies)

- This *User Guide*

- Instructions from your healthcare provider about PDM settings tailored to your needs. These settings include Basal Program, IC Ratio, Correction Factor, Target BG values, and duration of insulin action.

PDM Setup

Although PDM setup is easy, if you are a first-time user, your Omnipod® System trainer must guide you through the process. You can adjust these settings later as needed.

Avoid taking a long break during the setup process. If the PDM is idle for 60 minutes during the setup process, you must begin the setup process from the beginning.

Tip: *Use the pages at the end of this User Guide to write down all of your settings. This list will be helpful if you ever need to reset or replace your PDM.*

Insert the batteries

1. Open the battery compartment on the back of the PDM by pushing the compartment latch and lifting upward. No special tools are necessary.
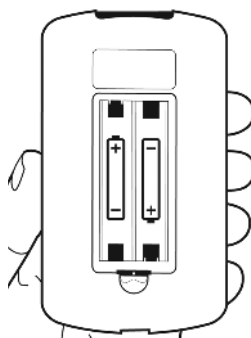
2. Insert two new AAA alkaline batteries into the compartment. The diagram inside the compartment shows you which direction to insert the batteries.

Caution: Only use AAA alkaline batteries to power the PDM. Never use old, used, or non-alkaline batteries; the PDM may not work properly. Do not use rechargeable batteries.

3. Replace the battery door.

4. Turn the PDM face up. The PDM powers on automatically.

Personalize your PDM

Username and screen color

1. After inserting the batteries, a Welcome message appears on the screen. Press **Next**.

2. Use the **Up/Down** button and the **middle soft key** to enter your user name (see "Entering text" on page 6).
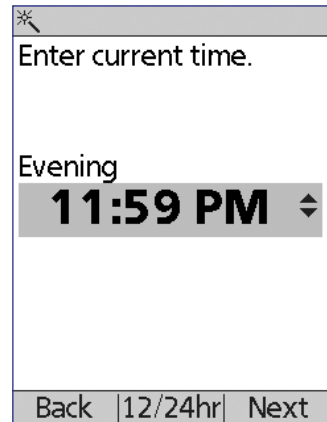
    Note: You must enter at least one letter or number.

3. When finished entering your username, press **Next**.

4. Use the **Up/Down** button to choose a background color for your ID screen.

5. Press **Next**.

Note: Each time you turn on your PDM, you will see your username and your selected screen color. Always identify the PDM as yours before using it.

Time and date

1. Press **12 / 24 hr** to choose your preferred time display. For example, six hours before midnight is:

    -   "6:00 PM" in 12 hr display

    -   "18:00" in 24 hr display

2. Use the **Up/Down** button to set the current time. Press **Next**.

3. Use the **Up/Down** button to set the current year, month, and day, pressing **Next** between each setting.

4. Use the **Up/Down** button to choose your preferred date format. Press **Next**.

5. Review the time and date, and press **Confirm**.

Basal and BG settings

Maximum Basal Rate

The Omnipod® System cannot deliver insulin at a basal rate that exceeds your Maximum Basal Rate. You can adjust your Maximum Basal Rate later, if your needs change.

1.   Use the **Up/Down** button to choose a Maximum Basal Rate.

2.   Press **Next**.

Define a Basal Program

Your Basal Program defines your daily schedule for continuous insulin delivery. The initial Basal Program is named "basal 1" and covers the full 24-hour period from midnight to midnight. For an explanation of basal rates, basal segments and Basal Programs, see page 134.

1.   Use the **Up/Down** button to choose the basal rate for the time segment that begins at midnight, then press **Next**.

2.   Press **Confirm** to accept this value as your initial basal rate.

   Note: Initially, this time segment spans the 24-hour period from midnight to midnight. You can segment the day into smaller periods of time in the following steps. The first segment of your Basal Program will always start at midnight, and the final segment will always end at midnight.

3. To set different values for different times of day, you must sub-divide the day by defining new time segments. To add a time segment:

   a. Choose [**add new**] and press **New**.

      Note: You can edit an existing segment by using the *Up/Down* button to select a segment you wish to change and pressing *Edit*.

   b. Enter a start time for the segment, then press **Next**.

   c. Enter an end time for the segment, then press **Next**.

   d. Enter the basal rate for the segment, then press **Next**.

   e. Press **Confirm** to accept the values for this segment.

   f. To add another time segment, return to step a.

      For a graphical illustration of this process, see "Working with Time Segments" on page 81.

4. When the desired number of time segments exist, press **Done**.

5. Review your Basal Program:

   • To see the Basal Program as a list, press **List**.

   • To return to the graph, press **Graph**.

Basal Program as list

Basal Program as graph

6. Press **Save** to store the Basal Program.

Note: You can rename this Basal Program or create additional Basal Programs after setup is complete (see "Basal Programs" on page 63).

Temp basal configuration

For an explanation about using temporary basal rates, called temp basals, see "Temporary basal rates" on page 135.

1. Choose a configuration for your temp basals:

%	To define your temp basals as a percentage of the currently active Basal Program.
U/hr	To define temp basals as a flat rate for the duration of the temp basal.
Off	To turn off the ability to use temp basals.

2. Press **Next**.

BG sound

If **BG sound** is turned on, the PDM beeps to alert you when a test strip is full. This lets you keep your eyes on your finger and the test strip, relying on your ears to tell you when the test strip is full.

1. Choose a BG sound setting:

    - Select **On** if you want to hear a beep when the test strip is full.

    - Select **Off** if you do not want to hear a beep when the test strip is full.

2. Press **Next**.

Upper and lower limits for BG Goal Range

To define the upper and lower limits of your BG Goal Range:

1. Use the **Up/Down** button to select the lower limit. Press **Next.**

2. Use the **Up/Down** button to select the upper limit. Press **Next.**

3. The next screen shows the selected upper and lower limits on a graph. Press **Save** to accept the limits.

Bolus Calculator settings

The Bolus Calculator suggests boluses for you based on your current blood glucose value and any food you are about to eat (see "The Bolus Calculator" on page 140 for a detailed explanation).

Turn the Bolus Calculator on or off

1. Choose your Bolus Calculator setting:

    - Select **On** to have the Bolus Calculator suggest boluses.

    - Select **Off** to do your own bolus calculations.

2. Press **Next**. If you turned the Bolus Calculator off, skip to "Other bolus settings" on page 21.

Target BG and Correct Above values

The Bolus Calculator aims to bring your blood glucose to the Target BG value. You can establish up to eight different blood glucose targets at different times of day.

For each Target BG that you set, you also set an accompanying Correct Above value. The Correct Above value can range from the Target BG to 200 mg/dL. The Bolus Calculator only suggests a correction bolus if your blood glucose is above the Correct Above value.

1. Use the **Up/Down** button to enter the Target BG for the time segment that starts at midnight. Initially, this segment covers 24 hours. Your Target BG must be between 70 - 200 mg/dL. Press **Next**.

2. Use the **Up/Down** button to enter the Correct Above value for the segment that starts at midnight. Press **Next**.

3. Press **Confirm** to accept these values for your initial segment.

4. If desired, add more time segments to your Target BG profile (for step-by-step instructions, see "Adding time segments" on page 20).

5. When the desired number of time segments exist, press **Done**.

6. Review the graph of your Target BG and Correct Above profile. Press **List** for a listing. Press **Graph** to see the graph again.

7. Press **Save** to store the profile.

Minimum BG for Calcs

If your blood glucose level is below the Minimum BG for Calcs that you specify, the Bolus Calculator is disabled (see "The Bolus Calculator" on page 140).

1. Use the **Up/Down** button to choose a Minimum BG for Calcs value. This value must be between 50 - 70 mg/dL.

2. Press **Next**.

IC Ratio

Your Insulin-to-Carbohydrate Ratio (IC Ratio) defines how many carbohydrates can be handled by one unit of insulin. The Bolus Calculator uses the IC Ratio to calculate the meal portion of a suggested bolus. You can create up to eight IC Ratio segments per day.

1. Use the **Up/Down** button to enter the IC Ratio for the time segment that starts at midnight. Your IC Ratio must be between 1 - 150 g carb/unit insulin. Press **Next**.

2. Press **Confirm** to accept this value as your initial IC Ratio.

3. If desired, add more time segments to your IC Ratio profile (for step-by-step instructions, see "Adding time segments" on page 20).

4. When the desired number of time segments exist, press **Done**.

5. Review the graph of your IC Ratio profile. Press **List** for a listing. Press **Graph** to see the graph again.

6. Press **Save** to store the profile.

Adding time segments

1. Choose [**add new**] and press **New**.

   Note: You can edit an existing segment by using the **Up/Down** button to select a segment you wish to change and pressing **Edit**.

2. Enter a start time for the segment, then press **Enter**.

3. Enter an end time for the segment, then press **Next**.

4. Enter a desired value for the segment, then press **Next**. If setting a Target BG value, enter a Correct Above value for the segment and press **Next**.

5. Press **Confirm** to accept the values for this segment.
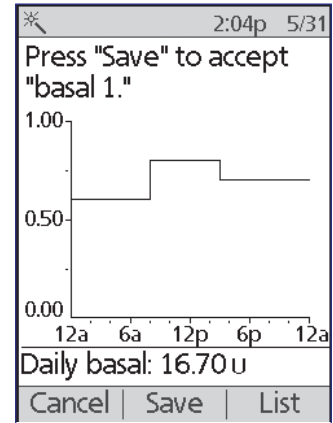
6. To define more time segments, return to step 1.

For a graphical illustration of this process, see "Working with Time Segments" on page 81.

Correction Factor

Your Correction Factor defines how much one unit of insulin lowers your blood glucose level. The Bolus Calculator uses the Correction Factor to calculate the correction portion of a suggested bolus. You can create up to eight Correction Factor segments per day.

1. Use the **Up/Down** button to enter the Correction Factor for the time segment that starts at midnight. Your Correction Factor must be between 1 - 400 mg/dL. Press **Next**.

2. Press **Confirm** to accept this value as your initial Correction Factor.

3. If desired, add more time segments to your Correction Factor profile (for step-by-step instructions, see "Adding time segments" on page 20).

4. When the desired number of time segments exist, press **Done**.

5. Review the graph of your Correction Factor profile. Press **List** for a listing. Press **Graph** to see the graph again.

6. Press **Save** to store the profile.

Reverse correction

There may be times when you are about to eat and your blood glucose level is below your Target BG level. If Reverse Correction is on, the Bolus Calculator decreases a suggested meal bolus to help counteract your low blood glucose reading.

1. Choose a setting for the Reverse Correction feature:

    - Select **On** if you want the Bolus Calculator to reduce its suggested meal bolus when your blood glucose is below your Target BG.

    - Select **Off** if you do not want the Bolus Calculator to adjust its suggested meal bolus according to your current blood glucose value.

2. Press **Next**.

Duration of insulin action

The duration of insulin action is the length of time that insulin stays active in your body. The Bolus Calculator uses this setting to determine how much insulin remains in your body from previous boluses (called insulin on board).

1. Use the **Up/Down** button to select your duration of insulin action.

2. Press **Next**.

Other bolus settings

Bolus increment

The bolus increment defines how much a single up or down click of the **Up/Down** button changes the bolus amount listed on the screen.

1. Use the **Up/Down** button to select your desired bolus increment.

2. Press **Next**.

Maximum Bolus

The Maximum Bolus sets the upper limit on the size of a bolus.

1. Use the **Up/Down** button to select your desired Maximum Bolus.

2. Press **Next**.

Extended bolus setting

Extending a bolus means that a meal bolus can be delivered over a prolonged period of time. For an explanation of extended boluses, see page 139.

1. Select a configuration for your extended bolus:

%	To specify the amount of the immediate portion of the bolus as a percent of the total bolus.
Units	To specify how many units of insulin should be delivered immediately.
Off	To turn off the ability to extend a bolus.

2. Press **Next**.

Pod settings

The next step is to choose how much advance notice you would like about the Pod running low on insulin or an upcoming Pod expiration.

1. Use the **Up/Down** button to select the insulin level at which you would like to receive a 'low reservoir' message. This volume can range from 10 to 50 units. Press **Next**.

2. Use the **Up/Down** button to specify how much advance warning you want about an upcoming Pod expiration. This setting can be from 1 to 24 hours. Press **Next**.

Activate Your First Pod

Congratulations! Your PDM is now ready for use. To activate a Pod now, press **Yes** and skip ahead to "Fill the Syringe with Insulin" on page 26 for step-by-step instructions for filling and activating your first Pod. If necessary, review Chapter 1 for an introduction to the PDM's screens and screen navigation shorthand.

Tip: *To adjust the PDM screen time-out and backlight time-out, see page 61.*

CHAPTER 3
Changing Your Pod

Begin the Pod Change Process

Your Pod should be replaced at least once every 48 to 72 hours (2 to 3 days) or after delivering 200 units of insulin. Consult with your healthcare provider and refer to the insulin labeling to determine if you should replace your Pod more often.

Warnings:

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

If you are a first-time Omnipod System user, your Omnipod System Trainer will guide you through the steps for initializing and applying your first Pod. Do NOT attempt to apply or use a Pod until you have been trained by your Omnipod System Trainer. Use of the System with inadequate training or improper setup could put your health and safety at risk.

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

Keep the Pod and its accessories, including the needle cap, away from young children, as they contain small parts that may be dangerous if swallowed.

Preliminary steps

1. Gather the necessary supplies:
    - A vial of rapid-acting U-100 insulin approved for use in the Omnipod® System
    - An unopened Pod
    - Alcohol prep swabs
    - Your PDM

2. Wash your hands before starting and keep them clean throughout the Pod change process.

3. Check the insulin for signs of deterioration.

4. Check the Pod's packaging for damage, then open it and inspect the Pod for signs of damage.

5. If the insulin or Pod is below 50°F (10°C), allow it to warm up to room temperature before proceeding.

Warnings:

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

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.

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

Do NOT use a Pod if it is past the expiration date on the package.

To minimize the possibility of site infection, do NOT apply a Pod without first using aseptic technique. This means to:
- Wash your hands
- Clean the insulin vial with an alcohol prep swab
- Clean the infusion site with soap and water or an alcohol prep swab
- Keep sterile materials away from any possible germs.

Prepare the PDM and deactivate the old Pod

To begin the Pod change process:

1. Navigate to the Pod change screen:

   Home > **More actions** > **Change pod**

2. If you are not wearing an active Pod, skip to step 6.

3. If a Pod is active, press **Confirm** to deactivate your Pod.

    If a temp basal or extended bolus is running, it is canceled when you press **Confirm**.

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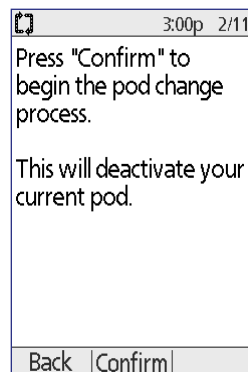
4. When deactivation is complete, remove the deactivated Pod.

    a. Gently lift the edges of the adhesive tape from your skin and remove the entire Pod.

        Tip: *Remove the Pod slowly to help avoid possible skin irritation.*

    b. Use soap and water to remove any adhesive that remains on the skin, or, if necessary, use an adhesive remover.

    c. Check the infusion site for signs of infection. See "Avoid Infusion Site Infections" on page 33.

    d. Dispose of the used Pod according to local waste disposal regulations.

5. After removing the old Pod, press **Next**.
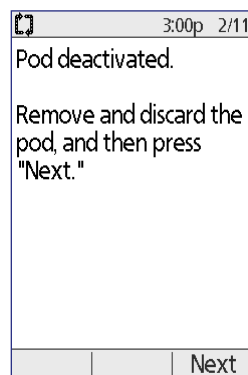
6. The screen asks if you'd like to activate a Pod now. Press **Yes**. Then put your PDM down without pressing any more buttons yet.

If you see a communication error message when you attempt to deactivate your Pod, see "Failure when deactivating a Pod" on page 103.

Fill the Syringe with Insulin

The next step is to fill the syringe that came with the Pod (the "fill syringe") with insulin:

1. Use an alcohol prep swab to clean the top of the insulin vial.

2. Securely twist the fill needle onto the fill syringe.

3. Pull outward to remove the protective cap from the needle. Save the cap; you will need it later.

4. Determine how much insulin you will put into the Pod. For example, to use the Pod for 48 hours, determine how much insulin you will use over the next 48 hours. Your healthcare provider can help you determine the correct amount.
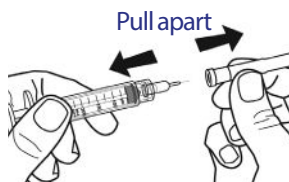
   Note: The Pod requires a minimum of 85 units of U-100 insulin to begin operation. The Pod can hold up to 200 units of U-100 insulin.

5. Draw air into the fill syringe up to the amount of insulin you want.

6. Insert the needle into the insulin vial and inject the air. Injecting air makes it easier to withdraw insulin from the vial.

7. Turn the vial of U-100 insulin and the fill syringe upside down. Pull down on the plunger to withdraw the desired amount of insulin from the vial into the fill syringe.

8. With the needle still in the vial, flick the side of the syringe with your fingertip to dislodge any air bubbles so they collect at the top of the syringe. Then push in the plunger to expel any air bubbles out of the syringe and into the insulin vial. Pull down on the plunger again, if necessary, to refill the fill syringe to the desired amount of insulin. Fill the syringe at least to the MIN (minimum) fill line.

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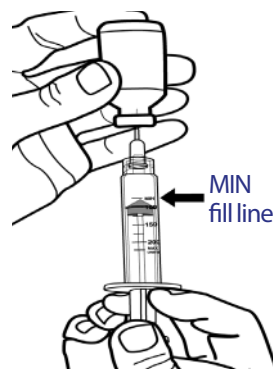
> **Warning:** Make sure there are no air bubbles or pockets of air in the fill syringe before filling a Pod with insulin. Air transferred from the fill syringe into the Pod may result in interrupted insulin delivery.

9. Remove the needle from the vial.

Fill and Activate a Pod

> **Warning:** Before filling a Pod, ensure that no other Pods are being activated within 24 inches (61 cm) of your PDM. This prevents activation of the wrong Pod.

Caution: Be sure to insert the fill syringe into the fill port and not at 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® System.

To fill the Pod with insulin:

1. Locate the arrow on the underside of the Pod. The arrow points to the insulin fill port.

   Tip: *You can leave the Pod in its tray during filling and activation.*

2. Insert the fill syringe straight down—not at an angle—into the fill port.

3. Depress the fill syringe plunger to completely empty the insulin into the Pod.
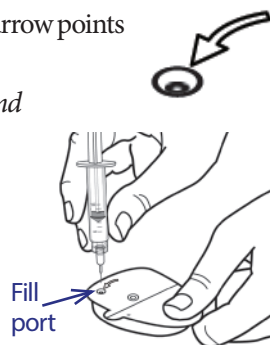
Fill
port

4. Listen for two beeps from the Pod during the filling process. Be sure to completely empty the fill syringe, even after hearing the two beeps.

   Note: The Pod must contain a minimum of 85 units of insulin in order to function. The Pod beeps twice after it has been filled with 85 units of insulin. If you have filled the Pod with more than 85 units and still do not hear the two beeps, please call Customer Care.

Warnings:

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

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

> 3:00p 2/11
> Fill a new pod with insulin.
>
> After filling pod, listen for 2 beeps, then press "Next."
>
> NOTE: Do not remove needle cap at this time.
>
> Cancel | Next |

5. Remove the needle from the insulin fill port. The port is self-sealing; insulin will not leak after the needle is removed.

6. Place the protective cap back on the needle and remove the needle from the fill syringe.

7. Place the PDM next to the Pod so they are touching. The Pod can be in its plastic tray during this process.
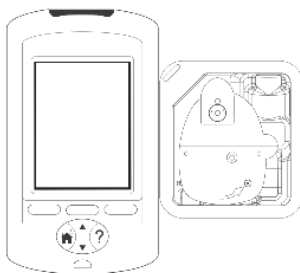
8. Press **Next**. A screen appears telling you that the Pod is priming.

9. The Omnipod® System performs a series of safety checks and automatically primes the Pod. Listen for the beeps that indicate that the Pod is successfully activated.

> 3:00p 2/11
>
> Priming

Note: The communication distance between the Pod and PDM is reduced during activation. Once activated, the Pod can receive commands only from the PDM that activated it.

Note: After filling the Pod with insulin, apply the Pod immediately. The Pod beeps every 5 minutes as a reminder. If you do not apply the Pod within 60 minutes, you must deactivate and dispose of it.
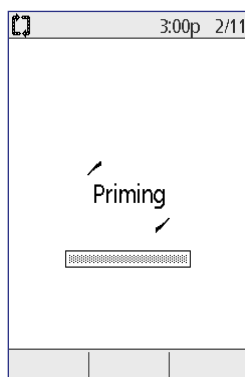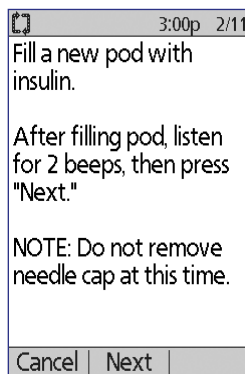
If you see a communication error message when you attempt to activate your Pod, see "Failure when activating or sending a command to a Pod" on page 101.

Select the Pod Site

Discuss suitable Pod placement sites with your healthcare provider using the following guidelines:

- Ideal sites have a layer of fatty tissue.

- Ideal sites offer easy access and viewing.

- The site should be at least 1 inch (2.5 cm) away from the previous site to avoid skin irritation.

Front   Back   Front   Back

- The site should be at least two inches (5 cm) away from your navel.

- Avoid sites where belts, waistbands, or tight clothing may rub against or dislodge the Pod.

- Avoid sites where the Pod will be affected by folds of skin.

- Avoid placing the Pod over a mole, tattoo or scar, where insulin absorption may be reduced.

- Avoid areas of the skin with an active infection.
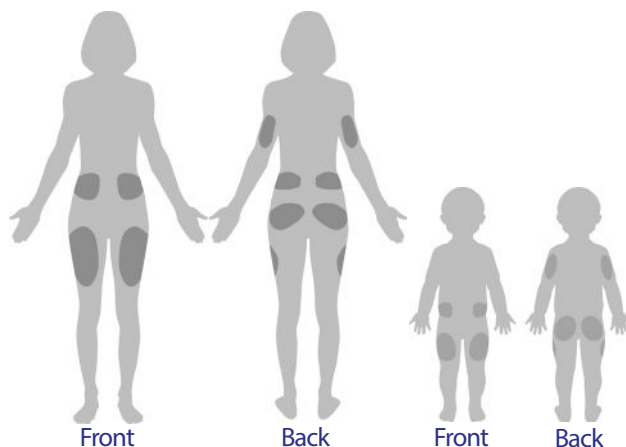
Prepare the Infusion Site

To reduce the risk of infection at the infusion site:

1. Wash your hands with soap and water.

2. Wash your selected Pod site with soap and water.

   Note: Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare provider how to treat any skin irritation.

3.   Dry the site with a clean towel.

4.   Use an alcohol prep swab to disinfect the site. Start at the center of the site and gently rub outward in a circular motion.

5.   Let the site air-dry thoroughly. Do not blow on the site to dry it.

Apply the Pod

The next step is to apply the Pod to your body:

1.   Remove the Pod's plastic needle cap on the underside of the Pod by placing your thumb on the bottom (flat edge) of the Pod's plastic cap and pulling the cap upwards. The cap snaps off. Throw the cap away.

When you remove the Pod needle cap, a drop of insulin may be visible at the end of the cannula or in the well.
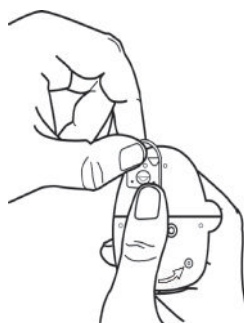
2.   If any of the following apply, press **Discard**, and then dispose of the Pod and begin again with a new Pod:

a.   The Pod is accidentally dropped, as this may compromise sterility

b.   The Pod or its adhesive pad is wet, dirty or damaged

c.   The cannula extends beyond the adhesive backing when the Pod needle cap is removed

> **Warning:**   Verify that the cannula does not extend beyond the adhesive backing once the needle cap is removed.
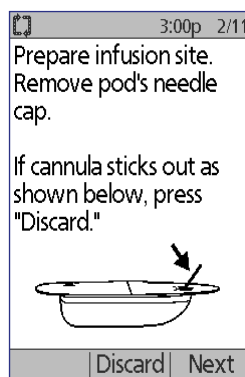
3.   Press **Next** if the Pod is in good condition.

4.   Using the pull tabs, remove and discard the white paper backing from the adhesive tape.

5.   Press **Discard** and dispose of the Pod if the adhesive pad is folded, torn or damaged, and begin again with a new Pod.

6. Orient the Pod so it is:

- Horizontal or diagonal on your abdomen, hip, lower back, or buttocks.

- Up and down or at a slight angle on your upper arm or thigh.

Suggested Pod orientation

Up, down, or slight angle

Horizontal or diagonal

Up, down, or slight angle
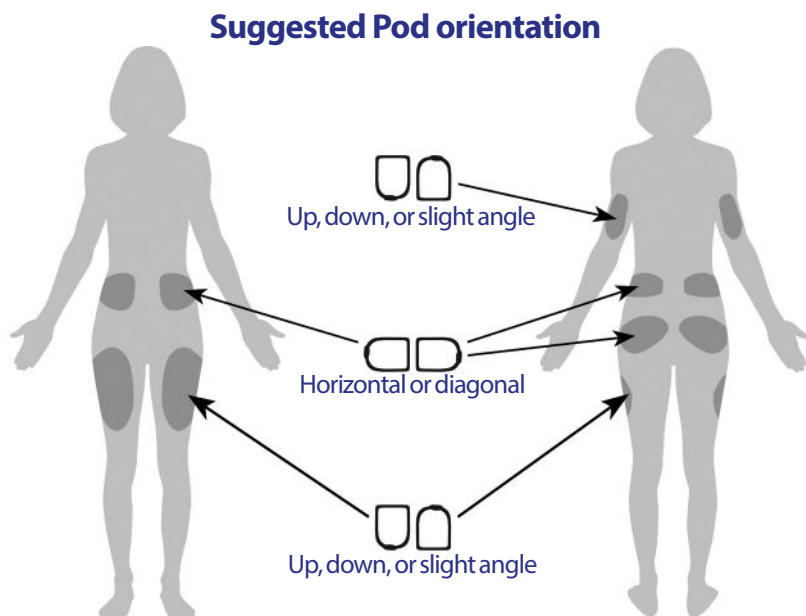
7. Apply the Pod to your selected site, pressing down firmly to secure the Pod to your skin.

The adhesive is designed for one-time use. Once a Pod is placed on your body, you cannot move that Pod to another site.

Note: The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products. Avoid getting body lotion, creams, or oils near the infusion site as these products may loosen the adhesive.

8. Press **Next**.

> 3:00p 2/11
> Remove pod's adhesive backing.
>
> If pod is wet or dirty, or adhesive is folded, press "Discard."
>
> If pod OK, apply to site.
>
> Back | Discard | Next

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

9. Press **Start**. After a few seconds, you hear a click as the cannula is inserted into your skin. If you were squeezing your skin, you can stop squeezing it after the cannula inserts.

Once the cannula is inserted, the Pod automatically fills the cannula with insulin. The Pod then begins delivering the basal rate of insulin according to the active Basal Program.

The cannula can be inserted only once with each Pod.

Caution: Be sure to check the alarm function at every Pod change (see "Check the alarms and vibration" on page 61).

3:00p 2/11

Press "Start" to insert cannula and begin basal delivery.

| Start |
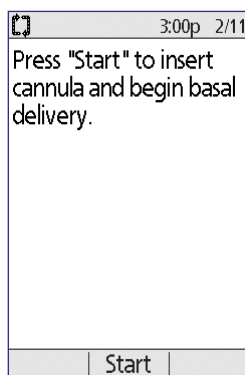
Check the Infusion Site

Following insertion of the cannula, check the infusion site:

1. Look through the viewing window to check that the cannula is inserted into the skin. The cannula is tinted light blue.

