omni**pod**®

insulin management
system

DASH®

User Guide

Omnipod DASH® Handbook

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: omnipod.com

Address: Insulet Corporation
   100 Nagog Park, Acton MA 01720

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

PDM Model PDM-USA1-D001-MG-USA1

Serial Number _____

Omnipod DASH® Insulin Management System Start Date _____

Healthcare Provider	Omnipod® System Trainer
Name	Name
Address	Address
Phone	Phone
Email	Email

Health Insurance	Pharmacy
Name	Name
Address	Address
Phone	Phone
Policy Number	Email

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Introduction

About This User Guide

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

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

Healthcare and treatment are complex subjects requiring the services of qualified healthcare providers. This *User Guide* is informational only and not intended as medical or healthcare advice or recommendations to be used for diagnosis, treatment, or for any other individual needs. This *User Guide* is not a substitute for medical or healthcare advice, recommendations, and/or services from a qualified healthcare provider. This *User Guide* may not be relied upon in any way in connection with your personal healthcare, related decisions, and treatment. All such decisions and treatment should be discussed with a qualified healthcare provider who is familiar with your individual needs.

This *User Guide* is periodically updated. Visit *www.omnipod.com* to see the most recent version and to find other helpful information. To access the User Guide in Spanish, see *www.omnipod.com*.

For instructions about how to use the CONTOUR® NEXT ONE Blood Glucose Monitoring System, see the CONTOUR® NEXT ONE Blood Glucose Monitoring System *User Guide*.

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.

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

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

Contraindications

Insulin pump therapy is NOT recommended for people who are:

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

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General Warnings

Warnings:

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

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

Warnings:

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

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

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

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

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

Working with Your Healthcare Provider

Insulin 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 to 15, then you need to deliver one unit of insulin to cover every 15 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.

Introduction

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

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

For technical questions about your CONTOUR® NEXT ONE Blood Glucose Monitoring System setup or operation, or to order CONTOUR® NEXT ONE BG meter products or supplies, see the CONTOUR® NEXT ONE instructions for use for Customer Service contact information.

Your healthcare provider will give you all the tools and training you need to be successful with the Omnipod DASH® System. As you become actively involved in your diabetes management, you can enjoy the flexibility that is possible with the Omnipod DASH® System.

Being actively involved means to frequently monitor your blood glucose levels, to learn how to operate your Omnipod DASH® System, to practice proper techniques, and to visit your healthcare provider regularly.

Safety Features

The Omnipod DASH® System's safety features include:

Automatic priming, safety checks, and insertion

When you activate a new Pod, the Omnipod DASH® System automatically primes and performs safety checks on the Pod, then inserts and primes the cannula (a small, thin tube). These safety checks take only a few seconds.

The Omnipod DASH® System also performs safety checks on the Personal Diabetes Manager (PDM) whenever the PDM is awake. If it detects any problems in the PDM or the Pod—or in the communication between them—it informs you with vibrations or beeps and on-screen messages.

Alarms and notifications

For your safety, the Omnipod DASH® 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 "Alarms, Notifications, and Communication Errors" on page 121.

Note: Brief alarm and notification messages appear on the Lock screen. You must unlock the screen and enter your personal identification number (PIN) to see the full alarm messages.

Note: Wake up your PDM periodically to confirm that there are no notification or alarm messages that require a response.

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

Software updates

Occasionally, an update may be provided for the PDM software. The PDM periodically checks for software updates if Wi-Fi is on. For information about checking for and installing software updates, see "Software update (Wireless update)" on page 106.

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CHAPTER 1
Your Omnipod DASH® Insulin Management System

Welcome

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

Features of the Omnipod DASH® 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.

Glucose readings: Your PDM can pair to and record blood glucose readings from the CONTOUR® NEXT ONE BG meter via Bluetooth® wireless technology. While the CONTOUR NEXT ONE BG meter is the only BG meter compatible for pairing to the PDM, you can also manually enter blood glucose readings from any BG meter into the PDM.

Record keeping: The PDM displays up to 90 days of information, including basal rates, bolus doses, carbohydrates, alarms, and blood glucose entries.

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

Terms and conventions used in this *User Guide*

Screen	Area of the PDM that displays menus, instructions, and messages.
Menu	List of options on the screen.
Icon	An image on the screen that indicates a menu option or that provides information.
Button	Physical buttons on the PDM, such as the Power button. Also, areas of the screen that you can tap to perform an action.
Field	The area of a screen where you enter information.

The Pod and PDM

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

The Pod

The Pod is a lightweight device that you fill with insulin and wear directly on your body. The Pod receives insulin delivery instructions from the PDM. The Pod then delivers insulin into your body through a small, flexible tube called a cannula.

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

The Pod that is used with the Omnipod DASH® System has a needle cap.

Top **Bottom**

Adhesive backing

Fill port

Air vent

Paper cover for adhesive backing

Needle cap

Viewing window
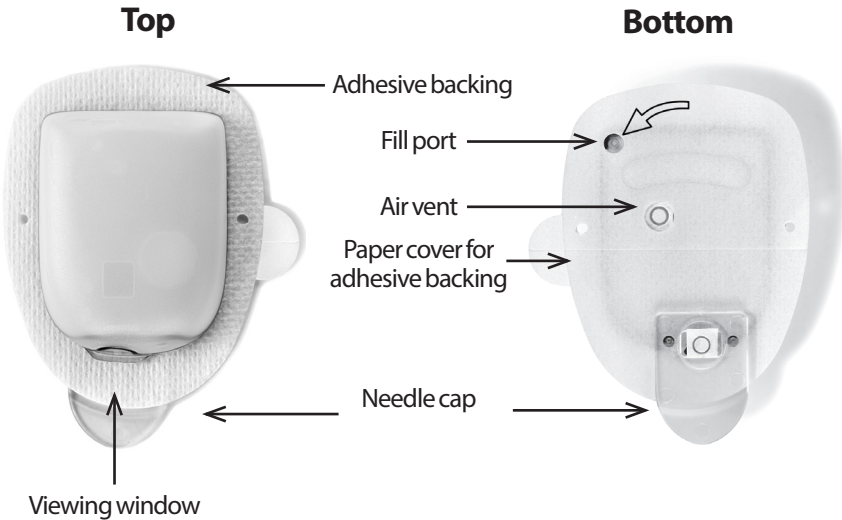
The Personal Diabetes Manager (PDM)

The PDM is a handheld device that controls and monitors the Pod's operations using wireless technology.

Micro-B USB port:
Used for charging the battery and exporting data

Sound/vibrate button

Power button: Used for wake/sleep and on/off

Touchscreen

3.8 U
IOB

Sep 28

Dashboard   Basal   Pod Info

LAST BOLUS
0.5 U
Today (12:01 am)

LAST BG
120 mg/dL
Today (Right Now)

Bolus

Back button   Not used   Not used

Navigating Screens and Entering Information

This section explains how to use the touchscreen, how to enter numbers or text into the PDM, and how this *User Guide* describes moving between PDM screens.

Touchscreen Basics

The PDM displays messages and options for you on its touchscreen. You communicate with the PDM by tapping or swiping your finger on the touchscreen.

Tapping and swiping

The basic instructions for interacting with the touchscreen are explained here.

	Tap	Touch the screen, then lift your finger up.
	Swipe	Touch a starting point and move your finger up, down, left, or right.
		Note: Scrolling and swiping are related actions. When you swipe up, the screen display scrolls up to show items that are currently off-screen.

Note: A screen protector may decrease the touchscreen sensitivity.

Screen time-out and brightness

The PDM screen turns black, called timing-out, after a period of inactivity. To control the screen time-out and brightness settings, see "Screen display" on page 101. The PDM screen dims 6-10 seconds before it times out. If the screen dims, touch the screen briefly to prevent the screen from timing out.

Entering Numbers and Text

Tapping fields to enter data

Fields allow you to specify values to be used by the PDM. Tapping an editable field (which is either framed by a box or underlined) opens a keypad, number pad or scroll wheel. Tap the letters or numbers or scroll the wheel to enter data for use in that field.

8 g   ⟵   Editable fields are underlined or framed by a box.

1 U   ⟵   Non-editable fields are not underlined or framed by a box.

Tapping <u>blue and underlined text</u> brings up a screen where you can view an explanation or enter data.

Using a keypad

Tapping in an editable field brings up a keypad. To bring up a different keypad, tap the ?123, ABC, or =\< in the lower left of a keypad.
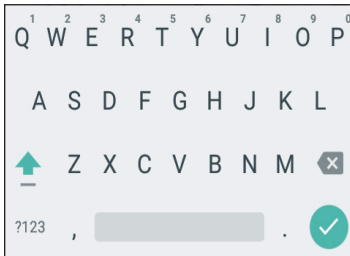
Tap a character to add it to the text field.

Touch a letter in the top row for a second to display other options such as a number or an accented letter such as é.

Tap the up-arrow (⬆) to toggle between uppercase and lowercase letters. Tap the up-arrow twice in rapid succession to type in ALL CAPITALS mode. Tap the up-arrow one more time to exit ALL CAPITALS mode.

Tap the spacebar icon (▭) to add a space between characters.

Tap the backspace icon (⌫) to delete the most recent entry from the entry field.

Tap the green checkmark (✓) to close the keypad when you have finished entering your text.

Note: The PDM considers CAPITAL and lowercase letters to be the same. In other words, the PDM considers "WEEKEND" and "weekend" to be the same name.

Using a number pad

1	2	3	-
4	5	6	,
7	8	9	⊠
.	0	_	✓
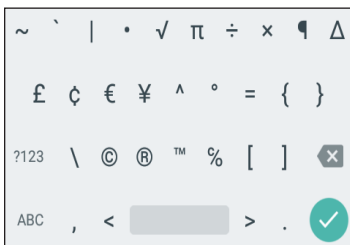
Tap a number to add it to the entry field. Tap the period (.) to add a decimal point. Tap the backspace icon (⊠) to delete the most recent entry from the entry field. The comma (,), dash (-), and underscore (_) are not used.

Tap the green checkmark (✓) to accept the entered number. You can also tap outside the number pad to accept the entered number.

Using a scroll wheel

0.85	U/hr
0.80	U/hr
0.75	U/hr
0.70	U/hr
0.65	U/hr
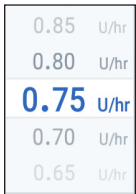
Place your finger on the scroll wheel. Move your finger up to select a smaller number and down to select a larger number. The faster you move your finger, the faster the wheel will scroll.

When your desired selection is shown in the center of the wheel, select the value by tapping it or by tapping outside the scroll wheel.

Using a slider

Use sliders to select a value from a scale. Place your finger on the small open circle and move your finger until your desired value is displayed. Depending on the on-screen graphic, you may move your finger vertically or in a circle to move the slider. Move your finger up or clockwise for a larger number and down or counterclockwise for a smaller number. Lift your finger when the desired value is displayed.

Move slider up or down

70
65
60
55
50
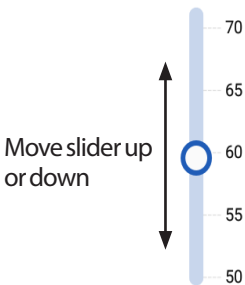
Move slider around the circle
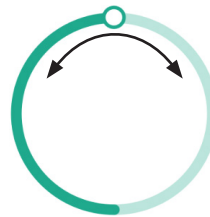
Selecting, Adding, and Deleting Items

Toggles

Tap a toggle to change the selection from one side to the other.

Toggles allow you to choose between two options or to turn a feature on or off. The toggle is on the right side and blue when a feature is on, and on the left and gray when a feature is off.

Checkboxes, radio buttons, and drop-down lists

Checkboxes are squares. Tap a checkbox to check or uncheck it. You can check more than one checkbox in a list.

Radio buttons are circles. Tap a radio button to select it. A dot appears inside the selected radio button. You can select only one radio button at a time. To deselect a radio button, tap the radio button next to a different option.
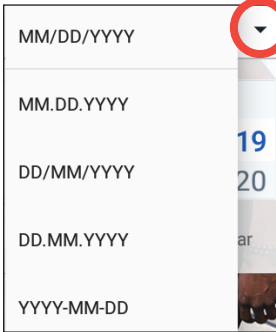
Drop-down lists are indicated by a down or up arrow next to an item. The currently selected setting appears to the left of the drop-down arrow. To select a different option, tap the down arrow to show the drop-down list of options. To replace the currently selected option at the top, tap the desired option from the drop-down list.

Tap the up arrow to hide the list of options.

A plus symbol in a circle indicates that you can add an item to a list. Tap the plus symbol to add the item to the list.

A red x in a circle indicates that you can remove an item from a list. To remove the item, tap the red x.

Navigation Icons and Navigation Shorthand

The PDM has buttons below the screen that can be used for navigation. In addition, some screen icons can be used for navigation.

Back arrow and back button

Many screens display a "back" arrow icon in the upper left corner. Tapping the back arrow returns to the previous screen.

Tapping the left-hand button below the PDM screen generally also returns to the previous screen.

Note: The middle and right-hand buttons below the PDM screen have no function.

Options icon
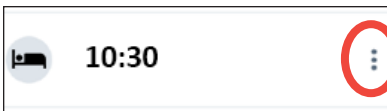
The Options icon (⋮) appears on the right-side of certain lists. Tapping the Options icon brings up a list of options relevant to the item on that row.

Navigation shorthand

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

- Menu icon (≡) > Pod > CHANGE POD

  tells you to:

  1. Tap the Menu icon (≡) in the upper left of the Home screen.
  2. Tap Pod to open the Pod screen.
  3. Tap CHANGE POD.

- Menu icon (≡) > History : Insulin & BG History

  tells you to:

  1. Tap the Menu icon (≡) in the upper left of the Home screen.
  2. Expand the History entry, if it is collapsed, by tapping anywhere in the row with the word "History."

     When expanded, selections for the Notifications & Alarms history screen and the Insulin & BG History screen appear.
  3. Tap Insulin & BG History.

- Settings icon (⚙) > Reminders > Pod Expiration

  tells you to:

  1. Tap the Settings icon (⚙) in the upper right of the Home screen.
  2. Tap Reminders.
  3. Tap Pod Expiration.

The Status Bar

Most screens have a status bar that shows you:

- The Pod status, including how much insulin is left in an active Pod

- Whether a temp basal rate is running

- Whether the PDM will vibrate for selected notifications

- The Bluetooth® icon

- If Wi-Fi is on, the strength of the Wi-Fi signal

- The status of the PDM's battery

- The current time
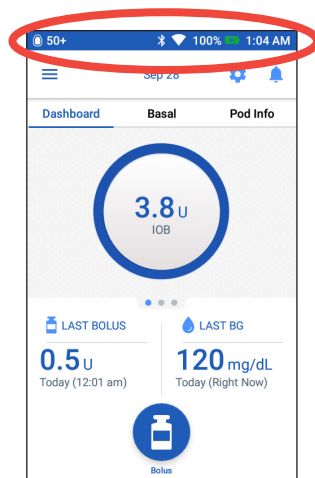
Status bar icon definitions:

	More than 50 units in Pod		Airplane mode on
	Between 50 and 26 units in Pod		Vibration mode on
	Between 25 and 5 units in Pod		Bluetooth® setting on
	Less than 5 units in Pod		Wi-Fi on: strong signal
	PDM unable to communicate with Pod; units in Pod shown as "- -" when unable to communicate.		Wi-Fi on: good signal
	No active Pod		Wi-Fi on: fair signal
	Temp basal rate active		Wi-Fi on: low signal
			Wi-Fi on: no signal

The PDM's battery icons, during normal operation and while charging, are:

		100% to 31% charge
		30% to 16% charge
		15% to 0% charge

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1 Omnipod DASH® Insulin Management System

For charging instructions, see"Charge the battery" on page 22.

The PDM's Lock and PIN Screens

After you set up your PDM, the Lock and PIN screens appear whenever you wake up your PDM. The Lock and PIN screens help confirm that you are using the correct PDM.

The Lock screen displays:

- Your selected background image
- Your customized message
- The amount of insulin on board, if the Bolus Calculator is on
- Today's date
- Any alarm or notification messages

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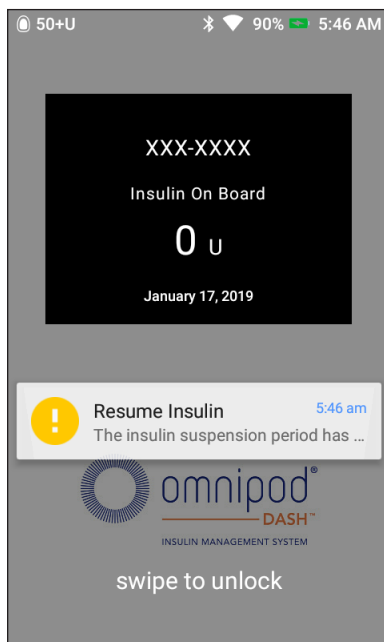
Unlock your PDM

In the remainder of this *User Guide*, instructions to "wake up" or "unlock" the PDM mean to do the following:

1. Press the Power button briefly. See the PDM image on page 3 for the location of the Power button.

2. Unlock the Lock screen by either swiping left to right or by swiping up from the bottom. The PIN screen appears.

3. Enter your 4-digit PIN.

4. Tap the checkmark. The Home screen or your most recent screen appears.

   Note: If a hazard alarm or an advisory alarm is occurring, the alarm message appears.

Lock your PDM

To lock your PDM when you are finished using it:

1.   Press the Power button briefly. This locks the PDM by putting it to sleep.

2.   Store your PDM in a safe, accessible location.

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

Forgot your PIN?

You can use the last four digits of the PDM's serial number as an alternate PIN:

1.   Find the serial number next to the $\boxed{\text{SN}}$ icon on the back of your PDM.

2.   Note the last four digits of the serial number.

3.   Enter those four digits on the PIN screen and tap the checkmark.

If you have problems with your PIN, call Customer Care.

The PDM's Home Screen

The Home screen provides information about recent boluses, blood glucose values, the active basal rate, and the active Pod. It also provides access to the PDM functions, alarm information, and settings. The Home screen also has a Bolus button to give quick access to the bolus screen.

Today's date   Settings icon

Status bar

Menu icon

Notifications & Alarms icon

Tab labels: The name of the visible tab is blue and underlined.

Dashboard	Basal	Pod Info

3.8 U
IOB

Tab area
The Dashboard tab is visible in this image.

LAST BOLUS   LAST BG

Amount and time of most recent bolus

0.5 U
Today (12:01 am)

120 mg/dL
Today (Right Now)

Value and time of most recent blood glucose reading

Bolus button

Bolus

The tab area of the Home screen can display bolus information on the Dashboard, basal information, or Pod information. To change which information is displayed:

- Tap Dashboard, Basal, or Pod Info to display each tab.

- Swipe right or swipe left in the middle section to move between the tabs.

Note: If an immediate bolus is running, a bolus progress bar is shown on the Home screen, and the Bolus button and three tabs are not visible (see "Immediate bolus progress" on page 64). A button to cancel the bolus is visible.

Dashboard tab

The Dashboard tab is available if the Bolus Calculator is on and is usually not available if the Bolus Calculator is off.

When the Bolus Calculator is on

When the Bolus Calculator is on, the Dashboard tab displays:

- IOB (insulin on board), when IOB is available.

- IOB is Not Available, when the Bolus Calculator is disabled. Tap the (i) icon for a list of reasons for the Bolus Calculator to be disabled.

A progress bar appears when a bolus is in progress (see "Tracking the Progress of a Bolus" on page 64).

When the Bolus Calculator is off

When the Bolus Calculator is off, there are usually only two tabs: Basal and Pod Info. The Dashboard tab displays only when an extended bolus is running (see "Tracking the Progress of a Bolus" on page 64).
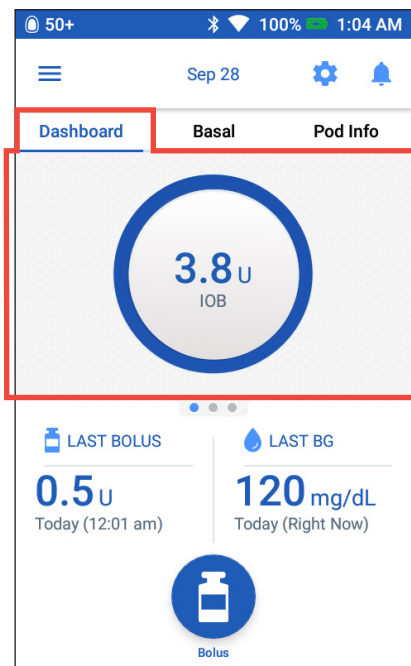
Basal tab / Temp Basal tab

This tab is labeled Basal or Temp Basal, depending on whether a Basal Program or temp basal is active.

Basal Program

By default, the Basal tab shows the name and graph of the active Basal Program.

A label below the Basal Program's name indicates whether the listed Basal Program is:

- Active—This program is running on the active Pod.

- Suspended—This program will resume when you resume insulin delivery.

- Current—There is no active Pod. This program will be sent to your next Pod during activation.

When there is an active Basal Program, a green line marks the current time. The numbers above the graph indicate the basal rate for each time segment.

The total daily amount of basal insulin is shown beneath the graph.
This total is the amount of insulin that the active Basal Program is scheduled to deliver in a 24-hour period. This total does not account for temp basals or boluses. To see the total amount of insulin that your Pod has actually delivered, including temp basals and boluses, see "Overview of the Insulin and BG History Screens" on page 90.

Tap VIEW to see details about other Basal Programs (see page 81).

Temp basal

If a temp basal is running, the Basal tab is labeled Temp Basal and is highlighted in green. It displays the temp basal graph and allows you to cancel the temp basal.
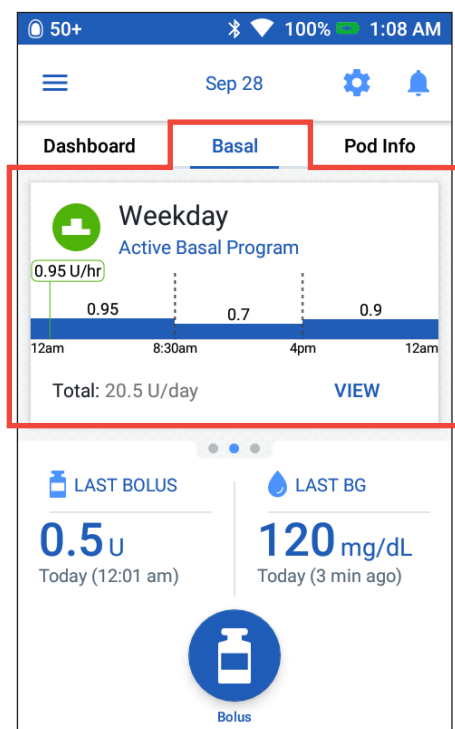
Pod Info tab

The **Pod Info** tab shows whether there is an active Pod, and, if so, how much insulin is left in the Pod and when the Pod will expire.