2. Check for pink coloring in the area on the top of the Pod shown in the figure. This is an additional check that the cannula was extended.

3. Check for wetness or the scent of insulin at the insertion site. The presence of either may indicate that the cannula has dislodged.

Viewing window — Check for pink here

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

---

4. If there is a problem with the cannula, press **No** and follow the on-screen instructions for deactivating your Pod. Then restart the process with a new Pod.

5. Press **Yes** if the cannula was properly inserted. The PDM shows the **Status** screen.

> 3:00p 2/11
>
> Pod is active.
>
> "basal 1" has been programmed.
> Check infusion site and cannula.
>
> Is cannula properly inserted?
>
> No | Yes
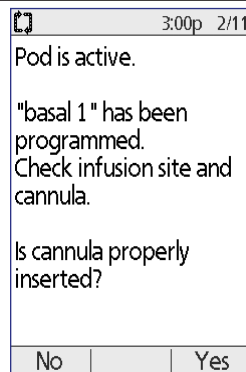
6. After 1.5 hours, the PDM prompts you to check your blood glucose level and to recheck the infusion site.

> 3:00p 2/11
>
> Reminder:
>
> Always check BG after a pod change.
>
> Check infusion site and ensure cannula is properly inserted.
>
> OK

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.
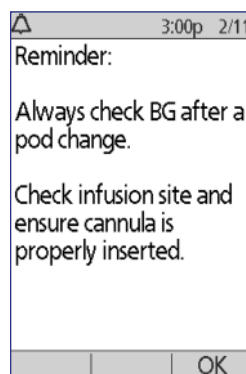
Avoid Infusion Site Infections

Check the infusion site at least once a day:

- Be aware of signs of infection, including pain, swelling, redness, discharge, or heat at the site. If you suspect an infection, immediately remove the Pod and apply a new one in a different location. Then call your healthcare provider.

- If you observe any problems with the Pod, replace it with a new Pod.

3 Changing Your Pod

Warnings:

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

If you observe blood in the cannula, check your blood glucose frequently to ensure that insulin delivery has not been affected. If you experience unexpectedly elevated blood glucose levels, change your Pod.

If an infusion site shows signs of infection:

*   Immediately remove the Pod and apply a new one at a different site.

*   Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

More Information about Pod Use

Tip: *You should change your Pod whenever you have used approximately 200 U of insulin or every 72 hours, whichever comes first. Develop a routine so you can change your Pod at a convenient time. If you know of an upcoming break in your routine that could interfere with changing your Pod, you can change your Pod early to avoid disruption in insulin delivery.*

For additional information on using your Pods as effectively as possible, see the following sections:

*   For care of your Pod, see "Pod and Insulin Care" on page 107.

*   To learn about the Pod alarms, see "Alarms, Notifications, and Other Messages" on page 93.

*   If your Pod sounds an alarm, first attempt to silence it with your PDM. If that is not successful, you can manually turn off the Pod alarm (see "Silencing an Alarm" on page 106.

*   To understand the Pod's informational and notification beeps, including which ones are optional, see "Notifications" on page 97 and "Informational Beeps" on page 99.

*   To understand how to handle situations where the PDM cannot communicate with your Pod, see "Pod Communication Failures" on page 100.

*   For an explanation of the how the PDM communicates with the Pod, see "PDM and Pod Interactions" on page 129.

CHAPTER 4
Checking Your Blood Glucose

About Blood Glucose Testing

Warnings:

Keep the blood glucose testing accessories away from young children, as they contain small parts that may be dangerous if swallowed.

Only use FreeStyle® test strips and FreeStyle® control solution with the Omnipod® System. Using other brands of test strips and control solutions with the System can produce inaccurate results.

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

If you are experiencing symptoms that are not consistent with your blood glucose reading and you have followed all instructions described in this *User Guide*, call your healthcare provider immediately.

Blood circulation is different between the finger and other test sites such as the upper arm and hand. You may see differences in blood glucose measurements between the other test sites and your finger after eating, taking insulin medication, or exercise.

You may see changes in blood glucose in blood samples from the finger sooner than in blood samples from alternate sites. Vigorous rubbing of the alternate test sites before lancing helps to minimize these differences.

Measurements obtained from sites other than the finger, palm or upper arm should not be used to calculate insulin doses with the Omnipod® System.

Do not use during xylose-absorption testing.

Objects that may be soiled with blood may then transmit pathogens. See "PDM cleaning and disinfecting" on page 111 for instructions on how to disinfect your PDM.

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

Severe dehydration and excessive water loss can cause falsely elevated blood glucose results. If you believe you are suffering from severe dehydration, consult your healthcare provider immediately.

> **Warnings:**
>
> Test results below 70 mg/dL mean low blood glucose (hypoglycemia).
>
> Test results greater than 250 mg/dL mean high blood glucose (hyperglycemia).
>
> If you get results below 70 mg/dL or above 250 mg/dL, but do not have symptoms of hypoglycemia or hyperglycemia (see "Living with Diabetes" on page 115), repeat the test. If you have symptoms or continue to get results that fall below 70 mg/dL or above 250 mg/dL, follow the treatment advice of your healthcare provider.

Note: Wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

Control solution

The FreeStyle Control Solution is a red liquid containing a fixed amount of glucose. It is available in Low, Normal, and High concentrations. Use control solution to ensure that your meter and test strips are working together properly and to practice testing without having to use your own blood. See the control solution instructions for information about handling and storing the control solution.

You should perform a control solution test when:

- You suspect that the built-in BG meter or test strips are not working properly.
- You think your BG readings are not accurate or are not consistent with how you feel.
- You drop or damage your PDM or expose it to liquids.
- Your healthcare provider advises you to do so.

When you perform a control solution test, if the reading is within the control solution acceptable range, the built-in BG meter is working properly.

With the built-in BG meter, checking your blood glucose requires a very small sample size, 0.3 microliters of blood.

Caution: Results from FreeStyle Control Solution tests do not reflect your blood glucose level.

You may want to test for low blood glucose when:

- You feel symptoms such as weakness, sweating, nervousness, headache, irritability, or confusion.
- You have delayed a meal after taking insulin.
- Your healthcare provider advises you to do so.

Using the Built-in BG Meter

If you plan to use a separate BG meter, skip to "Using a Separate BG Meter" on page 43.

FreeStyle Control Solutions and Test Strips must be purchased separately. Contact your pharmacy or call Customer Care.

Caution: Complete information on the FreeStyle Test Strips (such as interferences and performance) can be found in the test strip package insert. Please read all instructions provided on the test strip package insert before using the Omnipod® System and FreeStyle accessories.

Insert a test strip into the PDM

1. Turn on your PDM by pressing the **Home/ Power** button. Identify the PDM as yours and press **Confirm**.

    Tip: *You can also turn on the PDM by inserting the test strip into the test strip port.*

    Caution: If Auto-off is enabled, you should always turn on the PDM with the **Home/ Power** button prior to inserting a test strip (see "Auto-off" on page 133).

2. Insert a test strip into the PDM's test strip port. To do so, hold the bottom of the test strip and gently insert it into the test strip port until it stops.

    Note: The PDM will not perform a blood glucose test during Pod activation or while an alarm is sounding.

Insert test strip here

Sample can be applied here ...

... or here
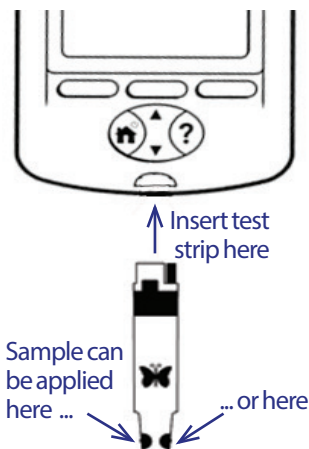
3.   When the PDM detects the test strip, the screen
      displays a code number for two seconds. Check that
      the code number matches the number on the test
      strip vial. If necessary, use the **Up/Down** button to
      adjust the code.

> **Warning:**   Always verify that the code on the
> PDM matches the code on the test strip vial.
> Failure to do so will result in an inaccurate
> reading.
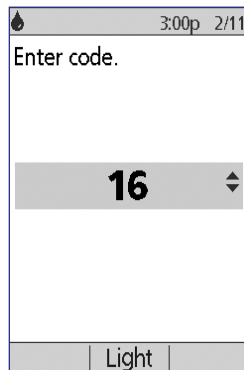
Note: If you need to adjust the code number after
the PDM has moved to the next screen, press the
Up/Down button. The code screen reappears and
you can adjust the number.

4.   Wait for the screen that says, "Apply a blood sample
      to the strip," along with an image of a blinking drop
      of blood.
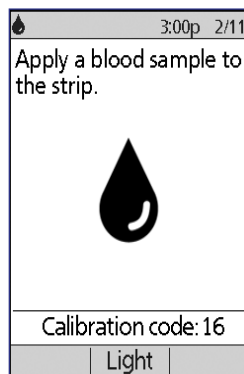
Test your blood glucose or control solution

> **Warnings:**
>
> **Do not**:
>
> - Press the test strip against your finger
> - Scrape the blood onto the test strip
> - Apply blood to the flat side of the test strip
> - Apply blood to the test strip when it is out of the BG meter
> - Put blood or foreign objects into the test strip port
> - Use blood from any site other than the finger
>
> If the device is being operated by a second person who is providing testing
> assistance to the user, the BG meter and lancing device should be disinfected
> prior to use by the second person (see the instructions that came with your
> lancing device and also see "PDM cleaning and disinfecting" on page 111).

Warnings:

To ensure accurate results, wash your hands and the test site (for example, your upper arm) with soap and water. Do not leave any cream or lotion on the test site. Thoroughly dry your hands and the test site.

Measurements obtained from testing should not be used to calculate insulin doses with the Omnipod System.

To test your blood glucose or to perform a control solution test:

1. Prepare a drop of blood or control solution:

   Blood:

      a. Lance your finger, following your lancing device instructions.

      b. Gently squeeze or massage your finger until a round drop of blood forms.

   Note: If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop of blood, or use the lancing device at a new site.

   Control solution: Prepare the control solution according to its instructions-for-use.

2. If necessary, turn the PDM back on.

3. To light up the test strip area, select the *Light* option. To turn the light off again, press the *Light* option again.

4. Position the PDM so the test strip's sample area meets the blood or control solution at a slight angle.
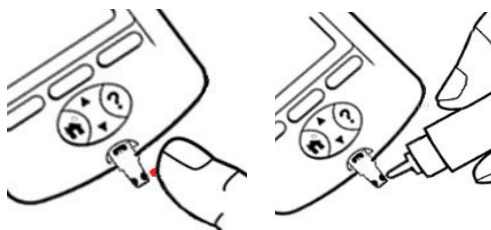
   Note: If you do not apply a drop of blood or control solution within two minutes of inserting the test strip, the PDM powers off. To restart the PDM, take out the unused strip and reinsert it, or press-and-hold the *Home/Power* button.

5. Gently touch the drop of blood or control solution to the sample area. The test strip wicks the drop inside.

   Note: Apply blood to one side of the test strip only.

4 Checking Your Blood Glucose

6. Continue to hold the test strip to the sample until the **Checking** screen appears. You will hear the PDM beep once if **BG sound** is set to on.

   If the PDM does not display "Checking" after five seconds, the sample may be too small. You can add more blood to the same edge of the strip up to 60 seconds after the first application.
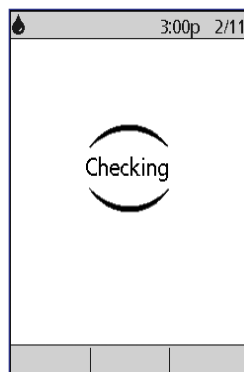
7. Continue to watch the PDM screen. When the blood glucose reading is complete, the result is displayed on the screen. Also, if **BG sound** is on, the PDM beeps twice.
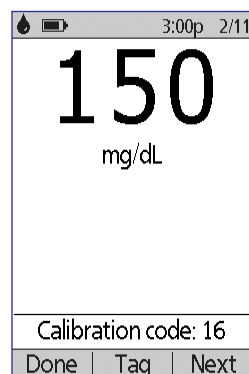
   Note: The higher your blood glucose level, the longer the test takes.

   Note: If the built-in BG meter is too cold or too hot, a thermometer symbol appears in the header bar of the screen indicating that the result is unreliable. The Bolus Calculator is temporarily disabled until the PDM returns to the proper temperature range. The blood glucose reading is saved in the BG history records, but it is tagged with a note saying that the meter temperature was out of range.
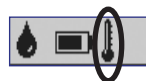
   Note: If you receive a "Meter Error" message when checking your BG, see "Errors in the Built-in BG Meter" on page 104.

8. Remove and dispose of the test strip (see the test strip instructions for use for disposal information). You can use a test strip only once. Used test strips are considered biohazardous material.

   Note: Wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

9. If this is a blood glucose reading (that is, not a control solution test), go to "Blood glucose results" on page 41.

Control solution results

If this is a control solution test, you must verify the results and tag it as a control solution.

Caution: If you fail to tag a control solution properly, its value is averaged into your blood glucose history records.

1. Compare the number displayed on the PDM screen to the range printed on the control solution vial.

2. If the number displayed is outside the range on the vial, follow the control solution instructions about retesting or call Customer Care.

3. If the number displayed is within the range on the vial, tag the reading as a control solution reading by pressing **Tag**. With **Control** highlighted, press **Select** and then **OK**.

4. Press **Done** to return to the **Status** screen.
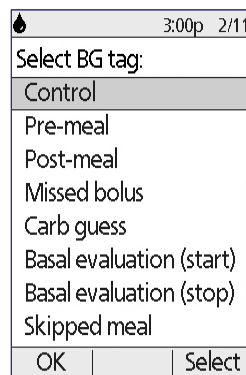
Blood glucose results

When the PDM displays your blood glucose result, it adds an on-screen message if the result is especially high or low (see "How the PDM reports blood glucose results" on page 43).

To bolus or not to bolus?

1. To add an informational tag to your blood glucose reading, see "Tagging the Blood Glucose Results" on page 44.

2. If you do not want to deliver a bolus, press **Done**.

3. If you want to deliver a bolus and:

   a. The Bolus Calculator is on, press **Next** and go to step 4 on page 46.

   Note: If your blood glucose reading is below your Minimum BG for Calcs or reads HIGH, the Bolus Calculator, even if turned on, is temporarily disabled. Follow your healthcare provider's treatment suggestions.

   b. The Bolus Calculator is off, press **Bolus** and go to step 4 on page 49.

   Note: If your blood glucose reading is below 70 mg/dL or reads HIGH, follow your healthcare provider's treatment suggestions.

Note: The blood glucose reading is automatically saved in your *BG history* records.

Low and high blood glucose readings

Warnings:

Blood glucose readings that are especially low or high can indicate potentially serious condition requiring immediate medical attention. If left untreated, this situation can quickly lead to diabetic ketoacidosis (DKA), shock, coma, or death.

Low readings

If your reading is below 70 mg/dL, the PDM displays: "Treat your low BG!" This indicates severe hypoglycemia (low blood glucose). If "LOW" also appears on the PDM, this indicates BG readings below 20 mg/dL.

Low reading with symptoms

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

Low reading without symptoms

If you get a "Treat your low BG!" reading, but have no symptoms of low blood glucose, then retest using a new test strip. If you still get a "Treat your low BG!" reading, perform a control solution test to ensure your system is working properly. If the system is working properly, follow your health care provider's recommendation to treat hypoglycemia.

High readings

If your reading is at or above 250 mg/dL, the PDM displays "Check for ketones!" This indicates severe hyperglycemia (high blood glucose). If "HIGH" also appears on the PDM, this indicates BG readings above 500 mg/dL.

High reading with symptoms

If you get a "Check for ketones!" reading and feel symptoms such as fatigue, thirst, excess urination, or blurry vision, follow your healthcare provider's recommendation to treat hyperglycemia.

High reading without symptoms

If you get a "Check for ketones!" reading, but have no symptoms of high blood glucose, then retest using a new test strip. If you still get a "Check for ketones!" reading, perform a control solution test to ensure your system is working properly. If the system is working properly, follow your healthcare provider's recommendation to treat hyperglycemia

How the PDM reports blood glucose results

When the PDM displays your blood glucose reading, it adds a warning message for high and low results.

Blood glucose result	Screen display	Screen warning message
Above 500 mg/dL	HIGH	Check for ketones!
250-500 mg/dL	BG reading	Check for ketones!
70-249 mg/dL	BG reading	
20-69 mg/dL	BG reading	Treat your low BG!
0-19 mg/dL	LOW	Treat your low BG!

The PDM records BG readings above 500 as "HIGH" and BG readings below 20 as "LOW." HIGH and LOW readings are saved in your **BG history**, but are not used in averages or other numerical calculations.

> **Warning:** "LOW" or "HIGH" blood glucose readings can indicate a potentially serious condition requiring immediate medical attention. If left untreated, these situations can quickly lead to diabetic ketoacidosis (DKA), shock, coma, or death. Consult your healthcare provider for how to treat high and low blood glucose levels.

Using a Separate BG Meter

You can measure your blood glucose using a separate BG meter and then use the PDM to deliver a bolus. You can also save this blood glucose reading in the PDM's **BG history** records.

To bolus

If you want to deliver a bolus when using a separate BG meter, go to "Delivering a Bolus of Insulin" on page 45. The blood glucose value you enter during the bolus process will be saved to your history records at that time.

To enter your blood glucose reading without bolusing

1. Check your blood glucose following the instructions included with your separate BG meter.

2. Turn on your PDM, if necessary, and navigate to:

   Home > More actions > Add BG reading

3. Use the **Up/Down** button to enter your measured blood glucose value.

4. Press **Tag** to add an informational note to your blood glucose reading (see "Tagging the Blood Glucose Results" on page 44).

5. Press **Next** and then press **Confirm** to save the reading in the **BG history** records.

See "How the PDM reports blood glucose results" on page 43 for a description of the messages displayed by the PDM for different ranges of blood glucose values.

Tagging the Blood Glucose Results

You can add an informational tag to your blood glucose reading for future reference. For example, you may tag the result as a pre- or post-meal test, or to indicate a level of exercise. You can add or change tags on your blood glucose results up to two hours after you enter the blood glucose value. To access the tags:

1. If necessary, bring up the tag screen by navigating to:

   Home > More actions > Assign/Edit BG tags

2. Use the **Up/Down** button to choose the first item you'd like to tag, and press **Tag**.

3. Use the **Up/Down** button to scroll along the list of potentials tags. Highlight a tag and press **Select**.

4. You can highlight and select up to two tags. You can remove a tag by highlighting it and pressing **Clear**.

5. Press **OK** when finished.
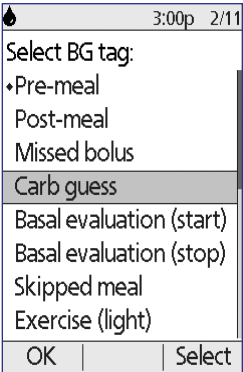
Note: You can add or edit tags for LOW and HIGH blood glucose readings just as you would for any other reading.

For information about adding custom tags or managing the tags list, see "BG tags" on page 80.

Delivering a Bolus of Insulin

Why Bolus?

You can deliver a bolus of insulin when you need to lower a high blood glucose level and when you are about to eat.

The Omnipod® Insulin Management System allows you to:

- Have the System's Bolus Calculator suggest a correction or meal bolus (see "Bolusing with the Bolus Calculator" on page 45).

- Calculate your own bolus (see "Manually-calculated Bolus" on page 48).

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

For an explanation of boluses and the Bolus Calculator, see page 140.

Note: Insulin sensitive patients should be aware that the accuracy of the device below 1U is ±0.05 units. For a dose of 0.05 units the actual bolus delivered may be as low as 0.00 units or as high as 0.10 units.

Bolusing with the Bolus Calculator

To change your personal settings, or to turn the Bolus Calculator on or off, see "Bolus Calculator Settings" on page 68.

Enter your BG and meal information

To deliver a bolus using the Bolus Calculator:

1. Measure your blood glucose. If using a separate BG meter, follow the instructions included with your BG meter. If you used the built-in BG meter, skip to step 4. For more information, see "Checking Your Blood Glucose" on page 35.

    Note: When your blood glucose result reads "HIGH" or is below your Minimum BG for Calcs, the Bolus Calculator is disabled.

2. Navigate to the bolus screen:
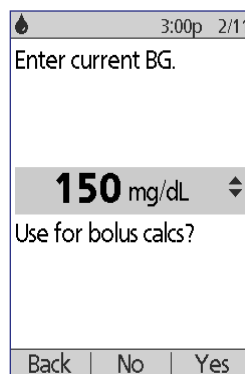
    Home > Bolus

3. Enter your blood glucose reading:

Note: While the Bolus Calculator can generate a suggested bolus dose based only on the carbohydrates in a meal, you should always enter a recent blood glucose reading for added safety and accuracy. This allows the Bolus Calculator to adjust the suggested bolus to account for your current blood glucose level.

- To enter a reading from a separate BG meter, use the **Up/Down** button to enter the blood glucose value, then press **Yes**. While the Bolus Calculator will use any blood glucose value you enter manually, you should only enter a BG value that was taken within the last 10 minutes.

- If you recorded a blood glucose value within the past 10 minutes, the screen automatically displays it. If you want the Bolus Calculator to use that value, press **Yes**.

- Press **No** to tell the Bolus Calculator to perform the calculation without accounting for your current BG value.
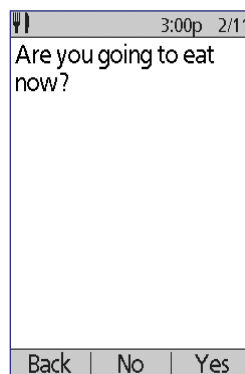
4. The next screen asks if you are going to eat now.

- If you are not going to eat, press **No**.

- If you are going to eat, press **Yes**. Then enter the grams of carbohydrates you are going to eat:

  - Use the **Up/Down** button to enter the grams of carbs in your meal, then press **Enter**.

  - Or, if you have defined one or more carb presets, either (1) select a carb preset, or (2) select **[enter manually]**, use the **Up/Down** button to enter the grams of carbs in your meal, and press **Enter**.

  To look up the grams of carbs in various foods, see "Food Library" on page 51. To create a carb preset, see "Carb presets" on page 71.

5. Review the BG value and, if eating, the carb value, then press **Confirm**.

Deliver the bolus

The Bolus Calculator calculates a suggested bolus and displays the result. It is called a suggested bolus because you must either confirm it or modify it.

1. Review the suggested bolus. If you wish, press the **Up/Down** button to increase or decrease the suggested bolus.

Note: The "Carbs" entry and the "Extend" soft key label only appear if you are going to eat. In addition, if the extended bolus option is off, the "Extend" soft key label does not appear on the screen. If insulin on board is a factor in the calculation, the screen shows "adjusted for IOB."

> **Warning:** If the suggested bolus exceeds your Maximum Bolus, "Exceeds max bolus" appears below the bolus. If you select **Enter** or **Extend**, a screen warns you that the suggested bolus exceeds your Maximum Bolus. Press **Confirm** to allow a one-time override of the limit or **Cancel** to disallow it. Allowing this override does not change your Maximum Bolus setting.

2. To deliver the entire bolus immediately, press **Enter**, then skip to step 4. (See "Immediate and Extended Boluses" on page 139 for more information.)

3. To extend the delivery of part or all of the meal bolus:

    a. Press **Extend.**

    b. Use the **Up/Down** button to enter the amount or percent of the bolus to deliver immediately. Press **Enter**.

    c. Use the **Up/Down** button to enter the duration of the extended portion. Press **Enter**.

    Note: Your "extended bolus" setting determines whether the screen displays percent (**%**) or units (**U**).

Note: You can only extend the meal portion of the bolus, and the extended bolus option must be turned on. To view the correction bolus and meal bolus portions of the suggested bolus, press the **Info** button.

4. If the BG reminder option is turned on and you want a reminder to check your blood glucose, press **Yes**. Use the **Up/Down** button to enter the time for the reminder. Press **OK**.

   See "BG reminders" on page 75 if you want to turn on or off the BG reminder. It is off by default.

5. Review the bolus and press **Confirm** to begin delivery.

After the bolus has started, the bolus amount and any entered BG and carb values are stored in your history records.

The screen displays a **Delivering bolus** message throughout the delivery of an immediate bolus.

3:00p 2/11	3:00p 2/11
Start bolus?	Start bolus?
Now: **2.00** U	
Ext: **3.00** U	**1.20** U
(1.0 hr)	
Total: **5.00** U	
Back Confirm	Back Confirm
With extended bolus	*Without extended bolus*

Tip: *Once a bolus is started, the Pod finishes delivering the bolus whether or not it is in range of the PDM.*

During the extended portion of a bolus, check the **Status** screen to see how much of the extended bolus remains to be delivered.

If you want to cancel or replace a bolus, see "Altering an Ongoing Bolus" on page 50.

To add an informational tag to the BG value used for this bolus, see "Tagging the Blood Glucose Results" on page 44.

Manually-calculated Bolus

If the Bolus Calculator is disabled or turned off, you must calculate a bolus amount yourself. This is called a manually-calculated bolus.

To deliver a manually-calculated bolus:

1. Measure your blood glucose. If using a separate BG meter, follow the instructions included with your BG meter. If you used the built-in BG meter, skip to step 4. For more information, see "Checking Your Blood Glucose" on page 35.

2. Calculate the combined correction and meal bolus. To look up the grams of carbs in various foods, see "Food Library" on page 51.

3. Navigate to the bolus screen:

   Home > Bolus

4. Enter your calculated bolus amount:

   - Use the **Up/Down** button to enter the bolus amount, then press **Enter**.

   - Or, if you have defined one or more bolus presets, either (1) select a bolus preset, or (2) select [**enter manually**], use the **Up/Down** button to enter the desired bolus amount, and press **Enter**.

   To create a bolus preset, see "Bolus presets" on page 74.

   Note: You can only give a bolus at or below the Maximum Bolus you have set. See "Maximum Bolus" on page 73 for information on resetting your Maximum Bolus. Consult your healthcare provider before changing this setting.

5. To deliver the entire bolus immediately, press **Enter**, and skip to step 7. (See "Immediate and Extended Boluses" on page 139 for more information):

6. To extend the delivery of part or all of a meal bolus:

   a. Press **Extend**.

   b. Use the **Up/Down** button to enter the amount or percent of the bolus to deliver immediately. Press **Enter**.

   c. Use the **Up/Down** button to enter the length of time for the extended portion. Press **Enter**.

   Note: Your "extended bolus" setting determines whether the screen displays percent (**%**) or units (**U**). If the extended bolus option is off, the "Extend" soft key label does not appear on the screen.

7. If the BG reminder option is turned on and you want a reminder to check your blood glucose, press **Yes**. Use the **Up/Down** button to enter the time for the reminder. Press **OK**.

   See "BG reminders" on page 75 to turn on or off the BG reminder. It is off by default.

8. Review the details of the bolus and press **Confirm** to begin the bolus delivery.

At this point, the bolus amount is stored in your history records.

The screen displays a **Delivering bolus** message throughout the delivery of an immediate bolus.

Tip: *Once a bolus is started, the Pod finishes delivering the bolus whether or not it is in range of the PDM.*

During the extended portion of a bolus, check the **Status** screen to see how much of the extended bolus remains to be delivered. You can use your PDM for other tasks during the extended portion of a bolus.

To add an informational tag to the BG value used for this bolus, see "Tagging the Blood Glucose Results" on page 44.

Altering an Ongoing Bolus

You can cancel an immediate or extended bolus, deliver an immediate bolus without canceling an ongoing extended bolus, or replace one extended bolus with a new extended bolus.

Note: You can give a new (immediate) bolus during an extended bolus without canceling the extended bolus. However, if you want to extend the new bolus, you must cancel the current extended bolus.