If the PDM cannot communicate with an active Pod, the **Pod Info** tab says "**No Pod Communication.**" Tap the ⓘ icon for a list of reasons why the PDM may not be able to communicate with the Pod.

Note: Even when there is no communication, the Pod continues delivering insulin according to the instructions it was given. See "What the Pod can do between PDM instructions" on page 148 for details.

Tip: *Bringing the PDM and the active Pod within 5 feet of one another may quickly restore their communication.*

If there is no active Pod, the **Pod Info** tab says "**No Active Pod.**" To set up a new Pod, see "Changing Your Pod" on page 37.

If there is an active Pod, tap VIEW POD DETAILS to bring up a screen that lets you deactivate or change your Pod.

The VIEW POD DETAILS screen shows:

- Amount of insulin in the Pod.
- Time of the last successful communication between the PDM and Pod.
- Date and time of the Pod's expiration.
- Any active reminders.
- A CHANGE POD button.

  Tip: *You can also access this screen by tapping* Menu icon (☰) > Pod.
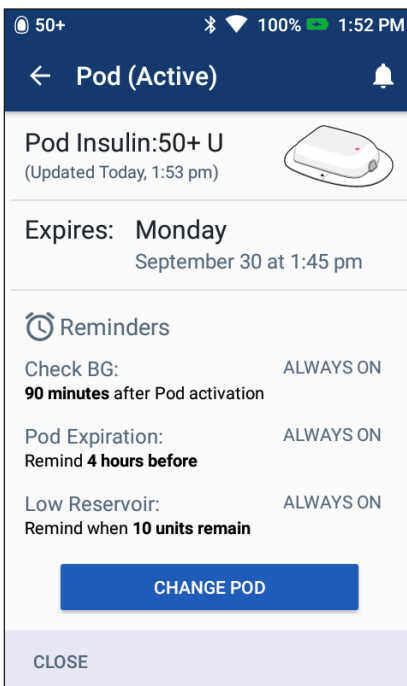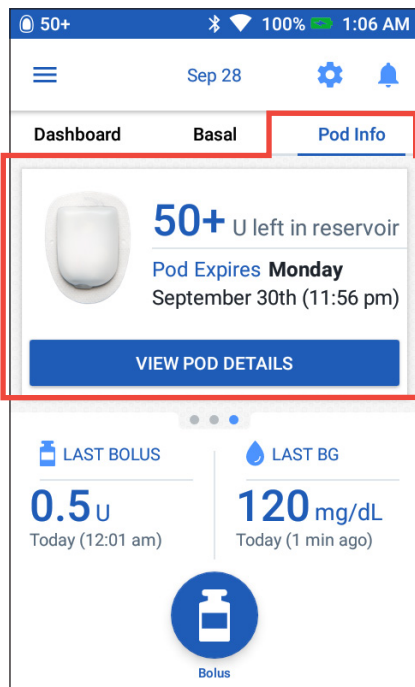
When your Pod will expire soon, a yellow **Change Pod soon** banner appears on the Pod Info tab. The yellow banner appears 12 hours before Pod expiration or at the time of your Pod expiration reminder, whichever is earlier.
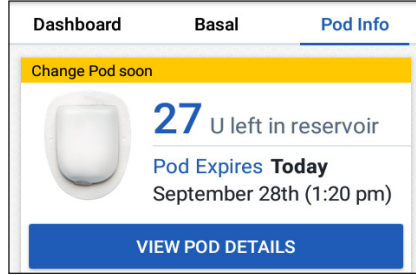
At six hours before Pod expiration, a red **Change Pod** banner appears on the Pod Info tab.
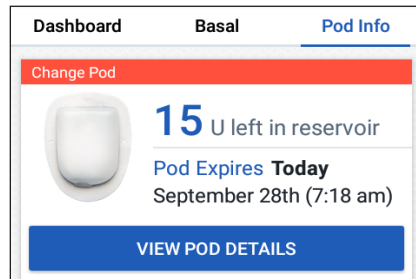
When less than five units of insulin remain in the Pod, a red **Low Reservoir** banner appears on the Pod Info tab. If the Pod will expire soon and there are less than five units of insulin in the Pod, the red **Low Reservoir** banner is displayed on the Pod Info tab.
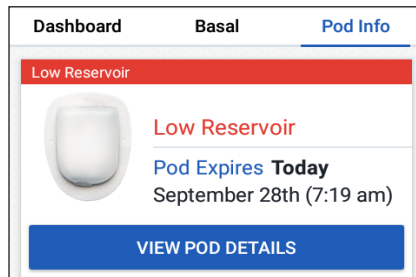
Note: If you change the date or time, the Pod expiration date and time are adjusted to match the new date and time.

Last BG section

The lower right side of the Home screen displays the value and time of your most recent blood glucose reading.
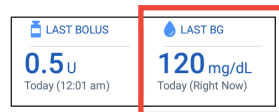
Last bolus section

The lower left side of the Home screen displays bolus information.

Between boluses

When a bolus is not being delivered, the section is labeled LAST BOLUS and shows the amount and time of the most recent bolus.

During a bolus when the Bolus Calculator is on

When a bolus is being delivered and the Bolus Calculator is on, the last bolus information is replaced by an estimate of the Insulin on Board (IOB):

- During an immediate bolus, the IOB estimate is updated every ten seconds.

- During an extended bolus, the IOB estimate includes IOB from previous boluses, an estimate of the amount already delivered from the ongoing bolus, and the amount projected to be delivered within the time period defined by your Duration of Insulin Action setting.
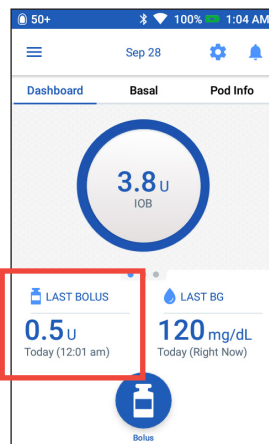
During a bolus when the Bolus Calculator is off

When a bolus is being delivered and the Bolus Calculator is off, the lower left of the screen shows the amount of the preceding bolus (not the ongoing bolus).

Bolus information if the PDM cannot communicate with the Pod

If the Pod is out of range of the PDM, and the PDM cannot confirm the recent bolus amount, an estimated bolus amount is shown. Once the Pod is in range again and the bolus delivery is confirmed, the confirmed bolus amount is shown.

Estimated and unconfirmed bolus amounts

The PDM estimates bolus amounts during an ongoing bolus and when the Pod is out of range. A gray icon (⚠) marks estimated bolus amounts. A yellow icon (⚠) marks unconfirmed bolus amounts (see "When the Pod has not confirmed bolus delivery" on page 97).

Bolus button

The Bolus button at the bottom of the Home screen provides access to the bolus screen. The Bolus button does not appear while an immediate bolus is being delivered, or when the Bolus Calculator is off and there is no active Pod.

The Home Page's Menu

The Menu on the Home page lets you access most of the PDM's functions. To display the Menu:

- Tap the Menu icon (☰) in the upper left corner of the Home screen.

- Place your finger on the far left of the PDM, and swipe right across the screen. Swipe left to hide the Menu.

Tap an option on the Menu to bring up the related screen.

Tip: *The Menu extends beyond the bottom of the screen. Swipe up or down to see all parts of the Menu.*

Frequent tasks

The first section of the Menu gives access to frequent tasks: activating a temp basal, changing your Pod, entering a blood glucose reading, and suspending or resuming insulin.

Special situations:

- Set Temp Basal is grayed-out if there is no active Pod, insulin is suspended, or a temp basal is already running.

- Set Temp Basal does not appear if the temp basal setting is turned off.

- Suspend Insulin changes to Resume Insulin if insulin delivery is suspended.

- Suspend Insulin is grayed-out if there is no active Pod.

Manage Programs & Presets

The next section allows you to create or activate Basal Programs, temp basal presets, and bolus presets (see "Managing Programs and Presets" on page 81).

Special situations:

- Temp Basal Presets is only visible if the temp basal setting is on.

- Bolus Presets is only visible if the Bolus Calculator setting is off.

Set Temp Basal

Pod

Enter BG

Suspend Insulin

MANAGE PROGRAMS & PRESETS

Basal Programs

Temp Basal Presets

Bolus Presets

Food Library

History ˄

Notifications & Alarms

Insulin & BG History

Settings ˄

PDM Device

Pod Sites

Reminders

Blood Glucose

Basal & Temp Basal

Bolus

About
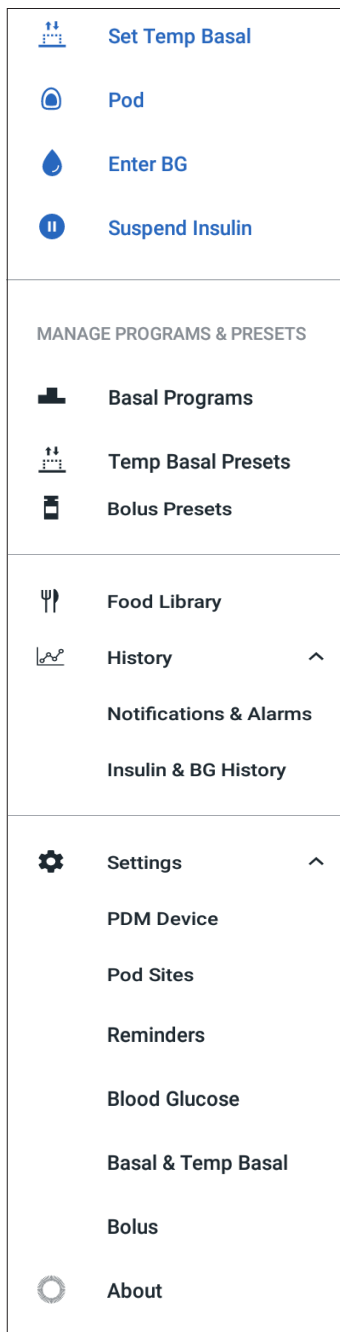
Food library

The Food Library option allows you to look up the carbohydrate content of various foods and to create food favorites (see "Using the Food Library" on page 66).

History menu

Tap the down arrow (∨) next to History to reveal the submenu:

- Notifications & Alarms history (see page 89)
- Insulin & BG History (see page 90)

Tip: *Tap the bell icon (🔔 or 🔔4) at the top-right of many screens to open the* Notifications & Alarms *history screen.*

Settings menu

Tap the down arrow (∨) next to Settings to reveal the submenu:

- PDM Device
- Pod Sites
- Reminders
- Blood Glucose
- Basal & Temp Basal
- Bolus

Tip: *Tap the Settings icon (⚙) at the top of the Home screen to open the Settings portion of the Menu.*

These settings allow you to change the time and date, turn Wi-Fi on or off, create or remove reminders, pair to a BG meter, turn the Bolus Calculator on or off, and much more. For more information, see "Adjusting Settings" on page 99.

About screen

The About screen displays details about your PDM, such as the software revision number, the Customer Care phone number, the PDM serial number, the Pod version number, the time of the most recent PDM-Pod communication, and other device and legal information.

Note: You can also find the PDM's serial number next to the 　SN　 icon on the back of your PDM.

PDM Messages to You

The PDM can deliver alarm messages, notifications, and confirmation messages.

Alarms

Hazard alarms and advisory alarms require your immediate attention (see "Alarms, Notifications, and Communication Errors" on page 121). If you ignore an alarm, you could develop hypoglycemia or hyperglycemia.

Hazard alarms (⚠) are accompanied by a continuous vibration or tone and interrupt anything else the PDM is doing except another hazard alarm. For example, a hazard alarm is issued if the Pod runs out of insulin.

Advisory alarms (🔸) alert you to some aspect of the PDM or Pod that needs your attention in the near future. For example, if the level of insulin in your Pod is getting low, the PDM issues an advisory alarm.

Notifications

Notifications (🕐) remind you about actions you may want to perform (see "Notifications List" on page 129). For example, you can set a reminder to tell you to measure your blood glucose after a specified amount of time.

Confirmation Messages

The PDM confirms that an instruction was successful by displaying a green banner with a confirmation message. The confirmation message disappears after several seconds.

Tip: *Swipe to the right on the message to dismiss it sooner.*

If an instruction is not successful, then the PDM displays a communication error message (see "Communication Errors" on page 132).
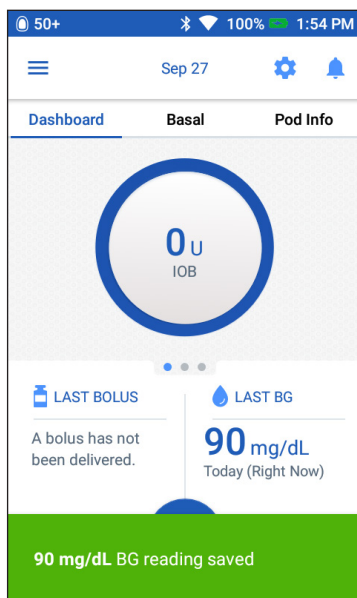
CHAPTER 2
Initial PDM Setup

This chapter guides you through setting up your first PDM or a replacement PDM.

If you are setting up a replacement PDM, be sure to unpair any BG meters paired to your old PDM before setting up your new PDM (see "Pairing, unpairing, or renaming a BG meter" on page 114). Then go to "Charge the battery" on page 22.

The Omnipod DASH® PDM Kit

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

After you unpack the Omnipod DASH® PDM Kit, use the "Contents" label on the side of the box to make sure you have everything.

The Omnipod DASH® PDM Kit contains:

- PDM & rechargeable battery
- USB cable & charger
- User Guide
- Carry case
- Quick Start Guide

You can obtain Pods by contacting Customer Care (see the first page of this *User Guide* for contact information).

Preparing for Your Training

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

If you have used an Omnipod® Insulin Management System in the past and are upgrading to the Omnipod DASH® System, contact Customer Care to find out about an online training module you can use before setting up your new system.

To get a head start on learning about the Omnipod DASH® System, review this *User Guide*, including the "Introduction" on page xi, "Your Omnipod DASH® Insulin Management System" on page 1, and "Taking Care of Your PDM and Pod" on page 137.

> **Warnings:**
>
> Do NOT use the Omnipod DASH® System before you have been trained. Inadequate training could put your health and safety at risk.
>
> Follow your healthcare provider's instructions for initializing the PDM. 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 (see "Prepare for Emergencies" on page 175).

Charge the battery

It is important to charge the PDM's battery before setting up your Omnipod DASH® System:

1. Install the rechargeable battery in the PDM, if necessary (see "Inserting or replacing the PDM battery" on page 143).

2. Assemble the charger by plugging the charger cable's USB Type A plug into the charger's wall adapter.

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

3. Plug the charger into a wall outlet.

4. Plug the charger cable's USB Micro-B plug into the PDM's Micro-B USB port.

5. Charge the PDM until the battery level icon shows 100% charge (see "The Status Bar" on page 9).

6. Disconnect the charger from the PDM and the wall outlet.

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

Items needed when you meet with your Omnipod DASH® System Trainer

- Your PDM
- Two Pods
- This *User Guide*
- A blood glucose meter (optional)
- Test strips and a lancing device (available from many pharmacies)
- Vial of rapid-acting U-100 insulin
- Alcohol prep swabs
- Instructions from your healthcare provider with PDM settings tailored to your needs. These settings include Basal Program, IC Ratio, Correction Factor, Target BG values, and Duration of Insulin Action.

General PDM Settings

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

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.*

Note: Tapping the back arrow ( ) returns you to the previous screen. However tapping the CANCEL button in any of these setup steps takes you to the first screen of each section and erases any entries in that section. A popup screen warns you that you could lose these entries.

Turning on and personalizing the PDM

1. Turn on the PDM by pressing and holding the Power button on the right side until the Omnipod® logo appears. The PDM runs through a series of checks.

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

    Note: You can press the Power button briefly to toggle the PDM between the wake and sleep modes. Omnipod DASH® System alarms will also wake the PDM from sleep mode.

2. When a screen with the Omnipod DASH® logo appears, use your finger to swipe from left to right across the screen.

    Note: If you see an unexpected screen instead of the Omnipod DASH® logo screen, see "Troubleshooting PDM Startup" on page 187.

3. Tap a language to select your preferred language for the PDM screens. Then tap the arrow (>).

    Note: The Food Library is only available when English is the selected language.

4. Review the terms and conditions (ToU - terms of use), including the End User License Agreement (EULA), Warranty, and Legal Notices as follows:

    a. Tap the HIPAA Privacy Policy, EULA, ToU, and Warranty link to read the Omnipod DASH® System's legal notices and privacy policy. Then tap AGREE.

    b. Tap the box to add a checkmark.

    c. Tap CONTINUE.

    Note: If you are under 18, your parent or guardian must accept for you.

5. Tap BEGIN SETUP.

6. Tap letters on the keypad to enter a personalized screen message (see "Selecting, Adding, and Deleting Items" on page 6). Then tap the checkmark.

    Note: You must enter at least one character.

    Tip: *Including a contact phone number in the message could help in recovering a misplaced PDM.*

7. Tap CONTINUE.

    A screen appears showing several background images.

8. Swipe right or left to see more images. Tap on your preferred image, then tap CONTINUE.
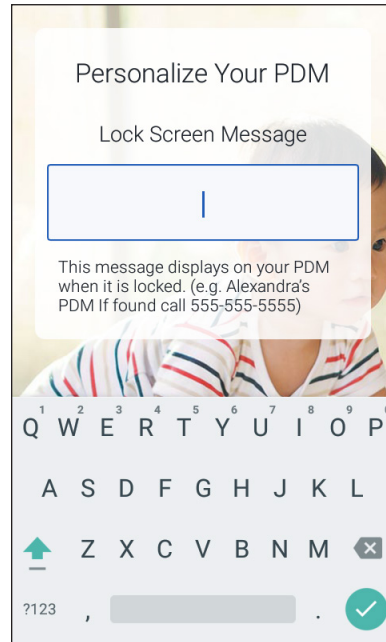
Note: When you wake up your PDM, you will see your personalized screen message and background image. Always confirm that the PDM is yours before using it.

Enter a PIN

To protect against unintentional screen touches, you must create a 4-digit personal identification number or PIN.

1. Choose four numbers to be your PIN. You will use this PIN number every time you wake up your PDM. You may want to record the PIN in a safe place.

    Tip: *To keep the PIN visible, tap the eye icon located to the right of the PIN entry fields. To hide the number, tap the eye icon again.*

2. On the number pad, tap each number of your PIN. Then tap the checkmark.

3. Enter the same four numbers again to confirm your PIN. Tap the checkmark.
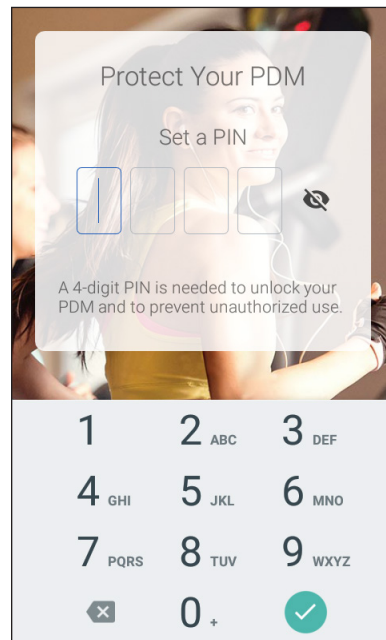
If the second PIN entry does not match the first, you must repeat the above steps.

Set the time zone and time

To set the current time zone and time:

1. Tap Select One to show the list of time zones.

2. Tap your time zone. You may need to swipe up or down to find your time zone.

3. Tap CONTINUE.

4. Tap the 12 hr / 24 hr toggle 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

5. Place your finger on the Hour scroll wheel. Slide your finger up or down to scroll the wheel up or down. Stop scrolling when the correct hour appears in the center of the wheel.

6. Scroll the Minute scroll wheel up or down until the correct minute appears in the center of the scroll wheel.

7. If using 12 hr time, scroll the right-most field and select AM or PM.

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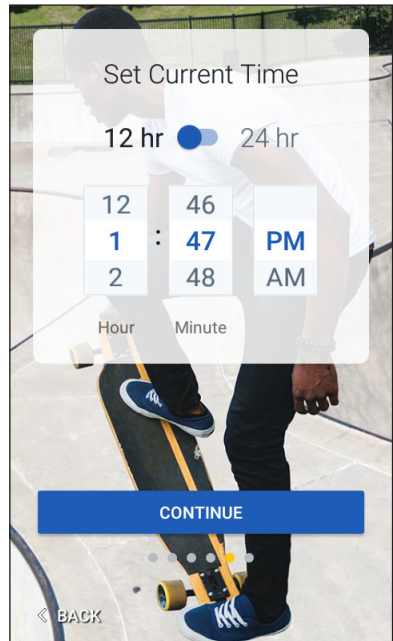
Caution: Check that you have set the time correctly. The time setting affects the operation of several Omnipod DASH® System features and can impact your insulin delivery.

Set the date

On the Set Current Date screen:

1. Tap MM/DD/YYYY to display a list of date formats. Tap the desired date format.

2. Set the Month, Day, and Year fields by scrolling their respective wheels one at a time.

3. Review the date and date format, then tap CONTINUE.

4. On the Confirm Time & Date screen, review the time zone, time, and date. If correct, tap CONTINUE.
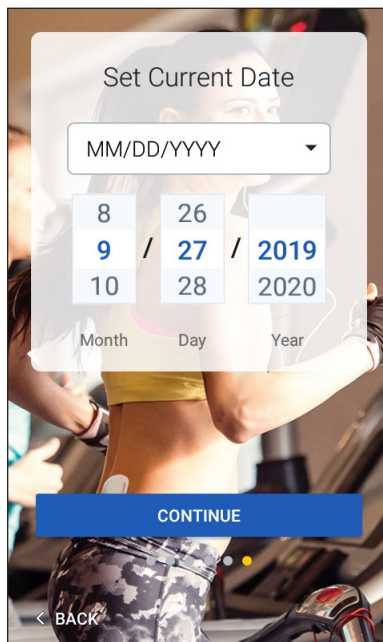
Basal Insulin Settings

Maximum Basal Rate

The Maximum Basal Rate sets the upper limit of any basal insulin rate that you can use.