Note: If you get a communication error message when you attempt to cancel a bolus, see "Failure when canceling a bolus" on page 102.

Cancel an immediate bolus

To cancel an active bolus while it is being delivered:

1. If necessary, turn on your device and confirm your ID.

2. If bolus delivery has not finished yet, press **Cancel** on the "Delivering bolus" screen. The Pod beeps to confirm that the bolus is canceled.

3. Press **OK**.
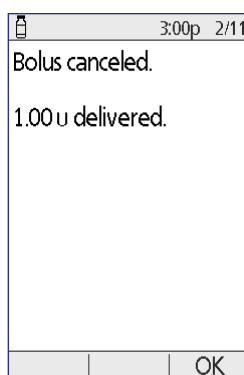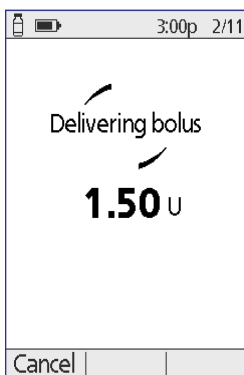
Cancel an extended bolus

To cancel an extended bolus:

1. If necessary, turn on your device and confirm your ID.

2. Choose **Home > Suspend/cancel.**

3. Choose **Cancel extended bolus**, then press **Select**.

4. Press **Confirm** to cancel the bolus. The Pod beeps when the bolus is canceled.

Replace an extended bolus

To replace an extended bolus with a new extended bolus:

1. Follow the instructions in "Bolusing with the Bolus Calculator" on page 45 or "Manually-calculated Bolus" on page 48 to specify the amount of the new bolus.

2. After entering the new bolus amount, press **Extend**. A screen appears telling you that an extended bolus is active.

3. Press **Yes** to cancel the extended bolus.
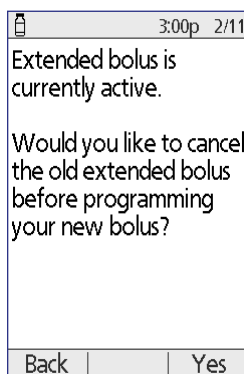
4. Press **Confirm**.
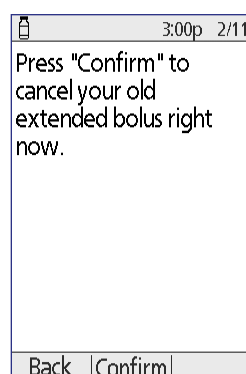
5. The next screen displays the undelivered amount of the old extended bolus. Write this number down if you want to add it to the new extended bolus.

6. Press **Next**.

7. To add the undelivered amount of the old bolus, use the **Up/Down** button to increase the bolus amount.

8. Press **Extend** and follow the on-screen instructions to begin delivery of the new extended bolus.
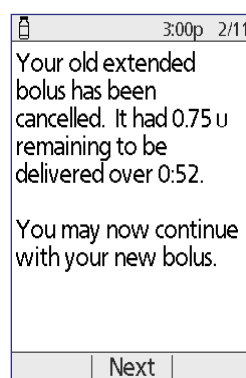
Food Library

The PDM includes a food library of over 1,000 common food items. You can use the food library to look up the carbs for a meal or snack. This data is for reference only; it cannot be used automatically by the Bolus Calculator.

The items in the food library come from the United States Department of Agriculture (USDA) database, USDA National Nutrient Database for Standard Reference.

To access the food library:

1. Navigate to the food library screen:

   Home > More actions > View food library

2. To browse a food category, scroll down to highlight the category, then press **Select**. Choose a subcategory and press **Select**. Choose a food item and press **View**.
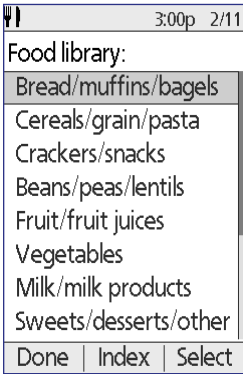
3. To see an alphabetic list of foods, press **Index**. Use the **Up/Down** button to enter the first letter of the food item and press **Select**. Choose a food item from the alphabetic list and press **View**.
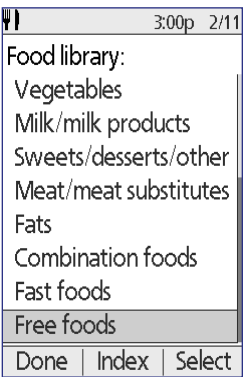
   The screen displays the food item's name, serving size, grams of carbs, fiber, fat, and protein, and total calories. Write down any useful information.

4. Press **OK** to return to the list of main food categories.

5. Press **Done** to return to the **More actions** menu or press the **Home** button to return to the **Home** screen.

CHAPTER 6
Modifying Basal Insulin Delivery

This chapter describes how to modify your basal insulin delivery using temporary basal rates or switching to a different Basal Program.

Using Temporary Basal Rates

Use a temporary basal rate, or "temp basal," to handle a temporary change in your routine. For example, a temp basal can be used when you are exercising or when you are sick. To understand how temp basals work, see "Temporary basal rates" on page 135.

Note: If temp basals are set to "off," you cannot activate a temp basal. To enable temp basals, see "Temp basal configuration" on page 66.

Tip: *If you find yourself repeatedly using the same temp basal settings, create a temp basal preset for speedy activation (see "Temp basal presets" on page 66).*

Activate a temp basal

Temp basals can last up to 12 hours. When they end, the PDM automatically reverts to delivering the scheduled Basal Program.

If you have already defined one or more temp basal presets and would like to activate one, go to "Activate a temp basal preset" on page 55.

1.   Navigate to the **Temp basal** screen:

     Home > Temp basal

2.   If you have not defined any temp basal presets, skip to step 4.

3.   Select [**enter manually**]. Or, to activate a temp basal preset, go to "Activate a temp basal preset" on page 55.

4. If temp basals are configured as a flat rate (**U/h**), skip to step 6. If temp basals are configured as a percent change (**%**), select **Increase** or **Decrease** depending on whether you want more or less insulin delivery in the near future.

5. Press **Next**.
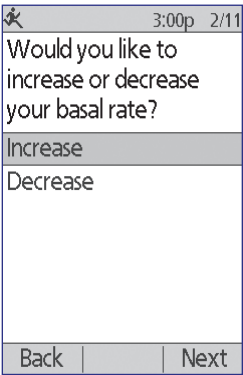
If temp basals are configured as a percent change (**%**), the screen on the left appears. If temp basals are configured as a flat rate (**U/hr**), the screen on the right appears.

6. Use the **Up/Down** button to specify the amount by which you would like to increase or decrease the basal rate.
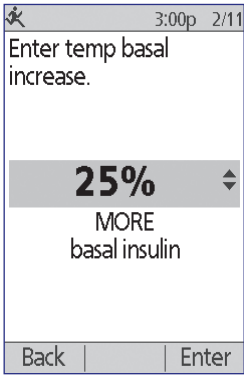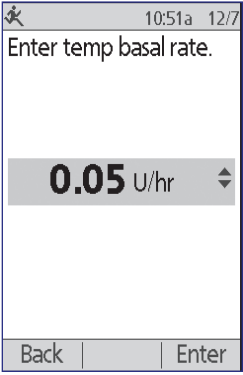
Temp basal set to %   *Temp basal set to U/hr*

Note: Decreasing a temp basal to OFF turns off insulin delivery for the specified time period. For more information, see "Temp basal limitations" on page 137. For a comparison of methods to stop insulin delivery, see "Methods to temporarily stop insulin delivery" on page 138.

7. When the screen shows the desired temp basal rate, press **Enter**.

8.   Use the **Up/Down** button to specify how long you want the temp basal to last.

9.   Press **Enter**.

10.   After reviewing the specified temp basal rate and duration, press **Confirm** to activate it.

After confirmation, the **Home** screen indicates that the temp basal is running and how much time remains. At the end of the temp basal time period you do not need to take any action, the Pod automatically switches back to the active Basal Program.

Activate a temp basal preset

A temp basal preset stores the details of a temp basal that you use frequently. Temp basal presets can be activated rapidly. To create or modify a temp basal preset, see "Temp basal presets" on page 66.

1.   Navigate to the **Temp basal** screen:

      Home > **Temp basal**

2.   The list of existing temp basal presets appears. Use the **Up/Down** arrow to highlight the desired temp basal preset.

      If you do not want to use one of the temp basal presets, select **[enter manually]** and go to step 4 on page 53.

3.   Press **Select**.

4.   If you want to change the duration of the temp basal, use the **Up/Down** button to change the duration.

5.   After reviewing the specified temp basal rate and duration, press **Confirm** to activate it.

Cancel a temp basal

A temp basal stops automatically at the end of its time period. To cancel a running temp basal:

1. From the **Home** screen, select **Suspend/cancel**.

2. Highlight **Cancel temp basal** and press **Select**.

3. Press **Confirm**.

The PDM cancels the temp basal and restarts the active Basal Program.

```
                         3:00p   2/11
Cancel temp basal
Suspend insulin delivery




    Back    |        | Select
```

Use beeps to monitor temp basal progress

You can, optionally, have the PDM or Pod beep at the beginning and end of a temp basal (see "Confidence reminders" on page 78). You can also, optionally, have the Pod beep every 60 minutes while a temp basal is running (see "Program reminders" on page 78).

Switching to a Different Basal Program

Some days have different routines than others, and so the PDM lets you create different Basal Programs to match the different routines. For example, you may use one Basal Program on weekdays and a different one on weekends.

To switch to a different Basal Program:

1. Navigate to:

    Home > **Settings** > **Basal programs**

    The active Basal Program is marked with a small diamond (◆).

2. Use the **Up/Down** button to highlight the Basal Program that you would like to activate.

3. Press **Enable**.

```
                         3:00p   2/11
Basal programs:
 ◆basal 1
  basal 2
  Weekend
  [add new]




  Back   | Enable |  Select
```
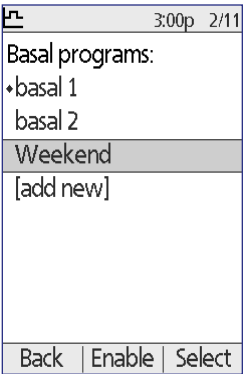
4.   Review the program's details. To see a graph of the program, press **Graph**.

5.   Press **Enable** to activate the selected Basal Program. The **Home** screen displays the name of the newly activated Basal Program.

Note: You must cancel a running temp basal prior to switching to a different Basal Program (see "Cancel a temp basal" on page 56). You can, however, switch Basal Programs when an extended bolus is running.

For instructions for adding or editing Basal Programs, see "Basal Programs" on page 63.

Suspending and Resuming Basal Insulin Delivery

Sometimes you may need to stop insulin delivery briefly. For example, you must suspend insulin delivery prior to editing an active Basal Program or resetting the time or date. The Omnipod® System lets you suspend all insulin delivery for up to two hours.

To help understand the difference between stopping insulin delivery using the suspend feature or the temp basal feature, see "Methods to temporarily stop insulin delivery" on page 138.

Suspend insulin delivery

1.   From the **Home** screen, press **Suspend**.

2.   Use the **Up/Down** button to specify the duration of the suspension. The suspension can last from 30 minutes up to 2 hours and can be adjusted in 30-minute increments.

3.   Press **Enter**.

4.   Press **Confirm** to confirm that you want to halt all insulin delivery.

The basal insulin delivery is suspended. The **Status** screen displays INSULIN SUSPENDED until you resume insulin delivery.

The Pod beeps every 15 minutes throughout the suspension period. At the end of the suspension period, the PDM and Pod sound two sets of beeps every three minutes, repeating every 15 minutes until you have resumed insulin delivery.

Note: Temp basals or extended bolus are automatically canceled when you suspend insulin delivery.

6 Modifying Basal Insulin Delivery

Resume insulin delivery before the suspension period ends

1. From the **Home** screen, choose **Resume**.

2. Press **Confirm** to restart the Basal Program scheduled for the current time.
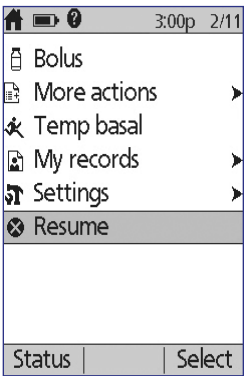
Resume insulin delivery after the suspension period ends

1. Turn on your PDM.

2. Press **OK** to resume insulin delivery.

3. The PDM activates the Basal Program that is scheduled for the current time and beeps to alert you that insulin delivery has resumed.

If you do not resume insulin delivery immediately when the suspension period ends, the PDM and Pod beep every 15 minutes until insulin delivery is resumed.
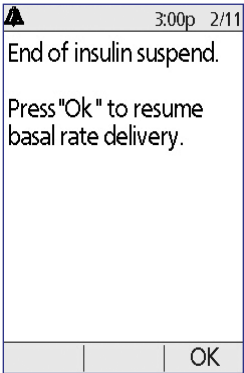
> **Warning:** Insulin delivery does not automatically resume at the end of the suspension period. You must press **OK** to resume insulin delivery. If you do not resume insulin delivery, you could develop hyperglycemia.

CHAPTER 7
Adjusting Settings

As your needs change, you may want to adjust various settings on your PDM.

Tip: *Some settings have defaults, but all settings can be changed.*

The screens shown here are the two main menu screens that give you access to your Omnipod® System settings: the **Settings** menu and the **System setup** menu.
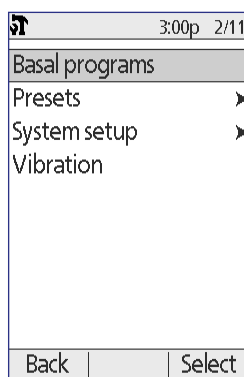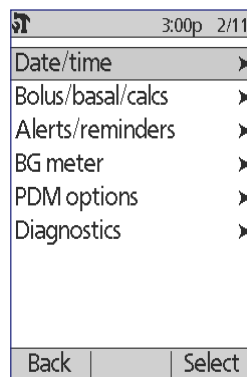
Home > Settings   *Home > Settings > System setup*

General PDM Settings

General PDM settings include your identification and general device settings.

Date and time

You may need to reset the date and time to adjust for daylight-savings time or changing time zones.

1.   If you have an active Pod, you must suspend it first: **Home > Suspend**

2.   Navigate to: **Home > Settings > System setup > Date / time**

3.   Choose the time, and press **Edit**. Use the **Up/Down** button to enter the new time. To change between AM/PM and a 24-hour clock, press **12/24hr**. Press **Enter**, then press **Confirm**.

4.   Choose the date, and press **Edit**. Change the year, month, day as desired, pressing **Next** between each screen. Choose the date format and press **Select**. Then press **Confirm**.

5.   If you suspended your Pod, press **Home** and **Resume** to resume insulin delivery.

Username and screen color

The **ID** screen settings are used to identify your PDM. Identifying the PDM as yours prior to using it helps ensure that you use the PDM that is tuned to control your Pod and that is programmed with your personal settings.

To change your **ID** screen settings:

1. **Home > Settings > System setup > PDM options > ID screen**

2. Choose **ID** and press **Select**. Enter the username you would like the PDM to display on the **ID** screen (see "Entering text" on page 6). Press **Save**.

3. Choose **Screen color** and press **Select**. Highlight the desired screen color and press **Select**.

Storing brief notes

You can store up to 20 lines of personal notes in the PDM, such as phone numbers, addresses, or prescription information. To view these notes, press the **Info** button from the **Home** screen.

1. **Home > My records > My info**

2. Highlight [**My info**] and press **Edit**. Enter the information you would like to store (see "Data Entry" on page 6), then press **Save**.

Vibrate and sound options

The PDM treats alarms and notifications differently. For safety reasons, alarms are always audible and cannot be set to vibrate; however, you can control whether certain notification beep or vibrate.

To change how the PDM issues BG reminders, missed bolus reminders, custom reminders, and "No active Pod" reminders:

1. **Home > Settings > Vibration**

2. Highlight your preferred option:

Vibrate	Vibration only
Vibrate then beep	If you do not respond after two rounds of vibrating reminders, the PDM beeps for subsequent reminders
Off (Beep only)	No vibration, just beeps

3. Press **Select**.

Check the alarms and vibration

To reassure yourself that your PDM and Pod's alarms and vibration functions are working properly, you can test them as follows:

1. If you have an active Pod, you must suspend it first: **Home > Suspend**

2. Go to: **Home > Settings > System setup > Diagnostics > Check alarms**

3. Press **Select** and then press **OK** to initiate the alarm check.

4. Listen and feel: The PDM beeps three times and vibrates three times. Then, if you are wearing a Pod, the Pod beeps several times and sounds the alarm tone for several seconds.

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

Lock or unlock the PDM buttons

You can lock the PDM to prevent accidentally changing Basal Programs or giving boluses. When the PDM is locked, you can still use the built-in BG meter, check your history records, view the food library, and unlock the PDM.

1. **Home > Settings > System setup > PDM options > PDM lock**

2. Choose **On** to lock the PDM or **Off** to unlock it. Then press **Select**.

Screen time-out

To preserve battery power, the PDM screen turns off if you have not pressed a button for the specified time interval. To change the amount of time before the PDM's screen goes blank:

1. **Home > Settings > System setup > PDM options > Screen time-out**

2. Select a screen time-out interval, then press **Select**.

Tip: *Set this time-out interval to the lowest setting to preserve battery life.*

Backlight time-out

The PDM's screen can dim prior to going blank. To change the amount of time before the PDM's screen dims:

1. **Home > Settings > System setup > PDM options > Backlight time-out**

2. Select a backlight time-out interval, then press **Select**.

Tip: *Set this time-out interval to the lowest setting to preserve battery life.*

Factory defaults settings

Reset PDM is a rarely-used function that returns all of the PDM's settings to the default factory settings.

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

To reset your PDM:

1. Prepare a list of your personalized settings so you can re-enter them after you reset your PDM. Consult with your healthcare provider to ensure that the settings are appropriate for you.

   Tip: *The pages at the end of this User Guide can be used to record your settings.*

2. If you have an active Pod, deactivate it: **Home > More actions > Change pod**.

3. Go to: **Home > Settings > System setup > Diagnostics > Reset PDM**

4. Press **Confirm** to delete your current user settings and return all user settings to the factory default values.

   Note: History records and IOB data are not deleted.

5. Follow the PDM setup directions starting at "Username and screen color" on page 15 to re-enter your personalized information.

Basal and Temp Basal Settings

The following sections describe how to change the settings that control basal insulin delivery—Maximum Basal Rate, Basal Programs, and temp basals.

Maximum Basal Rate

The Maximum Basal Rate defines an upper limit for any basal rate in your Basal Programs and temp basals. Consult your healthcare provider before changing this setting.

To change your Maximum Basal Rate:

1.   **Home** > **Settings** > **System setup > Bolus/basal/calcs > Max basal**

2.   Use the **Up/Down** button to specify your the Maximum Basal Rate, then press **Enter**.

Note: You cannot set a Maximum Basal Rate that is lower than the highest basal rate of an existing Basal Program, temp basal preset, or currently running temp basal.

Basal Programs

You can have between one and seven Basal Programs. Each Basal Program can contain from 1 to 24 basal rates.

Caution: Check with your healthcare provider before adjusting these settings.

The **Basal Programs** screen displays your existing Basal Programs. A diamond icon (◆) appears next to the active Basal Program.

Create a new Basal Program

Tip: *If your new Basal Program is similar to an existing Basal Program, you can save time by using the "copy" feature and modifying the copied program (see "Make a new Basal Program from an existing Basal Program" on page 65).*

To create a new Basal Program:

1.   **Home** > **Settings** > **Basal programs** > **[add new]**

 Note: The **[add new]** option is not available if you already have seven Basal Programs. In this case, you must first delete an existing Basal Program before you can create a new one (see "Delete a Basal Program" on page 65).

2.   Press **New**.

3.   Enter a meaningful name (see "Entering text" on page 6). Press **Next**.

 Alternately, you can use the default naming system, which assigns names in numerical order, such as basal 1, basal 2, basal 3.

4. The next steps are the same as those you performed when you set up your first Basal Program. Follow the on-screen instructions or see "Define a Basal Program" on page 16 for step-by-step instructions.

After you confirm your new Basal Program, the PDM stores it for your future use.

Basal Program as graph

Basal Program as list

Review a Basal Program

To review the details of a Basal Program:

1. **Home** > **Settings** > **Basal programs**

2. Highlight the Basal Program you would like to view, and press **Select**.

3. Highlight **View** and press **Select**.

4. A non-editable screen appears displaying the basal segments for the selected Basal Program. Press **List** or **Graph** to see the Program as text or a graph.

Modify a Basal Program

To modify a Basal Program:

1. **Home** > **Settings** > **Basal programs**

2. Highlight the Basal Program you would like to edit, and press **Select**.

   Note: To edit the active Basal Program, you must either suspend insulin delivery (**Home > Suspend**) or edit it when you have no active Pod during a Pod change.

3. Highlight **Edit** and press **Select**. A screen appears showing all of the basal segments for the selected Basal Program.

4. To add or edit segments, follow the on-screen instructions, or see "Adding time segments" on page 20 for step-by-step instructions.

5. To delete a segment:

   a. Select an adjacent segment and press **Edit**.

   b. Change the start time or end time so the adjacent segment covers the segment you are deleting (see "How to delete time segments" on page 82 for an illustration of the process).

   c. Optionally, change the value for the resulting longer segment.

   d. Press **Confirm**, then **Done,** then **Save.**

Rename a Basal Program

To rename a Basal Program:

1. **Home** > **Settings** > **Basal programs**

2. Highlight the Basal Program you would like to rename and press **Select**.

3. Highlight **Rename** and press **Select**.

4. Enter the new name (see "Entering text" on page 6) and press **Save**.

Make a new Basal Program from an existing Basal Program

To create a new Basal Program by copying an existing one:

1. **Home** > **Settings** > **Basal programs**

2. Highlight the Basal Program you would like to copy, and press **Select**.

3. Highlight **Copy** and press **Select**.

   Note: If you already have seven Basal Programs, you must first delete an existing Basal Program before you can create a copy (see "Delete a Basal Program" on page 65).

4. Enter a unique name for the new Basal Program (see "Entering text" on page 6) and press **Next**. A screen appears showing the renamed Basal Program with the original basal segments.

5. To edit or add new segments to create the new Basal Program follow the on-screen instructions or see "Adding time segments" on page 20. For an illustration of the process, see "Working with Time Segments" on page 81.

Delete a Basal Program

You can only delete a Basal Program that is not running; you cannot delete the active Basal Program. To delete a Basal Program:

1. **Home** > **Settings** > **Basal programs**

2. Highlight the Basal Program you would like to delete, and press **Select**.

3. Highlight **Delete**, then press **Select**, then press **Delete**

Temp basal configuration

To turn off the temp basal feature or change your temp basal configuration:

1. **Home** > **Settings** > **System setup** > **Bolus/basal/calcs** > **Temp basal**

2. Select a configuration for your temp basal:

%	Specify temp basals as a percentage of the currently active Basal Program.
U/hr	Specify temp basals as a flat rate for the duration of the temp basal.
Off	Turn off the ability to use temp basals or temp basal presets.

3. Press **Select**.

See "Temporary basal rates" on page 135 for a description of how temp basals work.

Temp basal presets

If there is a temp basal that you use often, you can create a "Temp basal preset" for rapid activation in the future. To activate a temp basal preset, see "Activate a temp basal preset" on page 55.

Create a new temp basal preset

1. **Home** > **Settings** > **Presets** > **Temp basal presets**

2. Use the **Up/Down** button to scroll down to **[add new]** at the bottom of the list. Press **New**.

    Note: You can only have seven temp basal presets. If you already have seven, **[add new]** does not appear. If necessary, you can delete an existing one.

3. Enter a name for the new temp basal preset (see "Entering text" on page 6). Press **Next**.

4. If temp basals are configured as percentages (%), select **Increase** or **Decrease** to specify whether this preset will deliver more or less insulin than the active Basal Program.

5. Use the **Up/Down** button to set the desired temporary change in the insulin delivery rate. Press **Next**.

6. Use the **Up/Down** button to set the duration for the temp basal preset. Press **Next**.

    Note: You will be able to modify the duration of a temp basal preset when you invoke it.

7. Press **Save**.

Edit or rename a temp basal preset

Note: You cannot edit a temp basal preset that is actively running.

1.   **Home > Settings > Presets > Temp basal presets**

2.   Highlight the temp basal preset you would like to change, scrolling down as needed if there is a long list. Press **Edit**.

3.   To rename the temp basal preset, select **Rename**, then enter the new name (see "Entering text" on page 6). Press **Save**.

4.   To edit the temp basal preset:

   a.   Select **Edit**.

   b.   Change the temporary basal rate, if desired. Press **Next**.

   c.   Change the duration of the temp basal, if desired. Press **Save**.

5.   Press **Done** to return to the **temp basal preset** screen.

Delete a temp basal preset

Note: You cannot delete a temp basal preset that is actively running.

1.   **Home > Settings > Presets > Temp basal presets**

2.   Highlight the temp basal preset you would like to delete, scrolling down as needed if there is a long list. Press **Edit**.

3.   Highlight **Delete**, and press **Select**.

4.   Press **Delete**. The temp basal preset is deleted.

Bolus Calculator Settings

> **Warning:** The Bolus Calculator displays a suggested bolus dose based on the personalized settings you have programmed into the PDM. Check with your healthcare provider before adjusting your Bolus Calculator settings.

The following sections describe how to edit individual Bolus Calculator settings.

Note: To review all of the Bolus Calculator settings sequentially, navigate to

Home > **Settings** > **System setup** > **Bolus/basal/calcs** > **Ratios/factors/targets** > **Review all settings**

and follow the on-screen instructions.

```
                  3:00p  2/11
Bolus calcs:  On
Ratios/factors/targets  ›
Temp basal:  U/hr
Extended:  Units
Bolus increment:  0.05 U
Max bolus:  8.00 U
Max basal:  1.50 U/hr


Back              |       Select
```

```
                  3:00p  2/11
Review all settings
Target BG
Min BG for calcs:
   70 mg/dL
IC ratio
Correction factor
Reverse correction:  On
Insulin action:  3.5 hr

Back              |       Select
```

Turn the Bolus Calculator on or off

To turn the Bolus Calculator on or off:

1. **Home** > **Settings** > **System setup** > **Bolus/basal/calcs** > **Bolus calcs**

2. To turn the Bolus Calculator off, select **Off** and press **Done**.

3. To turn the Bolus Calculator on, select **On** and press **Next**. The following screens guide you through the personalized Bolus Calculator settings. For detailed instructions, see the following pages or go to "Target BG and Correct Above values" on page 19.

   Note: If you have not previously set up the Bolus Calculator refer to "Bolus Calculator settings" on page 18 for step-by-step instructions.

Target BG and Correct Above value

The Bolus Calculator aims to bring your blood glucose to your Target BG value when calculating a correction bolus. However, the Bolus Calculator only calculates a correction bolus if your blood glucose is above your Correct Above setting. Your Target BG can range from 70 to 200 mg/dL, and your Correct Above setting can range from your Target BG to 200 mg/dL.

You can set different Target BG and Correct Above values for different times of day. To edit or add Target BG or Correct Above segments:

1.   **Home** > **Settings** > **System setup > Bolus/basal/calcs
     > Ratios/factors/targets > Target BG**

2.   Follow the on-screen instructions, or, for detailed instructions see "Adding time segments" on page 20. For an illustration of the process, see "Working with Time Segments" on page 81.

3.   Press **Done**, then **Save** when finished modifying the time segments.

Minimum BG for Calcs

Minimum BG for Calcs is a threshold that you set. If your BG reading is below your Minimum BG for Calcs, the Bolus Calculator is disabled and does not calculate a bolus. This value can range from 50 - 70 mg/dL and is a fixed value throughout the day.

1.   **Home** > **Settings** > **System setup > Bolus/basal/calcs
     > Ratios/factors/targets > Min BG for calcs**

2.   Use the **Up/Down** button to specify the minimum blood glucose for use by the Bolus Calculator, then press **Next**.

IC Ratio

The IC Ratio (Insulin to carbohydrate ratio) defines how many grams of carbohydrates are handled by one unit of insulin. The Bolus Calculator uses your IC Ratio to calculate a meal bolus when you are going to eat. Your IC Ratio can range from 1 to 150.

You can set different IC Ratios for different times of day, up to a total of eight. To edit existing time segments or add segments:

1.   **Home** > **Settings** > **System setup > Bolus/basal/calcs
     > Ratios/factors/targets > IC ratio**

2.   Follow the on-screen instructions, or, for detailed instructions see "Adding time segments" on page 20. For an illustration of the process, see "Working with Time Segments" on page 81.

3.   Press **Done**, then **Save** when finished modifying the time segments.

Correction Factor

The Bolus Calculator uses your Correction Factor to calculate a correction bolus when your blood glucose value is above your Correct Above setting (see "The Bolus Calculator" on page 140). Your Correction Factor can range from 1 to 300 mg/dL.

You can set different Correction Factors for different times of day, up to a total of eight. To edit existing time segments or add segments:

1. **Home** > **Settings** > **System setup** > **Bolus/basal/calcs**
    > Ratios/factors/targets > **Correction factor**

2. Follow the on-screen instructions, or, for detailed instructions see "Adding time segments" on page 20. For an illustration of the process, see "Working with Time Segments" on page 81.

3. Press **Done**, then **Save** when finished modifying the time segments.

Reverse Correction

The reverse correction setting determines how the Bolus Calculator handles meal boluses when your blood glucose value is below your Target BG (see "Reverse Correction" on page 142 for more details).

1. **Home** > **Settings** > **System setup** > **Bolus/basal/calcs**
    > Ratios/factors/targets > **Reverse correction**

2. Choose **On** or **Off**, and press **Next**.

Duration of insulin action

The Bolus Calculator uses your duration of insulin action setting to calculate the amount of insulin on board (IOB) from a previous bolus (see "Insulin on board" on page 142 for more details). Your duration of insulin action can range from 2 to 6 hours in 30-minute increments and is a fixed value throughout the day.

1. **Home** > **Settings** > **System setup** > **Bolus/basal/calcs**
    > Ratios/factors/targets > **Insulin action**

2. Use the **Up/Down** button to specify your duration of insulin action, then press **Done**.

3. If you have been reviewing all of the Bolus Calculator settings, the screen informs you that the setup is complete and the Bolus Calculator is On. Press **OK**.

Carb presets

Carbs presets are used to store the carbohydrate content of snacks or meals that you eat often. You can quickly select a carb preset when the Bolus Calculator asks how many carbs you are about to eat. You can create up to 36 carb presets.

Create a new carb preset

To save a frequently eaten food as a carb preset:

1. **Home** > **Settings > Presets > Carb presets**

2. Choose either **Favorites**, **Snacks** or **Meals** as the category for this carb preset, then press **Select**.

3. Choose [**add new**] and press **New**.

4. Enter a unique name to help you recognize this carb preset in the future (see "Entering text" on page 6), and press **Next**.

   Alternatively, you can choose to use the default name by pressing **Next**.

5. Enter the grams of carbohydrates in the food, then press **Next**.

6. The next step is to, optionally, specify the grams of fiber in the meal. Consult with your healthcare provider about whether or not to enter the fiber information.

   Note: If you enter the grams of fiber into your carb preset, the Bolus Calculator subtracts the grams of fiber from the grams of carbohydrates. Alternately, in step 5 above, you can enter the total grams of carbs minus the fiber yourself.

7. Press **Next**.

8. If you want, you can enter the grams of fat and protein and the total calories in the meal. Press **Next** after each entry. Entering these additional numbers is optional. The Bolus Calculator does not use them.

9. Press **Save** to add the new carb preset to the selected category.

Change the category for a carb preset

1. **Home** > **Settings > Presets > Carb presets**

2. Choose the category that contains the carb preset you want to change, then press **Select**.

3. Highlight the carb preset that you want to move, then press **Tag**.

4. Choose the new category, then press **Select**.

Edit or rename a carb preset

1. **Home** > **Settings > Presets > Carb presets**

2. Choose the category containing the preset you want to edit, then press **Select**.

3. Highlight the carb preset that you want to edit, then press **Edit**.

4. Press **Edit** again on the next screen.

5. To rename the preset, enter a new name (see "Entering text" on page 6).

6. Enter the grams of carbohydrates in the food, then press **Next**.

7. The next step is to, optionally, specify the grams of fiber in the meal. Consult with your healthcare provider about whether or not to enter the fiber information.

   Note: If you enter the grams of fiber into your carb preset, the Bolus Calculator subtracts the grams of fiber from the grams of carbohydrates. Alternately, in step 6 above, you can enter the total grams of carbs minus the fiber yourself.

8. Press **Next**.

9. If you want, you can enter the grams of fat and protein and the total calories in the meal. Press **Next** after each entry. Entering these additional numbers is optional.

10. Press **Done** to save the changes.

Delete a carb preset

1. **Home** > **Settings > Presets > Carb presets**

2. Choose the category containing the preset you want to edit, then press **Select**.

3. Highlight the carb preset that you want to edit, then press **Edit**.

4. Press **Delete**.

5. Press **Delete** again to permanently delete the carb preset.

Bolus Delivery Settings

Extended bolus configuration

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

1. **Home > Settings > System setup > Bolus/basal/calcs > Extended**

2. Select a configuration for your extended bolus:

%	Specify the amount of the immediate portion of the bolus as a percent of the total bolus. The remainder will be extended.
Units	Specify how many units of insulin should be delivered immediately. The remainder will be extended.
Off	Turn off the ability to extend a bolus.

3. Press **Select.**

Maximum Bolus

The Maximum Bolus defines the upper limit for a manually-calculated bolus. The Bolus Calculator warns you if it calculates a bolus that is over this amount. The largest allowed value of the Maximum Bolus is 30 units.

Caution: The Maximum Bolus default is 10 units. Check with your healthcare provider before adjusting this setting.

1. **Home > Settings > System setup > Bolus/basal/calcs > Max bolus**

2. Use the **Up/Down** button to specify the Maximum Bolus, then press **Enter.**

Bolus increment

The bolus increment setting defines how much one press of the **Up/Down** button changes the bolus amount shown on the screen. This determines how finely you can tune the specified bolus amount. The setting options are 0.05, 0.1, 0.5, or 1.0 U. For example, setting this to 1.0 U means that you will be able to request a bolus of 2 U or of 3 U, but not of 2.5 U.

1. **Home > Settings > System setup > Bolus/basal/calcs > Bolus increment**

2. Highlight the desired bolus increment, and press **Select**.

Bolus presets

Bolus presets allow you to store commonly used bolus amounts for quick retrieval in the future. Bolus presets are only used if the Bolus Calculator is off.

A bolus preset only stores the total number of units of insulin in a bolus. You will specify whether the bolus should be extended or not when you activate it.

You can set up to seven bolus presets. A bolus preset cannot exceed your Maximum Bolus.

Create a new bolus preset

1. **Home** > **Settings > Presets > Bolus presets**

2. Highlight **[add new]** and press **New**.

3. Enter a name for the new bolus preset (see "Entering text" on page 6), and press **Next**.

4. Use the **Up/Down** button to enter the amount of the bolus, and press **Next**.

5. Press **Save.**

Edit or rename a bolus preset

1. **Home** > **Settings > Presets > Bolus presets**

2. Highlight the bolus preset that you want to edit, then press **Edit**.

3. To rename the preset, highlight **Rename**, and press **Select**. Then enter a new name (see "Entering text" on page 6), and press **Next**.

4. To change the value of the preset, highlight **Edit**, and press **Select**.

5. Use the **Up/Down** button to enter the new value for the bolus, and press **Save**.

Delete a bolus preset

1. **Home** > **Settings > Presets > Bolus presets**

2. Highlight the bolus preset that you want to delete, then press **Edit**.

3. Highlight **Delete**, and press **Select**.

4. Press **Delete**.

Reminder and Notification Settings

Reminders and notifications are used to bring items related to system function to your attention (see "Notifications" on page 97 and "Informational Beeps" on page 99).

```
                        3:00p  2/11
BG reminder:  Off
Expiration:  4 hr
Low reservoir:  10.00 U
Auto-off:  Off
Bolus reminders:  Off
Program reminders:  On
Confidence reminders:
   On
Custom reminders
 Back    |        Select
```

BG reminders

If BG reminders are on, a screen is inserted into the bolus flow that asks if you would like to set a reminder to check your blood glucose. You can answer yes or no at that time.

To set a BG reminder:

1. **Home > Settings > System setup > Alerts/reminders > BG reminder**

2. Choose **On** to include the BG reminder query in the bolus flow. Choose **Off** to skip the BG reminder.

3. Press **Select**.

Pod expiration

The Pod expiration notification tells you when the Pod is nearing its expiration so you can plan for a Pod change at a convenient time. This notification can range from 1 to 24 hours before the Pod expiration advisory alarm sounds. At the selected time, the Pod and PDM beep and the PDM generates a message.

To set the timing of the Pod expiration notification:

1. **Home > Settings > System setup > Alerts/reminders > Expiration**

2. Use the **Up/Down** button to specify how long before your Pod expires that you would like to be notified, then press **Enter**.

7 Adjusting Settings

Low reservoir level

The Pod and PDM sound an advisory alarm when the insulin level in your Pod reaches the low reservoir setting. This setting can range from 10 to 50 units.

1.   **Home > Settings > System setup > Alerts/reminders > Low reservoir**

2.   Use the **Up/Down** button to specify the level of Pod insulin at which you would like to be notified, then press **Enter**.

Pod Auto-off

Consult your healthcare provider prior to changing the Auto-off setting. This feature requires active participation on your part. See "Auto-off" on page 133 to familiarize yourself with how this feature works.

To enable or disable Auto-off:

1.   **Home > Settings > System setup > Alerts/reminders > Auto-off**

2.   To disable Auto-off, select **Off** and press **Enter**.

3.   To enable Auto-off, use the **Up/Down** button to specify the length of time for the countdown timer. This setting can range from 1 to 24 hours.

     Example: If you choose three hours, you must activate your PDM once every three hours, day and night, to prevent the Auto-off alarm.

4.   Press **Enter**.

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

Bolus reminders

Bolus reminders prompt you to eat. If bolus reminders are enabled and the PDM has not delivered a bolus during a specified time interval, the PDM beeps and generates a message. The time interval can range from 1 to 4 hours, and you can set up to six separate bolus reminder time intervals.

Enable or disable bolus reminders

1.   **Home > Settings > System setup > Alerts/reminders > Bolus reminders**

2.   To enable all bolus reminders, choose **On** and press **Select**.

3.   To disable all bolus reminders, choose **Off** and press **Select**. The PDM remembers any previously set bolus reminders for later use.

Add a new bolus reminder

1. **Home > Settings > System setup > Alerts/reminders > Bolus reminders**

2. Highlight **On** and press **Select**.

3. Highlight [**add new**] and press **New**.

4. Use the **Up/Down** button to enter the start time for the interval, and press **Next**.

5. Use the **Up/Down** button to enter the end time for the interval, and press **Save**.

6. Press **Done**, and then press **Save**.

Edit a bolus reminder

1. **Home > Settings > System setup > Alerts/reminders > Bolus reminders**

2. Highlight **On** and press **Select**.

3. Highlight the time interval you would like to edit, and press **Edit**.

4. Highlight **Edit** and press **Select**.

5. Use the **Up/Down** button to enter the start time for the interval, and press **Next**.

6. Use the **Up/Down** button to enter the end time for the interval, and press **Save**.

7. Press **Done**, and then press **Save**.

Delete a bolus reminder

1. **Home > Settings > System setup > Alerts/reminders > Bolus reminders**

2. Highlight **On** and press **Select**.

3. Highlight the time interval you would like to delete, and press **Edit**.

4. Highlight **Delete** and press **Select**.

5. Press **Delete**, then press **Done**, then press **Save**.

7 Adjusting Settings

Program reminders

If program reminders are on, the Pod beeps every 60 minutes while a temp basal or extended bolus is in progress. See page 99 for more information about program reminders.

1.   **Home > Settings > System setup > Alerts/reminders >Program reminders**

2.   To enable program reminders, choose **On** and press **Select**.

3.   To disable program reminders, choose **Off** and press **Select**.

Exception: You cannot turn off beeps that occur during an ongoing temp basal set to deliver no (zero) insulin.

Confidence reminders

Turn on confidence reminders to have the Pod beep at the start and end of a bolus, an extended bolus, and a temp basal. Confidence notifications are especially useful when you are getting familiar with your PDM and Pod. See page 99 for more information about confidence reminders.

1.   **Home>Settings>System setup>Alerts/reminders>Confidence reminders**

2.   To enable confidence reminders, choose **On** and press **Select**.

3.   To disable confidence reminders, choose **Off** and press **Select**.

Exception: You cannot turn off beeps that occur at the start of a temp basal set to deliver no (zero) insulin.

Custom reminders

A custom reminder consists of a name and a time of day. You can set a one-time custom reminder or have the reminder repeat daily. Custom reminders repeat every 15 minutes until acknowledged. You can set up to four custom reminders. See page 99 for more information about custom reminders.

Add a new custom reminder

1.   **Home > Settings > System setup > Alerts/reminders > Custom reminders**

2.   Highlight **[add new]** and press **New**.

3.   If desired, enter a unique name for the custom reminder (see "Entering text" on page 6). Press **Next**.

4.   Use the **Up/Down** button to enter the time you would like the reminder to occur, and press **Next**.

5.   Choose **Daily** or **One time only** to specify whether the reminder repeats, then press **Select**.

View, edit or turn off a custom reminder

1.   **Home > Settings > System setup > Alerts/reminders > Custom reminders**

2.   Highlight the reminder of interest, and press **Edit**.

3.   The next screen displays the details of that reminder.

    a.   To make no changes, press **Done**.

    b.   To rename, highlight **Rename** and press **Select**. Enter the new name or time for the reminder (see "Entering text" on page 6), and press **Next**.

    c.   To change the time or frequency of a reminder, or to turn a reminder on or off, highlight **Edit** and press **Select**. Enter the time for the reminder, and press **Next**. Choose a frequency or set to Off, then press **Select**.

4.   Press **Done**.

Delete a custom reminder

1.   **Home > Settings > System setup > Alerts/reminders > Custom reminders**

2.   Highlight the reminder that you want to delete, and press **Edit**. The next screen displays the details of that reminder.

3.   Highlight **Delete**, and press **Select**.

4.   Press **Delete**.

BG Readings Settings

Upper limit and lower limit of the BG Goal Range

The upper and lower limit of your BG Goal Range are used in the history graphs and statistics to determine which blood glucose readings are within goal and which are above or below your goal.

Caution: Check with your healthcare provider before adjusting these settings.

1.   **Home > Settings > System setup > BG meter**

2.   Highlight **BG goal**, press **Select**, then press **Edit**.

3.   Enter the desired lower limit for the BG Goal Range, and press **Next**.

4. Enter the desired upper limit for the BG Goal Range, and press **Next**.

5. Press **Save**.

BG tags

BG tags are used to convey useful information about blood glucose readings. You can create up to 15 custom tags (which appear at the bottom of the tags list) and hide any of the standard tags you do not plan to use.

1. **Home > Settings > System setup > BG meter**

2. Highlight **Manage BG tag list**, and press **Select**.

3. To show or hide a standard tag on the **Standard BG tags** list, highlight the tag of interest and press **Show** or **Hide**. You may need to scroll down to find the tag or interest. Press **Done** when finished.

    A checkmark indicates the tags that will appear in the tags list used for tagging BG readings.

4. To add a custom BG tag, use the **Up/Down** button to scroll down to the **Custom BG tags** section, highlight **[add new]** and press **New**. Enter a name (see "Entering text" on page 6), and press **Save**. Then press **Done**.

5. To delete a custom BG tag, scroll down to highlight the tag of interest, and press **Delete**. Then press **Delete** again, then press **Done**.
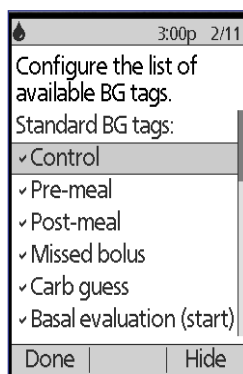
Built-in BG meter sound

You can control whether the built-in BG meter beeps when the test strip is full of blood or control solution.

1. **Home > Settings > System setup > BG meter**

2. Highlight **BG sound**, and press **Select**.

3. Choose **On** to enable the beeps or **Off** to disable the beeps. Then press **Select**.

Working with Time Segments

The Omnipod® System is active 24 hours a day, and therefore, your settings must cover the full 24 hours. While some settings have a constant value, the Basal Program's basal rates and the Bolus Calculator's Target BG, Correct Above, IC Ratio, and Correction Factor can vary throughout the day. This variability is created by dividing the midnight-to-midnight time period into multiple time segments with different values.

How to add time segments

The following figure shows how to add a time segment.

Goal: Sub-divide the day into multiple time segments

Your initial time segment has a single value and spans 24 hours, beginning at midnight and ending at the following midnight.
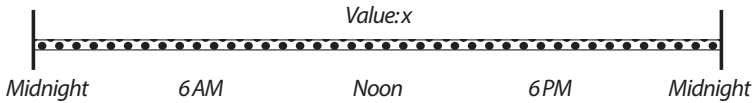
1. Add a single time segment in the middle of the initial segment by specifying the start and end times and a new value for the new segment. The result is that the day is divided into three time segments. The combined segments still span 24 hours.
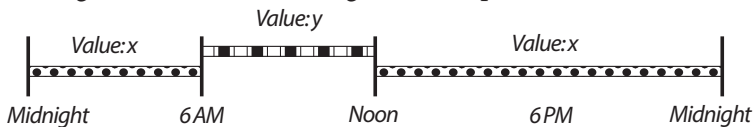
2. Continue to insert time segments, as needed.
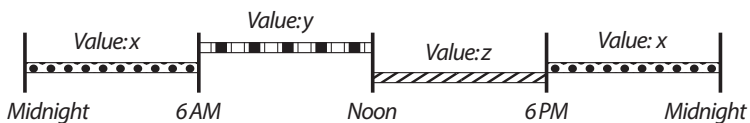
How to delete time segments

The following figure shows how to delete a time segment by extending an adjacent segment to cover the segment you wish to remove.

Goal: Delete time segment C (noon to 6 PM)

Option 1: Change the end time of segment B to 6 PM

Option 2: Change the start time of time segment D to noon
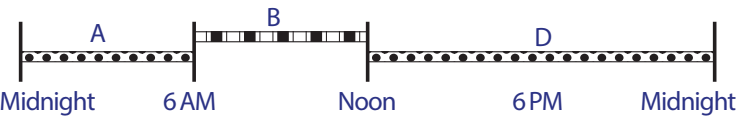
CHAPTER 8
Browsing Your Records

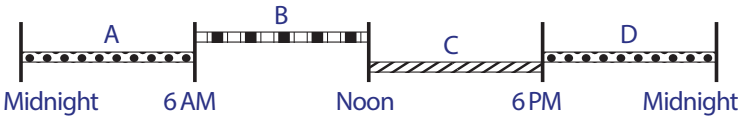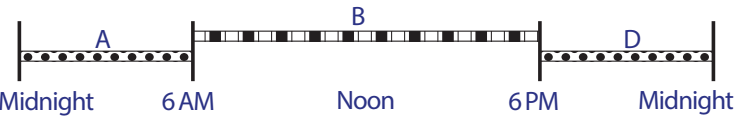The PDM history records contain information about your blood glucose readings, insulin delivery, carbohydrate entries, and alarms history. The history records can store over 90 days of information. Once the memory is full, new records begin to replace the oldest records. You can browse but not edit the information in your records.

Note: The data in memory is not at risk if the PDM battery runs out. The date and time may need to be reset, but the history records are unaffected.

Overview of the Records Screens

This section describes how to navigate your records and understand the meanings of the symbols used on the history screens.

The Records menu

To access the Records menu, navigate to:

Home > My records

The Records menu allows you to select a category of history records to view (insulin delivery, BG readings, alarms, or carbohydrates). You can also view all of your history records in one long chronological list.

The Records menu also gives you access to any personal notes you have stored.
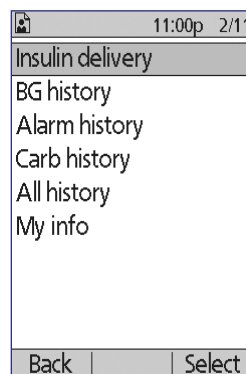
Selecting list items or dates

The middle soft key of many of the history screens toggles between **Event** and **Day**. Selecting **Event** or **Day** determines what happens when you press the **Up/Down** button as explained in the following sections.

Selecting Event

Selecting the **Event** option switches the highlighting from the date into the list of items.
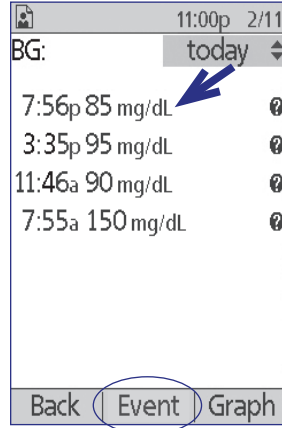
When the highlighting is in the list of items, pressing the **Up/Down** button allows you to:

- Scroll up or down to view list items that are off-screen.
- Scroll to a list item that has a "more info" () icon next to it. Once the list item is highlighted, you can see additional details about that item by pressing the **Info** button:
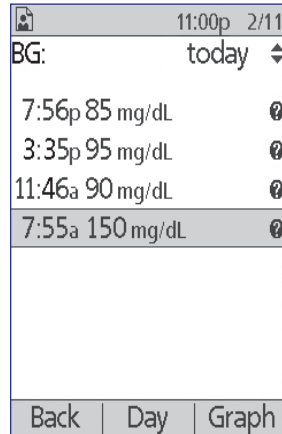
Selecting Day

Selecting the **Day** option switches the highlighting from the list to the date, which is located in the upper right-hand corner of the screen.

When the date is highlighted, pressing the **Up/Down** button changes the date to the preceding or next date. This allows you to access all of the daily records that are stored in your history.
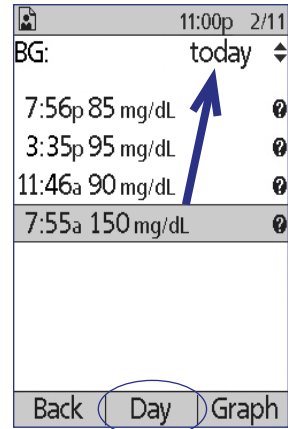
Meaning of icons used on record screens

The following symbols appear next to some of the records in the history screens:

Icon	Meaning
?	Additional details are available for this record. Highlight the record and press the **Info** button to view the details.
◆	Active Basal Program, active temp basal, or ongoing extended bolus.
e	Extended bolus.
☾	Insulin delivery spanned midnight. The record is listed on both days.
✓	Insulin delivery record is "unconfirmed." In this situation, the change in the basal or bolus insulin delivery was begun but the PDM has not received a status update from the Pod confirming the current status. If the PDM receives a status update confirming delivery, the PDM removes the checkmark symbol from the record.
⊖	Insulin delivery record is considered "lost." If the Pod is discarded without the PDM receiving a status update, any records marked "unconfirmed" are recategorized as "lost." In this situation, the PDM does not know at what point the basal or bolus delivery was halted. This means it cannot calculate how much insulin was actually delivered. Therefore, the PDM does not display insulin totals for any day containing "lost" records.

Insulin Delivery Records

You can view basal and bolus insulin delivery records as a (1) combined summary or (2) day-by-day list of individual events.

Combined basal and bolus summary

1. To see a summary of your daily basal and bolus insulin delivery, navigate to:

   Home > My records > Insulin delivery

   The screen shows the total number of units of insulin delivered via boluses and via the basal rate. The percentage of each is also listed.

2. To see the summary for a different day, use the **Up/Down** button to change the date listed in the upper right corner of the screen.

Note: The PDM does not display insulin totals for any day containing "lost" records. This is because it cannot calculate how much insulin was actually delivered on that day. (See "Meaning of icons used on record screens" on page 85.)

Bolus history

The bolus history screen displays a day-by-day list of the time and units of insulin delivered for each bolus. If a portion of a bolus was extended, the immediate portion and the extended portion (marked with an "e") are displayed on two separate lines. An extended bolus entry lists the duration as well as the units and start time. If a bolus was canceled, only the amount delivered before cancellation is shown.

1. To see your bolus records for a single day, navigate to:

   Home > My records > Insulin delivery > Bolus

2. Use the **Up/Down** button to view bolus data from different dates or to scroll through the items listed on the screen (see "Selecting list items or dates" on page 84).

A single bolus started at 2:37 pm. The extended portion is listed on the upper line; the immediate portion is listed below.

3.   To see additional details about a list item that has a ❓ icon next to it, use the **Up/Down** button in Event mode to highlight the list item, and then press the **Info** button.

Note: Boluses delivered with a syringe are not included in these records.

Both the bolus and the basal history screens include information about suspending or resuming insulin, and Pod changes.

Basal history

The basal history screen shows the basal insulin delivery for the selected day. This includes information about temp basals and any changes to the active Basal Program. The active Basal Program or temp basal is indicated by a diamond (◆) icon.

1.   To see the records of your basal insulin delivery for a single day, navigate to:

     Home > My records > Insulin delivery > Basal

2.   Use the **Up/Down** button to view basal rate data from different dates or to scroll through the items listed on the screen (see "Selecting list items or dates" on page 84).

3.   To see additional details about a list item that has a ❓ icon next to it, use the **Up/Down** button in Event mode to highlight the list item. Then press the **Info** button.
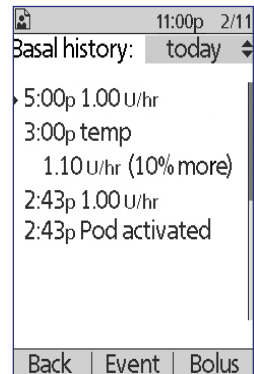
Temp basals are marked with the word "temp." If a temp basal is defined as a percent (%) of the active Basal Program, the percent increase or decrease is listed. For example, an entry showing "temp 1.10 U/hr (10% more)" means that you delivered a temporary basal rate of 1.10 units per hour, which was 10% more than the active Basal Program's basal rate for that time period.

8 Browsing Your Records

BG History Records

The PDM stores blood glucose (BG) records for the past 90 days. You can view individual readings, single-day summaries, and multi-day summaries.

Note: LOW and HIGH BG readings are included in the number of BG readings but not in calculations or averages.

Note: Readings that you have tagged as a control solution (see page 36) appear in the list of the current day's readings. However, control solution readings are not included in the number of BG readings, averages or calculations.

View BG records for one day

Your BG Goal Range defines the desired range for your blood glucose. To see a summary of your blood glucose records for a single day:

1. Navigate to:

   Home > My records > BG history

   The summary screen displays:

   - Total number of readings, listed as "(n= x)"
   - The average blood glucose reading for the day
   - The day's maximum and minimum blood glucose reading
   - Your BG Goal Range, and the percent of BG readings that were within the range, above the range, and below the range.

Summary screen

2. Use the **Up/Down** button to change the date displayed (see "Selecting list items or dates" on page 84).

3. To see a list of each BG reading for the selected day, press **List** (or, from the Status screen, navigate to **Home > My records > BG history > List**).

4. To see additional details about a list item that has a ❓ icon next to it, press **Event** and use the **Up/Down** button to highlight the list item, and then press the **Info** button. Press **Close** when done.

   The additional details screen shows the BG tags, if any. It also includes information about which BG readings were manually entered and whether there were issues with the built-in BG meter.

5.   To see a graph of all of the BG readings for the selected day, press **Graph**. (Alternatively, from the Status screen, navigate to: **Home > My records > BG history > Graph**).