1. Tap SET UP PROFILE.

2. Review the description of basal insulin, then tap the arrow (>).

3. Tap the Max Basal Rate field.

4. Scroll to your desired Maximum Basal Rate. When the correct number is in the center of the scroll wheel, tap the number to select it.

    Tip: *Alternatively, tapping outside of the scroll wheel selects the value in the center of the scroll wheel.*

5. Tap NEXT.
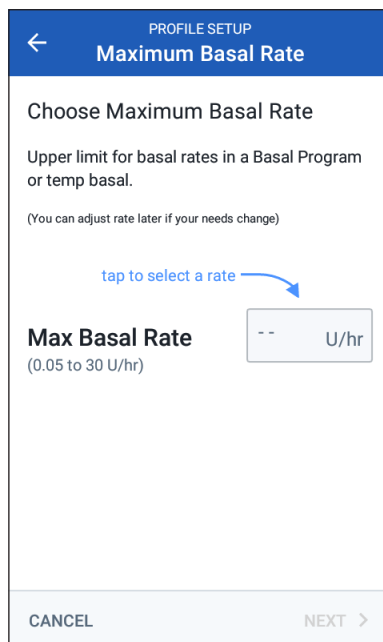
You can adjust your Maximum Basal Rate later, if your needs change.

Create a Basal Program

The next step is to define a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Basal Insulin Delivery" on page 149.

Name and tag the Basal Program

1. Review the description of Basal Programs, then tap NEXT.

2. The default name for the Basal Program is Basal 1. To change the name, tap the Program Name field and enter the new name (see "Selecting, Adding, and Deleting Items" on page 6) and then tap the checkmark.

3. Optional: To add a visual icon to your Basal Program, tap one of the tags. Tap the tag a second time to deselect it.

4. Tap NEXT.

Define the first segment

1. The Start Time for the first segment is always midnight. Tap the End Time field and scroll to select the desired end time.

2. Tap the Basal Rate field and scroll to select the basal rate for the segment.

PROFILE SETUP	PROFILE SETUP
← Basal Program	← Basal Program
Weekday: Segment 1 Graph: U/hr	Weekday: Segment 1 Graph: U/hr
12am 12am	0.75 12am 5am 12am
Start Time End Time	Start Time End Time
12:00 AM - --	12:00 AM - 5:00 AM
Night	Night Night
Basal Rate (up to 3 U/hr) -- U/hr	Basal Rate (up to 3 U/hr) 0.75 U/hr
CANCEL NEXT >	CANCEL NEXT >

The Maximum Basal Rate that you entered earlier is displayed under the Basal Rate text. You cannot enter a basal rate greater than this number.

Note: The two vertical blue lines on the graph near the top of the screen show the start and end time for the basal segment. The selected basal rate for the segment is shown between the two vertical lines.

3. Check the values of your start and end times and the basal rate. Then tap NEXT.

Define additional segments

If the Basal Program does not cover 24-hours, you must add additional segments:

1. Tap the End Time field and select the duration of the next segment.

2. Tap the Basal Rate field and select the basal rate for the segment.

3. Review the segment details and the graph.

4. Tap NEXT to move to the next segment.

5. Repeat the preceding steps as needed until your final segment ends at midnight.

After specifying a basal rate for the final segment, your Basal Program is complete.

Review the Basal Program

The next screen summarizes the start and end times, duration, and basal rate for each segment of the Basal Program.

1. Tap CONTINUE to review your Basal Program.

2. Check that the graph and the individual segment values are correct.

    The total daily amount of basal insulin to be delivered by this Basal Program is listed below the graph.

3. To change an end time or basal rate for a segment:

    a. Tap the row containing the segment you would like to change.

    b. Tap the End Time field, and enter the new end time for the segment.

    c. Tap the Basal Rate field, and enter the desired basal rate.

    d. Tap NEXT.

    e. Then define the end time and basal rate for any following segments, as needed.

	PROFILE SETUP	
←	**Basal Program**	

Weekday   Graph: U/hr

0.75   1   1.5   0.75

12am 5am 8am   5pm   12am

Total Basal: 25.5 U/day

Segment (Total: 4)	Start Time	End Time	Basal Rate U/hr
‹ 1	12:00 AM	- 5:00 AM	0.75
‹ 2	5:00 AM	- 8:00 AM	1
‹ 3	8:00 AM	- 5:00 PM	1.5
‹ 4	5:00 PM	- 12:00 AM	0.75

| CANCEL | | SAVE |
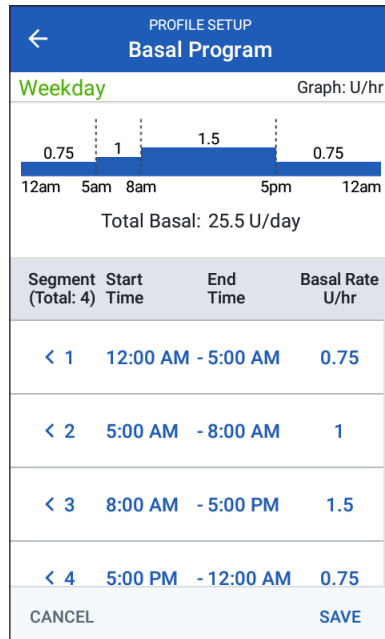
4. To add a new segment:

    a. Tap the row containing the start time of the new segment.

    b. Tap the End Time field, and enter the start time of the new segment as the end time of this segment.

    c. Change the basal rate, if necessary.

    d. Tap NEXT.

    e. Then define the end time and basal rate for any following segments, as needed.

5. To delete a segment:

    a. Note the end time of the segment you want to delete.

    b. Tap the segment that precedes the segment you want to delete.

    c. Tap the End Time field, and enter the end time of the segment you want to delete. This 'overwrites' the segment you want to delete.

    d. Tap NEXT.

    e. Then define the end time and basal rate for any following segments, as needed.

6. When the Basal Program is correct, tap SAVE.

Note: If the basal rate for a segment is 0 U/hr, the PDM displays a message calling this to your attention. Tap OK if the 0 U/hr rate is correct. Otherwise, tap CANCEL and edit the segment with the 0 U/hr rate.

Note: To create additional Basal Programs after setup is complete, see page 81.

Temp basal configuration

For a description of temporary basal rates, also called temp basals, see page 151.

1. If you want the ability to use temp basals, tap the toggle to the "on" position. The toggle is in the "on" position when it is in the right-hand position and is blue.

    If you turn temp basals on, percentages are used by default. To specify temp basals as a flat rate (U/hr), see "Temp basal" on page 116.

2. Tap NEXT.

Blood Glucose Settings

The blood glucose settings define what blood glucose readings are considered in range and allow you to pair to a CONTOUR® NEXT ONE BG meter.

Upper and lower limits for BG Goal Range

You can set the upper and lower limits of your BG Goal Range by using the number pad or the slider:

1. Review the description of blood glucose levels, then tap the arrow (>).

2. To define the lower limit, tap the Lower Limit field and type the number using the number pad.

   Tip: *Alternatively, you can touch the lower (red) circle with your finger and slide it up or down.*

3. To define the upper limit, tap the Upper Limit field or slide the upper (yellow) circle.

4. Review your upper and lower limits, and tap NEXT to save them.

PROFILE SETUP
BG Goal Range

Set upper and lower BG limits

These limits are used in BG history displays and in BG reading statistics.

200

175

150

Upper Limit 140 mg/dL

125

100

Lower Limit 70 mg/dL 75

CANCEL   NEXT >

Pair to a BG meter

If desired, you can pair your PDM to a CONTOUR® NEXT ONE BG meter (BG meter). Once paired, blood glucose readings can be transmitted via Bluetooth® wireless technology from your BG meter to your PDM.

Note: If you do not want to pair to a BG meter, tap SKIP. Then go to "Bolus Calculator Settings" on page 32

To pair a BG meter:

1. Turn off your BG meter, and place it within six feet of your PDM.

2. Turn on the blue light on your BG meter. To do so, press and hold the OK button on the BG meter until its white light changes to a flashing blue light.

3. On the PDM, tap START SEARCH.

    The PDM displays the model and serial number of any CONTOUR® NEXT ONE BG meters that are in range and available for pairing.

4. Turn your BG meter over to find its seven digit serial number. Verify that this number matches the one on the PDM screen.

5. On the PDM, tap PAIR below your BG meter's serial number.

    A Successfully Paired message appears.

    Note: If the BG meter is paired to another PDM, see "Pairing, unpairing, or renaming a BG meter" on page 114.

6. Tap OK. Verify that your BG meter is listed as paired.
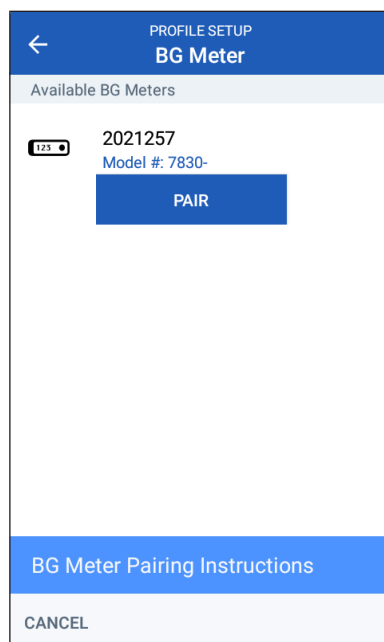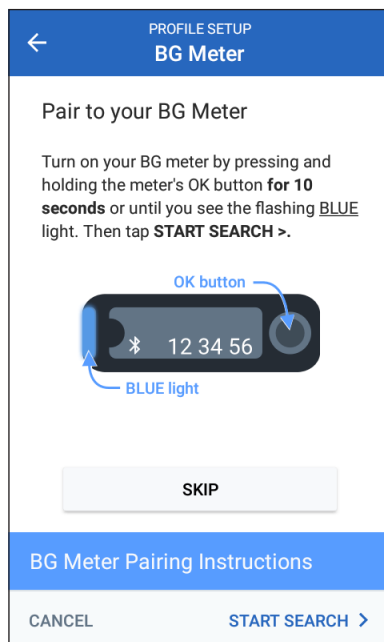
7. Optional: Rename your paired BG meter:

    a. Tap the Options icon (⋮) next to the paired BG meter. Then tap Edit.

    b. Tap the Name field and use the keypad to enter a new name for your BG meter, then tap the checkmark.

    c. Tap SAVE.

8. Tap NEXT.

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

Bolus Calculator Settings

The Bolus Calculator suggests boluses based on your current blood glucose value and any food you are about to eat (see "The Bolus Calculator" on page 156).

Turn the Bolus Calculator on or off

1. Review the description of insulin boluses, then tap the arrow (>).

2. Toggle the Bolus Calculator setting on or off:

    •   Select the On position (blue and to the right) to have the Bolus Calculator suggest boluses.

    •   Select the Off position (gray and to the left) to turn off the Bolus Calculator. You will have to calculate your own bolus amounts.

3. Tap NEXT.

4. If you turned the Bolus Calculator off, skip to "Other Bolus Settings" on page 36.

Target BG and Correct Above values

The Bolus Calculator aims to bring your blood glucose to the Target BG value if your current blood glucose level is above the Correct Above value. You can establish up to eight different blood glucose targets for different times of day.

Define the segments

Setting values for each segment follows the same pattern that you used to create your Basal Program:

1. Review the description of Target BG and Correct Above, then tap NEXT.

2. Tap the End Time field and enter an end time for the segment.

3. Tap the Target BG field and specify the Target BG for that segment.

4. Tap the Correct Above field and specify the Correct Above value for that segment.

5. Tap NEXT.

6. Repeat the above steps as needed until you have specified values for the segment that ends at midnight.

Review the Target BG and Correct Above values

1. Review the segments for the full 24 hour profile.

2. To change any of the entries:

   a. Tap the row containing the entry to be changed and enter the corrected value.

   b. Review and correct as needed any remaining segments.

3. When the segments and values are correct, tap SAVE.

PROFILE SETUP
← **Target BG & Correct Above**

Segment 1

Start Time	End Time
12:00 AM	- --

Night

Target BG
(70 to 200 mg/dL)   -- mg/dL

Correct Above
(Target BG to 200 mg/dL)   -- mg/dL

CANCEL   NEXT >

PROFILE SETUP
← **Target BG & Correct Above**

Review the values entered for each time segment.

Start Time	End Time	Target BG mg/dL	Correct Above mg/dL
< 12:00 AM - 6:00 PM		100	110
< 6:00 PM - 12:00 AM		105	115

CANCEL   SAVE

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 156).

1. To enter your Minimum BG for Calcs, tap the Min BG for Calcs field and enter the number on the number pad.

   Tip: *Alternatively, touch the blue circle and slide it to the desired number.*

2. Tap NEXT.

Insulin to Carb Ratio

Your Insulin to Carbohydrate Ratio, or "IC Ratio," defines how many carbohydrates are covered 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. Review the description of IC Ratio, then tap NEXT.

2. Enter the end time.

3. Enter the IC Ratio value in the 1 Unit of Insulin Covers field.

4. Tap NEXT.

5. Add additional segments as necessary until the final end time is midnight.

6. Review your 24-hour IC Ratio segments. Tap any entry to correct it.

7. When the segments and values are correct, tap SAVE.

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. Review the description of Correction Factor, then tap NEXT.

2. Enter the end time.

3. Enter the Correction Factor in the 1 Unit of Insulin Decreases BG by field.

4. Tap NEXT.

5. Add additional segments as necessary until the final end time is midnight.

6. Review your Correction Factor segments. Tap any entry to correct it.

7. When the segments and values are correct, tap SAVE.

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.

1. Toggle the Reverse Correction button on or off:

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

   - Select the Off position if you do not want the Bolus Calculator to adjust the suggested meal bolus based on a low blood glucose value.

2. Tap 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 or IOB).

1. Tap the Duration of Insulin Action field and use the scroll wheel to specify your Duration of Insulin Action.

2. Tap NEXT.

Other Bolus Settings

The remaining bolus settings are used whether the Bolus Calculator is on or off.

Maximum Bolus

The PDM will not let you request a bolus above the Maximum Bolus setting. You will see a message if the Bolus Calculator calculates a bolus that is above this amount.

1. Tap the Max Bolus field and use the number pad to specify your Maximum Bolus. Tap the checkmark to close the number pad.

2. Tap NEXT.

Extended bolus setting

Extending a bolus means that a meal bolus can be delivered over a prolonged period of time. For a description of the extended bolus feature, see page 155.

1. Toggle the Extended Bolus button to turn the extended bolus feature on or off.

2. Tap COMPLETE.
   The PDM restarts.

PDM Setup Complete

Congratulations! Your PDM is now ready for use. When you are ready to activate your first Pod, go to "First Time Activating a Pod" on page 38.

Tip: *To adjust the PDM screen time-out or screen brightness, see "Screen display" on page 101.*

Note: Confidence reminders and program reminders are turned on by default. These reminders cause the PDM or Pod to beep at the beginning and end of boluses and temp basals, and also once an hour during a long-lasting bolus or temp basal. For more information, see "Confidence reminders" and "Program reminders" on page 112.

CHAPTER 3
Changing Your Pod

Beginning the Pod Change Process

Changing your Pod consists of deactivating your current Pod and activating a new Pod.

Your Pod should be changed 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 change 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.

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

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

The steps for deactivating or activating a Pod depend on whether you have an active Pod or not:

- If this is your first time activating a Pod, go to "First Time Activating a Pod" on page 38.
- If you currently have an active Pod, go to "Deactivate an Active Pod" on page 38.
- If you have already deactivated your most recent Pod, go to "No Active Pod" on page 39.

Tip: *Software updates require that you deactivate your Pod. Connect to Wi-Fi periodically so the PDM can check for software updates. If there is a "Wireless Update" message on the Lock screen, be sure to install the software update after you deactivate your Pod (see "Software update (Wireless update)" on page 106).*

First Time Activating a Pod

Your Omnipod DASH® System trainer will help you set up your first Pod.

After completing the PDM setup flow, the Home screen displays "No Active Pod."

1. Tap SET UP NEW POD.
2. Go to "Preliminary Pod Change Steps" on page 40.

Deactivate an Active Pod

To deactivate and remove an active Pod:

1. Navigate to the Pod change screen:

   Home > Pod Info tab > VIEW POD DETAILS

   or
   Menu icon (≡) > Pod

2. Tap CHANGE POD, then tap DEACTIVATE POD.

   If a temp basal or extended bolus was running, it is canceled now.

   If you see a communication error message, see "Error when deactivating a Pod" on page 134.

   > **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.

50+ ⚡ 100% 1:52 PM

← Pod (Active)

Pod Insulin:50+ U
(Updated Today, 1:53 pm)

Expires: Monday
September 30 at 1:45 pm

⏰ Reminders

Check BG: ALWAYS ON
90 minutes after Pod activation

Pod Expiration: ALWAYS ON
Remind 4 hours before

Low Reservoir: ALWAYS ON
Remind when 10 units remain

CHANGE POD

CLOSE
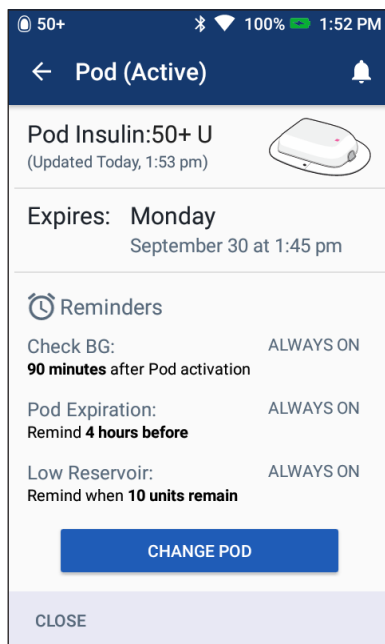
3. When the green banner tells you to remove your Pod, remove the deactivated Pod from your body:

   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 49).

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

4. To activate a new Pod, tap SET UP NEW POD.

5. Go to "Preliminary Pod Change Steps" on page 40.

No Active Pod

If you have no active Pod and are ready to activate a new Pod:

1. Navigate to the Pod change screen:

   Home > Pod Info tab > SET UP NEW POD

   or

   Menu icon (≡) > Pod > SET UP NEW POD

2. Go to "Preliminary Pod Change Steps" on page 40.
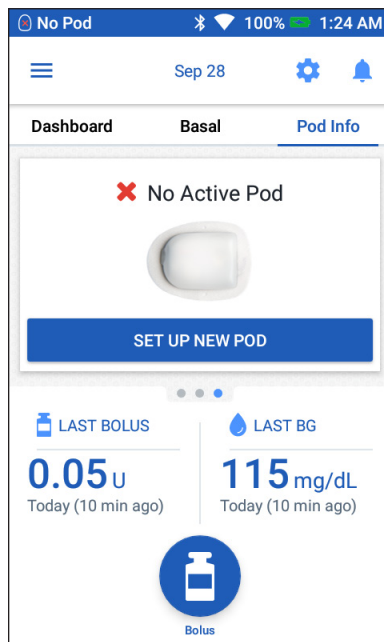
Preliminary Pod Change Steps

Warnings:

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

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.

1. Gather the necessary supplies:

   - A vial of rapid-acting U-100 insulin cleared for use in the Omnipod DASH® System

   - An unopened DASH® Pod (look for the Omnipod DASH® logo on the Pod tray lid)

   - Alcohol prep swabs

   - Your Omnipod DASH® PDM

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

3. Check the insulin for signs of deterioration according to the manufacturer's instructions for use.

4. Check the Pod's packaging for damage. If undamaged, 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.

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.

Pull apart

4. Determine how much insulin you will put into the Pod. For example, to use the Pod for 72 hours, determine how much insulin you will use over the next 72 hours. Your healthcare provider can help you determine the correct amount.
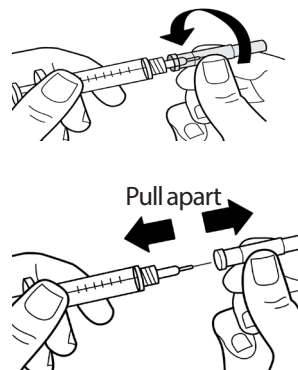
   Note: The Pod requires a minimum of 85 units of rapid-acting U-100 insulin to begin operation. The Pod can deliver up to 200 units of rapid-acting U-100 insulin.

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 rapid-acting 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.

   - Fill the syringe at least to the MIN (minimum) fill line.

   - To fill the Pod with enough insulin to deliver 200 units, pull the plunger down until it stops. This will be below the 200 mark.

MIN
fill line

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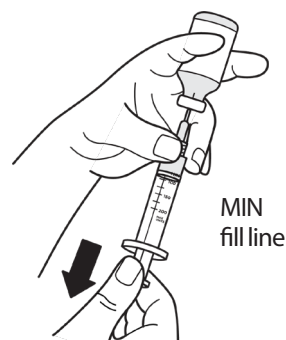
> **Warning:** Make sure there are no air bubbles or pockets of air in the fill syringe before filling a Pod with insulin. Air transferred from the fill syringe into the Pod may result in interrupted insulin delivery.

9.   Remove the needle from the vial.

Fill, Pair, and Apply the Pod

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

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

Fill the Pod with insulin

To fill the Pod with insulin (screen step ①):

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 pairing.*

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

3.   Depress the fill syringe plunger to transfer the insulin into the Pod.

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.

Note: After filling the Pod, continue to the next step immediately. If two hours pass before pairing the filled Pod to the PDM, the Pod becomes unusable.
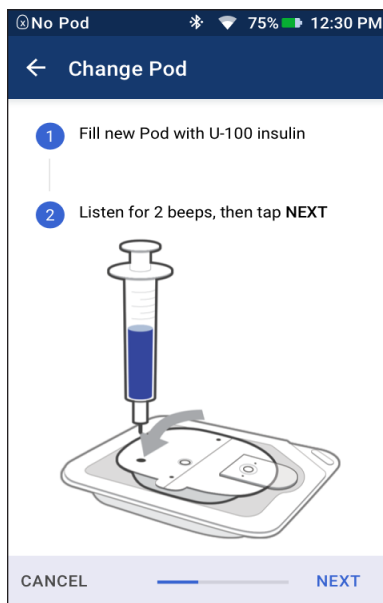
> **Warnings:**
>
> NEVER use a Pod if you feel resistance when you depress the plunger.
> This condition can result in interrupted insulin delivery.
>
> NEVER inject air into the fill port. Doing so may result in unintended or
> interrupted insulin delivery.