The two horizontal dashed line on the graph show the upper and lower limits of your BG Goal Range. The vertical axis (y-axis) has a maximum value of 300 mg/dL if all the BG readings were below 300 or 500 mg/dL if any BG reading was above 300 mg/dL.

The data markers used on the graph have the following meaning:
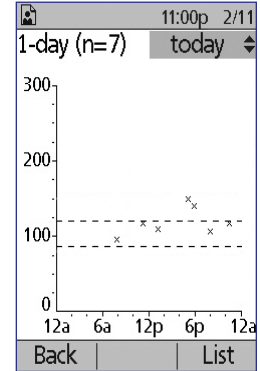
Marker	Meaning
⋀	A HIGH reading (over 500 mg/dl)
✕	A numerical reading
⋁	A LOW reading (under 20 mg/dL)

View BG records for multiple days

To see a seven-day summary of your blood glucose records:

1.   Press **Trends** from the single-day list or graph (or, from the **Status** screen, navigate to: **Home > My records > BG history > Trends**).

The summary screen for multiple days is quite similar to the summary screen for one day (see the Summary screen on the previous page). The summary screen displays:

- The number of days included in the summary
- Total number of BG readings for the multi-day period, listed as "(n=_x_)"
- The average number of BG readings per day
- The average blood glucose level for the multi-day period
- The maximum and minimum blood glucose reading during the multi-day period
- Your BG Goal Range, and the percent of BG readings that were within the range, above range, and below range.

2.   To see a larger or smaller multi-day period, press the middle soft key. This allows you to rotate among a 7-day, 14-day, 30-day, 60-day, and 90-day summary.

3. Press **Graph** to see a graph of the multi-day period. Graphs are not available for 60-day and 90-day periods.

4. Press **Stats** to see the text summary of the multi-day period.

5. Press **Back** to return to viewing single-day data.

Alarm History Records

The PDM lists the entire alarm history on a single screen. This history can contain over 90 days of alarm records.

1. To see the alarm history, navigate to:

   Home > My records > Alarm history

2. Use the **Up/Down** button to scroll down the list.

3. To see additional details about a list item that has a ❓ icon next to it, press **Event** and use the **Up/Down** button to highlight the list item, and then press the **Info** button. Press **Close** when done.

Carbohydrate History Records

The carbohydrate records store the date, time, and grams of carbohydrates you have entered.

1. To see a daily record of your carbohydrate entries, navigate to:

   Home > My records > Carb history

2. Use the **Up/Down** button to view individual carbohydrate entries from different dates or to scroll through the items on the list (see "Selecting list items or dates" on page 84).

Combined Listing of All History Data

The PDM can display all of your history records on a single screen:

1. To see a combined record of all of your history records for a day, navigate to:

   Home > My records > All history

2. Use the **Up/Down** button to view history records from different dates or to scroll through the items on the list (see "Selecting list items or dates" on page 84).

3. To see additional details about a list item that has a ❓ icon next to it, use the **Up/Down** button in Event mode to highlight the list item, and then press the **Info** button. Press **Close** when done.

## My Info

To view any brief notes that you have entered using the My info feature (see "Storing brief notes" on page 60):

1. Navigate to:

   Home > My records > My info

2. Press **Back** or the **Home** button when done.

Note: You can also view any My info notes by pressing the **Home/Power** button and then pressing the **Info** button.

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CHAPTER 9
Alarms, Notifications, and Other Messages

Overview

> **Warnings:**
>
> Respond to hazard alarms as soon as possible. Pod hazard alarms indicate that insulin delivery has stopped. Failure to respond to a hazard alarm can result in hyperglycemia.
>
> If you need to return the PDM for replacement, contact your healthcare provider for instructions about using injections.

The Omnipod® System generates the following types of alarms and messages:

- **Hazard alarms** are high priority alarms that indicate a serious problem has occurred and the Pod must be removed.

- **Advisory alarms** are low priority alarms that indicate that a situation exists that needs your attention.

- **Notifications** remind you about an action you may want to perform.

- **Informational beeps** are informational only; no action is needed.

- **Communication failures** occur when the PDM is unable to communicate with the Pod.

- **BG meter errors** occur when the built-in BG meter cannot perform an accurate test.

To make you aware of an alarm, notification, or other message, the Pod sounds a tone and the PDM can sound a tone or vibrate. The PDM can also display an on-screen message. This chapter explains these sounds and messages.

To check whether sounds and vibrations are functioning properly, see page 61.

Priority of alarms, notifications, and informational beeps

Hazard alarms take priority over advisory alarms. Advisory alarms take priority over notifications and informational beeps. If multiple advisory alarm events occur, their messages are delivered in the order in which they occur. If multiple notifications occur, their messages are also delivered in the order in which they occur.

9 Alarms, Notifications, and Other Messages

Hazard Alarms

Hazard alarms make you aware of serious situations. For hazard alarms that originate in the Pod, the Pod sounds a continuous tone broken up periodically by a series of beeps and the PDM sounds a continuous tone. For hazard alarms that originate in the PDM, the PDM sounds a continuous tone and the Pod remains silent.

When you hear a continuous tone, turn on your PDM to read the alarm message.

PDM message	Description	What to do
Pod expired. Insulin delivery stopped. Change Pod now.	The Pod has reached the end of its operating life. Pod and PDM sound alarm.	Press **OK**. Change Pod. Check blood glucose.
Empty reservoir. Insulin delivery stopped. Change Pod now.	The Pod's insulin reservoir is empty. Pod and PDM sound alarm.	Press **OK**. Change Pod. Check blood glucose.
Auto-off. Remove Pod now.	Insulin delivery has stopped. This alarm can be turned on or off. Pod and PDM sound alarm.	Press **OK**. Change Pod. Check blood glucose.
Occlusion detected. Insulin delivery stopped. Change Pod now.	The Pod's cannula is blocked so insulin cannot pass through. Pod and PDM sound alarm.	Press **OK**. Change Pod. Check blood glucose.
Pod Error. Insulin delivery stopped. Change Pod now.	The Pod detects an unexpected error. Pod and PDM sound alarm.	Press **OK**. Change Pod. Check blood glucose.
System Error. Remove Pod now. Call customer support: 800.591.3455.	An unexpected error is detected in the Pod or PDM. The Pod, PDM, or both may sound the alarm.	Press **OK**. Remove Pod. Call Customer Care immediately. Check blood glucose.

PDM message	Description	What to do
PDM Error. Remove Pod now. Call customer support: 800.591.3455.	The PDM detects an unexpected error. PDM sounds alarm.	Press **OK**. Remove Pod. Call Customer Care immediately. Check blood glucose.
PDM Error. Memory corruption. Press "OK" to reset PDM and delete all user settings. History records will not be deleted.	A memory corruption error occurs after the PDM is reset. PDM sounds alarm.	Press **OK**. Change Pod. Check blood glucose.
PDM Error. Press OK to reset clock.	Time and date need to be reset after a PDM error. PDM sounds alarm.	Press **OK**. Reset clock. Change Pod. Check blood glucose.
Pod deactivation required. Press "OK" to deactivate.	If a Pod is active during a PDM error requiring a clock reset, you must replace the Pod. PDM sounds alarm.	Press **OK**. Change Pod. Check blood glucose.

If a temp basal or extended bolus was running when an alarm occurred, the PDM reminds you of this.

Tip: *If you follow the PDM's instructions and are still not able to silence an alarm, see "Silencing an Alarm" on page 106.*

Advisory Alarms

Advisory alarms inform you of a situation that needs your attention in the near future.

Warnings:

Three advisory alarms (Pod expiration advisory, low reservoir, and Auto-off) escalate and result in a stoppage of insulin delivery if ignored. Be sure to respond to all advisory alarms when they occur.

The low reservoir advisory alarm will escalate to an empty reservoir hazard alarm when insulin is depleted. Be sure to respond to the advisory alarm when it occurs.

PDM message	Beeps	Description	What to do
Pod expiration advisory. Change Pod now.	2 sets of 4 beeps repeating periodically. Repeats every 15 minutes during the last hour of the Pod's life. Pod and PDM beep.	Pod expiration advisory alarm. Your Pod will expire soon. Escalates to Pod expired hazard alarm if ignored.	Press **OK**. Change Pod.
Low reservoir. Replace Pod soon. 🍶 < x > U	2 sets of 4 beeps every minute for 3 minutes. Repeats every 60 minutes until acknowledged. Pod and PDM beep.	Low reservoir advisory alarm. The volume of insulin in the Pod reservoir is below the value you specified.	Press **OK**. Change Pod.
Auto-off alert	§ 2 sets of 4 beeps every minute for 15 minutes. Pod and PDM beep.	Your PDM has not communicated with your Pod within the time period you selected. Escalates to Auto-off hazard alarm if not acknowledged within 15 minutes.	Press **OK**. This resets the Auto-off countdown timer to the beginning.

PDM message	Beeps	Description	What to do
End of insulin suspend. Press OK to resume basal rate delivery.	2 sets of 4 beeps every minute for 3 minutes. Repeats every 15 minutes until insulin delivery is resumed. Pod and PDM beep.	Time period for insulin suspension has passed. If you do not resume insulin delivery, you could develop hyperglycemia.	Press **OK** to restart the scheduled Basal Program.
Stuck key detected. Check <button> to resolve. For technical support refer to your User Guide.	2 sets of 4 beeps, repeat every 5 min. PDM beeps.	The specified PDM button is stuck.	Press the button to unstick it. If this does not work, call Customer Care.
USB device ready. PDM functionality is disabled while USB is connected.	2 sets of 4 beeps, repeats every 5 min. PDM beeps.	A USB cable is plugged into your PDM.	Unplug the PDM cable to restore PDM functionality.

§ To turn on or off, see "Pod Auto-off" on page 76.

Notifications

Notifications remind you about various actions you may want to perform.

PDM message	Beeps	Description	What to do
Expiration alert. Pod expires at <time, date>.	2 sets of 4 beeps every minute for 3 minutes. Repeats every 15 minutes until acknowledged. Pod and PDM beep.	User-set Pod expiration notification. Tells you when the Pod expiration advisory alarm will occur.	Press **OK**. Change Pod.

9 Alarms, Notifications, and Other Messages

PDM message	Beeps	Description	What to do
Reminder: No active Pod.	* 2 sets of 4 beeps, repeat every 15 min. PDM beeps.	You need to activate a new Pod to begin basal insulin delivery.	Press **OK**. Activate a new Pod.
Reminder: Always check BG after a pod change. Check infusion site and ensure cannula is properly inserted.	* 2 sets of 3 beeps, repeat every 5 min. PDM beeps.	Reminds you to check your blood glucose 90 minutes after a Pod change.	Press **OK**. Check blood glucose.
Reminder: Check BG.	* § 2 sets of 3 beeps, repeat every 5 min. PDM beeps.	Reminds you to check your blood glucose after a bolus.	Press **OK**. Check blood glucose.
Reminder: Missed bolus. Meal bolus not delivered during reminder period <start time> - <end time>	* § 2 sets of 3 beeps, repeat every 15 min. PDM beeps.	You have not delivered a bolus within the time period you have specified.	Press **OK** to acknowledge the bolus reminder.
Low PDM batteries. Change batteries soon.	No beeps.	The PDM batteries are low.	Replace the batteries as soon as you can.
<User-defined custom message>	* § 2 sets of 3 beeps, repeat every 15 min. PDM beeps.	Custom reminder with a message of your choice.	Press **OK**.

* To set to vibrate and/or beep, see "Vibrate and sound options" on page 60.

§ To turn on or off, see "BG reminders" on page 75, "Bolus reminders" on page 76, "Custom reminders" on page 78.

Informational Beeps

Informational beeps let you know that normal events are occurring as expected. The PDM does not show an explanatory message.

Event	Beep from Pod	Beep from PDM	Beep pattern	Comment
Start of Temp basal, bolus or extended bolus		✓	Two beeps	To turn these beeps on or off, see "Confidence reminders" on page 78.
End of Temp basal, bolus, or extended bolus	✓		Single beep	
Temp basal, ongoing	✓		Single beep, repeats every 60 min	To turn these beeps on or off, see "Program reminders" on page 78.
Extended bolus, ongoing	✓		Single beep, repeats every 60 min	
Temp basal cancellation	✓		Single beep	Cannot turn these beeps off.
Bolus cancellation	✓		Single beep	
Extended bolus cancellation	✓		Single beep	
Pod deactivated		✓	Two beeps	Cannot turn these beeps off.
Pod activation in progress	✓		2 sets of 4 beeps, repeat every 5 min	
Pod activated	✓		Two beeps	
Pod prime complete		✓	Two beeps	
Basal Program activated, updated, or resumed		✓	Two beeps	Cannot turn these beeps off.
Start of insulin suspension		✓	Two beeps	Cannot turn these beeps off.
Insulin suspension, ongoing	✓		Single beep, repeats every 15 min	

Event	Beep from Pod	Beep from PDM	Beep pattern	Comment
Test strip filled		✓	Single beep	
BG reading done		✓	Two beeps	
A non-functional button is pressed		✓	Single beep	Cannot turn these beeps off.

Pod Communication Failures

When you turn on your PDM or use it to send a command to your Pod, the PDM broadcasts the request to the Pod. If that communication request fails, the PDM attempts to reestablish communication.

The following sections describe situations that can result in communication failures and what action you should take.

Failure to receive a Pod status

PDM message	What to do
((•)) ▲	If the PDM does not get a status update from the Pod shortly after you turn on the PDM or press **Status**, the PDM continues to send the request. You have two choices: Wait while the PDM attempts to communicate or press **Skip**.
Pod status not available. Last status: today <time>	After you press **Skip** or if the communication attempt times out, "Pod status not available" is shown in the lower section of the Status screen. Press **Status** to send another status request. Press **Home** to go to the **Home** screen.

Failure when activating or sending a command to a Pod

PDM message	What to do
Communication error. Move PDM close to pod.	During activation, place the PDM so it touches the Pod. After activation, hold the PDM within 5 ft (1.5 m) of the Pod.

If the communication problem persists:	
Communication error. Move to a new area and then press "Retry."	Move across the room or to a different location. Press **Retry**. The PDM attempts to send the command again.
Communication timeout. Press "Ok" to check pod status.	Press **OK**. The PDM request a status update from the Pod.
Communication timeout. Press "Ok" to check pod status or press "Discard" to deactivate pod.	Press **OK** to resend the Pod status request, or press **Discard** to begin the deactivation process. If you press **Discard**, go to "Failure when deactivating a Pod" on page 103."

If the communication is reestablished before timeout:	
Communication successful.	Your last command was successfully sent to the Pod. Press **OK**.

If the communication is reestablished after timeout:	
Communication error. Last bolus command not received. Refer to settings or history screens to review last action.	Due to the delay in establishing communication, your last command was not sent to the Pod. (Note: If your last command was not about a bolus, the word "bolus" is replaced by the last command that you issued.) Press **OK**. Reissue your last command, if desired.

Failure when canceling a bolus

PDM message	What to do
Communication error. ((•)) ▲ Move PDM close to Pod.	When an attempt to cancel a bolus is not immediately successful, the PDM displays this screen. Move your PDM closer to your Pod.
Communication error. Bolus status unknown. Move to a new area and then press "Retry," or press "Discard" to deactivate pod.	If the PDM still cannot communicate with the Pod, the PDM displays this message. Move to a new location and press **Retry**. If the communication error persists, press **Discard** to deactivate the Pod. Remove your old Pod and activate a new Pod.
Communication timeout. Bolus status unknown. Press "Ok" to check pod status or press "Discard" to deactivate pod.	If you pressed **Retry** on the previous screen and the PDM still cannot communicate with the Pod, the PDM displays the message shown here. Press **OK** to check the Pod status. If communication is reestablished, see page 101. Press **Discard** to deactivate the Pod and go to "Failure when deactivating a Pod" on page 103.

If at any point in this process the PDM can communicate again with the Pod, it displays a "Communication successful" message. After you press **OK**, the PDM tells you how much of the bolus was delivered before it was canceled.

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

Failure when deactivating a Pod

PDM message	What to do
Communication error. Remove pod. To retry deactivation, press "Retry." Otherwise, press "Discard."	An attempt to deactivate the Pod fails. Remove your Pod. Press **Retry** to try deactivating the Pod again, or press **Discard** to break the link between the PDM and the unresponsive Pod. Activate a new Pod.

Warning: If you are unable to deactivate a Pod, it continues to pump insulin. Be sure to remove the failed Pod before you activate a new Pod to prevent hypoglycemia.

Special situation

A special situation exists if a bolus was being delivered when communication was lost, because the PDM does not know how much of the bolus was delivered. This causes the Bolus Calculator to be temporarily disabled because it cannot calculate a valid IOB (insulin on board). The Bolus Calculator is re-enabled when no insulin remains in your body from the old bolus. This length of time is determined by your duration of insulin action.

PDM message	What to do
Due to a recent clock reset or unconfirmed bolus information, bolus calculations cannot be used until <time>.	The Bolus Calculator is disabled until the listed time. Press **OK**. You can deliver a manually-calculated bolus if you want.

9 Alarms, Notifications, and Other Messages

Errors in the Built-in BG Meter

If there is a problem in the blood glucose meter, test strip, sample, or results, the PDM gives three beeps and displays a meter error number. Use the meter error number to look up corrective actions in the following table.

PDM message	Possible causes	What to do
Meter Error 1 See user manual for further instructions	4 possibilities: Blood sample is too small. Problem with the test strip. Problem with the meter. Very low blood glucose: less than 20 mg/dL.	If you have symptoms, such as weakness, sweating, nervousness, headache, irritability, or confusion, follow your healthcare provider's advice for treating hypoglycemia. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. If the control solution test does not work, or the error persists, call Customer Care.
Meter Error 2 See user manual for further instructions	4 possibilities: Problem with the test strip. Problem with the meter. Very high blood glucose: above 500 mg/dL. HIGH control solution applied when temperature is too cold.	If you have symptoms, such as thirst, fatigue, excess urination or blurry vision, follow your healthcare provider's advice for treating hyperglycemia. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. If the control solution test does not work or the error persists, call Customer Care.

PDM message	Possible causes	What to do
Meter Error 3 See user manual for further instructions	3 possibilities: Incorrect test procedure; for example, putting blood on the test strip before the blood drop screen appears. Problem with the test strip. Problem with the meter.	Be sure you see the blinking blood drop screen before you apply blood or control solution. Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. If the control solution test does not work or the error persists, call Customer Care.
Meter Error 4 See user manual for further instructions	2 possibilities: Problem with the test strip. Problem with the meter.	Conduct a control solution test using a new test strip. If the results of the control solution test are within the range printed on the side of the test strip vial, retest using blood and a new test strip. If the control solution test does not work or the error persists, call Customer Care.
Meter Error 6 See user manual for further instructions	Blood sample was applied while the code number was being changed.	Retest using a new test strip. Do not press any buttons while applying blood or control solution to the test strip. If the error persists, call Customer Care.

Silencing an Alarm

Pod alarm: If you respond to a Pod alarm but the PDM cannot shut off the alarm, the Pod alarm continues. To permanently silence a Pod alarm:

1. If the Pod is on your body, remove it.

2. Peel back a little bit of the adhesive pad from the bottom of the Pod at the square end (see figure).

3. Locate the alarm shut-off port to the right of the gold circle. The alarm shut-off port can be felt with a fingernail or paper clip as a soft plastic.

   Alarm shut-off port

   Gold circle

   Fill port

4. Firmly press a paper clip or similar item straight down into the alarm shut-off port until the alarm stops.

   Note: *Press down firmly.* The paper clip may go in a little bit and then stop. You must continue pressing down, very hard, until the alarm stops. You need to apply enough force to break a thin layer of plastic.
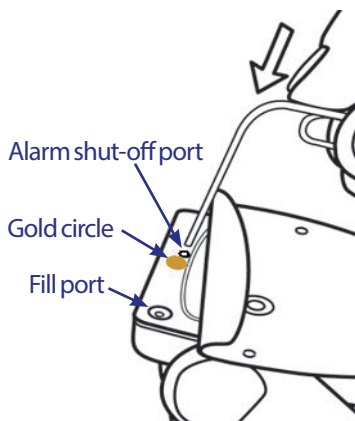
PDM alarm: If you cannot turn off a PDM alarm using the PDM's soft keys, you can silence the PDM alarm as follows:

1. Turn the PDM over and remove the door of the battery compartment.

2. Leaving the batteries in place, locate the small alarm reset hole, surrounded by green, in the cutout below the batteries.

   Alarm reset hole

3. Gently press a paper clip or similar item into the hole to stop the alarm.

   Note: *Press down gently.* You are pressing a small button; you are not trying to break anything.
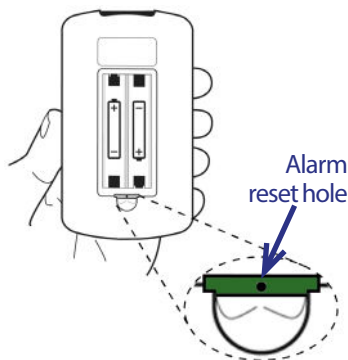
This action silences the PDM's alarm. Your history records and personal settings are preserved.

CHAPTER 10
Taking Care of Your PDM and Pod

The Omnipod® Insulin Management System has no user-serviceable parts. If you require assistance operating or maintaining the Omnipod® System, call Customer Care.

> **Warnings:**
>
> Store all Omnipod® 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.

Pod and Insulin Care

To order all Omnipod® System products and supplies, call Customer Care.

Pod and insulin storage

Extreme heat or cold can damage Pods and cause them to malfunction. If Pods are exposed to extreme temperatures, inspect them carefully before use.

It is especially important to store your insulin in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discolored. Insulin that is cloudy or discolored may be old, contaminated or inactive. Check the insulin manufacturer's instructions for use and expiration date.

Pods and the environment

Avoid extreme temperatures

The Pod's operating temperature is between 40°F and 98.6°F (between 4.4°C and 37°C). Under normal circumstances, your body temperature keeps the Pod well within this range.

> **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.

If you remove your Pod to avoid exposing it to extreme temperatures, remember to check your blood glucose levels frequently. Check with your healthcare provider for guidelines on removing the Pod for extended periods.

Water and your Pod

The Pod is waterproof up to a depth of 25 feet (7.6 meters) for up to 60 minutes (IP28). After swimming or similar exposure to water, rinse off the Pod with clean water and gently dry it with a towel.

> **Warning:** Do NOT expose your Pod to water at depths greater than 25 feet (7.6 meters) or for longer than 60 minutes. Check the infusion site often to make sure the Pod and soft cannula are securely applied and in place. If the cannula is not properly inserted, hyperglycemia may result. Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.

Cleaning your Pod

Pods are waterproof. If you need to clean a Pod, gently wash it with a clean, damp cloth, or you can use mild soap and water. However, do not use strong detergents or solvents, as they can damage the Pod's casing or irritate the infusion site.

Caution: Hold the Pod securely and take care while cleaning it, so the cannula doesn't kink and the Pod doesn't become detached from your skin.

PDM Care

This section describes proper care of your PDM.

PDM storage

When you are not using your PDM, store it in a convenient, nearby location that is cool and dry.

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

If the PDM is not safe from children or others who may press the buttons by accident, consider using the optional PDM lock safety feature to prevent unwanted program changes (see "Lock or unlock the PDM buttons" on page 61).

PDM and the environment

Avoid extreme temperatures

Extreme operating temperatures can affect the PDM's battery and interfere with Omnipod® System operation. Avoid using the PDM in temperatures below 40°F (4.4°C) or above 104°F (40°C).

Water and your PDM

The PDM is not waterproof. Do not place it in water or leave it near water where it can accidentally fall in. If it gets wet:

1. Dry the outside of the PDM with a clean, lint-free cloth.

2. Open the battery compartment, remove the batteries and discard them.

3. Use a clean, lint-free cloth to gently absorb any water in the battery compartment.

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

4. Leave the battery compartment door open until the PDM is thoroughly dry.

5. Do not put in fresh batteries or attempt to use the PDM until it has thoroughly air-dried.

6. Call Customer Care if the PDM does not work after the above steps.

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

Electrical interference

The PDM is designed to withstand normal radio interference and electromagnetic fields, including airport security and cellular phones. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. In most cases, interruptions are easy to resolve (see "Pod Communication Failures" on page 100).

USB cable

When you use a USB cable to upload your records to another device, disconnect the USB cable as soon as you are finished.

> **Warning:** Only connect a USB cable to your PDM when downloading data to a computer. Never connect a USB cable to anything else. Other PDM functions are disabled while a USB cable is connected, and the PDM cannot communicate with the Pod.

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.

Caution: Never attempt to test your blood glucose while your PDM is connected via USB cable to another device. Doing so could result in electrical shock.

Replacing the PDM's batteries

The PDM requires two (2) AAA alkaline batteries. You can purchase them at most grocery, hardware or convenience stores.

Caution: AAA alkaline batteries are used to power the PDM. Do not use any other type of batteries. Never use old or used batteries; the PDM may not work properly. Using any kind of batteries other than alkaline may reduce battery life and cause damage to the PDM. Do not use rechargeable batteries.

Under normal use, a pair of batteries powers the PDM for at least three weeks. The battery life indicator on the PDM shows the battery power level (see "PDM battery level indicator" on page 7).

The PDM automatically alerts you when its battery power gets low. When you see the "Low PDM battery" message, press **OK** to remove the message. Replace the batteries as soon as you can.

When your PDM alerts you that battery power is getting low, the PDM maximizes the remaining battery life by:

- Turning off your vibration alert (if set)
- Disabling bright mode
- Disabling the test strip port light

Once the batteries are replaced, these functions resume.

Note: The history data is retained in memory even if the battery runs out.
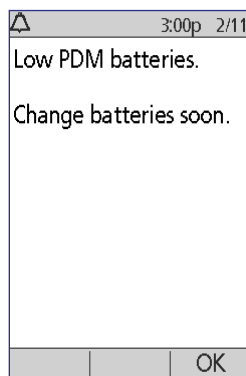
> **Warning:** The PDM remembers the date and time for up to two hours after the batteries run out or are removed. After that, the date and time may need to be reset. If there is an active Pod, it will have to be replaced.

To replace the batteries:

1. Turn the PDM over.

2. Open the battery compartment on the back of the PDM by pushing the compartment latch inward and then upward. No special tools are necessary.

The battery compartment is on the back of the PDM.

3. Insert two new AAA alkaline batteries into the compartment. The diagram inside the compartment shows you which direction to insert the batteries.

4. Replace the battery door.

5. Turn the PDM face up. The PDM powers on automatically.
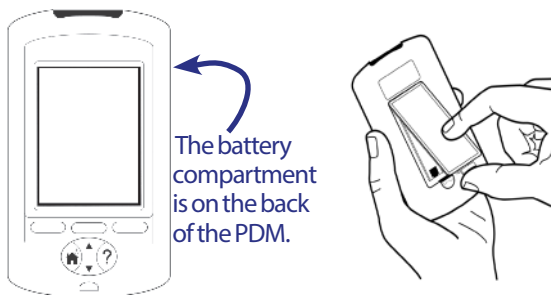
The PDM is now ready to use. Dispose of the old batteries in accordance with local waste disposal regulations.

PDM cleaning and disinfecting

The basics

Cleaning is meant to keep your PDM free from dirt, stains, or impurities; unsoiled. Disinfecting is the process of destroying pathogenic organisms or rendering them inert. The validated guidelines below are for cleaning and disinfection of the PDM.

Always keep your PDM test strip port and USB port free of debris and liquids. Dirt, dust, blood, and control solution can impair the functionality of your PDM or damage it.

Caution: Do not use IV Prep wipes, alcohol wipes, soap, detergent, or solvents. The PDM is not waterproof. Do not immerse it or place it in or near water.

Caution: If the built-in BG Meter is being operated by a second person who is providing testing assistance to the user, the BG Meter and lancing device should be disinfected prior to use by the second person.

Note: After cleaning or disinfecting your PDM, perform a control solution test to ensure that the Omnipod® System functions properly (see "Test your blood glucose or control solution" on page 38).

Note: Wash your hands thoroughly with soap and water after handling the BG Meter, lancing device, or test strips.