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 syringe needle and remove the needle from the fill syringe.

Pair the PDM and Pod

To pair the PDM and Pod (screen step ➁):

1. Place the PDM next to the Pod so they are touching. The Pod should be in its plastic tray during this process.

2. Tap NEXT.

    - If more than one filled DASH Pod is in range, the PDM informs you of this. Move at least 15 feet (4.5 m) away from any other DASH Pod and tap TRY AGAIN.

    - If only one Pod is in range, the Omnipod DASH® System performs a series of safety checks and primes the Pod.

3. Listen for the tone from the PDM that indicates that the Pod is paired to the PDM and is ready to be applied.
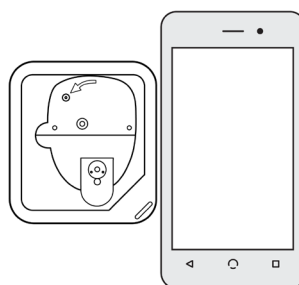
Note: After pairing, the PDM should always be able to communicate with a Pod that is up to 5 feet (1.5 m) away. Depending on the location, the PDM may be able to communicate with a Pod that is as much as 50 feet (15 meters) away.

Note: After pairing, the Pod beeps every 5 minutes until you apply it. If you do not apply it within 60 minutes after pairing, the Pod becomes unusable.

If you see a communication error message when you attempt to pair your Pod, see "Communication Errors" on page 132.

Prepare the Pod site

Select the Pod infusion site (screen step ③):

Guidelines for Pod site selection

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.

- 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.

Pod site map (optional)

The Pod site map is an optional feature that helps you track your current and recent Pod site locations. This option only appears if the Pod Sites setting is turned on (see "Pod Sites Setting" on page 108).

Front   Back

Front   Back
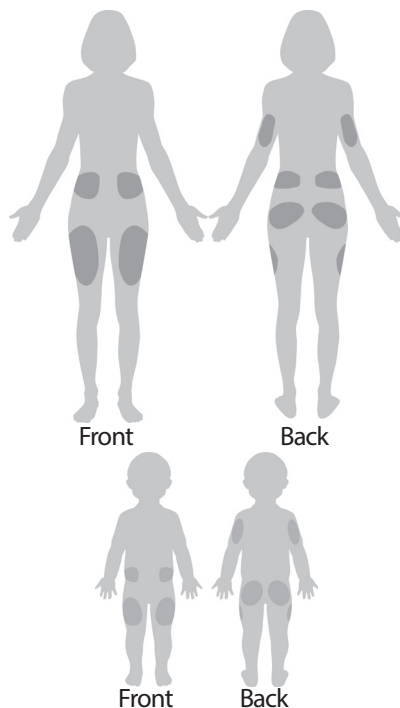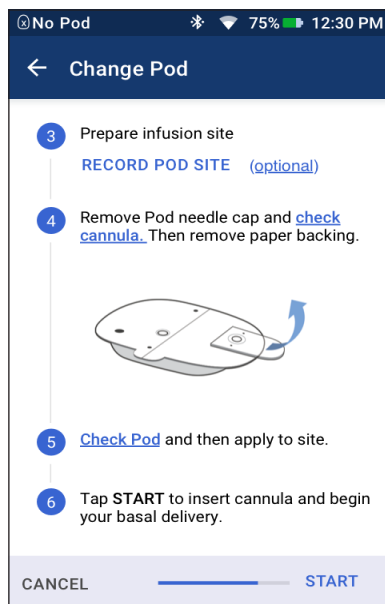
1. Tap RECORD POD SITE to bring up the Record Pod Site screen.

2. Tap the FRONT or BACK tab to select an area of your body for your Pod. To help you avoid recent Pod sites, the screen indicates the two most recent dates that each site was selected.

3. Tap a circle to indicate the location on your body where you will place your new Pod. A blue dot appears inside the selected circle. Tap again to deselect the location.
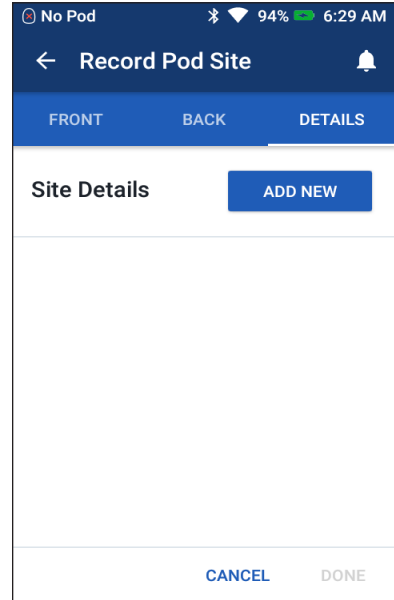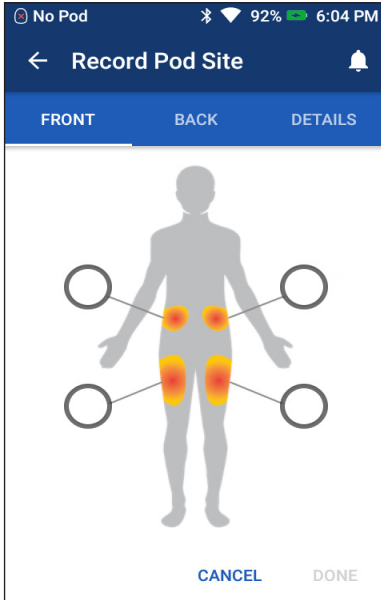
4. Tap the DETAILS tab to add a detail about the placement of this Pod. For example, you could add a detail that says "Facing up" or "Facing down" to describe the Pod's orientation.

    a. To add a new detail, tap ADD NEW and type in the new detail. Tap ADD when done. The new detail is added to the list.

        Note: The PDM considers uppercase letters and lowercase letters to be identical. For example, you can only use one of the following details: "Facing up," "FACING UP," or "facing Up," because the PDM considers these to be identical entries.

    b. Select a detail for the new Pod by tapping the circle next to that detail. You may only add one detail for each Pod. Tap again to deselect the detail.

    Note: To delete a site detail, tap the ⊗ next to the detail.

5. Tap DONE when finished to return to the Change Pod screen.

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 infusion 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 infusion site with a clean towel.

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

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

Remove the Pod's needle cap

Remove the Pod's needle cap (screen step (4)):

1.   Turn the Pod so the needle cap is up and facing you.

2.   Place your thumb on the bottom (flat edge) of the cap and pull the cap upwards. The cap snaps off. Throw the cap away.

     When you remove the cap, a drop of insulin may be visible at the end of the cannula or in the well.

3.   If any of the following apply, tap CANCEL, and then dispose of the Pod and begin again with a new Pod:

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

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

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

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

4.   Using the pull tabs, remove the white paper backing covering the adhesive pad. Be careful not to remove the adhesive pad itself. Do not allow the adhesive to fold back on itself.
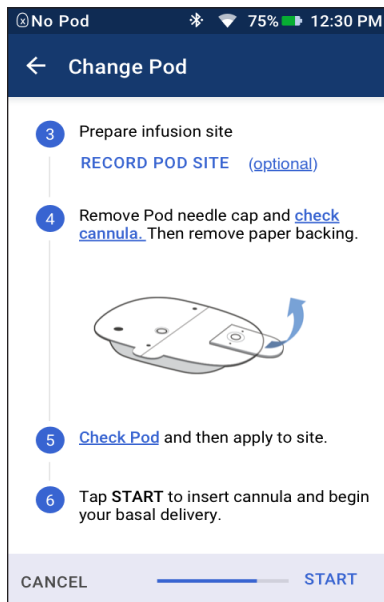
Apply the Pod

Inspect and apply the Pod (screen step 5):

1. Examine the Pod. Tap CANCEL and dispose of the Pod if the adhesive pad is folded, torn, or damaged, and begin again with a new Pod.

2. 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.

3. Apply the Pod to the selected infusion site, pressing down firmly to secure the Pod to your skin.
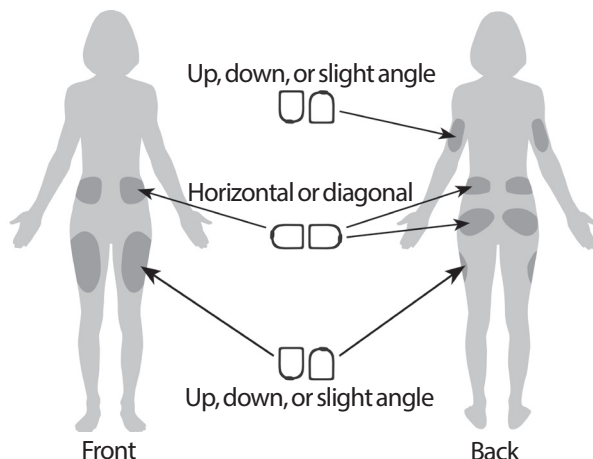
    The adhesive is designed for one-time use. Once a Pod is placed on your body, you cannot move that Pod to another infusion site.

Up, down, or slight angle

Horizontal or diagonal

Up, down, or slight angle

Front   Back

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

Begin insulin delivery

Begin insulin delivery (screen step 6):

> **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.

1. If you applied the Pod to a lean area, squeeze the skin around the Pod.

2. Tap START.
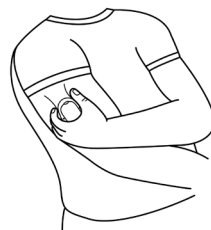
3.   Confirm that the Pod is securely attached to your body, then tap CONFIRM.

4.   If you are squeezing your skin, stop squeezing when the PDM asks if the cannula is properly inserted.

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 alarms" on page 105).

Check the Infusion Site

Following insertion of the cannula, check the Pod and infusion site:

1.   Look through the viewing window on the edge of the Pod to verify that the cannula is inserted into the skin. The cannula is tinted light blue.

2.   Verify that there is a pink color in the area indicated in the figure. This is an additional check that the cannula was inserted.

3.   Verify that there is no wetness or scent of insulin at the infusion site. The presence of either may indicate that the cannula has dislodged.

Check here for light blue cannula

Check here for pink color
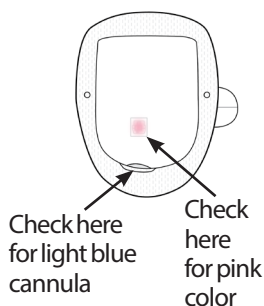
> **Warning:** Check the infusion site after insertion to ensure that the cannula was properly inserted. If the cannula is not properly inserted, hyperglycemia may result.

4.   If the cannula is not properly inserted, tap NO. Then tap DEACTIVATE POD. Restart the process with a new Pod.

5.   If the cannula is properly inserted, tap YES.

      A green banner notifies you that the Pod setup is complete. The screen shows details about the Pod and a list of reminders.

6.   Review the list of active reminders, then tap CLOSE.

Note: Ninety minutes after Pod activation, a Check BG reminder prompts you to check your blood glucose level and infusion site. This additional safety feature helps ensure that the cannula was properly inserted.

> **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 infusion site. If you suspect an infection, immediately remove the Pod and apply a new Pod in a different location. Then contact your healthcare provider.

- If you observe any problems with the Pod, replace it with a new 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 an infusion site shows signs of infection:
>
> - Immediately remove the Pod and apply a new Pod at a different infusion site.
>
> - Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

More Information about Pod Use

Tip: *Develop a routine so you can change your Pod at a convenient time. If you know of an upcoming event that could interfere with changing your Pod, you can change your Pod early to avoid a 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 137.

- To learn about the Pod alarms, see "Alarms, Notifications, and Communication Errors" on page 121.

- If a Pod alarm is sounding, 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 135).

- To understand the Pod's informational and notification beeps, including which beeps are optional, see "Notifications List" on page 129 and "Informational Signals List" on page 131.

- To understand how to handle situations where the PDM cannot communicate with your Pod, see "Communication Errors" on page 132.

- If the Home: Pod Info tab says "No Pod Communication:"

  - To find the last time the PDM successfully communicated with the Pod navigate to: Menu icon (☰) > Pod.

  - If you are unable to restore communication with the Pod and want to change to a new Pod, navigate to: Menu icon (☰) > Pod > CHANGE POD.

- For a description of the how the PDM communicates with the Pod, see "PDM and Pod Interactions" on page 145.

CHAPTER 4
Entering Blood Glucose Readings

About Blood Glucose Testing

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

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.

To enter your blood glucose reading into the PDM:

- From a paired BG meter, go to the following section.
- When not using a paired BG meter, go to page 53.

To pair to a new BG meter, go to "Pairing, unpairing, or renaming a BG meter" on page 114.

Entering Your Blood Glucose Reading from a Paired BG Meter

To record a blood glucose reading from a paired BG meter:

1. Check your blood glucose following the CONTOUR® NEXT ONE BG meter's instructions for use.
2. Turn on your BG meter, if necessary, and place it next to your PDM (no more than six feet away).
3. Go to the Enter BG screen on your PDM:
   Menu icon (≡) > Enter BG

4. Tap SYNC BG METER.

   The PDM imports all new blood glucose readings and saves them in your history records.

   Note: An exception is if the PDM and BG meter's clocks differ by more than five minutes (see "PDM and Paired BG Meter Interaction" on page 149).

   For the meaning of the screen's colors and messages, see "How Blood Glucose Readings are Displayed" on page 55.

   Note: You cannot edit the value or time of blood glucose readings from a paired BG meter.

5. Optional: To add one or more informational tags to the blood glucose reading shown in the circle, see "Tagging Your Blood Glucose Reading" on page 54.

6. After the blood glucose reading and any tags are entered, do one of the following:

   - Tap ADD TO CALCULATOR to save any tags and enter the blood glucose reading into the Bolus Calculator. Then go to "Bolusing with the Bolus Calculator" on page 57. If the Bolus Calculator is off or disabled or if insulin is suspended, ADD TO CALCULATOR does not appear.

   - Tap SAVE to save any tags in the history records. If you accessed this screen from the Bolus Calculator, SAVE does not appear.

   - Tap CANCEL to exit the screen without saving the tags. Any imported blood glucose readings have already been saved.
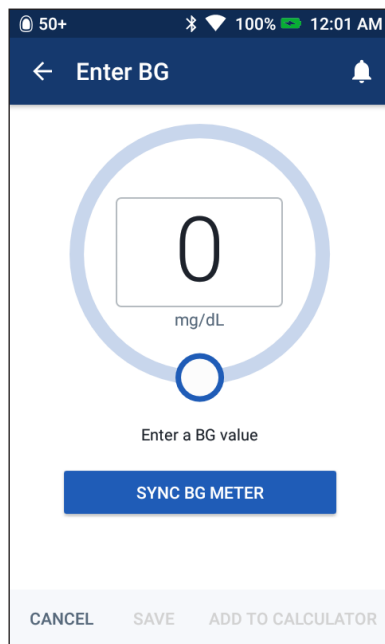
Entering Your Blood Glucose Reading Manually

To manually enter your blood glucose reading:

1. Check your blood glucose following the BG meter's instructions for use.

2. Go to the Enter BG screen on your PDM:
   Menu icon (☰) > Enter BG

3. Manually enter or edit a blood glucose value as follows:

   a. Tap the box inside the circle.

   b. Use the number pad to enter your blood glucose reading.

   c. Tap the checkmark to close the number pad.

   Note: Alternatively, you can enter a blood glucose reading using the circular slider (see "Using a slider" on page 6). When using the slider, "+" and "-" buttons appear briefly. Tap these buttons to make small adjustments to the blood glucose number.

   Note: When you enter a blood glucose reading above 600 mg/dL, the PDM stores it as "HI". When you enter a blood glucose reading below 20 mg/dL, the PDM stores it as "LO".

   For the meaning of the screen's colors and messages, see "How Blood Glucose Readings are Displayed" on page 55.

4. Optional: To add one or more informational tags to the blood glucose reading shown in the circle, see "Tagging Your Blood Glucose Reading" on page 54.

5. After the blood glucose reading and any tags are entered, do one of the following:

   - Tap ADD TO CALCULATOR to save any tags and enter the blood glucose reading into the Bolus Calculator. Then go to "Bolusing with the Bolus Calculator" on page 57. If the Bolus Calculator is off or disabled or if insulin is suspended, ADD TO CALCULATOR does not appear.

   - Tap SAVE to save the blood glucose reading and any tags in the history records. If you accessed this screen from the Bolus Calculator, SAVE does not appear.
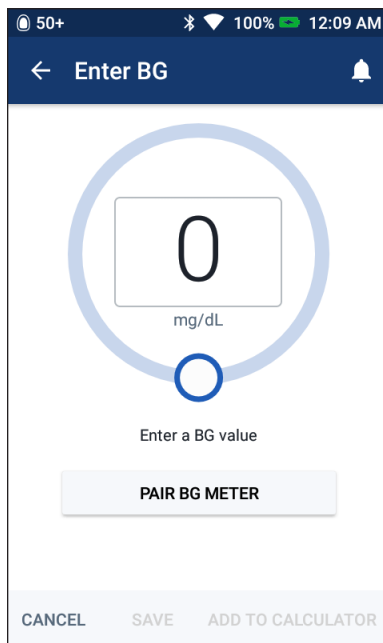
- Tap CANCEL, then YES, to exit the screen without saving the blood glucose reading or tags.

The PDM records the current time as the time of the blood glucose reading.

Tagging Your Blood Glucose Reading

Tag a blood glucose reading

You can add informational tags to your blood glucose reading for future reference. For example, you may tag the blood glucose reading as pre-meal.

To add a tag to the current blood glucose reading or to a control solution reading:

1. Tap ADD TAGS.

2. Tap a tag to select it. You can add up to four tags.

3. To remove a tag, tap the tag again to deselect it.

You can add or remove tags for LO and HI blood glucose readings just as you would for any other reading.

Control solution readings

As a rule, a control solution reading from a paired BG meter is automatically tagged as a control solution. This reading is not included in history averages.

Do not manually enter control solution readings from a non-paired BG meter. You cannot tag manually-entered readings with a Control tag, which means you cannot prevent them from being averaged into your blood glucose history records.
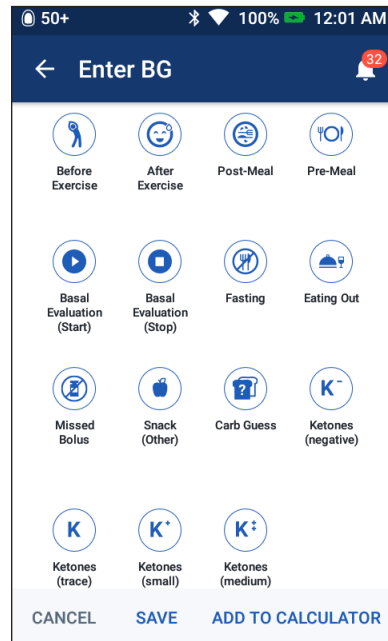
How Blood Glucose Readings are Displayed

The PDM displays the blood glucose reading inside a colored circle. The circle is:

- Yellow if your blood glucose is above your BG Goal Range.
- Green if your blood glucose is within your BG Goal Range.
- Red if your blood glucose is below your BG Goal Range.

To change your BG Goal Range, see "BG Goal Range" on page 114.
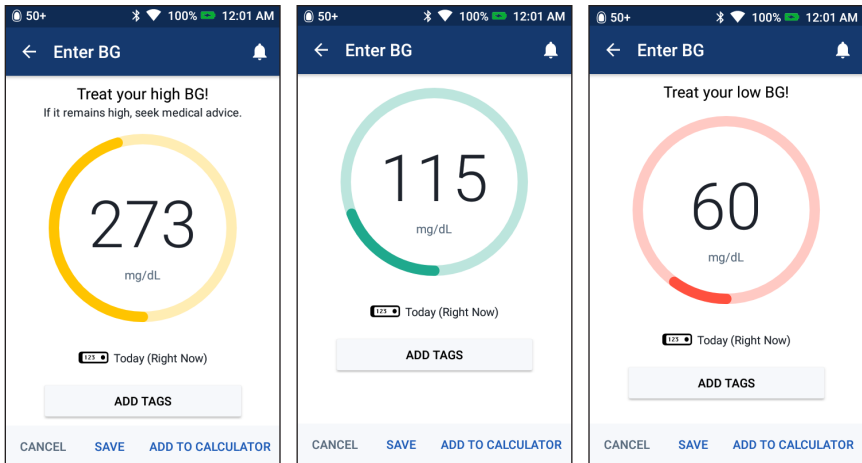
The PDM adds a warning message for high and low blood glucose readings.

Blood glucose reading	Screen display	Screen warning message
Above 600 mg/dL or HI	HI	Treat your high BG! If it remains high, seek medical advice.
251-600 mg/dL	<BG reading>	Treat your high BG! If it remains high, seek medical advice.
70-250 mg/dL	<BG reading>	
20-69 mg/dL	<BG reading>	Treat your low BG!
0-19 mg/dL or LO	LO	Treat your low BG!

If the blood glucose is HI or above 600 mg/dL, the PDM records "HI" in the history. This indicates severe hyperglycemia (high blood glucose). If the blood glucose reading is LO or below 20 mg/dL, the PDM records "LO" in the history. This indicates severe hypoglycemia (low blood glucose). HI and LO readings are saved in your blood glucose history, but are not used in averages.

Warnings:

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

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

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

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

CHAPTER 5
Delivering a Bolus of Insulin

A bolus of insulin is used to lower a high blood glucose level and to cover the carbohydrates in a meal. Bolus insulin is delivered, when requested, in addition to insulin from a Basal Program or temp basal. For more information about boluses, see page 155.

> **Warning:** When using the extended bolus function, check your blood glucose levels more frequently to avoid hypoglycemia or hyperglycemia.

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

If the Bolus Calculator is set to 'off' or is temporarily disabled, go to "Manually-calculated Bolus" on page 62.

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

The Bolus Calculator calculates a suggested bolus amount of insulin to correct an elevated blood glucose level (a correction bolus) and/or to cover carbohydrates in a meal (a meal bolus). For details about how the Bolus Calculator works, see page 156.

If you enter a blood glucose value but not carbs, the Bolus Calculator calculates a correction bolus only. If you enter carbs but not a blood glucose value, the Bolus Calculator calculates a meal bolus only. If you enter both a blood glucose value and carbs, the Bolus Calculator uses both factors to calculate a suggested bolus.

To change your personal settings used by the Bolus Calculator, or to turn the Bolus Calculator on or off, see "Bolus Calculator settings" on page 117.

Enter your meal information

To enter the carbohydrates, or "carbs," for your meal:

1. On the Home screen, tap the Bolus button ( ).

   Tip: *If you do not want to use the Bolus Calculator and already know the amount of the bolus you want to deliver, tap the* Total Bolus *field to bring up*

the number pad. Enter the bolus amount and tap the checkmark. Then go to "Delivering an immediate or extended bolus" on page 59.

2. To enter carbs manually, tap the Enter Carbs field. Enter the grams of carbs and tap the checkmark.

    Note: Consult your healthcare provider about how to calculate the grams of carbs.

3. Optional: To look up carbs in the Food Library, tap FOOD LIBRARY and select the food for your meal (see "Add carbs to the Bolus Calculator" on page 67).

    Note: Even though the Food Library may list grams of fiber in addition to grams of carbs, the Bolus Calculator does not subtract fiber from the carb value. Consult your healthcare provider about whether you should make an adjustment for fiber.

4. Review the suggested meal bolus, which is shown next to the grams of carbs.

🔋 50+	✱ ▼ 100% ▭ 1:54 PM
← **Bolus Calculator**	🔔

Enter Carbs	Meal Bolus
0 g	**0** U

FOOD LIBRARY

BG	Correction Bolus
– –	**0** U

ENTER BG

Total Bolus
CALCULATIONS

0 U

IOB of 0 U

CANCEL   EXTEND BOLUS   CONFIRM

5. Optionally, tap CALCULATIONS to see the details of the bolus calculations.

Note: If you have entered your blood glucose reading, the meal bolus may have been adjusted for:

- Insulin on board (IOB) from a previous correction bolus.
- Reverse correction, if this feature is turned on and your blood glucose is below your Target BG.

  For more information, see "Bolus Calculator rules" on page 163.

Note: If you have not entered your blood glucose reading, the Bolus Calculator does not adjust the meal bolus for IOB.

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 blood glucose reading:

1. Tap ENTER BG.

If the PDM has a blood glucose reading from within the past 10 minutes, that value automatically appears in the BG field. If you want the Bolus Calculator to use that value, skip the next step.

2. Enter your blood glucose reading:

- To use a paired BG meter—After measuring your blood glucose on the paired BG meter, tap SYNC BG METER. The blood glucose reading appears on the PDM screen.

- To manually enter a blood glucose reading—Tap the box in the circle and enter the blood glucose reading. Alternatively, slide the indicator along the circle to enter the blood glucose reading.

  While the Bolus Calculator will use any blood glucose value you enter manually, you should only enter a blood glucose value that was taken within the last 10 minutes.

  For the meaning of the colors and messages displayed on the Enter BG screen, see "How Blood Glucose Readings are Displayed" on page 55.

3. Optional: To tag the blood glucose reading, tap ADD TAGS and tap a tag. Tap again to deselect a tag. You can add up to four tags.

4. Tap ADD TO CALCULATOR. The Bolus Calculator screen reappears.

5. Review the suggested correction bolus, which is shown next to the blood glucose value. The correction bolus has been adjusted for any insulin on board (IOB) (see "Bolus Calculator rules" on page 163).

Delivering an immediate or extended bolus

The Total Bolus field shows the proposed bolus. The amount of any IOB adjustment appears below the Total Bolus field.

To review and deliver the bolus:

1. Review the suggested bolus. To adjust it, tap the Total Bolus field and enter a revised bolus.

2. To review the Bolus Calculator's calculations, tap CALCULATIONS. You may need to swipe up or down to see all of the calculations. Tap CLOSE when done (see "Bolus Calculator equations" on page 162 for details).

3. To deliver the entire bolus immediately, tap CONFIRM and skip to step 5.

50+U   ✳ 📶 90% 🔋 5:47 AM

← **Bolus Calculation** 🔔①

Correction Bolus   **1 U**

BG = 150, Target BG = 100
Correction Factor = 50
(150-100) / 50 ≈ 1 U

Meal IOB adjustment

Meal IOB = 0 U
1 U - 0 U = 1 U

Correction IOB adjustment

Correction IOB = 0 U
1 U - 0 U ≈ 1 U

Meal Bolus   **4 U**

Carbs = 60 g, IC Ratio = 15 g/U
60 / 15 ≈ 4 U

Correction IOB adjustment

CLOSE

---

4. To extend some or all of a meal bolus:

   a. Tap EXTEND BOLUS.

      Note: The EXTEND BOLUS option is available when there is a meal bolus and the extended bolus setting is enabled.

   b. Tap the Now field and type in the percentage of the bolus to be delivered immediately. Alternatively, tap the Extended field and enter the percentage to be extended.

      The number of units to be delivered now and over the extended period appear below the percentage (%).

      Note: You can only extend the meal portion of the bolus. A correction portion of the bolus, if any, is always delivered immediately.

50+   ✳ 📶 100% 🔋 1:54 PM

← **Extended Bolus** 🔔

Now   Extended

40 %   **60** %

1.60 U   *2.40 U*

Duration   **0.5** hrs
(0.5 to 8 hrs)

Total Bolus   **5 U**

Meal Bolus   4 U

Correction Bolus   1 U

CANCEL   CONFIRM

---

   c. Tap the Duration field and enter the duration for the extended portion of the bolus.

   d. Tap CONFIRM.

5.   Review the bolus details on the Confirm Bolus screen.

Immediate bolus: The screen for an immediate bolus shows the carbs and blood glucose values used for the bolus calculation and also the total bolus.

The total bolus includes any IOB adjustments and any adjustments you made to the calculated bolus.

Grams of carbs
Blood glucose value

Adjusted for IOB of x U means the Bolus Calculator took IOB into account (see page 145–page 170).

Extended bolus: In addition to the information on the immediate bolus screen, the extended bolus screen also shows how much of the bolus will be delivered immediately and how much will be extended.

The entire correction bolus is delivered immediately.

Only the meal bolus can be extended.

% of **meal** bolus to be given immediately

% of **meal** bolus to be given over the extended period

6. Optional: Set up a reminder to check your blood glucose:

    a. Tap CREATE BG REMINDER.

    b. Tap the Check BG in field and enter the time for the reminder.

    c. Tap SAVE.

    Note: The CREATE BG REMINDER button appears only if the "Check BG after Bolus" reminder setting is turned on. To turn this setting on or off, see "Check BG after Bolus reminders" on page 110.

7. Tap START to begin the bolus.

The Home screen tracks the delivery of an immediate or extended bolus (see "Tracking the Progress of a Bolus" on page 64).

Manually-calculated Bolus

A manually-calculated bolus is a bolus that you calculate yourself. If the Bolus Calculator is set to 'off' or is temporarily disabled, you must enter a manually-calculated bolus.

A bolus cannot be greater than your Maximum Bolus setting (see "Maximum Bolus" on page 117).

To deliver a manually-calculated bolus:

1. On the Home screen, tap the Bolus button ( ).

    The Bolus screen appears.

    Note: A different screen appears if the Bolus Calculator is active (see page 58).

2. Enter the bolus amount using one of the following methods:

    - Tap the Total Bolus field and enter the bolus amount. Then tap the checkmark.

    - Tap SELECT FROM PRESETS and select the desired preset from the list. This option is only available if the Bolus Calculator is turned off. To create or edit a bolus preset, see "Bolus Presets" on page 87.
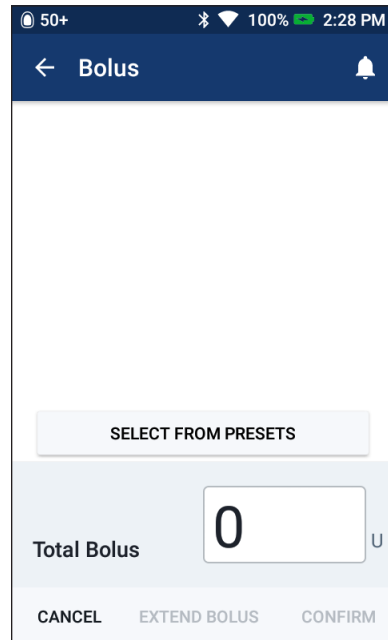
3. To deliver the entire bolus immediately, tap CONFIRM. Then skip to step 5.

4. To extend the bolus:

    a. Tap EXTEND BOLUS.

       Note: The EXTEND BOLUS option is only available if extended boluses are enabled (see page 117).

    b. Tap the Now field and type in the percentage of the bolus to be delivered now. Alternatively, tap the Extended field and enter the percentage to be extended.

       The number of units to be delivered now and over the extended period appear below the percentage (%).

       Note: You can extend the entire bolus.

    c. Tap the Duration field and enter the duration for the extended portion of the bolus.

    d. Tap CONFIRM.

5. Review the bolus details on the Confirm Bolus screen.

6. Optional: Set up a reminder to check your blood glucose as follows:

    a. Tap CREATE BG REMINDER.

    b. Tap the Check BG in field and enter the time for the reminder.

    c. Tap SAVE.

    Note: The CREATE BG REMINDER button appears only if the "Check BG after Bolus" reminder setting is turned on. To turn this setting on or off, see "Check BG after Bolus reminders" on page 110.

7. Review the bolus details, then tap START to begin the bolus.

The bolus amount and details about the bolus preset, if a preset was used, are stored in your history records. The Home screen tracks the delivery of an immediate or extended bolus (see "Tracking the Progress of a Bolus" on page 64).

Tracking the Progress of a Bolus

During a bolus, the Home screen displays a progress bar.

Immediate bolus progress

During an immediate bolus, the Home screen displays a Bolus in Progress message along with a progress bar and details.

If the Bolus Calculator is on, an estimate of the IOB is displayed in the lower left of the screen.

If the Bolus Calculator is off (not shown), the amount of the last completed bolus is displayed in the lower left of the screen.

You cannot use your PDM during an immediate bolus.

To cancel or replace a bolus, see "Altering a Bolus in Progress" on page 65.

Extended bolus progress

During an extended bolus, the Home screen's Dashboard tab displays an Extended Bolus in Progress message along with a progress bar and other details.

Note: If the Bolus Calculator is off, the Dashboard tab only appears when an extended bolus is in progress.

If the Bolus Calculator is on, the displayed IOB is updated with estimated amounts from the ongoing bolus.

If the Bolus Calculator is off (not shown), the amount of the last completed bolus is displayed in the lower left of the screen.

You can use your PDM for most actions during an extended bolus.

Unless you cancel the bolus, the Pod finishes delivering a bolus whether or not it is in range of the PDM. To cancel or replace a bolus, see "Altering a Bolus in Progress" in the next section.
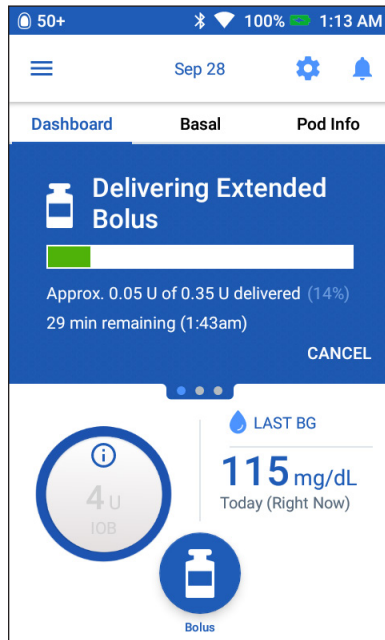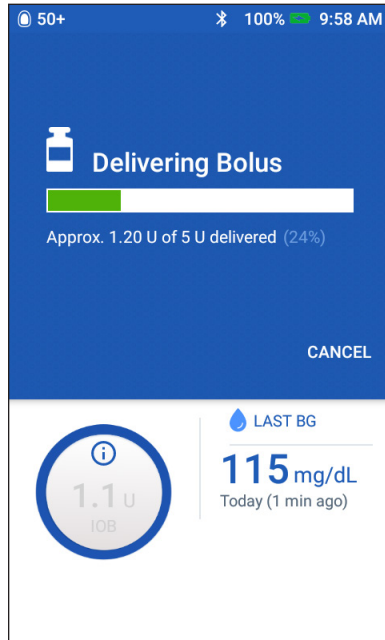
Altering a Bolus in Progress

When an immediate bolus is in progress, you must cancel it before performing any other action.

During an extended bolus, you can:

- Cancel the bolus.
- Deliver a new immediate bolus and continue the extended bolus in progress.
- Replace the bolus in progress with another bolus.

If you get a communication error message when canceling a bolus, see "Error when sending insulin instructions to the Pod" on page 133.

Cancel a bolus

To cancel an immediate or extended bolus:

1. On the Home screen (immediate bolus) or the Home screen's Dashboard tab (extended bolus), tap CANCEL.

2. Tap YES to confirm canceling the bolus. The Pod beeps to confirm that the bolus is canceled.
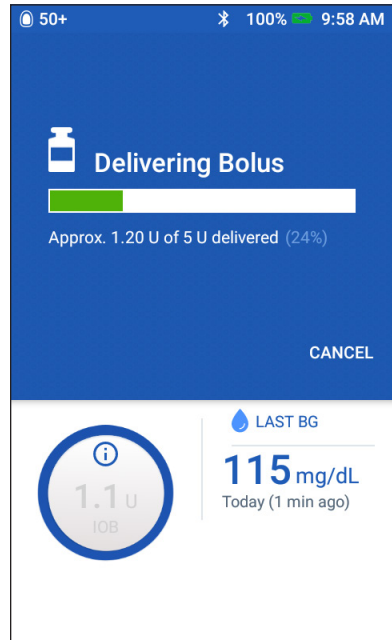
Deliver a new bolus during an extended bolus

To deliver an immediate bolus while an extended bolus is in progress:

1. On the Home screen, tap the Bolus button.

2. Enter the carbs and blood glucose information. Then tap CONFIRM.

3. Tap START.

The new bolus is delivered, and the extended bolus continues.

Replace an extended bolus

To replace an extended bolus in progress with a new extended bolus, you must cancel the ongoing bolus first.

1. On the Home screen, tap the Bolus button ( ).

2. Enter the amount of the new bolus (see "Bolusing with the Bolus Calculator" on page 57 or "Manually-calculated Bolus" on page 62).

3. Tap EXTEND BOLUS. A screen appears telling you that an extended bolus is already active.

4. Tap CANCEL & CREATE NEW to cancel the active bolus. The PDM tells you how much of the bolus was undelivered.

5. Select how to handle the undelivered bolus amount:

   - If you want to add the undelivered bolus amount to the new extended bolus, tap ADD TO TOTAL BOLUS. Verify that the new total bolus is correct. Then tap EXTEND BOLUS.

     Note: The Bolus Calculator considers this added amount to be a user adjustment to the new bolus. This added amount will be delivered over the same duration as the new extended bolus.

   - If you do not want to add the undelivered bolus amount to the new extended bolus, tap NO.

6. Return to the extended bolus flow:

   - If the Bolus Calculator is on, go to step 4 on page 60.

   - If the Bolus Calculator is off, go to step 4 on page 63.

Using the Food Library

Note: The Food Library is only available when English is the selected language.

The Food Library has a MY FOODS list and a BROWSE list.

The BROWSE list contains thousands of common foods. You can create a smaller list of your favorite foods on the MY FOODS list.

When you are about to eat, you can use the MY FOODS list or the BROWSE list to transfer the number of carbs in a meal to the Bolus Calculator.

To access the Food Library, do one of the following:

- From the Home screen, tap:

  Menu icon (≡) > Food Library

- From the Bolus Calculator screen, tap FOOD LIBRARY.

Tap MY FOODS or BROWSE to switch between the lists. A blue underline indicates whether the MY FOODS or BROWSE list is showing.
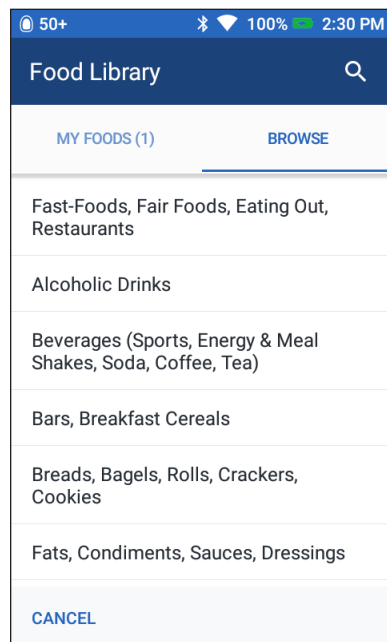
All individual food items on the BROWSE list are marked with a heart. If the heart is an outline (♡), that food does not appear on the MY FOODS list. If the heart is solid (♥), you have added that food to the MY FOODS list. Foods with a solid heart (♥) are considered "favorite" foods.

The back (<) arrow takes you to the previous screen in the Food Library.

Note: The total grams of carbs on the BROWSE list includes grams of fiber. The Bolus Calculator does not automatically subtract fiber from a carbs value when importing carbs from the Food Library. Consult your healthcare provider about how to account for fiber when calculating a bolus.
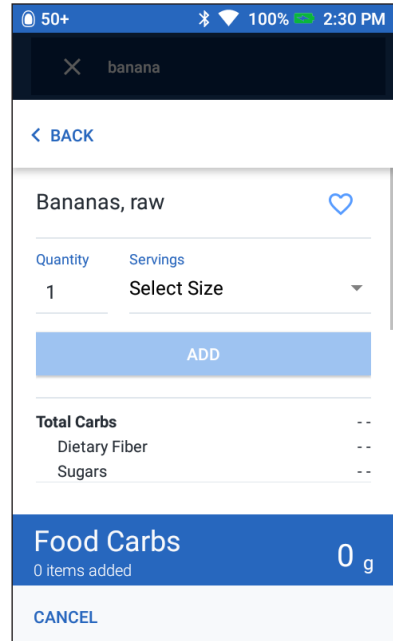
Add carbs to the Bolus Calculator

Add carbs to the Bolus Calculator from the BROWSE list

To add carbs to the Bolus Calculator from a food listed on the BROWSE list:

1. Locate the food you are going to eat (see "Search for a food on the BROWSE list" on page 69).

2. Tap Quantity to specify how many servings of the food you will eat.

3. If the food has multiple serving sizes, tap Servings to specify the serving size and measurement units.

4. Tap ADD to add the number of carbs in the food to the total carbs displayed in the Food Carbs banner.

    Note: The ADD button is disabled if you have not specified a serving size.

    To remove the food from the Food Carbs total, tap REMOVE.
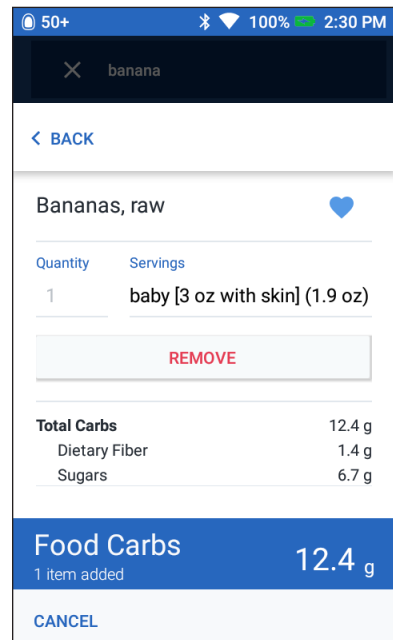
5.   Optional: Add additional foods:

    a.   Tap the back (<) arrow or use the search function to navigate to the next food item. Then tap to select the food item.

    b.   Tap ADD. This adds the carbs from the new selection to the total carbs in the Food Carbs banner.

    c.   Repeat this step until the Food Carbs banner shows the total carbs for your entire meal.

    Tip: *Tap the Food Carbs banner to see the foods that are included in the total.*

6.   Tap ADD TO CALCULATOR. The Bolus Calculator screen appears with the total number of carbs entered in the Enter Carbs field.

    Note: The ADD TO CALCULATOR option does not appear if the Bolus Calculator is off or disabled.

Add carbs to the Bolus Calculator from the MY FOODS list

To add carbs to the Bolus Calculator from a food listed on the MY FOODS list:

1.   Open the MY FOODS list:

    Menu icon (☰) > Food Library

2.   Tap the MY FOODS list.

3.   Optional: To filter the MY FOODS list:

    a.   Tap the down arrow beneath the MY FOODS heading. A drop-down list of food tags appears. The number of food items with each tag is shown in parentheses. The default category is All, which shows the entire MY FOODS list.

    b.   Tap a tag. The list is filtered to show only food items with that tag.

4.   Tap the plus sign (+) next to the food's name to add that food's carbs to the total in the Food Carbs banner. A checkmark replaces the plus (+) sign to show that the food's carbs have been added.
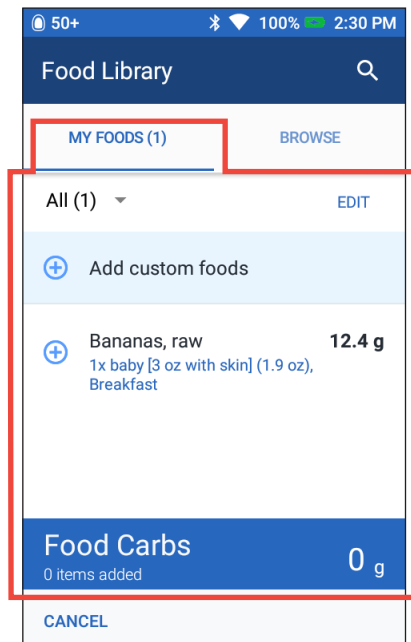
    Tip: *If you want to view the food details before adding its carbs, tap the name of the food instead of tapping the plus sign (+). Then tap ADD to add the number of carbs to the total in the Food Carbs banner.*

50+   ☆ ▼ 100% 🔋 2:30 PM

Food Library   🔍

MY FOODS (1)   BROWSE

All (1) ▼   EDIT

⊕   Add custom foods

⊕   Bananas, raw   12.4 g
     1x baby [3 oz with skin] (1.9 oz),
     Breakfast

Food Carbs   0 g
0 items added

CANCEL

To remove a food from the Food Carbs total, tap the checkmark next to that food.

5.   Repeat the preceding steps until the Food Carbs banner shows the total carbs for your entire meal.

   Tip: *Tap the Food Carbs banner to see the foods that are included in the total.*

6.   To transfer the total carbs from the Food Carbs banner to the Bolus Calculator, tap ADD TO CALCULATOR. The Bolus Calculator screen appears with the total number of carbs entered in the Enter Carbs field.