Cleaning the PDM

If the battery compartment becomes soiled, gently shake out the debris or use a dry, lint-free cloth to remove it.

1. Turn off your PDM before cleaning or disinfecting.

2. Using a Dispatch® Hospital Cleaner Disinfectant Towel with Bleach (EPA Reg. No. 56392-8), wipe the outer surfaces of the PDM to remove any dirt or soiled areas.

   Note: Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8) can be obtained online from major retailers, including Amazon (www.amazon.com) and Clorox Professional Products Co. (healthcare@clorox.com, 1-800-234-7700).

3. Allow the surface to remain wet for one minute prior to use.

Caution: While cleaning, do NOT allow debris or liquid to get into the test strip port, USB port, speaker or power button.

Disinfecting the PDM

You should disinfect your PDM once a week as follows:

1. Perform a cleaning as outlined in the previous section.

2. Disinfect the PDM surface by wiping it with a fresh Dispatch® Hospital Cleaner Disinfectant Towel with Bleach.

3. Allow the surface to remain wet for one minute before using the device.

Note: Cleaning and disinfection of the PDM has only been validated using Dispatch® Hospital Cleaner Disinfectant Towels with Bleach. Other cleaning agents may not provide effective cleaning or disinfection, or may damage the PDM.

A cycle consists of one cleaning plus one disinfection wipe. The cleaning and disinfection guidelines were validated by exposing test PDMs to the number of cycles that would be experienced with one cycle per week over the warrantied life of the device (4 years). In addition, the testing supports an additional two cleanings per week over the 4 year life of the device:

	Recommended Procedure	# Wipes Tested
Cleaning	2 cleanings x 52 weeks x 4 years	416 wipes
Cycle	1 cycle/week x 52 weeks x 4 years	416 wipes
Total		832 wipes

Checking the PDM for deterioration

Every time you clean or disinfect your PDM, you should also examine the entire PDM for discoloration, cracks, or separations. Also check for deteriorating performance, such as illegible messages, button malfunction, or repeated communication failures. If any signs of deterioration are observed, stop using the device and call Customer Care if there are questions or for information about device replacement.

References

For more information, see:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm234889.htm

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

If you drop the PDM

The PDM is built to withstand daily wear and tear, but shock or a severe impact can damage it. If you drop the PDM or if it is otherwise subjected to severe impact:

1. Inspect the outside of the PDM for visible signs of damage.

2. Press and hold the **Home/Power** button to see whether the PDM turns on and whether the LCD screen is damaged.

3. Inspect the inside of the battery compartment for visible signs of damage.

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

If you are unable to use your PDM's built-in BG Meter, use a backup BG Meter to check your blood glucose.

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

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CHAPTER 11
Living with Diabetes

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

Before deciding on the Omnipod® System, you and your healthcare provider discussed the benefits of the Omnipod® System, as well as the responsibilities that come with insulin pump therapy. Remember: safe use begins and ends with you. If you have questions or doubts about being able to safely use the Omnipod® System at any time, consult your healthcare provider immediately.

Daily Activities

To ensure proper Omnipod® System operation and your continued good health, check your Pod site, your PDM messages, and your blood glucose frequently.

Infusion site checks

At least once a day, use the Pod's viewing window to inspect the infusion site. Check the site for:

*   Leakage or scent of insulin, which may indicate the cannula has dislodged
*   Signs of infection, such as pain, swelling, redness, discharge or heat

> **Warnings:**
>
> If you suspect an infection, immediately remove the Pod and apply a new Pod in a different location. Then call your healthcare provider.
>
> If you see blood in your 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.

Tip: *Consider making infusion site checks a part of your daily routine, like showering or brushing your teeth.*

Check your blood glucose frequently

When you routinely check your blood glucose level, you can identify and treat high or low blood glucose before it becomes a problem.

Check your blood glucose:

- At least 4 to 6 times a day: when you wake up, before every meal, and before going to bed

- Whenever you feel nauseated or sick

- Before driving a car

- Whenever your blood glucose has been running unusually high or low, or if you suspect that your blood glucose is high or low

- Before, during, and after exercise

- As directed by your healthcare provider

Prepare for Emergencies

Tip: *Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.*

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

Prepare an emergency kit to keep with you at all time. The kit should include:

- Several new, sealed Pods

- Extra new PDM batteries (at least two AAA alkaline; do not use rechargeable batteries)

- A vial of rapid-acting U-100 insulin (see the Introduction for insulins approved for use in the Omnipod® System)

- Syringes or pens for injecting insulin

- Blood glucose test strips

- Additional blood glucose meter

- Ketone test strips

- Lancing device and lancets

- Glucose tablets or another fast-acting source of carbohydrate

- Alcohol prep swabs

- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted

- A signed letter from your healthcare provider explaining you need to carry insulin supplies and Omnipod® System equipment

- Phone numbers for your healthcare provider and/or physician in case of an emergency

- Glucagon kit and written instructions for giving an injection if you are unconscious (see "Avoid Lows, Highs, and DKA" on page 119)

Traveling and Vacations

Plan for changing time zones

If you're planning a vacation or business trip to a different time zone, you may need to adjust your Basal Programs. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct Basal Program can be more challenging. Your healthcare provider can help with these adjustments.

Take enough supplies

Keep your emergency kit with you during trips or vacations (see "Prepare for Emergencies" on page 116). It may be difficult or impossible to get insulin or supplies in an unfamiliar place. If traveling by air, be sure to pack your supplies in your carry-on luggage. When packing for travel, take more supplies than you think you'll need. Be sure to include an additional blood glucose meter and written prescriptions for all medications and supplies. Generic medications may be easier to find than brand names outside your country.

> **Warning:** When you travel outside the country or for long periods of time, be sure to take extra Pod supplies. Prior to departure, call Customer Care to inquire about additional Omnipod® System supplies for your trip.

Airport issues

When traveling by plane, you should familiarize yourself with the airport's security procedures and prepare your diabetes supplies for the security process.

Prepare for your travel:

*   Airport security checks and screening procedures are subject to change, so review the airport website and the TSA website for travel updates prior to your trip.

*   Pack extra supplies and hypoglycemia treatments.

*   Carry contact information for your physician.

*   Arrive at the airport 2-3 hours prior to your flight.

To ensure that airport security checks run smoothly, be sure the following items are easily accessible.

*   All diabetes supplies are in your carry-on luggage.

*   Carry a signed letter from your healthcare provider explaining that you need to carry insulin supplies and Omnipod® System equipment.

*   Bring prescriptions for all medications and supplies with their original prescription labels.

Airport security offers the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. You must request this before the screening process begins. Your medical supplies should be in a separate bag when you approach the security officer.

To prevent contamination or damage to your supplies, you should be asked at the security checkpoint to display, handle, and repack your own supplies during the visual inspection process. Any medication and/or associated supplies that cannot be cleared visually must be submitted for X-ray screening.

If you are concerned about going through the walk-through metal detector, notify the security officer that you're wearing a pump. You should advise the security officer that the insulin pump cannot be removed because it is inserted with a catheter (tubing) under the skin.

Visit the TSA Contact Center if you have any further questions or concerns.

Note: Pods and PDMs can safely pass through airport X-ray machines (see the "Omnipod® System Notice Concerning Interference" on page 160).

Keep supplies accessible

On airplanes, trains, and buses, keep these items with you, rather than checking them:

- Personal Diabetes Manager (PDM)

- An emergency kit

- Vials of insulin (cargo area temperatures may affect insulin)

- A signed letter from your healthcare provider explaining you need to carry insulin supplies and Omnipod® System equipment

- Prescriptions for insulin and supplies

- Snacks, in case food is not available

- Bottled water (especially on planes) to prevent dehydration

- The name and phone number of a physician at your final destination, in case of emergency.

Avoid Lows, Highs, and DKA

You can avoid most risks related to using the Omnipod® System by practicing proper techniques and by acting promptly at the first sign of hypoglycemia, hyperglycemia, or diabetic ketoacidosis. The easiest and most reliable way to avoid these conditions is to check your blood glucose often.

General precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.

- Tell your healthcare provider if you have extreme highs or lows, or if highs or lows are occurring more often than usual.

- If you have technical problems with your Omnipod® System and cannot resolve them, do not hesitate to call Customer Care.

Hypoglycemia (low blood glucose)

Hypoglycemia can occur even when a Pod is working properly. Never ignore the signs of low blood glucose, no matter how mild. If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness. If you suspect that your blood glucose level is low, check your blood glucose level to confirm.

Symptoms of hypoglycemia (low blood glucose)

Never ignore the following symptoms, as they could be a sign of hypoglycemia:

- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling in the lips or tongue
- Anxiety
- Irritability

Warnings:

Hypoglycemia unawareness is a condition in which you do not realize when your blood glucose level is low. If you are prone to hypoglycemia unawareness, you may want to use the PDM's blood glucose reminder and check your blood glucose more frequently (see "BG reminders" on page 75).

Make sure your blood glucose is at least 100 mg/dL before driving or working with dangerous machinery or equipment. Hypoglycemia may cause you to lose control of a car or dangerous equipment. Also, when you focus intently on a task, you may miss the symptoms of hypoglycemia.

Even if you cannot check your blood glucose, do NOT wait to treat symptoms of hypoglycemia, especially if you are alone. Waiting to treat symptoms could lead to severe hypoglycemia, which can quickly lead to shock, coma or death.

Teach people you trust (like family members and close friends) how to give a glucagon injection. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.

To avoid hypoglycemia (low blood glucose)

- Work with your healthcare provider to establish individualized BG Targets and guidelines.

- Keep a fast-acting carbohydrate with you at all times to respond quickly to low blood glucose. Examples of fast-acting carbs are glucose tablets, hard candies or juice.

- Teach your friends, family members and colleagues to recognize the signs of hypoglycemia, so they can help if you develop hypoglycemia unawareness or a severe adverse reaction.

- Keep a glucagon injection kit with your emergency supplies. Teach friends and family members how to give a glucagon injection in case you have severe hypoglycemia and become unconscious.

    Periodically check the expiration date of your glucagon kit to make sure it has not expired.

Note: Always carry medical identification (such as an emergency wallet card) and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

Again, *frequent blood glucose checks are the key to avoiding potential problems.* Detecting low blood glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in any and all areas listed above.

To treat hypoglycemia (low blood glucose)

Any time your blood glucose is low, treat it immediately according to your healthcare provider's instructions. Check your blood glucose every 15 minutes while you are treating, to make sure you don't overtreat the condition and cause blood glucose levels to rise too high. Contact your healthcare provider as needed for guidance.

Possible causes of hypoglycemia	Suggested action
Incorrect Basal Program	Confirm that the correct Basal Program is active.
	Confirm that the PDM time is set correctly.
	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or Bolus too large	Take bolus with food.
	Check blood glucose before giving a meal bolus. If necessary, adjust the bolus.
	Check the bolus size and timing.
	Do not overcorrect for post-meal glucose levels.
	Check carb intake.
	Consult your healthcare provider for guidance.

Possible causes of hypoglycemia	Suggested action
Incorrect Target BG level or Incorrect Correction Factor or Incorrect IC Ratio	Consult your healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia or Hypoglycemia unawareness	Consult your healthcare provider about hypoglycemia unawareness and about raising Target BG levels.
Unplanned physical activity	Consult your healthcare provider about using a temp basal (temporary basal rate).
Prolonged or intense exercise	Adjust insulin delivery as instructed by your healthcare provider. Check blood glucose before, during and after activity and treat as necessary. **Note:** Effects of exercise can last several hours—even a full day—after activity ends. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Low carbohydrate intake prior to activity	Check blood glucose before activity. Consult your healthcare provider for guidance.
Alcohol consumption	Check blood glucose before going to bed. Consult your healthcare provider for guidance.

Hyperglycemia (high blood glucose)

Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If an occlusion (interruption of insulin delivery from the Pod) occurs, your blood glucose can rise rapidly.

> **Warnings:**
>
> An occlusion may result from a blockage, Pod malfunction, or from using old or inactive insulin (see "Occlusion detection" on page 157). If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.
>
> Hyperglycemia symptoms can be confusing. Always check your blood glucose before you treat for hyperglycemia.

Symptoms of hyperglycemia (high blood glucose)

Never ignore the following symptoms, as they could be a sign of hyperglycemia:

- Fatigue
- Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

To avoid hyperglycemia (high blood glucose)

Check your blood glucose

- At least 4–6 times a day (when you wake up, before each meal, and before going to bed)
- If you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low
- If you suspect that your blood glucose is high or low
- Before, during and after exercise
- As directed by your healthcare provider

To treat hyperglycemia (high blood glucose)

Always check your blood glucose levels frequently while treating hyperglycemia. You don't want to over-treat the condition and cause your blood glucose level to drop too far.

1. Check your blood glucose level. The result will help you to find out how much insulin is needed to return your blood glucose to your blood glucose goal.

2. If your blood glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.

3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.

4. Check blood glucose again after 2 hours.

5. If blood glucose levels have not decreased, take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.

6. If you feel nauseated at any point, check for ketones and call your healthcare provider immediately (see "Diabetic ketoacidosis (DKA)" on page 126).

7. If blood glucose remains high after another 2 hours (a total of 4 hours), replace the Pod. Use a new vial of insulin to fill the new Pod. Then, contact your healthcare provider for guidance.

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

8. Investigate possible causes for hyperglycemia to avoid similar problems in the future (see the following table).

Possible causes of hyperglycemia	Suggested action
Expired insulin or Insulin exposed to extreme temperatures	Deactivate and remove the used Pod. Apply a new Pod filled from a new vial of insulin.
Infusion site in or near a scar or mole	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Infected infusion site	Deactivate and remove the used Pod. Apply a new Pod in a different location and consult your healthcare provider.
Dislodged cannula	Deactivate and remove the used Pod. Apply a new Pod in a different location. **Note:** Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.

Possible causes of hyperglycemia	Suggested action
Empty Pod	Deactivate and remove the used Pod.
	Apply a new Pod in a different location.
Incorrect Basal Program	Confirm that the correct Basal Program is active.
	Confirm that the PDM time is set correctly.
	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or Bolus too small	Check carb intake.
	Take bolus with food.
	Check blood glucose before giving meal bolus. If necessary, adjust bolus.
	Consult your healthcare provider for guidance.
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type.
	Consult your healthcare provider about using the extended bolus option.
Less activity than normal	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Blood glucose value greater than 250 mg/dL (with ketones present) before exercise.	Do not exercise when ketones are present.
	Note: Blood glucose increases with exercise when ketones are present.
	Consult your healthcare provider for guidance.
Infection or illness or Medication change	See "Sick days" on page 127.
	Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain or Menstrual cycle or Pregnancy	Consult your healthcare provider for guidance.

Diabetic ketoacidosis (DKA)

Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If insulin delivery from the Pod is interrupted (an occlusion), your blood glucose can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but preventable—emergency that can occur if you ignore high blood glucose levels.

Warnings:

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

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

Symptoms of DKA

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose and check for ketones to rule out DKA.

To avoid DKA

The easiest and most reliable way to avoid DKA is by checking your blood glucose at least 4–6 times a day. Routine checks allow you to identify and treat high blood glucose before DKA develops.

To treat DKA

- Once you have begun treatment for high blood glucose, check for ketones. Check for ketones any time your blood glucose is 250 mg/dL or above.
- If ketones are negative or trace, continue treating for high blood glucose.
- If ketones are present, and you are feeling nauseated or ill, immediately call your healthcare provider for guidance.
- If ketones are positive, but you are not feeling nauseated or ill, replace the Pod, using a new vial of insulin.

- Check blood glucose again after 2 hours. If blood glucose level has not declined, immediately call your healthcare provider for guidance.

Handling Special Situations

Sick days

Any physical stress can cause your blood glucose to rise, and illness is a physical stress. Your healthcare provider can help you make a plan for sick days. The following are only general guidelines.

When you are ill, check your blood glucose more often to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose to rule out DKA (see "Diabetic ketoacidosis (DKA)" on page 126).

To handle sick days:

- Treat the underlying illness to promote faster recovery.

- Eat as normally as you can.

- Adjust bolus doses, if necessary, to match changes in meals and snacks.

- Always continue your basal insulin, even if you are unable to eat. Contact your healthcare provider for suggested basal rate adjustments during sick days.

- Check your blood glucose every 2 hours and keep careful records of results.

- Check for ketones when blood glucose is 250 mg/dL or higher.

- Follow your healthcare provider's guidelines for taking additional insulin on sick days.

- Drink plenty of fluids to avoid dehydration.

- Call your healthcare provider if symptoms persist.

Exercising, playing sports, or working hard

Check your blood glucose levels before, during and after exercising, playing sports, or doing unusually hard physical labor.

The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products.

Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

For some contact sports, you may want to remove the Pod.

Be sure to check your blood glucose levels before removing the Pod and after applying a new one. Pods are designed for one-time use. Do not attempt to reapply a Pod that has been removed.

Tip: *If possible, plan removal times to coincide with a scheduled Pod replacement.*

If you will need to remove the Pod for more than one hour, ask your healthcare provider to recommend appropriate guidelines.

X-rays, MRIs, and CT scans

The Pod and PDM can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

> **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.

Surgery or hospitalization

For scheduled surgeries or hospitalization, you should tell the physician/surgeon or hospital staff about your Pod. It may be necessary to remove it for certain procedures or treatments. Remember to replace the basal insulin that was missed while the Pod was removed. Your healthcare provider can help you prepare for these situations.

CHAPTER 12
Understanding PDM and Pod Function

PDM and Pod Interactions

This section describes how the PDM controls the Pod, and what the Pod can do without input from the PDM.

Pod actions controlled by the PDM

The Pod requires input from the PDM in order to:

- Become activated or deactivated
- Change to a different Basal Program
- Start a bolus or temp basal
- Cancel a bolus or temp basal
- Suspend or resume insulin delivery

Pod activation

Pods are dormant until they are activated by a PDM. Once activated, the Pod and PDM that activated it are linked together, which means that they can only communicate with each other even if there are other Pods and PDMs within range. During Pod activation, the PDM transfers the active Basal Program details to the Pod.

The PDM's communication range is reduced during activation. Therefore, the PDM should touch the Pod (in or out of its tray) during Pod activation. As an added precaution, do not activate your Pod in the same area that someone else is activating a Pod.

How close do the PDM and Pod need to be after activation?

After activation, the PDM's communication range increases to 5 feet (1.5 meters). If you want to deliver a bolus, change the basal rate, or receive status updates from the Pod, make sure the PDM is within 5 feet (1.5 meters) of the Pod.

When you are not actively using the PDM, store it in a nearby location, such as inside a shirt pocket or in a drawer, briefcase, or purse.

Status checks: How the PDM checks Pod function

The PDM periodically checks to see if the Pod is functioning properly. These "status checks" are done:

- When you turn on the PDM and press **Confirm** on the **ID** screen.

  Note: Turning on the PDM by inserting a test strip into the built-in BG meter does not trigger a status check.

- When you navigate to the **Status** screen

- When the PDM sends an instruction to the Pod; for example, starting or canceling a bolus or temp basal

- After 30 minutes of inactivity, even if the PDM is turned off. In other words, after 30 minutes of inactivity, the PDM wakes itself up and sends a status check request to the Pod.

  Note: If the Pod is out of range, the PDM goes back to sleep. It does not sound an alarm even if the Pod is sounding an alarm.

  Note: If Auto-off is enabled, this 30-minute-of-inactivity status check is disabled. This prevents the status check from resetting the Auto-off countdown timer (see "Auto-off" on page 133).

Results of status check

During a status check, the PDM collects information from the Pod about bolus deliveries, temp basals, the active Basal Program, reservoir volume, the time until Pod expiration, and any alarm situations.

The PDM displays the results of the status check as follows:

- If the Pod is sounding an alarm, the PDM displays an alarm message instead of the **Status** screen.

- The **Status** screen's header bar displays the PDM battery level and the current Pod reservoir volume (see "The Header Bar" on page 7).

- The **Status** screen displays information about an ongoing or completed bolus, how much insulin is currently being delivered (basal and bolus), the Pod's expiration date and time, and any current notification.

- If the PDM cannot communicate with the Pod to complete a status check, the PDM displays a communication error message (see "Pod Communication Failures" on page 100).

Timing of alarms and notifications originating in the Pod

If the Pod is sounding an alarm, the PDM also sounds an alarm as soon as it is aware of the alarm. However, there may be a delay before the PDM sounds an alarm that originates in the Pod.

- If the PDM and Pod are in range of each other and:

  - you use the PDM, the PDM checks the Pod's status. If the PDM finds that the Pod is sounding an alarm, the PDM sounds an alarm as soon as the status check is complete.

  - you do not use the PDM, the PDM's alarm is delayed until it wakes itself up to perform a status check, which could mean a delay of up to 30 minutes.

- If the PDM is out of range, the PDM does not sound a Pod-originated alarm even if the Pod is sounding an alarm.

Therefore, if you hear a Pod alarm, bring your PDM in range of your Pod and turn on your PDM. This triggers a status check which results in a message explaining the alarm.

As with alarms, if a notification originates in your Pod, there may be a delay of up to 30 minutes before an in-range PDM begins to beep.

When the PDM cannot communicate with the Pod

When you turn on your PDM, it attempts to establish communication with the active Pod. Usually, communication occurs quickly. Occasionally, communication takes longer, and the PDM screen's header bar displays the communication icon during the delay:

The PDM cannot communicate with the Pod when:

- A USB cable is plugged into the PDM's USB port.

- The PDM and Pod are separated by more than 5 feet (1.5 meters).

- The PDM's batteries are dead.

- There is too much outside interference (see "Omnipod® System Notice Concerning Interference" on page 160).

For instructions on handling communication problems, see "Pod Communication Failures" on page 100.

Pod deactivation

"Deactivation" uncouples a PDM and Pod from each other. Deactivation has the following outcomes:

- It stops the current Pod's insulin delivery.

- It permanently silences any alarms from that Pod.

- It frees the PDM to activate a new Pod.

Note: Deactivation does not occur automatically when the Pod expires or runs out of insulin. In these situations, you must still use the PDM to deactivate the current Pod before the PDM can activate a new Pod.

Discarding a Pod

If the PDM is unable to "deactivate" the Pod, it asks if you want to "discard" the Pod. "Discarding" breaks the link between the PDM and the Pod so the PDM can activate a new one, but it does not stop the Pod from delivering insulin.

If you "discard" a Pod, be sure to remove and dispose of the old Pod before activating a new Pod. To prevent the "discarded" Pod from sounding an alarm at a later time, follow the instructions for silencing the Pod alarm on page 106. If a "discarded" Pod sounds an alarm, the alarm will stop after 15 hours.

What the Pod can do between PDM instructions

Once activated, the Pod can perform the following without input from the PDM:

- Deliver insulin according to the active Basal Program's schedule. The Pod has a built-in clock that allows it to track the timing of the Basal Program.

- Stop delivery of a temp basal at the scheduled time and resume delivery of the active Basal Program.

- Complete delivery of a bolus or extended bolus.

- Track the amount of insulin remaining inside the Pod.

- Track the amount of time until Pod expiration.

- Perform self-checks to identify a malfunction such as an occlusion in the cannula. Sound an alarm if needed.

- Stop insulin delivery if the Auto-off feature is enabled and you have not used the PDM within the specified period of time (see "Auto-off" on page 133).

PDM's self-checks

The PDM checks itself for errors whenever it is being operated. Also, once a day, the PDM wakes up and performs a series of self-diagnostic tests. If the self-diagnostic tests detect an error, the PDM sounds a hazard alarm and displays an explanatory message (see "Hazard Alarms" on page 94).

Auto-off

The optional Auto-off feature is useful if you are prone to hypoglycemia unawareness. When you enable the Auto-off feature, you define a length of time for an Auto-off countdown timer, which will sound an alarm if you do not use your PDM within that amount of time. (To enable or disable Auto-off, see "Pod Auto-off" on page 76.)

Resetting the Auto-off countdown timer

While anything that causes the PDM to communicate with the Pod resets the Auto-off countdown timer to the beginning, a status check is the simplest way to do this. A status check is triggered whenever you turn on your PDM and confirm your **ID** screen. Therefore, if Auto-off is enabled, make sure the PDM is in range of the Pod, then turn on your PDM and confirm your **ID** screen frequently to reset the timer and prevent the alarm from sounding.

Tip: *If Auto-off is enabled, begin your blood glucose tests by turning on the PDM rather than by inserting a test strip in the test strip port. Activating your PDM by inserting a BG test strip into the test strip ports does not reset the Auto-off countdown timer and so does not prevent the Auto-off alarm from sounding..*

Auto-off advisory alarm

If you have not used your PDM within the amount of time specified by the Auto-off countdown timer, the Pod and PDM sound an advisory alarm every minute for 15 minutes. The PDM also displays an on-screen message.

> **Warning:** The Auto-off advisory alarm will escalate to the Auto-off hazard alarm if ignored and will result in the deactivation of your Pod. Be sure to respond to the advisory alarm when it occurs.

Auto-off hazard alarm

If you do not use your PDM within 15 minutes of the onset of the Auto-off advisory alarm, the Pod stops delivering insulin and sounds a hazard alarm. Press **OK** to silence the alarm and deactivate your Pod.

Basal Insulin Delivery

Even without eating, our bodies need a small, constant supply of insulin for normal daily living, which is referred to as "basal" insulin. In people without diabetes, the pancreas continuously delivers this basal insulin. For people using the Omnipod® Insulin Management System, the Pod mimics a healthy pancreas by delivering basal insulin at the rate that you program into the PDM.

Approximately 50% of a person's total daily insulin dose typically comes from basal insulin delivery; the remaining 50% typically comes from bolus doses.

This section describes the Omnipod® Insulin Management System's two modes for delivering continuous basal insulin: Basal Programs and temp basals.

Basal Programs

A basal rate is the number of units of insulin delivered per hour.

A basal segment defines the time of day during which a given basal rate is delivered.

A collection of basal segments covering a midnight-to-midnight period is called a "Basal Program." In other words, a Basal Program describes the rate of insulin delivery throughout an entire 24-hour period.
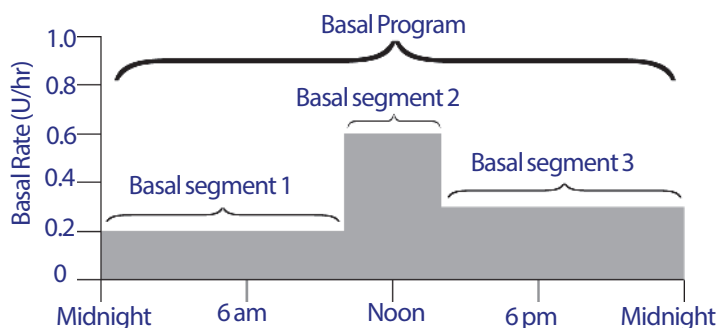
Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver more or less insulin at certain times of day. For example, you could deliver a lower rate of insulin during the night and a higher rate during the day. This figure shows a Basal Program with three basal segments.

To create the Basal Program shown in the preceding figure, the following basal segments are programmed into the PDM:

Time segment	Basal rate	
1: Midnight–10:00 am	0.20 U/hr	Between midnight and 10:00 am, the Pod delivers 0.20 units of insulin per hour.
2: 10:00 am–2:00 pm	0.60 U/hr	Between 10:00 am and 2:00 pm, the Pod delivers 0.60 units of insulin per hour.
3: 2:00 pm–midnight	0.30 U/hr	Between 2:00 pm and midnight, the Pod delivers 0.30 units of insulin per hour.