   Note: The screen reads REPLACE CALCULATOR CARBS instead of ADD TO CALCULATOR if you had already entered carbs into the Bolus Calculator.

   Note: The ADD TO CALCULATOR option does not appear if the Bolus Calculator is off or disabled.

Search for a food on the BROWSE list

Search using the search icon

To search for a specific food:

1.   Open the Food Library:

   Menu icon (☰) > Food Library

2.   Tap the search icon (🔍) on the upper right of the screen.

   Note: The search function only searches for foods from the BROWSE list. It does not search the MY FOODS list.

3.   Type in a search word.

   After three letters are entered, the screen shows a list of foods that begin with those letters. To narrow down a long list, you can continue typing your word.

   Note: Tap the "x" next to the search term to exit the search.

4.   Tap the checkmark to close the keypad. The screen displays food items matching your search term.

5.   Swipe up or down as needed to locate the desired food. Then tap to select it.
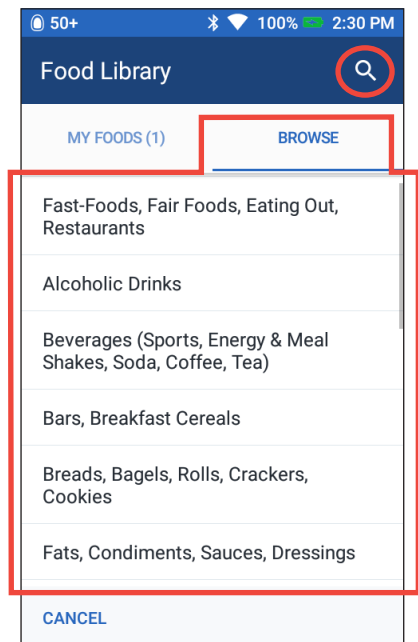
Search by browsing the food categories

The BROWSE list displays food categories listed in alphabetic order.

To browse food categories:

1. Open the Food Library's BROWSE list:

   Menu icon (☰) > Food Library

2. Tap the BROWSE list.

3. Swipe up or down as needed and tap the desired category of food.

4. Continue selecting sub-categories until a list of individual foods is displayed.

5. Swipe up or down as needed to locate the desired food. Then tap to select it.

Create a list of favorite foods on the MY FOODS list

Foods on the MY FOODS list are considered "favorites." The MY FOODS list can contain up to 50 items. This section explains how to create food favorites on the MY FOODS list by:

- Adding foods from the BROWSE list.

- Creating a meal by combining two or more foods from the BROWSE tab.

- Creating a custom food by entering a name and number of carbs.

Add foods from the BROWSE list

To add a food item from the BROWSE list to the MY FOODS list:

1. Navigate to the BROWSE list:

   Menu icon (☰) > Food Library

2. Tap the BROWSE list.

3. On the BROWSE list, locate the food you would like to add to MY FOODS (see "Search for a food on the BROWSE list" on page 69).

4. Tap the outline of a heart (♡) next to the food.

5. To change the name of the food on the MY FOODS list:

   a. Tap the checkmark next to Keep existing name. The checkmark disappears.

50+	✳ ▼ 100% 🔋 2:31 PM

✕ corn

My Foods: Adding favorites

White Sweet Corn, raw

☑ Keep existing name

Quantity   Servings
1   ear [4 oz with cob, 6" lo.. ▾

+ Create New Meal

Tags

| Breakfast | Lunch | Dinner | Snack |
| Beverage | Custom | Meal | |

CLOSE   ♥ SAVE TO MY FOODS
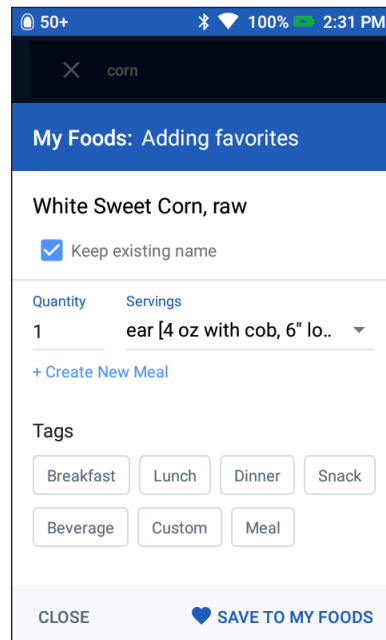
   b. Tap Enter New Name and type in a descriptive name. Tap the checkmark on the keypad.

6. Optional: Tap Quantity to specify how many portions of the food you will eat.

7. If the food has multiple serving sizes, tap Servings to specify the serving size and measurement units.

8. Optional: To help locate the food in the future, tap one or more tags. Swipe up as necessary to view the tags. Tap a tag again to deselect it.

9. Tap SAVE TO MY FOODS. The food is marked with a solid heart (♥) indicating that the food is a "favorite" and appears in both the BROWSE and MY FOODS lists.

Create a meal by combining foods from the BROWSE list

To combine two or more foods into a meal on the MY FOODS list, you must first create a new meal containing only one food. Once you have an existing meal, you can add additional foods to that meal.

To create a new meal or to add foods to an existing meal:

1. Navigate to the BROWSE list:

    Menu icon (☰) > Food Library

2. Tap the BROWSE list.

3. On the BROWSE list, locate the first food you would like to add to the meal (see "Search for a food on the BROWSE list" on page 69).

4. Tap the outline of a heart (♡) next to the food.

5. Optional: Tap Quantity to specify how many portions of the food you will eat.

6. If the food has multiple serving sizes, tap Servings to specify the serving size and measurement units.

7. To create a new meal:

    a. Tap Create a new meal.

    b. Tap the Create A New Meal field. Type in a descriptive name for the meal. Tap the checkmark when finished.

    c. Optional: Add one or more tags to help you find the food in the future.

    d. Tap SAVE TO MY FOODS to save this new meal.

        The food is marked with a solid heart (♥) indicating that the food is a "favorite" and was added to the MY FOODS list.

8. To add a new food to an existing meal:

    a. Repeat steps 1 - 6 above.

    b. Tap the Add To A Meal (optional) field and tap the name of the desired meal.

    c. Optional: Add one or more tags to help you find the food in the future.

    d. Tap SAVE TO MY FOODS to add the food to the meal.

    e. Repeat this step to add additional food items to the meal.

Note: The food items that make up the meal are shown immediately below the meal in the MY FOODS list. To remove a food item from a meal, see "Removing foods from the MY FOODS list" on page 73.

Create a custom food

Use the custom food feature to add carb information about any food.

To add a custom food:

1. Navigate to the MY FOODS list:
    Menu icon (≡) > Food Library

2. Tap the MY FOODS list.

3. Tap Add custom foods.

4. Tap the Food Title field and type in a descriptive name for your custom food.

5. Tap the Carbs field and enter the total number of carbs for the food item(s).

6. Optional: Tap the Fiber field and enter the amount of fiber for the food item.

    Note: Consult your healthcare provider about how to enter the carbs and fiber values. The Bolus Calculator does not subtract fiber from the carb value.

7. To add one or more tags to your custom food, tap the desired tags.

    Note: You may need to swipe up to see additional tags. The Custom tag is automatically added to a custom food. Tap any selected tag to remove it.

    Tip: *Tags are a quick way to filter your MY FOODS list. Select multiple tags for any foods that belong to more than one food category.*

8. To create a different custom food, tap ADD ANOTHER ITEM. Swipe up to see a new set of name and carb fields. Repeat the preceding steps.

9. When done, tap SAVE TO MY FOODS. Your custom foods are displayed on the MY FOODS list for quick access in the future.

Removing foods from the MY FOODS list

To delete a food or meal from the MY FOODS list:

1. Navigate to the MY FOODS list:
    Menu icon (☰) > Food Library

2. Tap the MY FOODS list.

3. Tap EDIT.

4. Locate the food or meal you would like to remove, and tap the red x (⊗) next to its name.

5. Tap YES to remove the food item from MY FOODS.

If the food was originally added from the BROWSE list, it remains listed on the BROWSE list with an open heart icon (♡).

If a deleted food is also part of a meal, deleting the individual food also deletes the food from that meal and subtracts the carbs from the meal's total carbs.

Note: When on the BROWSE list, if you tap the filled heart icon (♥) and tap YES, the icon changes to an open heart (♡). That food is removed from the MY FOODS list. If the food is also part of a meal on the MY FOODS list, this action also removes the food from the meal and subtracts the food's carbs from a meal's total carbs.

Note: You cannot delete or edit foods listed on the BROWSE list.
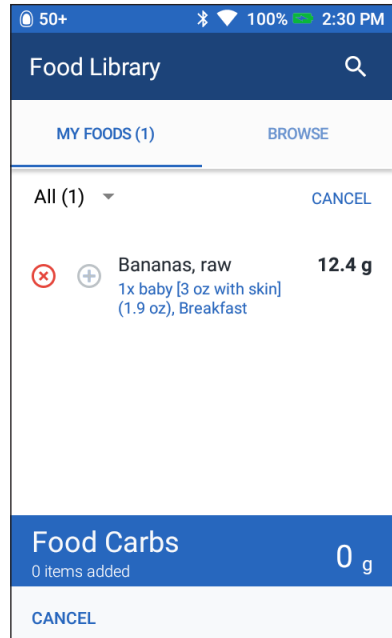
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CHAPTER 6
Modifying Basal Insulin Delivery

This chapter describes how to modify your basal insulin delivery by using temporary basal rates or by switching to a different Basal Program (see "Temporary basal rates" on page 151).

To create a new Basal Program, see page 81. To edit an existing Basal Program, see page 83.

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. When a temp basal ends, the PDM automatically reverts to delivering the scheduled Basal Program.

You cannot activate or cancel a temp basal during an immediate bolus, but you can activate or cancel a temp basal while an extended bolus is running.

To create a temp basal preset for a frequently used temp basal, see "Create a new temp basal preset" on page 85.

To activate a temp basal preset, see "Activate a temp basal preset" on page 77.

Tip: *By default, the PDM or Pod sounds a tone at the beginning and end of a temp basal and every 60 minutes while a temp basal is running. To turn these on or off, see "Informational Signals List" on page 131.*

Activate a temp basal

You can only activate a temp basal if the temp basal setting is on. To turn on the temp basal setting, see "Temp basal" on page 116.

To define and activate a temp basal:

1. Navigate to: **Menu icon** (☰) > **Set Temp Basal**.

    The screen shows a graph of the active Basal Program.

    Note: To activate a temp basal preset, tap **SELECT FROM PRESETS** and go to step 2 of "Activate a temp basal preset" on page 77.

2. Tap the Basal Rate field and enter the desired change in the basal rate:

   - If temp basals are configured as a percent (%) change, scroll the wheel up or down to define the percent change to the active Basal Program. An up arrow indicates increasing the basal rate above that of the active Basal Program. A down arrow indicates decreasing the basal rate below that of the active Basal Program.

   - If temp basals are configured as a flat rate (U/hr), scroll the wheel to select the basal rate for the entire temp basal period.

   To change whether temp basals are configured as percent (%) or U/hr, see "Temp basal" on page 116.
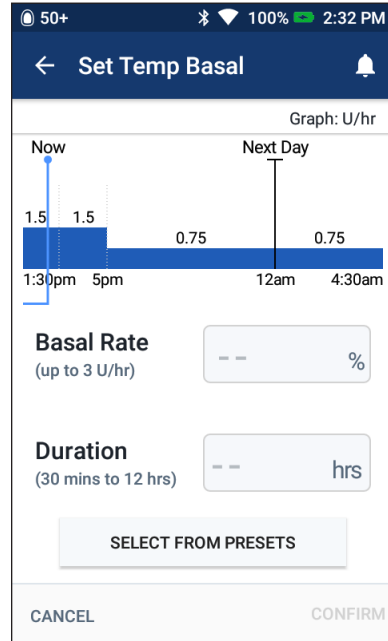
   Note: The scroll wheel will not scroll above your Maximum Basal Rate. To adjust your Maximum Basal Rate, see "Maximum Basal Rate" on page 116.

   Tip: *You can turn off insulin delivery for the duration of the temp basal by setting a decrease of 100% or setting the temp basal to 0 U/hr. For more information, see "Temp basal limitations" on page 153 and "Methods to temporarily stop insulin delivery" on page 154.*

3. Tap the Duration field and enter the temp basal duration (between 30 minutes and 12 hours).

   Examine the temp basal graph at the top of the screen. The proposed temp basal is superimposed on the active Basal Program.

   - The lighter blue shaded area shows the proposed temp basal rate for each segment.

   - If you set a decrease, the active Basal Program is shown as a dotted line.

4. Tap CONFIRM to continue.

5. Review the temp basal details. If corrections are needed, tap on the row that you would like to change. Then enter your corrections and confirm them.

   Note: If necessary, the PDM limits the basal rate of any segment that would exceed your Maximum Basal Rate setting. This is indicated by a red line on the graph and the word "Max."

6. To activate the temp basal, tap ACTIVATE. Then tap ACTIVATE again.

After activation, the Home screen's Basal tab, renamed Temp Basal, indicates that the temp basal is running and how much time remains. At the end of the temp basal time period, the Pod automatically resumes the active Basal Program.

Activate a temp basal preset

A temp basal preset stores the details of a temp basal that you use frequently. To create or modify a temp basal preset, see "Temp Basal Presets" on page 85.

To activate a temp basal preset:

1. Navigate to:

    Menu icon (☰) > Temp Basal Presets

2. Swipe to scroll up or down, and tap the temp basal preset you want to activate.

    Note: Tap EDIT if you want to modify the preset.

3. To activate the temp basal, tap ACTIVATE, and then tap ACTIVATE again.

Cancel a temp basal

A temp basal stops automatically at the end of its time period and the last active Basal Program resumes. To cancel a temp basal before the end of its time period:

1. Navigate to the Home screen's Temp Basal tab.

2. Tap CANCEL.

3. Tap YES to confirm cancellation. The PDM cancels the temp basal and resumes the active Basal Program.
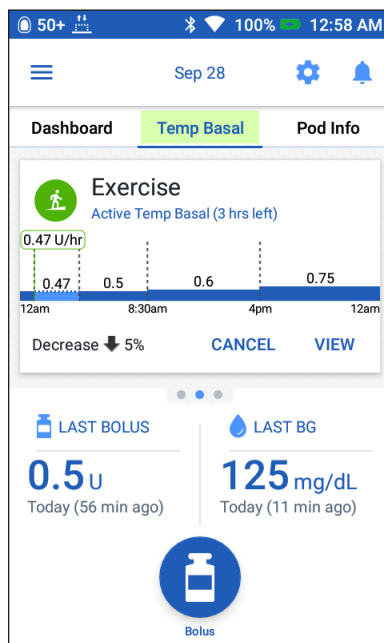
Switching to a Different Basal Program

Different days can have different routines. The PDM lets you create different Basal Programs for your different routines. For example, you may use one Basal Program on weekdays and a different one on weekends.

To create, edit, or delete a Basal Program, see "Basal Programs" on page 81.

To switch to a different Basal Program:

1. Navigate to: Menu icon (☰) > Basal Programs.

    A list of Basal Programs appears with the current Basal Program at the top.

2. Select a different Basal Program in one of the following ways:

    -   To see a graph of an inactive Basal Program prior to activating it, tap on the name of that Basal Program. Then tap ACTIVATE.

        Tip: *Double-tap the graph to see an expanded view of the Basal Program. Swipe horizontally to view basal rates for later or earlier times.*

    -   Tap the Options icon (⁝) to the right of an inactive Basal Program, then tap Activate.

3. Tap ACTIVATE again to replace the current Basal Program with the newly selected one.

Note: You must cancel a running temp basal prior to switching to a different Basal Program (see "Cancel a temp basal" on page 77). You can, however, switch Basal Programs when an extended bolus is running.

Note: If one or more segments are set to deliver 0 U/hr, the PDM notifies you that insulin delivery will stop during those segments.

Suspending and Resuming 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 DASH® System lets you suspend all insulin delivery for up to two hours.

For the difference between stopping insulin delivery using the suspend feature or the temp basal feature, see "Methods to temporarily stop insulin delivery" on page 154.

Suspend insulin delivery

To suspend insulin delivery:

1. Navigate to: Menu icon (☰) > Suspend Insulin.

2. Tap the Suspend Insulin for field. Scroll the scroll wheel to specify the duration of insulin suspension. The suspension can last 30 minutes, 1 hour, 1.5 hours, or 2 hours.

3. Tap SUSPEND INSULIN.

4. Tap YES to confirm that you want to stop all insulin delivery.

   The basal insulin delivery is suspended.

The Home screen displays a yellow banner stating that "Insulin delivery is suspended."

Note: The Pod beeps every 15 minutes throughout the suspension period. At the end of the suspension period, insulin delivery does not automatically resume. The Pod and PDM notify you every minute for three minutes, and repeat this notification every 15 minutes until you have resumed insulin delivery.

Note: Temp basals or extended bolus are automatically canceled when you suspend insulin delivery.
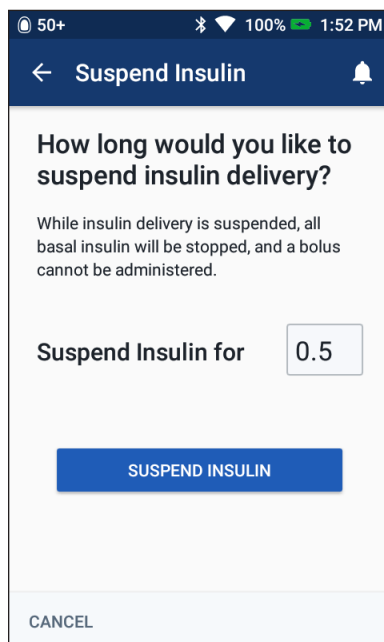
Resume insulin delivery before the suspension period ends

1. Navigate to:

   Menu icon (≡) > Resume Insulin

   or

   If the Bolus Calculator is on, tap the large circle showing the IOB on the Home screen's Dashboard tab.

2. Tap RESUME INSULIN to confirm restarting the Basal Program scheduled for the current time.

The PDM beeps to confirm that insulin delivery has resumed.
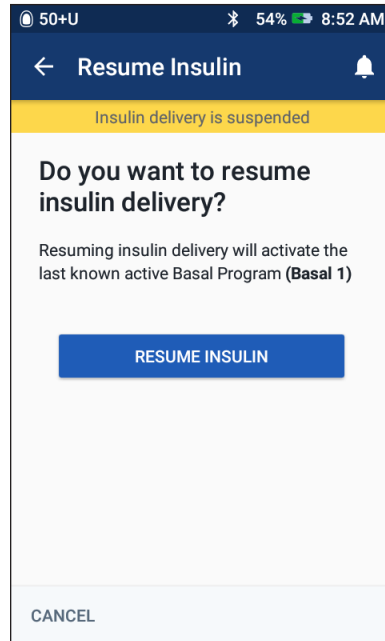
Resume insulin delivery after the suspension period ends

1. Wake up your PDM, if necessary.

2. Tap RESUME INSULIN to resume insulin delivery.

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, this screen reappears and 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 tap RESUME INSULIN to resume insulin delivery. If you do not resume insulin delivery, you could develop hyperglycemia.
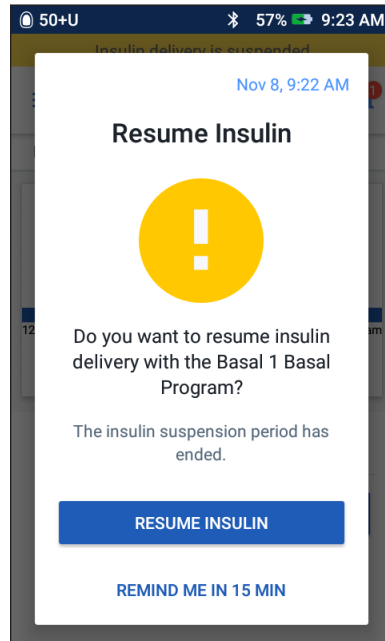
CHAPTER 7
Managing Programs and Presets

This chapter describes how to create, edit, and delete Basal Programs, temp basal presets, and bolus presets. Once set up, you can activate these quickly at a later time.

Basal Programs

You can create up to 12 Basal Programs. Each Basal Program can contain from one to 24 basal rates.

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

Create a new Basal Program

To create a new Basal Program:

1. Navigate to the Create Basal Program screen:

   Menu icon (≡) > Basal Programs

2. Tap CREATE NEW.

   Note: If you already have 12 Basal Programs, CREATE NEW does not appear. If necessary, you can delete an existing Basal Program.

3. Optional: Tap the Program Name field and enter a descriptive name for your new Basal Program. Tap the checkmark to save the name. The default name for the Basal Program is "Basal" followed by a number.

4. Optional: Tap a tag to appear next to the name of the new Basal Program. Tap a second time to deselect the tag. If you do not select a tag, a default tag is used.

5. Tap NEXT.

6. Define the basal segments one at a time. For each segment:

    a. Tap the End Time field and select the end time for the segment.

    b. Tap the Basal Rate field and select the desired basal rate for the segment.

    c. Tap NEXT.

    d. Repeat these steps until your final segment ends at midnight.

7. When your Basal Program covers 24 hours, tap CONTINUE.

8. A screen appears showing the full Basal Program as a graph and as a list. Review the Basal Program to be sure all the values are correct.

    Tip: *Double-tap the graph to see an expanded view of the Basal Program. Swipe horizontally to view basal rates for later or earlier times.*

    To edit any of the segments in the Basal Program, see steps 7-9 under "Edit or rename a Basal Program" on page 83.

9. Tap SAVE to store the new Basal Program.

10. If you have an active Pod and you want to use the new Basal Program now, tap ACTIVATE to start using the new Basal Program. If you do not want to use the new Basal Program now, tap NOT NOW.
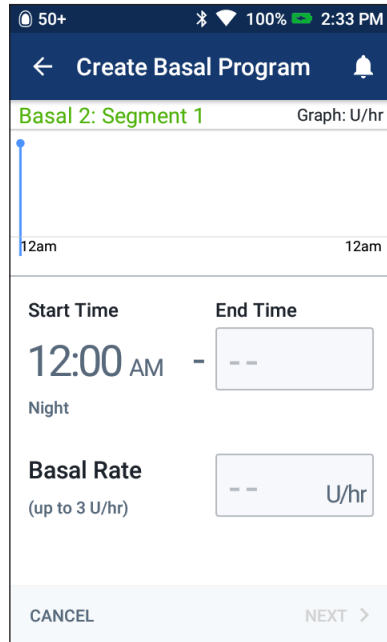
Review all Basal Programs

1. Navigate to the list of Basal Programs:

    Menu icon (☰) > Basal Programs

2. A graph of the current Basal Program is shown at the top of the screen (see "Basal tab / Temp Basal tab" on page 14 for details about the graph).

3. Swipe to scroll up or down if the list of Basal Programs is long.

4. Tap on the name of a non-active Basal Program to see its graph and basal rates. Tap outside the graph to close that graph.

Edit or rename a Basal Program

To edit or rename a Basal Program:

1. Write a list of all of the revised basal segments to guide you through re-entering the values for each segment.

   Tip: *You can write this list on the pages at the end of this User Guide.*

2. Navigate to the list of Basal Programs:

   Menu icon (☰) > Basal Programs

3. Swiping up or down as necessary, select the Basal Program to edit:

   - To edit the active Basal Program, tap EDIT beneath the graph of the active program. Then tap SUSPEND INSULIN.

   - To edit an inactive Basal Program, tap the Options icon (⋮) next to the Basal Program you would like to edit. Then tap Edit.
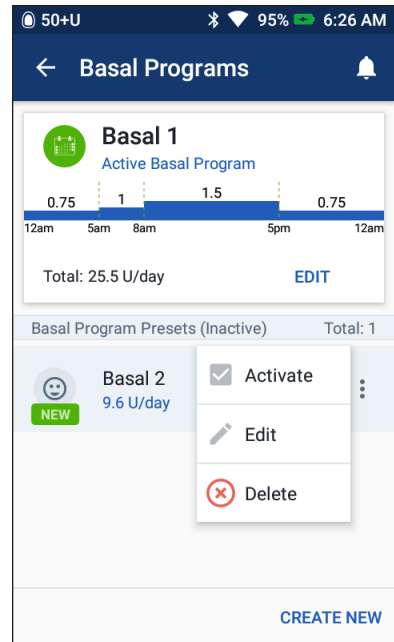
4. To rename the Basal Program, tap the Program Name field and enter the new name.

5. To change the tag, tap a different tag. Tap again to deselect a tag.

6. Tap NEXT.

7. To change an end time or basal rate for a segment:

   a. Tap the row containing the segment you would like to change.

   b. Tap the End Time field, and enter the new end time for the segment.

   c. Tap the Basal Rate field, and enter the desired basal rate.

   d. Tap NEXT.

   e. Then define the end time and basal rate for any following segments, as needed.

8. To add a new segment:

   a. Tap the row containing the start time of the new segment.

   b. Tap the End Time field, and enter the start time of the new segment as the end time of this segment.

   c. Change the basal rate, if necessary.

   d. Tap NEXT.

   e. Then define the end time and basal rate for any following segments, as needed.

9. To delete a segment:

   a. Note the end time of the segment you want to delete.

   b. Tap the segment that <u>precedes</u> the segment you want to delete.

   c. Tap the End Time field, and enter the end time of the segment you want to delete. This 'overwrites' the segment you want to delete.

   d. Tap NEXT.

   e. Then define the end time and basal rate for any following segments, as needed.

10. When the Basal Program is correct, tap SAVE.

11. To activate the newly edited Basal Program:

    - If you edited the current Basal Program, tap RESUME INSULIN.

    - If you edited an inactive Basal Program and you have an active Pod, tap ACTIVATE.

12. If you do not want to activate this Basal Program, tap NOT NOW.

Delete a Basal Program

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

1. Navigate to the list of Basal Programs:

    Menu icon (☰) > Basal Programs

2. Tap the Options icon (⋮) next to the Basal Program you want to delete.

3. Tap Delete.

4. Tap DELETE to confirm deletion of the Basal Program.

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 page 77. To turn on or off the ability to activate temp basals, or to change between specifying the temp basal as a percentage or in U/hr, see page 116. You can create up to 12 temp basal presets.

Create a new temp basal preset

To create a new temp basal preset:

1. Navigate to the Temp Basal Presets screen:

    Menu icon (☰) > Temp Basal Presets

2. Tap CREATE NEW.

    Note: If you already have 12 temp basal presets, CREATE NEW does not appear. If necessary, you can delete an existing preset.

3. Optional: Tap the Preset Name field and enter a descriptive name for your preset. The default name for the preset is "Temp Basal Presets" followed by a number.

4. Optional: Tap a tag to appear next to the name of the new preset. Tap a second time to deselect the tag. If you do not select a tag, a default tag is used.

5.   Tap NEXT.

6.   Tap the Basal Rate field and scroll to the desired value.

7.   Tap the Duration field and enter a duration for the preset. The temporary change to the Basal Program is shown on the graph.

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

8.   Tap CONFIRM.

9.   Tap SAVE to save this as a temp basal preset.

10. If you would like to start this temp basal now, tap ACTIVATE. Otherwise, tap NOT NOW. This choice does not appear if a temp basal is already running.
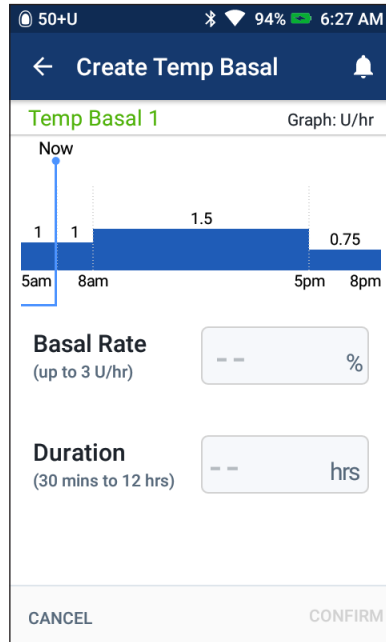
Edit or rename a temp basal preset

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

1.   Navigate to the Temp Basal Presets screen:

     Menu icon (≡) > Temp Basal Presets

2.   Swipe up or down as needed to find the preset that you want to edit. Then tap the Options icon (⋮) and tap Edit.

3.   To rename the preset, tap the Preset Name field and enter the new name.

4.   To change the tag, tap a different tag. Tap again to deselect a tag.

5.   Tap NEXT.

6.   Change the basal rate and duration as desired.

7.   Tap CONFIRM.

8.   Tap SAVE to save your changes.

9.   If you would like to start this temp basal now, tap ACTIVATE. Otherwise, tap NOT NOW. This choice does not appear if a temp basal is already running.

Delete a temp basal preset

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

To delete a temp basal preset:

1. Navigate to the Temp Basal Presets screen:

    Menu icon (≡) > Temp Basal Presets

2. Tap the Options icon (⋮) next to the preset you want to delete.

3. Tap Delete.

4. Tap DELETE to confirm deletion of the preset.

Bolus Presets

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

A bolus preset stores the units of insulin in a bolus. You can choose to extend some or all of the bolus preset 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

To create a new bolus preset:

1. Navigate to the Bolus Presets screen:

    On the Home screen, tap the Bolus button (💉)

    or

    Menu icon (≡) > Bolus Presets

2. Tap SELECT FROM PRESET.

3. Tap CREATE NEW.

    Note: If you already have seven bolus presets, CREATE NEW does not appear. If necessary, you can delete an existing preset.

4. Optional: Tap the Preset Name field and enter a descriptive name for your preset. The default name for the preset is "Bolus Preset" followed by a number.
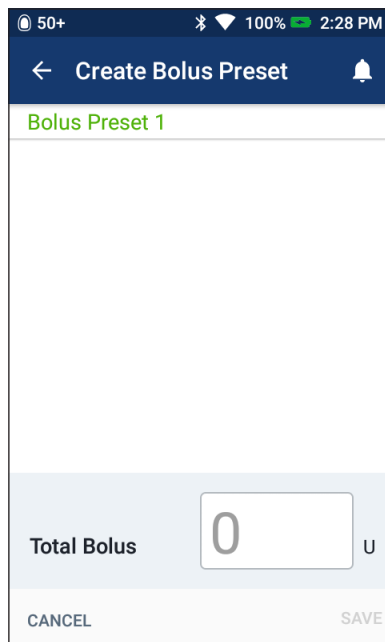
5. Optional: Tap a tag to appear next to the name of the new preset. Tap a second time to deselect the tag. If you do not select a tag, a default tag is used.

6. Tap NEXT.

7. Tap the Total Bolus field and enter the units of insulin for the bolus preset.

8. Tap SAVE to save the new bolus preset.

Edit or rename a bolus preset

To edit or rename a bolus preset:

1. Navigate to the Bolus Presets screen:

   Menu icon (☰) > Bolus Presets

2. Tap the Options icon (⋮) next to the name of the preset you want to edit.

3. Tap Edit.

4. To rename the preset, tap the Preset Name field and enter the new name.

5. To change the tag, tap a different tag. Tap again to deselect a tag.

6. Tap NEXT.

7. To change the bolus amount, tap the Total Bolus field and enter the units of insulin.

8. Tap SAVE to save your changes.

Delete a bolus preset

To delete a bolus preset:

1. Navigate to the Bolus Presets screen:

   Menu icon (☰) > Bolus Presets

2. Tap the Options icon (⋮) next to the name of the preset you want to delete.

3. Tap Delete.

4. Tap DELETE to confirm deletion of the preset.

CHAPTER 8
Browsing Your PDM Records

Your PDM records are displayed on:

- Notifications & Alarms screens

- Insulin & BG History screens, which show insulin, blood glucose, carbohydrate, and Pod events

The PDM can store 90 days of history records. 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 stored in the PDM is preserved if the PDM battery runs out. You may need to reset the date and time, but PDM records are unaffected.

Notifications & Alarms Screens

To review past alarms and notifications:

1. Tap the bell icon (🔔) found in the upper right of many screens. If you have new notifications, the number of new notifications appears in a red circle next to the bell icon (🔔4).

   Note: Alternatively, navigate to: Menu icon (☰) > History : Notifications & Alarms.

2. Messages from today are displayed first, followed by messages from previous days. Swipe up to see additional messages.

3. To display a specific date range, tap FILTER BY DATE.

   a. Tap the starting date on the calendar. Tap the "<" arrow to view an earlier month.

   b. Tap END at the top of the screen.

   c. Tap the ending date for the time range.

   d. Tap OK.

4.   When finished, tap the back arrow (⬅) in the upper left of the screen.

New notifications have a blue icon (🕐). When a notification has been displayed on this screen and you have exited by tapping the back arrow (⬅), the icon will be gray (🕐) the next time you view this screen.

For a description of the alarms and notifications, see page 121.

Overview of the Insulin and BG History Screens

To access your insulin and blood glucose records, navigate to:

Menu icon (☰) > History : Insulin & BG History

You have the option of viewing records for one day or for multiple days.

One day

	BG mg/dL	Bolus U	Carbs g
6:23 am	150	2.50	60
6:23 am	150		
6:22 am	118		
6:19 am	Extended Bolus delivered: 2.40 U over 0.5 hrs		
5:40 am	Extended Bolus started:		

One day screen summary:

- Current BG Goal Range: 70 to 140 mg/dL
- Today, September 27
- Row 1: 130 mg/dL (Average BG), 33% (BGs in Range), 67% (BGs Above), 0% (BGs Below)
- Row 2: 3 (Total BGs), 150 mg/dL (Highest BG), 90 mg/dL (Lowest BG)
- Insulin & Carbs — Row 3: 5.9 U (Total Insulin), 15% 0.9 U (Basal Insulin), 85% 5 U (Bolus Insulin), 60 g (Total Carbs)

Multiple days

- January 18 - 24
- Current BG Goal Range: 70 to 140 mg/dL
- Row 1: 137 mg/dL (Average BG), 64% (BGs in Range), 30% (BGs Above), 6% (BGs Below)
- Row 2: 4 (Avg Readings per Day), 28 (Total Number of BG Readings), 369 mg/dL (Highest BG), 64 mg/dL (Lowest BG)
- Insulin & Carbs — Row 3: 23.4 U (Average Total Insulin), 48% 11.23 U (Average Basal Insulin), 52% 12.17 U (Average Bolus Insulin), 163 g (Average Total Carbs)

	BGs in Range %	Total Insulin U	Total Carbs g
Jan 24	50	14.3	120
Jan 23	100	23	132
Jan 22	100	20.35	220
Jan 21	86	30.5	146
Jan 20	67	19	186

Left margin labels:
- Date selection
- Summary section
  - Row 1
  - Row 2
  - Row 3
- Details section
- Swipe up to see the Details section

Date Selection

When you first access the History screens, information from the current day is displayed. You can view records from a different day or a range of dates.

Previous date arrow (single day view only) — `< | History | 1 Day |` — Date range selector

`< Today, September 27` — Date(s) being displayed

[screen shows: 50+ 100% 2:32 PM]
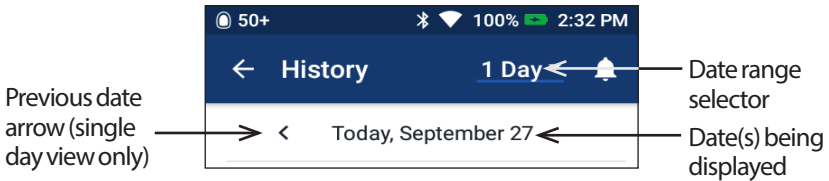
One day

To view records from today or a recent day:

1. Navigate to: Menu icon (≡) > History : Insulin & BG History.

   Today's history records are displayed.

2. To view a recent date, tap the previous date arrow (<).

3. To move forward in time, tap the next date arrow (>). This arrow is not visible when today's records are displayed.

Range of days

To view records from a range of dates, or to quickly find a day from weeks or months ago:

1. Navigate to: Menu icon (≡) > History : Insulin & BG History.

2. Tap the date range selector.

3. Choose 1, 7, 14, 30, 60 or 90 days to select the number of days to display. Select a larger number to display older data.

   The multi-day screen appears showing the selected range of dates.

4. To see details for a single day in the date range:

   a. Swipe up to see the details section of the multi-day screen.

   b. Tap the desired date to view its one-day history screen.

   The one day History screen for that date appears.

Summary Section

The upper section of the History screens summarizes the records for the day or date range.

Summary item	Description
Row 1 (see page 90)	
Current BG Goal Range	Lower limit and upper limit of your BG Goal Range.
Average BG	The average of all blood glucose readings, including readings from a paired BG meter and manually-entered readings. LO and HI blood glucose readings are excluded.
BG in Range	Percentage of blood glucose readings within your BG Goal Range.
BGs Above	Percentage of blood glucose readings above the upper limit of your BG Goal Range.
BGs Below	Percentage of blood glucose readings below the lower limit of your BG Goal Range.
Row 2 (see page 90)	
Avg Readings per Day	Average number of blood glucose readings per day. **Note:** Appears in multiple day view only.
Total Number of BG Readings	Total number of blood glucose readings in the day (or date range).
Highest BG	Highest blood glucose reading in the day (or date range).
Lowest BG	Lowest blood glucose reading in the day (or date range).

Summary item	Description
Row 3 (see page 90)	
Total Insulin Average Total Insulin	Total insulin (basal + bolus) delivered for the day or average total insulin delivered for the date range.
Basal Insulin Average Basal Insulin	Amount of basal insulin delivered for the day or average delivered for the date range. This includes insulin delivered by the Basal Program, adjusted for temp basals, periods of insulin suspension, and Pod deactivation. Shown as a percent of the total (or average total insulin). Also shown in units.
Bolus Insulin Average Bolus Insulin	Amount of insulin delivered via boluses for the day or average for the date range. This includes boluses calculated by the Bolus Calculator and any manually-calculated boluses. Shown as a percent of the total (or average total insulin). Also shown in units. If you cancel a bolus before it has completed, only the amount actually delivered is included.
Total Carbs Average Total Carbs	Sum of all meal carbohydrates (in grams) entered into the Bolus Calculator for the day or average for the date range.

Note: If the PDM has not received confirmation from the Pod that the basal, bolus, or total insulin delivery finished, the summary circles include a gray or yellow exclamation point similar to the ones shown in "When the Pod has not confirmed bolus delivery" on page 97.

Note: Percentages may not add to 100 due to rounding.

For the summary calculations, see page 171.

Details Section

Swipe up on the history screens to see the details section.

One day view

The details section of the one day History screen shows individual records listed by time of day.

BG, Bolus and Carbs column headings →

Tap a down arrow to display more details. Tap again to hide the details.

Banners indicate PDM or Pod events that continue until a change is signaled on a new banner. →

Swipe to see more records.

Today, January 17			
	BG mg/dL	Bolus U	Carbs g
6:23 am	150	2.50	60
6:23 am	150		
6:22 am	118		
6:19 am	Extended Bolus delivered: 2.40 U over 0.5 hrs		
5:49 am	Extended Bolus started: 2.40 U over 0.5 hrs		
5:47 am	150	5	60
5:47 am	150		

Multiple day view

The details section of the multiple day History screens list the individual days in the selected range. The columns show the percent (%) of blood glucose readings within the BG Goal Range, the total daily insulin delivered, and the total daily grams of carbs.

Tap a row to view its one day History screen. →

Swipe to see more records.

	BGs in Range %	Total Insulin U	Total Carbs g
Jan 24	50	14.3	120
Jan 23	100	23	132
Jan 22	100	20.35	220

Blood glucose details

The icon displayed with a blood glucose entry indicates the source of the blood glucose reading and whether the blood glucose reading was in range. The blood glucose icons are:

	Paired BG meter	Manual BG entry
Above BG Goal Range		
Within BG Goal Range		
Below BG Goal Range		

Tapping a row with a blood glucose reading expands the row to show any applied tags and whether the blood glucose reading was from a paired BG meter or was entered manually.

If a control solution reading was imported from a paired BG meter or tagged as a control reading, the words "control solution" appear next to the reading. These control readings are not included in the blood glucose summaries.

Bolus details

The icon displayed with a bolus entry indicates whether the Bolus Calculator was used:

- The insulin bottle icon ( ) indicates that the Bolus Calculator was enabled.
- The syringe icon ( ) indicates the Bolus Calculator was disabled or off.

Immediate and extended boluses

The bolus amount listed next to the bolus icon is the sum of an immediate bolus plus any extended portion of the bolus. If you canceled an immediate or extended bolus, the amount listed is the amount that was actually delivered.

Tapping a row with a bolus entry brings up additional details about the bolus, including:

- Whether the bolus was calculated by the Bolus Calculator or was a manually-calculated bolus.

- The name of the bolus preset, if used.

- The VIEW BOLUS CALCULATIONS button if the Bolus Calculator was used. Tapping this button brings up a screen showing calculation details and whether you made a manual adjustment to the calculated bolus.

  You may need to swipe up or down to see all of the calculations. Tap CLOSE when done (see "Bolus Calculator equations" on page 162 for details).

- If you canceled an immediate bolus, the amount originally scheduled for delivery.

- For an extended bolus, the amount delivered now and extended. Also the percentage (%) of the meal bolus delivered now and extended.

- If a bolus is ongoing, unconfirmed, or lost, how much of the bolus has been confirmed.
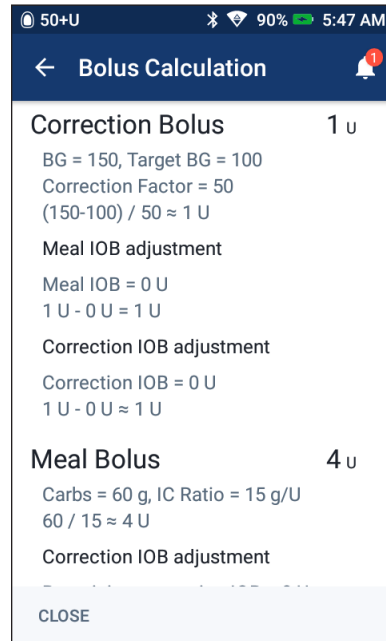
Extended bolus events

A bolus icon and banner indicate an extended bolus event:

- An Extended Bolus started banner marks the time when the immediate bolus has finished and the extended bolus begins. In addition to the start time of the bolus, the banner lists the number of units extended and the duration of the extension.

- An Extended Bolus completed banner marks the end of the extended bolus.

- An Extended Bolus canceled banner marks the cancellation of an extended bolus and states the amount of the bolus that was actually delivered.
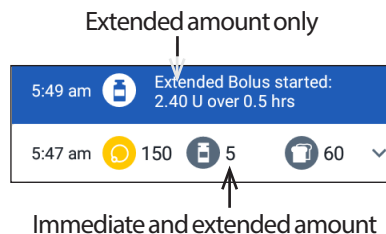
When the Pod has not confirmed bolus delivery

After you confirm the amount of a bolus that you want delivered, a bolus instruction is sent to your Pod. When the Pod completes delivery, it sends a confirmation to the PDM that the bolus was delivered.

Before the PDM receives confirmation from the Pod that the bolus has been delivered, the PDM estimates the amount delivered. During this time, the History screens use a gray exclamation icon to indicate that the bolus is estimated.

In most cases, once a PDM and Pod are back in range, the Pod confirms the bolus delivery. However, in rare cases, the Pod is unable to confirm bolus delivery due to a communication error. If you tap the DISCARD POD option in this situation, the History screens use a yellow exclamation icon to mark the bolus as "unconfirmed."

If a Pod is discarded with an unconfirmed bolus, the basal and total insulin amounts for that day are also marked as unconfirmed with a yellow exclamation icon. The listed bolus amount includes the amount that was scheduled for delivery up until the Pod was discarded.

Carbs details

A carbs icon ( ) is displayed next to carbohydrate entries used by the Bolus Calculator. Tapping the row displays a note about whether the carbs were from the Food Library or entered manually.

Basal rate details

Basal Programs

A Basal Program icon and banner indicate the activation of a Basal Program and the reactivation of a Basal Program at the end of a temp basal or insulin suspension.

Temp basals

A temp basal icon and banner indicate the start, end, or cancellation of a temp basal.

If a temp basal was defined as a percent (%) of the active Basal Program, the banner displays the percent increase or decrease as well as the duration. If a temp basal was defined as a flat basal rate (U/hr), the banner displays the temp basal rate and the duration.

If a temp basal preset was used, the banner displays the name of the preset.

Tapping a Temp Basal started banner displays a graph and a list of basal rates associated with each time segment.

If a temp basal was canceled, the Temp Basal started banner contains the initially scheduled duration and the Temp Basal canceled banner contains the actual duration.