You may have different routines on different days of the week; for example your weekend routine may differ from your weekday routine. To handle these predictable changes in your routine, you can create up to seven different Basal Programs (see "Basal Programs" on page 63). This figure shows two possible Basal Programs, one for weekdays and the other for weekends.
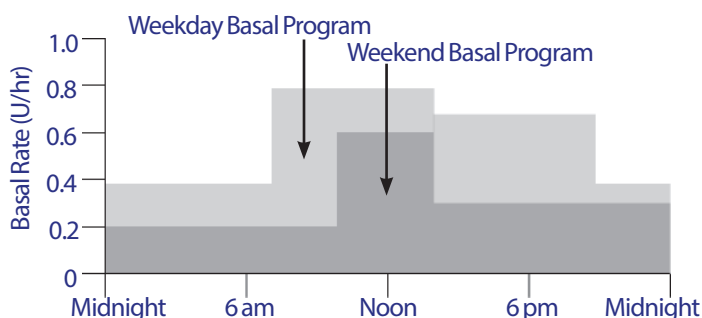
Temporary basal rates

The ability to set temporary basal rates, or "temp basals," is an important feature of the Omnipod® Insulin Management System. A temp basal lets you override the currently running Basal Program by setting a different basal rate for a predetermined period of time.

For example, if you are going cross-country skiing for several hours, you could set a temp basal to lower your basal rate during and after your exercise (see "Using Temporary Basal Rates" on page 53).

Temp basals can last between 30 minutes to 12 hours. At the end of the specified time, the Pod automatically reverts to the active Basal Program.

Temp basal settings: Units per hour (U/hr) or percent (%)

Temp basals can be set using percent (%) or units per hour (U/hr).

Setting temp basals to units per hour (U/hr) means that the Pod delivers insulin at a flat rate for the duration of the temp basal. In other words, the details of the currently scheduled Basal Program are ignored during these temp basals (see the upper two graphs in the following figure).

Setting temp basals to percent (%) means insulin delivery follows the pattern defined by the currently scheduled Basal Program, but increases or decreases the insulin delivery by the specified percentage. For example, the following figure shows that a 50% increase raises the Basal Program's insulin delivery by 50%, while a 50% decrease lowers the Basal Program's insulin delivery by 50%.
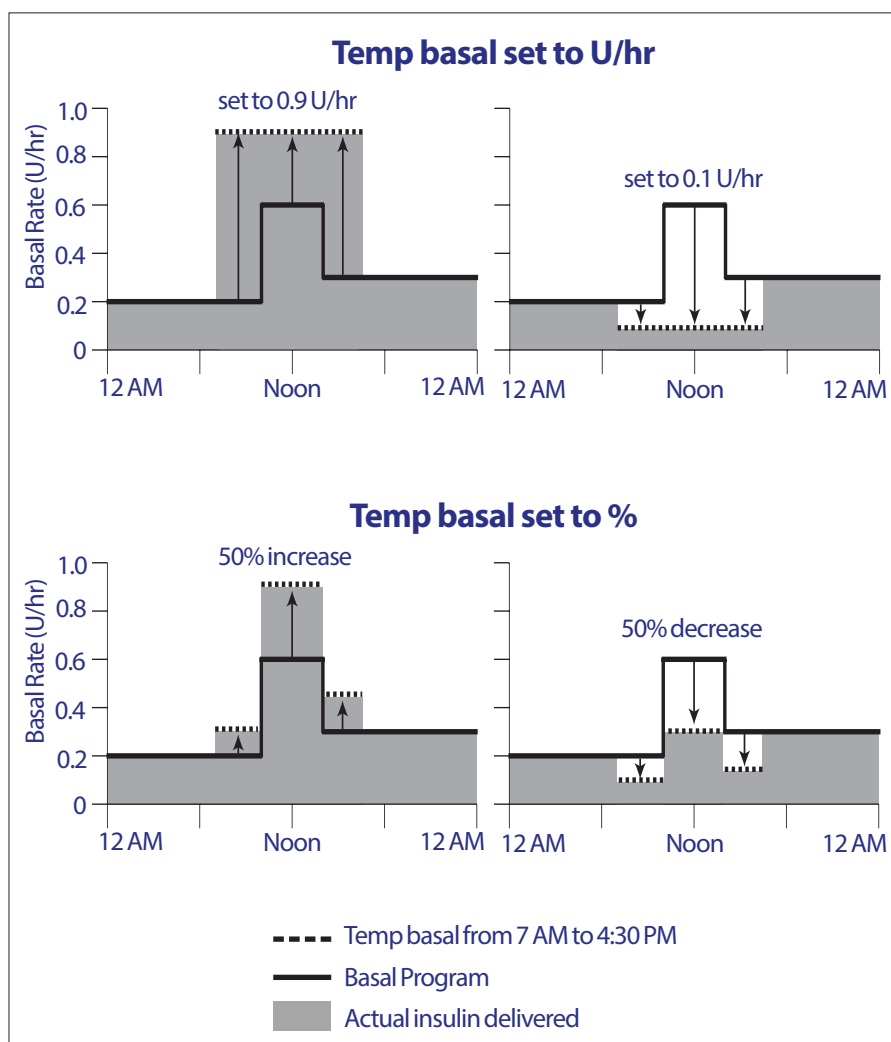
The calculations for the 50% increase temp basal in the preceding figure are:

Time segment boundaries*	Basal rate of Basal Program (U/hr)	50% increase (U/hr)	Resulting temp basal rate: (U/hr)
Midnight–7:00 am	0.20		
7:00 am–10:00 am	0.20	0.20 x 50%=0.10	0.20 + 0.10 = 0.30
10:00 am–2:00 pm	0.60	0.60 x 50%=0.30	0.60 + 0.30 = 0.90
2:00 pm–4:30 pm	0.30	0.30 x 50%=0.15	0.30 + 0.15 = 0.45
4:30 pm–midnight	0.30		

* Time segments are defined by the currently scheduled Basal Program.

Temp basal limitations

Prohibited temp basals (%): When using percent (%), you cannot set a temp basal that results in a flow of less than 0.05 U/hr. For example, if the flow rate for a basal segment is 0.10 U/hr, then you cannot create a temp basal of 60% less as that would result in a flow of 0.04 U/hr.

Also, you cannot set a temp basal of 0%, as there would be no change from the active Basal Program.

Maximum temp basal (%): When using percent (%), you can set the temp basal up to 95% more than your active Basal Program's rate with the following exception: You cannot set a temp basal that would go above your Maximum Basal Rate during any time segment covered by the temp basal duration.

Maximum temp basal (U/hr): When using a flat rate (U/hr), you cannot set a temp basal above your Maximum Basal Rate.

Using temp basals to turn off basal insulin delivery: You can set a temp basal to turn off basal insulin delivery for a set period of time. This occurs if you decrease the temp basal amount until the screen reads "Off." The Pod beeps at the start and end of a temp basal period of no basal insulin. You can still deliver boluses when using a temp basal to turn off basal insulin delivery.

> **Tip:** *Turning off basal insulin delivery in this way, rather than using the Suspend and Resume feature, is useful if you want your Basal Program to automatically resume when the temp basal ends (see "Methods to temporarily stop insulin delivery" on page 138).*

Temp basal presets

Some temporary changes in your daily routine are easy to predict, and you may know from experience how they affect your insulin needs. For example, you might join a summer soccer league or occasionally attend an exercise class. For women, your monthly hormonal change can affect blood glucose in a predictable manner.

To handle predictable, short-term changes, you can define temp basal presets (see "Temp basal presets" on page 66). Once stored, a temp basal preset can be activated quickly at a later time (see "Activate a temp basal preset" on page 55).

Methods to temporarily stop insulin delivery

There may be times when you want to stop all insulin delivery, or at least all basal insulin delivery, for a period of time. If you do not want to discard your current Pod, you can request a temporary halt of insulin delivery in two ways:

- Suspend insulin delivery (via Home > Suspend)
- Select a temp basal decrease of Off (via Home > Temp basal)

The following table compares these two options for pausing insulin delivery.

	Suspend insulin	**Temp basal "Off"**
Effect on basal and bolus insulin delivery	No basal delivery No bolus delivery	No basal delivery Boluses allowed
Minimum duration for stopping insulin	30 min	30 min
Maximum duration for stopping insulin	2 hrs	12 hrs
Insulin delivery resumes automatically	No	Yes
Screen display at end of specified duration	"End of insulin suspend. Press OK to resume basal rate delivery."	Status screen shows that Basal Program is active.
Beeps while insulin is suspended	Every 15 min	At beginning and every 60 min
Beeps at end of specified duration	Every 15 min until you press Resume	One beep, then insulin resumes automatically
Must be used when	Editing an active Basal Program Changing the time or date Testing alarm and vibrate feature	Use is never required
How to cancel	Home > Resume	Home > Suspend/cancel

Immediate and Extended Boluses

A bolus is an extra dose of insulin that is delivered in addition to the continuous basal rate of insulin delivery. Boluses are used to bring down high blood glucose levels and to handle the carbohydrates (carbs) in a meal.

You have the option of delivering the entire bolus at once, referred to as an "immediate bolus" or, simply, as a "bolus." Alternatively, you can spread out the delivery of all or part of a meal bolus over a specified period of time, referred to as an "extended bolus."
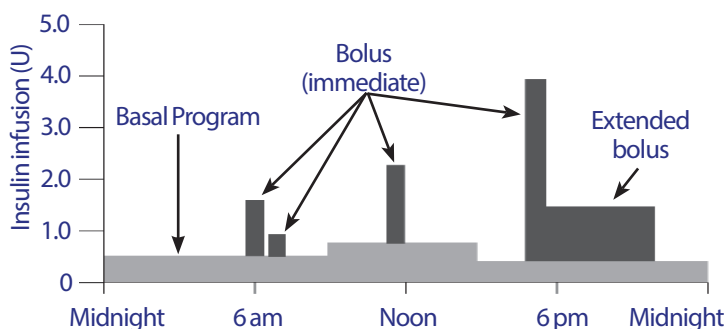
You may want to extend a bolus if your meal contains high-fat or high-protein foods, as these foods slow down digestion and therefore slow down the post-meal rise in your blood glucose.

> **Warning:** When using the extended bolus function, check your blood glucose levels more frequently to avoid hypoglycemia or hyperglycemia.

Manually-calculated Boluses

A manually-calculated bolus is a bolus that you have calculated yourself, without the help of the Bolus Calculator. Manually-calculated boluses can be used when the Bolus Calculator is set to off or if the Bolus Calculator is disabled (see "Maximum Bolus" on page 140). Consult your healthcare provider for instructions about how to calculate a bolus.

You can extend some or all of a manually-calculated bolus.

If there is a bolus amount that you deliver frequently, you can create bolus presets (see "Bolus presets" on page 74) which can be activated quickly at a later time.

Note: You can only use bolus presets if the Bolus Calculator is off.

The Bolus Calculator

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

Bolus Calculator boluses

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

- **Correction bolus**: Used to lower blood glucose when it gets too high.
- **Meal bolus**: Used to handle carbohydrates (carbs) in a meal.

Extended boluses

When using the Bolus Calculator, you can extend some or all of a meal bolus, but a correction bolus cannot be extended. Any correction bolus is always delivered first. In the following example, three units of insulin are extended:

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

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

Extend = 3 units (3 units meal bolus)
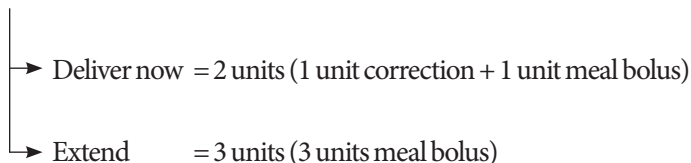
Maximum Bolus

The PDM does not allow you to increase a bolus above your Maximum Bolus setting. However, if necessary to cover your meal carbs and blood glucose value, the Bolus Calculator is allowed to suggest a bolus that is above your Maximum Bolus. In this case, the screen displays a message to inform you that the suggested bolus is greater than your Maximum Bolus setting.

Controlling the bolus amount

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

When the Bolus Calculator does not work

The Bolus Calculator does not work when it is "disabled" or when it is "turned off." You control whether the Bolus Calculator is turned on or off, but the PDM controls when it is disabled. It can only be disabled if it is turned on.

If you turn the Bolus Calculator off, the PDM does not track IOB and does not suggest a bolus.

If you turn the Bolus Calculator on, the PDM may disable it in a few situations. Being disabled means that the Bolus Calculator is temporarily unable to calculate a suggested bolus. It can, however, track IOB when disabled.

The Bolus Calculator is disabled when:

- Your blood glucose reading is below your Minimum BG for Calcs or reads "HIGH." The Bolus Calculator remains disabled until your blood glucose reading is within those limits or for ten minutes, whichever comes first.

- There is an unconfirmed bolus when the PDM discards a Pod. The Bolus Calculator remains disabled until a complete duration of insulin action period passes.

- You change the time or date or there is an internal clock reset. The Bolus Calculator remains disabled until a complete duration of insulin action period passes.

- A USB cable is connected. The Bolus Calculator remains disabled until you disconnect the USB cable.

The Bolus Calculator is *partially* disabled when:

- The built-in BG meter is too hot or too cold during a BG test. In this case, the Bolus Calculator does not calculate a correction bolus until the PDM returns to a normal operating temperature. It can, however, calculate a meal bolus.

Factors used in the Bolus Calculator's calculations

The Bolus Calculator calculates a total bolus from the following factors:

- Your current blood glucose level, Target BG, Correct Above threshold, and Correction Factor

- The carbohydrates you are about to eat and your IC Ratio

- Your duration of insulin action and insulin on board (IOB)

- Your Minimum BG for Calcs

- Reverse correction, if it is enabled

Target BG

When calculating a correction bolus, the Bolus Calculator aims to bring your blood glucose down to the Target BG.

Correct Above threshold

The Bolus Calculator only suggests a correction bolus if your blood glucose reading is above your Correct Above setting. This feature can prevent corrections to blood glucose values that are only slightly higher than your Target BG.

Insulin on board

Insulin on board (IOB) is the amount of insulin still active in your body from preceding boluses. IOB from previous correction boluses is referred to as correction IOB. IOB from previous meal boluses is referred to as meal IOB.

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

The amount of time the insulin remains "on board" or "active" depends on your duration of insulin action setting.

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

Duration of insulin action

The Bolus Calculator uses your duration of insulin action setting to calculate the insulin on board from prior boluses.

Minimum BG for Calcs

The Bolus Calculator does not suggest a bolus if your blood glucose reading is below your Minimum BG for Calcs level.

Reverse Correction

If the Reverse Correction setting is turned on and your blood glucose level is below your Target BG, the Bolus Calculator subtracts a correction amount from the meal portion of the bolus. This feature allows a portion of an upcoming meal to be allocated towards raising a low blood glucose level.

If the Reverse Correction setting is turned off, the Bolus Calculator suggests the full meal bolus even if your blood glucose level is below your Target BG.

Boundaries of the Bolus Calculator suggestions

The following figure shows the boundaries between the types of calculations performed by the Bolus Calculator. For example, the Bolus Calculator suggests a meal bolus, but not a correction bolus, if your blood glucose reading is between your Target BG and your Correct Above settings. If your blood glucose is above 500 mg/dL, the reading is recorded as "HIGH" and the Bolus Calculator cannot calculate a bolus.
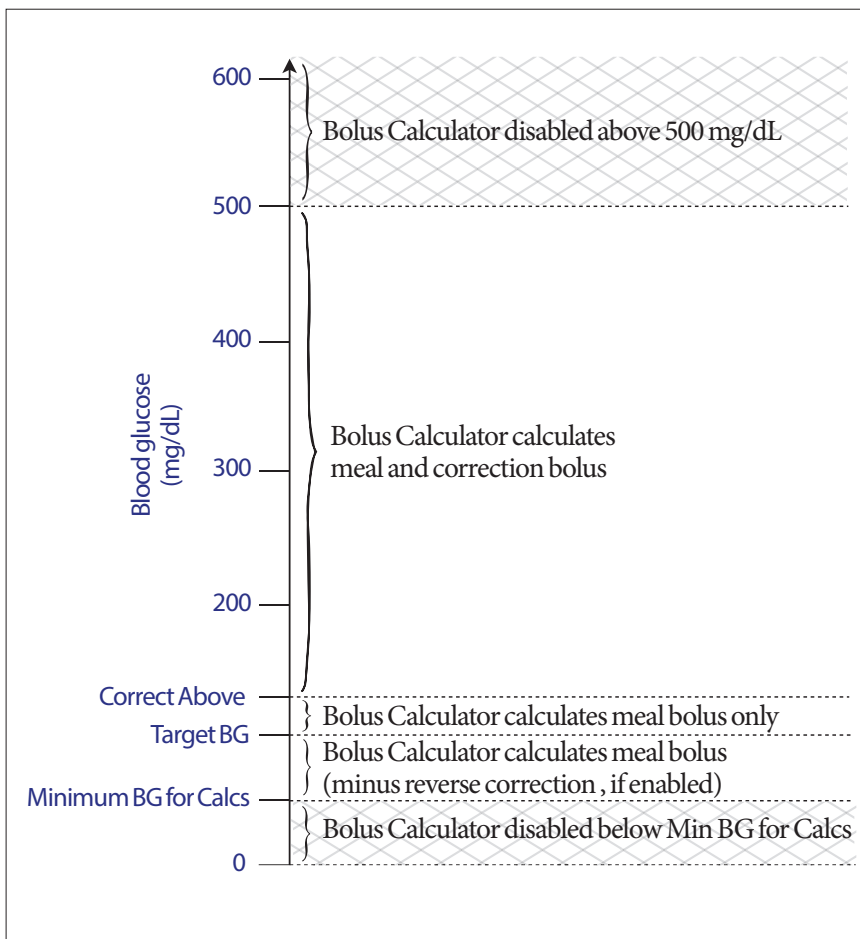
Insulin on board (IOB)

After a bolus is delivered, the amount of insulin that is active in the body decreases over several hours. The Bolus Calculator approximates this decrease in insulin by calculating an 'insulin on board' (IOB) value. The calculated IOB value decreases over time and reaches zero at the time set by the Duration of Insulin Action value. For example, if your Duration of Insulin Action is 4 hours and an 8 unit bolus is given at 6 pm, the IOB amount decreases steadily over time as shown in this graph.
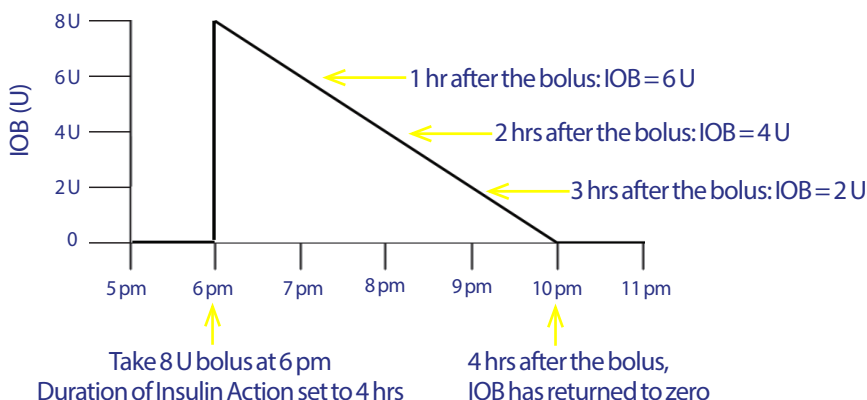
Types of IOB: meal IOB, correction IOB, or both

A bolus, and the IOB from that bolus, can be entirely meal, entirely correction, or both. The following graphs show how the IOB from a 4 U total bolus decreases over time with a Duration of Insulin Action of 4 hours.

Entirely meal

A meal bolus is calculated when you are eating a meal and your blood glucose is less than your Correct Above value. The IOB from this bolus is entirely meal IOB.
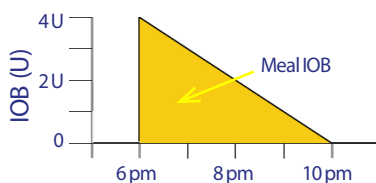
Entirely correction

A correction bolus is calculated when you are not eating and your blood glucose is above your Correct Above value. The IOB from this bolus is entirely correction IOB.
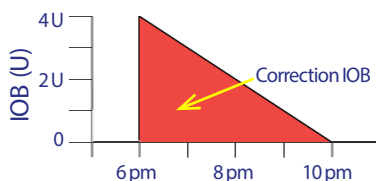
Both meal and correction

When you are eating and your blood glucose is above your Correct Above value, the total bolus includes a meal bolus and a correction bolus component. Likewise, the IOB from this bolus has a meal IOB and a correction IOB component.
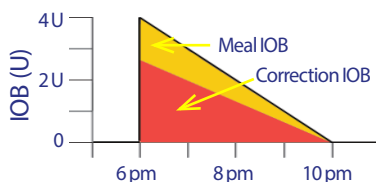
Bolus Calculator equations

The Bolus Calculator first calculates a preliminary correction and meal bolus. It then adjusts these preliminary values for IOB, if applicable. The final suggested bolus is equal to the sum of the resulting correction bolus and meal bolus.

Preliminary bolus calculations

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

Example: Target BG: 100 mg/dL, current BG: 200 mg/dL, Correction Factor (CF): 50

$\dfrac{200 \text{ mg/dL [current]} - 100 \text{ mg/dL [target]}}{50 \text{ [CF]}} = 2 \text{ U preliminary correction bolus}$

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

Example: Carb intake: 45 grams of carb, IC ratio: 15

$\dfrac{45 \text{ (carbs)}}{15 \text{ (IC Ratio)}} = 3 \text{ U preliminary meal bolus}$

Reverse correction bolus calculation: If the Reverse Correction feature is turned on and if your current BG is below your Target BG but above your Minimum BG for Calcs, the Bolus Calculator subtracts a correction amount from the preliminary meal bolus.

Meal bolus with reverse correction = Reverse correction + prelim. meal bolus

Example: Target BG: 100 mg/dL, current BG: 75 mg/dL, Correction Factor: 50, Preliminary meal bolus: 1.5 U

$\dfrac{75 \text{ mg/dL [current]} - 100 \text{ mg/dL [target]}}{50 \text{ [CF]}} = -0.5 \text{ U reverse correction}$

- 0.5 U (reverse correction) + 1.5 U (prelim meal bolus) = 1.0 U meal bolus

A reverse correction is only applied to the meal bolus. The meal bolus is reduced by -0.5 units.

Insulin on board (IOB) calculations

$$\frac{\text{Duration of insulin action} - \text{time since previous bolus}}{\text{Duration of insulin action}} \text{ x previous bolus}$$

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

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

Correction IOB example

Duration of insulin action: 3 hours
Time since previous correction bolus: 1 hour
Previous correction bolus: 3 U

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

In other words, one hour after your previous correction bolus, your body has used up only 1 unit of the correction bolus. The remaining two units of insulin are still in your body working to correct your blood glucose level. Accounting for IOB in bolus calculations prevents the delivery of too much insulin when correcting a high BG or eating a meal.

Meal IOB example

Duration of insulin action: 3 hours
Time since previous meal bolus: 2 hours
Previous meal bolus: 4.5 U

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

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

Meal IOB is only used to reduce a correction bolus; it is does not reduce a new meal bolus. The correction bolus is only reduced until it becomes 0 units.

Final suggested bolus calculations

Correction bolus = (preliminary correction bolus - meal IOB) - correction IOB

> **Note:** The Correction bolus is never reduced below 0 U. Any correction IOB that was unused in the above calculation is carried over to use in the following calculation.

Meal bolus = preliminary meal bolus - unused correction IOB

Suggested bolus = correction bolus + meal bolus

Bolus Calculator rules

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

- Suggested bolus doses are rounded down to the nearest 0.05U.

- If the total of the suggested bolus calculation (correction bolus plus meal bolus) is less than zero, the suggested bolus dose is 0.00U.

- The Bolus Calculator does not suggest a bolus dose if your current blood glucose (BG) reading is below your Minimum BG for Calcs.

- The Bolus Calculator suggests a correction bolus only when your BG reading is above your Correct Above threshold.

- Meal IOB, which is insulin on board from a previous meal bolus, is subtracted first from the current correction bolus, if any, until the correction bolus is zero. However, any remaining meal IOB is *never* subtracted from the current meal bolus.

- Correction IOB, which is insulin on board from a previous correction bolus, is then subtracted from the current correction bolus, if any remains, until the correction bolus is zero. At that point, any remaining correction IOB is subtracted from the current meal bolus.

- The calculated insulin on board is rounded up to the nearest 0.05U.

- A reverse correction only occurs if the meal bolus is greater than 0.00U.

- If your blood glucose value is below your Target BG value and Reverse Correction is on, the reverse correction bolus is subtracted from the suggested meal bolus. If Reverse Correction is off, the Bolus Calculator does not subtract insulin from the suggested meal bolus dose.

If you manually increase or decrease the suggested bolus, the following rules apply:

- If you increase a suggested bolus, the increase is applied to the meal bolus unless there is no meal bolus, in which case it is applied to the correction bolus.

- If you decrease a suggested bolus, the decrease is applied to the meal bolus until it reaches zero; then it is applied to the correction bolus. If there is no meal bolus, the decrease is applied to the correction bolus.

Bolus Calculator examples

Example 1: Eating, BG above target, no IOB

Target BG (target):	100 mg/dL
Current BG (current):	150 mg/dL

IC Ratio:	1:15
Correction Factor (CF):	50
Carb intake:	45 grams carbohydrate (carbs)
Meal IOB:	0 U
Correction IOB:	0 U

Correction bolus

$$\frac{150 \text{ mg/dL [current]} - 100 \text{ mg/dL [target]}}{50 \text{ [CF]}} = 1 \text{ U preliminary correction bolus}$$

Meal bolus

$$\frac{45 \text{ (carbs)}}{15 \text{ (IC Ratio)}} = 3 \text{ U preliminary meal bolus}$$

Note: There is no IOB, so the preliminary correction and meal boluses are not reduced.

Suggested bolus dose

= 1 U correction bolus + 3 U meal bolus = 4 U insulin

Example 2: Not eating, BG above target, 1 U meal IOB, 1 U correction IOB

Target BG (target):   100 mg/dL
Current BG (current):   150 mg/dL

IC Ratio: 1:15
Correction Factor (CF):   50
Carb intake: 0 grams carbohydrate (carbs)
Meal IOB: 1 U
Correction IOB: 1 U

Preliminary correction bolus

$$\frac{150\ \text{mg/dL [current]} - 100\ \text{mg/dL [target]}}{50\ \text{[CF]}} = 1\ \text{U preliminary correction bolus}$$

Preliminary meal bolus

$$\frac{0\ \text{[carbs]}}{15\ \text{[IC Ratio]}} = 0\ \text{U preliminary meal bolus}$$

Correction bolus

= 1 U preliminary correction - 1 U meal IOB - 1 U correction IOB
= 0 U

Note: A bolus can never be less than zero, therefore the correction bolus is zero (and not -1). However, there is one unused (remaining) correction IOB.

Meal bolus

= 0 U preliminary meal bolus - 1 U unused correction IOB
= 0 U (because a bolus can never be less than zero)

Suggested bolus dose

= 0 U correction bolus - 0 U meal bolus
= 0 U insulin

Example 3: Eating, BG at target, 1 U meal IOB

Target BG (target):	100 mg/dL
Current BG (current):	100 mg/dL

IC Ratio:	1:15
Correction Factor (CF):	50
Carb intake:	45 grams carbohydrate (carbs)
Meal IOB:	1 U
Correction IOB:	0 U

Preliminary correction bolus

$$\frac{100\,\text{mg/dL [current]} - 100\,\text{mg/dL [target]}}{50\,\text{[CF]}} = 0\,\text{U correction bolus}$$

Preliminary meal bolus

$$\frac{45\,\text{[carbs]}}{15\,\text{[IC Ratio]}} = 3\,\text{U}$$

Correction bolus

= 0 U preliminary correction - 1 U meal IOB - 0 U correction IOB
= 0 U (because a bolus can never be less than zero)

Meal bolus

= 3 U preliminary meal bolus - 0 U unused correction IOB
= 3 U

Note: A meal IOB is never subtracted from a meal bolus. It is only subtracted from a correction bolus.

Suggested bolus dose

= 0 U correction bolus + 3 U meal bolus
= 3 U insulin

Example 4: Eating, BG above target, 1 U correction IOB

Target BG (target):	100 mg/dL
Current BG (current):	150 mg/dL
IC Ratio:	1:15
Correction Factor (CF):	50
Carb intake:	60 grams carbohydrate (carbs)
Meal IOB:	0 U
Correction IOB:	1 U

Preliminary correction bolus

$$\frac{150 \text{ mg/dL [current]} - 100 \text{ mg/dL [target]}}{50 \text{ [CF]}} = 1 \text{ U correction bolus}$$

Preliminary meal bolus

$$\frac{60 \text{ [carbs]}}{15 \text{ [IC Ratio]}} = 4 \text{ U}$$

Correction bolus

= 1 U preliminary correction - 0 U meal IOB-1 U correction IOB
= 0 U

Meal bolus

= 4 U preliminary meal bolus - 0 U unused correction IOB
= 4 U

Suggested bolus dose:

= 0 U correction bolus + 4 U meal bolus

= 4 U insulin

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Appendix

Summary of Settings and Options

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

Time	12-hour or 24-hour clock
Date	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr
Basal rate	Units/hr. Range: 0.05 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	7
Basal rate segments	24 per program
Temp basal	%, units/hr, or Off. Default is Off Duration: 30 min to 12 hrs in 30-min increments
Temp basal (set to %)	Range: 0 U/hr ("Off") to 95%MORE of current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 0 U/hr ("Off") to Maximum Basal Rate
Temp basal presets	7
BG Goal Range for blood glucose history	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments
BG reminder	On or Off. Default is Off. Maximum of 4 active at one time Reminder can occur between 30 min to 4 hrs after bolus is started. Set in 15-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, Off
BG Meter sound	On or Off. Default is On.
Bolus Calculator	On or Off. Default is On.
Target BG value	8 time segments; 70 to 200 mg/dL in 1 mg/dL increments
Correct Above threshold	8 time segments; Target BG to 200 mg/dL in 1 mg/dL increments
Minimum BG for Calcs	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL

Insulin-to-carb (IC) ratio	8 time segments; 1 to 150 g carb/U in 1g carb/U increments
Correction (sensitivity) factor	8 time segments; 1 to 400 mg/dL in 1 mg/dL increments
Reverse correction	On or Off. Default is On.
Duration of insulin action	2 to 6 hours in 30-minute increments
Bolus increment	0.05, 0.1, 0.5, or 1.0 units. Default is 0.1 units
Maximum Bolus size	0.10-30U in 0.05U increments. Default is 10 units.
Extended bolus	%, Units, or Off. Default is Off 30 minutes to 8 hours in 30-minute increments
Bolus preset	Max of 7. Cannot exceed the Maximum Bolus.
Carb preset	Max of 36. Range: 0-300 g
Suspend	30 minutes to 2 hours
Low reservoir volume advisory	10 to 50 units in 5-unit increments. Default is 10.0 U
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours
Auto-off timer	Off, or 1 to 24 hours in 1-hour increments. Default is Off
PDM lock	On or Off. Default is Off
History storage	5400 records/90 days
Language	English

Pod Specifications

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

Weight (without insulin): 0.88 oz (25 grams)

Operating temperature range: Pod operating environment of 40°F to 98.6°F (4.4°C to 37°C).

> **Note:** The Pod temperature equilibrates to 73°F to 98.6°F (22.7°C to 37°C) when worn on the body.

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

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

Reservoir volume (deliverable): 200 units

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

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

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

Insulin concentration: U-100

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

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

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

Operating atmospheric pressure: 696 hPA to 1060 hPA

Storage atmospheric pressure: 696 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.0 U

Flow Capability:

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

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

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

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

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

Appendix
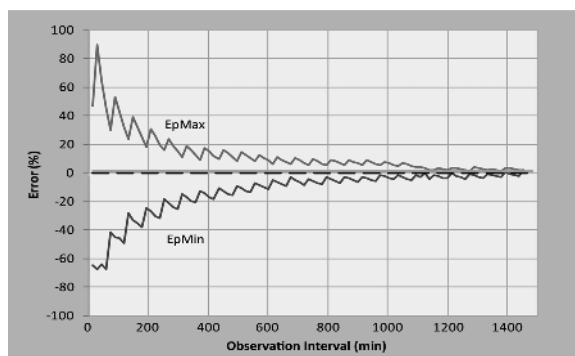
PDM Specifications

Size: 2.4" wide x 4.4" long x 0.98" high (6.21 cm x 11.25 cm x 2.5 cm)

Weight: 125 grams (4.41 oz)

Screen: 1.4" wide x 1.9" long (3.6 cm x 4.8 cm); 2.4" diagonal (6.1 cm) LCD

Battery: Powered by 2 AAA batteries

Battery life: Approximately 3 weeks

Operating temperature range: 40°F to 104°F (4.4°C to 40°C)

Storage temperature range: -20.2°F to 140°F (-29°C to 60°C)

Operating relative humidity range: 15% to 90% non-condensing

Storage relative humidity range: 10% to 90% non-condensing

Operating atmospheric pressure: 696 hPA to 1062 hPA

Storage atmospheric pressure: 703 hPA to 1062 hPA

Communication distance: The PDM and Pod should be

- At startup: Adjacent and touching, either in or out of tray, to ensure proper communication during priming.
- During normal operation: Within 5 feet (1.5 m) of each other.

Waterproof rating: IP22 (avoid liquid)

Alarm type: Audible. Output: ≥ 50 db(A) at 1 meter

Notification type: Audible and vibratory

Warranty: 4 Year Limited (PDM)

Built-in BG Meter Specifications

Assay method: Coulometric electrochemical sensor

Calibration: Plasma equivalent

Hematocrit: 15% to 65%

Measurement units: mg/dL

Result range: 20 to 500 mg/dL

Sample: Whole blood, capillary

Sample size: 300 nanoliters (0.3 microliters)

Test time: Results obtained in 7 seconds or less

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. If the Omnipod® System detects an occlusion, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

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

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

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

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

> **Warning:** At very low flow rates, checking your blood glucose frequently may give you an early indication of an occlusion.

Appendix

PDM Icons

This section defines the images found on the PDM screens.

Icon	Meaning	Icon	Meaning
	Home/Power		More actions
	Bolus		Communication
	Pod change		Up/Down
	Diagnostics/settings		Up/Down (on color)
	Temp basal		Status
	Suspend/cancel		Text entry right
	Basal Program		Submenu
	Hazard alarm (Alternating/flashing image)		Home screen
	Advisory alarm		Apply blood sample/Blood glucose records
	Alert		Insulin gauge
	Battery full		Setup Wizard
	Battery 3/4 full		PDM lock
	Battery 1/2 full		Information/Support
	Battery 1/4 full		My records
	Battery empty		"Lost" history record

Icon	Meaning	Icon	Meaning
◆	Active/default program or selected BG tag	🌙	"Delivery Spans Midnight" history record
🌡	Built-in BG meter temperature out-of-range	✓	"Unconfirmed" history record

Omnipod® System Label Symbols

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

Symbol	Meaning	Symbol	Meaning
Do not reuse symbol	Do not reuse	MR	MR non-safe
⚠	Caution: Consult User Guide	Non-pyrogenic symbol	Non-pyrogenic fluid path
Refer to manual symbol	Refer to Instruction Manual	Do not use if damaged symbol	Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide	Type BF symbol	Type BF applied part
Date of manufacture symbol	Date of manufacture	Manufacturer symbol	Manufacturer
LOT	Batch code	Keep dry symbol	Keep dry
Use by symbol	Use by	Temperature limit symbol	Temperature limit
REF	Reference number	Humidity symbol	Humidity limitation
SN	Serial number	Atmospheric pressure symbol	Atmospheric pressure limitation
IP28	Waterproof to 25 feet (7.6 meters) for up to 60 minutes	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
IP22	Avoid liquid		

Appendix

Omnipod® System Notice Concerning Interference

The Omnipod® Insulin Management System (both the Pod and the PDM) complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.

2. These devices must accept any interference received, including interference that may cause undesirable operation.

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

Both the Pod and the PDM generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications of other devices. There are no guarantees that interference will not occur in a particular installation. If the Omnipod® System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

*   Move or relocate the Omnipod® System.

*   Increase the distance between the Omnipod® System and the other device that is emitting or receiving interference.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod® System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod® System fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

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

Care should be taken if the Omnipod® System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod® System should be observed to verify normal operation in this setting.

The Omnipod® System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod® System communicates with the following characteristics:

Frequency: 433 Mhz, FSK modulation, with an effective radiated power of 13mW

The Omnipod® System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

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

Customer's Bill of Rights

Mission Statement

Insulet Corporation is dedicated to designing, developing, and distributing products that provide superior treatment options and lifelong health benefits for people with diabetes.

Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod® Insulin Management System. The System consists of the handheld, wireless Personal Diabetes Manager (PDM), which programs the Pod with insulin delivery instructions, and the compact, lightweight Pod, which is worn discreetly beneath clothing and delivers insulin based on instructions from the PDM. The PDM contains a fully integrated blood glucose meter and is very similar in materials, construction, and appearance to a personal digital assistant. The Pod features no tubing and virtually pain-free automated cannula insertion.

Compliance

The Omnipod® Insulin Management System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

Supply Shipment

Insulet Corporation contacts customers to schedule quarterly supply shipments approximately two weeks prior to delivery.

Inquiries

Representatives are available to answer product-related inquiries 24 hours per day at our toll free number, 1-800-591-3455 (from outside the United States, 1-978-600-7850). For all other questions, concerns, or complaints, please contact us between the hours of 8:30am and 6:00pm Eastern Time, Monday through Friday, at 1-800-591-3455 (from outside the United States, 1-978-600-7850). We will respond immediately whenever possible; some issues may take up to 14 days to resolve.

CHAP Accredited

Insulet Corporation has been accredited by the Community Health Accreditation Program (CHAP) since 2007. To learn more about CHAP or to communicate concerns that you have been unable to resolve directly with the company, please visit www.chapinc.org or call CHAP at 1-800-656-9656.

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.

2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.

3. Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice later in this section.

4. Receive a timely response to your request for service.

5. Receive continued service.

6. Select the medical equipment supplier of your choice.

7. Make informed decisions regarding your care planning.

8. Understand what services will be provided to you.

9. Obtain an explanation of charges, including policy for payment.

10. Agree to or refuse any part of the plan of service or plan of care.

11. Voice complaints without fear of termination of service or other reprisals.

12. Have your communication needs met.

You have the responsibility to:

1. Ask questions about any part of the plan of service or plan of care that you do not understand.

2. Use the equipment for the purpose for which it was prescribed, following instructions provided for use, handling care, safety and cleaning.

3. Supply Insulet Corporation with insurance information necessary to obtain payment for services.

4. Be accountable for charges not covered by your insurance. You are responsible for settlement in full of your account.

5. Notify us immediately of:

    a. Equipment failure, damage or need of supplies.

    b. Any change in your prescription or physician.

    c. Any change or loss in insurance coverage.

    d. Any change of address or telephone number, whether permanent or temporary.

Appendix

Limited Express Warranty, Disclaimer, and Limitation of Remedies for the PDM and Pods

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE OMNIPOD® INSULIN MANAGEMENT SYSTEM PERSONAL DIABETES MANAGER AND PODS (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

<u>Limited Warranty Coverage for the Omnipod® System Personal Diabetes Manager</u>

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Insulet Corporation warrants to you, the original purchaser of the Omnipod® Insulin Management System ("Omnipod® System"), that, if Insulet Corporation determines, during the period of four (4) years from the date of purchase, that the Omnipod® System Personal Diabetes Manager ("PDM") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet Corporation will either repair or replace, at its sole option, the PDM.

This four-year (4) warranty period applies only to new PDMs and, in the event the PDM is repaired or replaced, the warranty period shall not be extended or reset. Thus, if Insulet Corporation replaces a PDM under this Limited Express Warranty, the warranty coverage for the replacement PDM shall expire four (4) years from the date of purchase of the original PDM.

<u>Limited Warranty Coverage for the Omnipod® System Pods</u>

Subject to this Limited Express Warranty, Insulet Corporation warrants to you, the original purchaser of the Omnipod® System, that, if Insulet Corporation determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod® System Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet Corporation will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e. occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet Corporation of the claim).

This eighteen (18) month and seventy-two (72) hour warranty period applies only to new Pods and, in the event a Pod is replaced, the warranty period shall not be extended or reset. Thus, if Insulet Corporation replaces a Pod under this Limited Express Warranty, the warranty coverage for the replacement Pod shall expire either eighteen (18) months from the manufacture date of the original Pod or seventy-two (72) hours from the time of activation of the original Pod, whichever occurs first.

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

<u>Claim Procedure</u>

To be eligible for this Limited Express Warranty, you must notify Insulet Corporation of the claimed defect with the PDM or the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). For a claim involving the PDM, you must provide the PDM serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the PDM and/or the Pod, the manufacture date of the Pod and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet Corporation elects to repair the PDM (which may include,

but is not limited to, a repair kit or replacement part(s) Insulet Corporation provides) or refers you to a third party, you must obtain a prior authorization and return the PDM or the Pod to Insulet Corporation. The PDM or Pod must be properly packaged and returned to Insulet Corporation according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a prior authorization, Insulet Corporation will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the PDM or Pod to Insulet Corporation under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet Corporation, except those performed or provided by third parties to which you were explicitly referred by Insulet Corporation.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, Insulet Corporation may require that you provide a valid proof of purchase, manufacture or activation. Your failure to provide a valid proof of purchase, manufacture or activation, as determined by Insulet Corporation, may result in the denial of coverage under this Limited Express Warranty.

Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental or other transfer of the PDM or of the Pod to any other person or entity.

This Limited Express Warranty will apply only if the PDM or the Pod at issue has been used in accordance with the Omnipod® System User Guide and/or other written instructions provided by Insulet Corporation. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE PDM OR THE POD HAVE BEEN:

- Altered, changed or modified by any person or entity other than Insulet Corporation;

- Opened, serviced or repaired by any person or entity other than Insulet Corporation;

- Damaged by an act of God or other "force majeure" like event;

- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage;

- Damaged by wear and tear, causes unrelated to defective materials or workmanship or other circumstances outside of the reasonable control of Insulet Corporation.

This Limited Express Warranty does not apply to test strips, batteries, other accessories, or related products provided by third parties (e.g., data management tools, CGMs).

This Limited Express Warranty does not extend to design defects (i.e. claims that the PDM or the Pod should have been designed in a different way).

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

REPAIR OR REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE PDM OR THE POD IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF INSULET CORPORATION. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE SO LONG AS INSULET CORPORATION IS WILLING AND ABLE TO REPAIR OR REPLACE A PDM OR A POD WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER PRESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN THE PDM OR A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

Important Additional Provisions

INSULET CORPORATION DOES NOT WARRANT THE SUITABILITY OF THE PDM OR THE POD OR THE OMNIPOD® SYSTEM FOR ANY SPECIFIC PERSON AS HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction. The above Limited Express Warranty applies only to PDMs and the Pods that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. INSULET CORPORATION'S LIABILITY IN SUCH JURISDICTIONS SHALL BE LIMITED TO THE MAXIMUM EXTENT PERMITTED BY LAW. SUCH LIMITATIONS SHALL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING: ANY IMPLIED WARRANTIES THAT CANNOT BE DISCLAIMED UNDER THE LAW OF A PARTICULAR JURISDICTION ARE LIMITED, TO THE EXTENT ALLOWED BY LAW, TO THE TIME PERIOD COVERED BY THE ABOVE LIMITED EXPRESS WARRANTY, OR TO THE APPLICABLE TIME PERIOD PROVIDED BY LAW, WHICHEVER PERIOD IS SHORTER.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet Corporation and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet Corporation and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a PDM, a Pod, or an Omnipod® System. No employee, agent or other representative of Insulet Corporation or any other party is authorized to make any product warranty or agreement applicable to a PDM, a Pod, or an Omnipod® System in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod® System, please return any Omnipod® System products (including any PDM and Pods) to Insulet Corporation in exchange for a full refund. Failure to return such Omnipod® System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Rev: 11/2017

HIPAA Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

This notice of privacy practices (the "HIPAA Privacy Notice") describes how we may use and disclose your Medical Information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act, and all regulations issued thereunder ("HIPAA"). It also describes your rights to access and control your Medical Information. As used herein, "Medical Information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. Most uses or disclosures of your Medical Information constituting psychotherapy notes will be made only after receiving your written authorization. We will not use or disclose your Medical Information for purposes of marketing, except as permitted by law and/or outlined in this HIPAA Privacy Notice. We will not sell your Medical Information, without first obtaining your written authorization. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations where we may use or disclose your Medical Information without your prior written authorization, as described further below:

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided By Us

Treatment, Payment and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

Appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

Family, Friends and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities, or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.

Inmates: We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and good order of the correctional institution.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Non-identifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a request to review your Medical Information, please download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment, payment or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. Except as otherwise provided in this HIPAA Privacy Notice, we are not required to agree to a restriction that you may request. We are required to agree to your request to restrict disclosure of your Medical Information to a health plan if (i) the disclosure is to carry out payment or healthcare operations and is not otherwise required by law; and (ii) your Medical Information pertains solely to a healthcare item or service for which you or someone (other than the health plan) on your behalf, has paid us in full. If we agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications From Us By Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer.

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, for notification purposes, for national security or intelligence purposes, to correctional institutions or law enforcement officials, or as part of a limited data set. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under applicable law. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

You Have The Right to Obtain a Copy of this HIPAA Privacy Notice: You have the right to obtain a paper copy of this HIPAA Privacy Notice from us, upon request, even if you have agreed to accept this notice electronically. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at

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and follow the directions included on that form.

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our legal duties and privacy practices with respect to Medical Information, and to notify you if there is a breach resulting in disclosure of your unsecured Medical Information.

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our Website at www.MyOmnipod. com. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form:

What To Do If You Have a Problem or Question

If you have any further questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us in writing or by phone at:

Insulet Corporation
Attn: Privacy Officer
100 Nagog Park
Acton, MA 01720
866-941-0155

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling (877) 696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

Revision Dates: April 1, 2009, September 20, 2013, April 22, 2014 and September 2, 2014

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Glossary

A1c (see Hemoglobin A1c)

Activation: The process of linking the PDM to a Pod so that the Pod only responds to commands from that specific PDM.

Advisory alarm: A series of beeps and message on the screen advising about an action that you may want to take to prevent a serious problem.

Aseptic technique: A method for maintaining sterilization and preventing contamination.

Basal Program: A daily schedule for continuous insulin delivery. It consists of one or more time segments (called basal segments), each defining a basal rate, that together cover the 24-hour period from midnight to midnight.

Basal rate: A small amount of insulin that is delivered continuously over a period of time. Basal rates are specified in units per hour (U/hr).

Basal segment: The time period during which a specific basal rate is delivered.

BG Goal Range: A user-defined range of desired blood glucose values. This range is used in the history records to indicate which blood glucose values fall within this range.

Blood glucose / Blood glucose level: The amount of glucose, or sugar, in the blood.

Blood glucose meter: A device used to check blood glucose content.

Bolus Calculator: A feature that suggests meal and correction bolus doses based on your current blood glucose, amount of carbohydrates you are about to eat, insulin-on-board, and several user-specific settings.

Bolus dose: A dose of insulin taken to correct an elevated blood glucose level (a correction bolus) or to cover carbohydrates in a meal or snack (a meal bolus).

Bolus preset: A specified bolus dose of insulin that is assigned a custom name and stored by the PDM for reuse at a later occasion.

Calorie: A unit of measurement used to express the energy value of food. Calories come from the carbohydrate, protein, and fat in food and drink.

Cannula: A small, thin tube inserted below the skin, which serves to introduce a liquid medication into the body.

Glossary

Carbohydrate (carbs): One of the three main energy sources in food. (The other two are protein and fat.) Foods that contain carbohydrates include starches, sugars, vegetables, fruits, and dairy products.

Carbohydrate bolus (see meal bolus)

Carb preset: The number of carbohydrates contained in a favorite food item, snack, or entire meal that is assigned a custom name and stored by the PDM for reuse at a later occasion. You can, optionally, also set the fat, protein, fiber, and total calories for each carb preset.

Correction bolus: An amount of insulin taken to compensate for high blood glucose levels.

Correct Above threshold: The blood glucose level above which you would like to take insulin to reduce an elevated blood glucose.

Correction Factor (also known as sensitivity factor): A value that indicates how much one unit of insulin will lower your blood glucose. For example, if your Correction Factor is 50, one unit of insulin lowers your blood glucose by 50 mg/dL.

Deactivate: Preferred method for dissociating the PDM from the active Pod. Deactivation turns off insulin delivery in the Pod and then dissociates the PDM from that Pod.

Diabetes, diabetes mellitus: A condition characterized by hyperglycemia (high blood glucose) resulting from the body's inability to use blood glucose for energy. In type 1 diabetes, the pancreas no longer makes insulin and therefore blood glucose cannot enter many cell types to be used for energy. In type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly.

Diabetic ketoacidosis (DKA): A serious condition in which extremely high blood glucose levels and a severe lack of insulin cause the body to break down fat and protein for energy. The breakdown of fat or protein releases ketones into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.

Duration of insulin action: The length of time that insulin remains active and available in your body after a bolus. This duration can vary greatly depending on the type of insulin you take.

Extended bolus: A feature of the Omnipod® System that allows a meal bolus dose to be delivered over an extended period of time.

Fat: One of the three main energy sources in food. (The other two are carbohydrate and protein.) Fat provides 9 calories per gram. Foods high in fat include oils, margarine, salad dressings, red meat, and whole-milk dairy foods.

Fiber: The indigestible part of plant foods. Foods that are high in fiber include broccoli, beans, raspberries, squash, whole-grain bread, and bran cereal. Fiber

is a type of carbohydrate, but it does not raise blood glucose levels as other carbohydrates do.

Food Library: A reference library of over 1,000 common food items showing each item's carbohydrate, fat, protein, fiber, and calories for a single portion.

Glucose: A simple sugar (also known as dextrose) used by the body for energy. Without insulin, many cells in the body cannot use glucose for energy.

Hazard alarm: A continuous sound and a screen message from the PDM or Pod indicating that an error has occurred or that insulin delivery has stopped. Alarms require your immediate attention.

Healthcare provider: A professional who practices medicine or teaches people how to manage their health.

Hemoglobin A1c (HbA1c): A test that measures a person's average blood glucose level over the past two to three months. Also called glycosylated hemoglobin, the test measures the amount of glucose that sticks to hemoglobin in red blood cells, which is proportional to the average amount of glucose in the blood over an extended time period.

Hyperglycemia (high blood glucose): A higher-than-normal level of glucose in the blood; generally above 250 mg/dL.

Hypoglycemia (low blood glucose): A lower-than-normal level of glucose in the blood; generally below 70 mg/dL.

Hypoglycemia unawareness: A condition in which a person does not feel or recognize the symptoms of hypoglycemia.

Infusing: Introducing a liquid substance under the skin into the body.

Infusion site: A place on the body where a Pod's cannula is inserted.

Insulin: A hormone that helps the body use glucose for energy. The beta cells of a healthy pancreas make insulin.

IC Ratio (Insulin-to-Carbohydrate Ratio): Number of grams of carbohydrate covered by one unit of insulin. For example, if your IC Ratio is 1:15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

Insulin on board (IOB) (active insulin): The amount of insulin that is still "active" in the body from a previous bolus dose. The Bolus Calculator tracks IOB for you. The amount of time insulin remains "on board" or "active" depends on your duration of insulin action setting.

In vitro: Literally, "in glass." Refers to a biological procedure taking place outside the body rather than in a living organism.

Ketoacidosis (see diabetic ketoacidosis)

Ketones: Acidic by-products that result from the breakdown of fat for energy. The presence of ketones indicates that the body is using stored fat and muscle (instead of glucose) for energy.

Manually-calculated bolus: A bolus amount of insulin chosen by you (not calculated by the Bolus Calculator).

Maximum Basal Rate: Upper limit for basal rates in a Basal Program or temp basal.

Maximum Bolus: The largest bolus that you can request from the PDM. The Bolus Calculator warns you if it calculates a bolus that is over this amount.

Minimum BG for Calcs: The minimum blood glucose reading at which the Bolus Calculator calculates a meal bolus. The Bolus Calculator is disabled below this value. "For Calcs" means "for use in the Bolus Calculator's calculations."

Meal bolus (also known as carbohydrate bolus): An amount of insulin administered before a meal or snack to ensure that blood glucose levels stay within the desired BG Goal Range after a meal.

Neonate: A baby less than four weeks old.

Notifications: An on-screen reminder or informational message.

Occlusion: A blockage or interruption in insulin delivery.

Preset: Defines a value that you want to enter quickly and often.

Protein: One of the three main energy sources in food. (The other two are carbohydrate and fat.) Protein contains 4 calories per gram. Foods high in protein include meat, poultry, fish, legumes and dairy products.

Reverse correction (negative correction): If your blood glucose level is below your Target BG, the Bolus Calculator uses your Correction Factor to reduce a portion of a meal bolus dose. This is an optional feature, which should be turned on or off according to the advice of your healthcare provider.

Sensitivity factor (see Correction Factor)

Soft key: A button on the PDM whose label or function appears on the screen directly above the button. The label changes depending on the screen.

Target BG: The blood glucose level that the Bolus Calculator tries to achieve. You can define different Target BGs for different time periods. For example, you can have one Target BG before meals, a different one after meals, and yet another at night.

Temp basal: A temporary basal rate that is used to cover predictable, short-term changes in basal insulin need. Temp basals are often used during exercise and for sick-day insulin adjustments.

Temp basal preset: An adjustment in a basal rate, in either % or U/hr, that can be assigned a custom name and stored by the PDM for reuse at a later occasion.

Time segment: A defined period of time during a 24-hour day. Time segments are used to define basal segments in a Basal Program, and also to define Target BG segments, IC Ratio segments, and Correction Factor segments.

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My PDM Settings

Use these pages to keep track of your important PDM settings. Remember to update your information if you change or add settings.

Basal Program 1

Name_____   **Basal rate**

midnight	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr

Basal Program 2

Name_____   **Basal rate**

midnight	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr

Basal Program 3

Name_____   **Basal rate**

midnight	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr

Basal Program 4

Name_____   **Basal rate**

midnight	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr
_____	to	_____	_____ U/hr

Target BG

Time segment	**Target BG:** Bolus Calculator aims for this value	**Correct Above:** Suggest correction if BG is above
midnight to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL
_____ to _____	_____ mg/dL	_____ mg/dL

My PDM Settings

Correction Factor

Correction Factor for each time segment		1 unit of insulin decreases BG by
midnight to _____	_____	mg/dL
_____ to _____	_____	mg/dL
_____ to _____	_____	mg/dL
_____ to _____	_____	mg/dL
_____ to _____	_____	mg/dL
_____ to _____	_____	mg/dL
_____ to _____	_____	mg/dL
_____ to _____	_____	mg/dL

Insulin-to-Carbohydrate Ratio (IC Ratio)

IC Ratio for each time segment		1 unit of insulin covers
midnight to _____	_____	g carb
_____ to _____	_____	g carb
_____ to _____	_____	g carb
_____ to _____	_____	g carb
_____ to _____	_____	g carb
_____ to _____	_____	g carb
_____ to _____	_____	g carb
_____ to _____	_____	g carb

Duration of Insulin Action

Time that insulin remains "active" in the body after a bolus _____ hrs

Temp Basal Presets

Name	Rate	(circle measurement)
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %

Bolus Presets

Name	Units
_____ _____	U
_____ _____	U
_____ _____	U
_____ _____	U
_____ _____	U
_____ _____	U
_____ _____	U

Carb Presets

Name	Grams of carbohydrates
_____ _____	g carb
_____ _____	g carb
_____ _____	g carb
_____ _____	g carb
_____ _____	g carb
_____ _____	g carb
_____ _____	g carb

My Notes

My Notes

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INSULIN MANAGEMENT SYSTEM

Welcome, Podder® !

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