Basal rate at midnight

The first entry for each day is a banner displaying the status of the basal insulin delivery at midnight. If a Basal Program or temp basal was carried over from the day before, the banner indicates that this is a continued program. If insulin was suspended at midnight, the banner states this.

Pod details

A Pod icon and banner mark the activation and deactivation (or discarding) of each Pod. Tapping a Pod banner displays the Pod's lot number and sequence number.

Insulin suspended and resumed details

An Insulin Delivery Suspended icon and banner indicate the time that an insulin suspension began.

An Insulin Delivery Resumed icon and banner indicate the time that insulin delivery was restarted after a suspension.

Time change details

A Time Change banner appears if you change the time setting. A Time zone changed banner appears if you change the time zone.

The records below the banner show the old time and the records above the banner show the new time.

Date change details

A DATE CHANGED banner appears if you change the date setting.

When the date is changed, two History screens are created for the current day. One screen shows the old date with the history records from midnight up to the time of the date change. The second screen shows the new date with the history records from the time of the date change up to the following midnight.

CHAPTER 9
Adjusting Settings

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

Many settings use toggles to turn settings on or off. When the button is blue and on the right side, the setting is on. When the button is gray and on the left, the setting is off. Tapping anywhere on the button toggles it between the left and right sides.

You can see an on-screen description of some settings by tapping the name of the setting. If a description is available, the screen expands to show the information. Tap the setting name again to hide the description.

Note: Some settings have default values, but all user settings can be changed.

PDM Device Settings

The PDM Device settings allow you to control network connectivity, your personal identification settings, date and time, and other general device settings.

Network connectivity

These settings turn airplane mode or Wi-Fi on or off, and let you connect to Wi-Fi networks or BG meters. The Wi-Fi and airplane mode setting are always adjusted at the same time: When you turn airplane mode on, the PDM automatically turns Wi-Fi off. When you turn Wi-Fi on, the PDM automatically turns airplane mode off.

Bluetooth® wireless technology is always on whether the PDM is awake or asleep. Airplane mode does not turn the Bluetooth® setting off.

Airplane mode

There are two methods for toggling airplane mode on or off. Both methods toggle Wi-Fi, but leave the Bluetooth® setting on.

- To turn airplane mode on or off via the PDM Settings:
    a. Navigate to: Settings icon (⚙) > PDM Device.
    b. Tap the Airplane Mode toggle to turn airplane mode on or off.

- To turn airplane mode on or off via the Power button:

  a. Press and hold the Power button until a screen appears with an Airplane Mode option.

  b. Tap Airplane Mode to toggle between on and off.

Wi-Fi

To manage the PDM's Wi-Fi connection:

1. Navigate to: Settings icon (⚙) > PDM Device > Wi-Fi.

2. Tap the toggle to toggle Wi-Fi on or off. When the Wi-Fi toggle is set to on, the PDM scans for available Wi-Fi networks.

3. To connect to or remove a Wi-Fi network, tap Wi-Fi to display a list of available Wi-Fi networks. Then:

   - To connect to a new network, tap the name of the desired network. Enter the network password, if necessary.

   - To remove a network, tap the name of the network. Then tap FORGET.

4. Tap the "back" button below the PDM screen when finished.

Note: The PDM can only connect to standard Wi-Fi networks, which are networks that only require a name and a password. The PDM cannot connect to Wi-Fi networks that require additional steps such as accepting Terms and Conditions.

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

Bluetooth®

This option lets you pair to, rename, or remove a BG meter. These actions are described in "Pairing, unpairing, or renaming a BG meter" on page 114.

Omnipod DISPLAY®

The Omnipod DISPLAY® app is a smartphone application that lets you see your PDM data on your phone. The PDM and phone use Bluetooth® wireless technology to communicate.

Note: While pairing to the Omnipod DISPLAY® app, the PDM does not check Pod status.

To pair your PDM to Omnipod DISPLAY® on your phone:

1. Place your PDM and phone next to each other.

2. On your phone:

   a. Download and install the Omnipod DISPLAY® application or unpair from an older PDM.

      b.   Follow the on-screen instructions until you get to the pairing screen.

      c.   Make sure that the Bluetooth® setting is on.

      d.   Tap Next.

3.   On your PDM:

      a.   Navigate to: Settings icon (⚙) > PDM Device > Omnipod DISPLAY®.

      b.   If your PDM is already paired to an Omnipod DISPLAY® on one phone and you want to pair to a different phone, tap UNPAIR, then tap UNPAIR again.

      c.   Tap GET STARTED.

      A confirmation code appears on the PDM and the phone.

4.   If the confirmation code on your PDM and phone match:

      a.   On your phone, tap YES. The phone pairs to the PDM.

      b.   On your PDM, after your PDM and phone successfully pair, tap OK.

For information about using Omnipod DISPLAY®, see the *Omnipod DISPLAY® User Guide*.

Screen display

Use the screen display settings to control the screen time-out and brightness.

Screen time-out

To preserve battery power, the PDM screen turns black if you have not used it for the specified time interval. To change the time interval:

1.   Navigate to: Settings icon (⚙) > PDM Device > Screen Time-Out.

2.   Tap a screen time-out interval to select it.

    Tip: *A shorter time-out interval extends the battery charge.*

3.   Tap SAVE.

Screen brightness

To adjust the brightness of the PDM screen:

1.   Navigate to: Settings icon (⚙) > PDM Device > Brightness.

2.   Place your finger on the blue dot of the slider. Slide your finger to the right to increase the screen brightness. Slide your finger to the left to decrease the screen brightness.

    Tip: *Lower screen brightness extends the battery charge.*

Lock screen

You can edit your Lock screen message, background image, and your PIN. The lock screen message, image, and PIN help ensure that you are using the correct PDM.

Lock screen message

To change your Lock screen message:

1. Navigate to: Settings icon (⚙) > PDM Device > Message.

2. Tap the Lock screen message field and enter the message you want the PDM to display when you turn it on.

3. Tap SAVE.

Lock screen background

To change the background image on the Lock screen:

1. Navigate to: Settings icon (⚙) > PDM Device > Background.

2. Tap the background image you want to use.

3. Tap SAVE.

PIN

To change your personal identification number or PIN:

1. Navigate to: Settings icon (⚙) > PDM Device > PIN.

2. Enter your current PIN.

3. Enter the new four-digit PIN.

   Tip: *Tap the eye icon to display or hide the PIN numbers.*

4. Tap the checkmark to accept the PIN.

5. Re-enter the new PIN, and then tap the checkmark.

Date and time, and language

You may need to reset the date and time to adjust for daylight-savings time or changing time zones or when you replace the PDM's battery. The PDM does not automatically adjust time, date, or time zone. If you are traveling to a different time zone, see "Plan for changing time zones" on page 176.

If you do change the date or time, the change is noted on the Home and History screens. The Pod expiration time on the Pod Info tab is adjusted to reflect the new date and time.

You can also change the language used on the PDM screens.

Date and date format

To change the date:

1. If you have a paired BG meter, sync your BG meter to import any recent blood glucose readings:

    Menu icon (☰) > Enter BG > SYNC BG METER

2. Navigate to: Settings icon (⚙) > PDM Device > Date.

3. To change the date format, tap the upper box with the date format and select the desired date format.

4. To change the date:

    a. If you have an active Pod, tap SUSPEND INSULIN and tap YES.

    b. Scroll the Month, Day, or Year fields to the desired values.

5. Tap SAVE, then tap CONFIRM.

6. If you suspended insulin, tap YES to resume insulin delivery.

7. If you changed the date and have a paired BG meter, sync your BG meter:

    Menu icon (☰) > Enter BG > SYNC BG METER.

    The PDM updates the date on your BG meter. This ensures that future blood glucose readings are marked with the correct date.

Time zone

To change the time zone:

1. If you have a paired BG meter, sync your BG meter to import any recent blood glucose readings:

    Menu icon (☰) > Enter BG > SYNC BG METER

2. Navigate to: Settings icon (⚙) > PDM Device > Time Zone.

3. If you have an active Pod, tap SUSPEND INSULIN and tap YES.

4. Tap the time zone field and select the desired time zone from the drop-down list.

5. Tap SAVE, then tap CONFIRM.

    The PDM changes the time to match the new time zone.

6. If you suspended insulin, tap YES to resume insulin delivery.

7. If you changed the time zone and have a paired BG meter, sync your BG meter: Menu icon (☰) > Enter BG > SYNC BG METER.

    The PDM updates the time on your BG meter. This ensures that future blood glucose readings are marked with the correct time.

Time and time format

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

To change the time:

1. If you have a paired BG meter, sync your BG meter to import any recent blood glucose readings:

    Menu icon (☰) > Enter BG > SYNC BG METER

2. Navigate to: Settings icon (⚙) > PDM Device > Time.

3. To change the time format, tap the toggle to choose between 12 hr format (AM/PM) and 24 hr format.

4. To change the time:

    a. If you have an active Pod, tap SUSPEND INSULIN and tap YES.

    b. Scroll the Hour and Minute fields to the desired values. If using 12 hr format, select between AM and PM.

5. Tap SAVE, then tap CONFIRM.

6. If you suspended insulin, tap YES to resume insulin delivery.

7. If you changed the time and have a paired BG meter, sync your BG meter: Menu icon (☰) > Enter BG > SYNC BG METER.

    The PDM updates the time on your BG meter. This ensures that future blood glucose readings are marked with the correct time.

Language

To change the language used on PDM screens:

1. Navigate to: Settings icon (⚙) > PDM Device > Language.

2. Tap the current language, and select the desired language from the drop-down list.

3. If you have selected a language other than English, tap OK on a message stating that the Food Library is only available when English is the selected language.

4. Tap SAVE.

5. Tap RESTART PDM.

    Note: Restarting the PDM will not deactivate your Pod. The Pod will continue to deliver insulin according to the active Basal Program's schedule and will deliver any extended bolus in progress.

Diagnostics

Check alarms

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

1. Navigate to: Settings icon (⚙) > PDM Device > Check Alarms.

2. If you have an active Pod, tap SUSPEND INSULIN and tap YES.

3. Tap CHECK ALARMS to initiate the alarm check.

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

5. If the Pod alarms did not work properly, tap NO. Then either tap CHECK AGAIN to retry testing the alarms, or tap DONE and activate a new Pod.

6. If the PDM alarms did not work properly, tap NO. Then either tap CHECK AGAIN to retry testing the alarms or call Customer Care.

7. If the beeps and vibrations worked properly, tap YES. If you suspended insulin to check the alarms, tap YES to resume insulin delivery.

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

Reset PDM

Reset PDM is a rarely-used function that erases many of your personal settings.

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

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

Note: The Reset PDM option does not delete history records.

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: *Record your current settings on the pages at the end of this User Guide.*

2. Navigate to: Settings icon (⚙) > PDM Device > Reset PDM.

3. If you have an active Pod, tap DEACTIVATE POD, then tap DEACTIVATE POD again.

4. Tap RESET PDM, and then tap RESET PDM again.

   This deletes your current user settings.

5. Follow the PDM setup directions in "Initial PDM Setup" on page 21 to re-enter your personalized information or call Customer Care for assistance.

Software update (Wireless update)

It is important to make sure that your PDM software is kept up to date. When a software update is available, you will receive a notification on the Lock screen, as long as your PDM is connected to Wi-Fi.

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

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

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

Before you begin

Before you begin downloading and installing a software update, make sure the following requirements are met:

- No active Pod. If you have an active Pod, deactivate it.

- Wi-Fi is ON. If your Wi-Fi is OFF, turn it ON and connect to a Wi-Fi network. (See "Wi-Fi" on page 100.)

- PDM battery charge is at least 30%. If below 30%, plug in the PDM until the charge is above 30%.

After you confirm meeting these requirements, proceed to the following steps.

Downloading and installing a software update

To download and install a software update:

1. Navigate to: Settings icon (⚙) > PDM Device.

    The screen shows the current software version.

2. Tap Software Update.

3. Tap CHECK FOR UPDATES, then tap OK, I UNDERSTAND.

    The Wireless Update screen appears. If an update has been detected, the screen will display a Download button. If an update has not been detected, the screen will display a Check for Updates button.

4. To download the available update, tap Download.

    Note: While you can pause or cancel the download, it is recommended that you allow the download to finish. The update has finished downloading when the circle in the middle of the screen says "100%."

    Note: If an update has not been detected, tap Check for updates to trigger a check. If the screen tells you that the software is up-to-date, tap the triangular (back) button below the PDM screen to exit.

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

5. Tap Install Now.

    Note: If a message appears saying that the battery charge is less than 30%, tap OK and recharge the battery.

    Note: To install at a later time, (not recommended) tap Install Later. Then select a delay of 1 hour, 4 hours, or 8 hours, and tap OK. If you do not select a delay, the default delay of 4 hours is used. The Lock screen shows a "Wireless Update" reminder until you have installed the update. If you are using your PDM after the delay period has elapsed, a reminder message appears.

6. Read the message about battery power and PDM use during the software installation, and plug in your PDM if the charge is below 30%. Once above 30%, tap OK.

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

7. Wait for several minutes while the software update is installed.

As installation proceeds, several screens appear, including an image of a green robot. When installation is complete, the Lock screen appears.

The PDM remembers your personal settings and history records.

After the software installation is complete, the PDM will restart and display a message.

8. Tap OK on the message saying that the update was successful.

It is now okay to activate a new Pod.

Pod Sites Setting

The Pod Sites setting controls whether a diagram of the body is available when you activate a new Pod. You can use this body diagram during Pod activation to review where you placed your recent Pods and to mark where you place the new Pod.

To turn the Pod Sites setting on or off:

1. Navigate to: Settings icon (⚙) > Pod Sites.

2. Tap the toggle to turn the Pod Sites setting on or off. If you want the ability to record your Pod site on the diagram, turn Pod Sites on. If you do not want to use this diagram, turn it off.

3. Tap SAVE.

Reminder Settings

Reminders and notifications bring items related to PDM and Pod function to your attention (see "Notifications List" on page 129 and "Informational Signals List" on page 131).

Pod expiration

The Pod expiration notification tells you when the Pod is nearing its expiration so you can plan to change your Pod at a convenient time. You can set this notification to appear from 1 to 24 hours before the Pod expiration advisory alarm. At the selected time, the Pod and PDM vibrate or beep and the PDM displays a message.

To set the timing of the Pod expiration notification:

1. Navigate to: Settings icon (⚙) > Reminders > Pod Expiration.

2. Tap the Pod Expiration field and select how long before your Pod expires that you would like to be notified.

3. Tap SAVE.

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.

To set the insulin level for the low reservoir advisory alarm:

1. Navigate to: Settings icon (⚙) > Reminders > Low Reservoir Level.

2. Tap the Low Reservoir Level field and select the level of Pod insulin at which you would like to be notified.

3. Tap SAVE.

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 148 for a description of how this feature works.

To enable or disable Auto-off:

1. Navigate to: Settings icon (⚙) > Reminders > Pod Auto-Off.

2. Tap the Pod Auto-Off toggle to enable or disable the Auto-off feature.

3.   If Auto-off is enabled, tap the Inactivity Timer field and select the length of time for the countdown timer. This setting can range from 1 to 24 hours.

   Example: If you choose 10 hours, you must wake up your PDM and unlock it at least once every 10 hours, day and night, to prevent the Auto-off alarm.

4.   Tap SAVE.

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

Check BG after Bolus reminders

Turn on Check BG after Bolus reminders if you want a reminder to check your blood glucose after you deliver a bolus. If BG reminders are on, you can define the timing of the BG reminder at the time that you give a bolus.

To enable BG reminders:

1.   Navigate to: Settings icon (⚙) > Reminders.

2.   Tap the Check BG after Bolus toggle to enable or disable the Check BG after Bolus reminders.

Missed bolus reminders

If the Omnipod DASH® System does not deliver a meal bolus or a manually-calculated bolus during the missed bolus time period, the PDM vibrates or beeps and displays a reminder. You can set time intervals from 30 minutes to 4 hours. You can set up to six missed bolus reminders per day.

Note: To add, edit, or delete missed bolus reminders, the missed bolus reminders toggle must be set to on.

Enable or disable all missed bolus reminders

To enable or disable the ability to use missed bolus reminders:

1.   Navigate to: Settings icon (⚙) > Reminders.

2.   Tap the Missed Bolus toggle to enable or disable all missed bolus reminders.

If you disable these reminders, the PDM saves any previously set reminders for later use.

Enable or disable a single missed bolus reminder

To turn an individual missed bolus reminder on or off:

1. Navigate to: Settings icon (⚙) > Reminders > Missed Bolus.

2. Tap the toggle next to an individual missed bolus reminder to turn it on or off.

Add a new missed bolus reminder

To add a new missed bolus reminder:

1. Navigate to: Settings icon (⚙) > Reminders > Missed Bolus.

2. Tap Add Reminder.

    The Add Reminder button does not appear if missed bolus reminders are disabled.

3. Tap the toggle to select Single Reminder or Recurring Reminder.

    •   For single reminders, tap the Reminder date field and select the date for the reminder.

    •   For recurring reminders, specify the days of the week for the reminder by tapping the boxes next to the desired days. A selected box has a checkmark in it.

4. Tap the No bolus between field and select the start of the missed bolus time interval.

5. Tap the next field and select the end of the time interval.

6. Tap SAVE.

Edit a missed bolus reminder

To edit a missed bolus reminder:

1. Navigate to: Settings icon (⚙) > Reminders > Missed Bolus.

2. Tap the name of the reminder you would like to edit.

3. Make the desired changes to the frequency, day(s), or interval start or end time.

4. Tap SAVE.

Delete a missed bolus reminder

To delete a missed bolus reminder:

1. Navigate to: Settings icon (⚙) > Reminders > Missed Bolus.

2. Tap the name of the reminder you would like to delete.

3. Tap DELETE.

4. Tap YES to confirm deletion.

Confidence reminders

When confidence reminders are on, you will hear a tone at the start and end of a bolus, extended bolus, or temp basal:

- The PDM beeps at the start.
- The Pod beeps at the end.

Confidence reminders are especially useful when you are getting familiar with your PDM and Pod. To turn confidence reminders on or off:

1. Navigate to: Settings icon (⚙) > Reminders.

2. Tap the Confidence Reminders toggle to turn confidence reminders on or off.

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

Program reminders

When program reminders are on, the Pod beeps every 60 minutes while a temp basal or extended bolus is in progress. To turn program reminders on or off:

1. Navigate to: Settings icon (⚙) > Reminders.

2. Scroll down and tap the Program Reminders toggle to turn program reminders on or off.

Note: You cannot turn off beeps that occur during 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 4 custom reminders.

Enable or disable all custom reminders

To enable or disable the ability to display custom reminders:

1. Navigate to: Settings icon (⚙) > Reminders.

2. Scroll down and tap the Custom Reminders toggle to enable or disable all custom reminders.

If you disable these reminders, the PDM saves any previously set reminders for later use.

Note: To add, edit, or delete custom reminders, the custom reminders toggle must be set to on.

Edit or turn on or off an individual custom reminder

If custom reminders are enabled, you can edit or turn on or turn off an individual custom reminder:

1. Navigate to: Settings icon (⚙️) > Reminders > Custom Reminders.

2. Tap the name of a custom reminder.

3. Tap the toggle next to Custom Reminder to turn this custom reminder on or off.

4. Make any desired changes to the frequency, day(s), time, name, and text.

5. Tap SAVE.

Add a new custom reminder

To add a new custom reminder:

1. Navigate to: Settings icon (⚙️) > Reminders > Custom Reminders.

2. Tap Add Reminder.

3. Tap the toggle to select Single Reminder or Recurring Reminder.

    •   For single reminders, tap the Reminder date field and select the date for the reminder.

    •   For recurring reminders, specify the days of the week by tapping the boxes next to the days you want. A selected box has a checkmark in it.

4. Tap the Reminder time field and select the time for the reminder. The PDM will vibrate or beep one minute after this reminder time.

5. Tap the Reminder Name field and enter a descriptive name for the reminder. The name can have up to 32 characters.

6. Tap the Reminder Text field and enter a message to be displayed on the screen at the reminder time. The message can have up to 64 characters.

7. Tap SAVE.

Delete a custom reminder

To delete a custom reminder:

1. Navigate to: Settings icon (⚙️) > Reminders > Custom Reminders.

2. Tap the name of the custom reminder that you would like to delete.

3. Tap DELETE.

4. Tap YES to confirm deletion.

Blood Glucose Settings

The Blood Glucose settings allow you to change the BG Goal Range and to pair or unpair BG meters.

BG Goal Range

The goal of using the Omnipod DASH® System is to keep your blood glucose within a certain range. This is called your BG Goal Range. You define this range by setting the upper and lower limits of your BG Goal Range. The history graphs and the Enter BG screens use the BG Goal Range to determine which blood glucose readings are within your goal and which are above or below your goal.

Note: The Bolus Calculator does not use the BG Goal Range values to calculate a bolus.

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

To set the upper and lower limit of your BG Goal Range:

1. Navigate to: Settings icon (⚙) > Blood Glucose > BG Goal Range.

2. Set the limits of the BG Goal Range:

    a. Tap the Upper Limit field and enter the desired value. You can also touch the upper (yellow) circle and slide it up or down to change the upper limit.

    b. Tap the Lower Limit field and enter the desired value. You can also touch the lower (red) circle and slide it up or down to change the lower limit.

3. Tap SAVE.

Pairing, unpairing, or renaming a BG meter

The PDM uses Bluetooth® wireless technology to communicate with CONTOUR® NEXT ONE BG meters. A paired BG meter can transmit your blood glucose readings wirelessly to the PDM. The PDM can pair to five BG meters.

To pair, unpair, or rename a BG meter:

1. Turn off your BG meter, and place it within six feet of your PDM.

2. Turn on the blue light on your BG meter. To do so, press and hold the OK button on the BG meter until its white light changes to a flashing blue light.

3. On your PDM, navigate to:

    Settings icon (⚙) > Blood Glucose > Pair BG Meter

    or

    Settings icon (⚙) > PDM Device > Bluetooth

The PDM scans for available CONTOUR® NEXT ONE BG meters, and then displays a list of paired and available BG meters.

4. Turn your BG meter over to find its seven digit serial number. Verify that this number matches the one on the PDM screen.

5. To pair to a new BG meter:

    a. Tap PAIR below your BG meter's serial number.

        Note: A CONTOUR® NEXT ONE BG meter can only be paired to one PDM at a time. If the BG meter is currently paired to another PDM, you must unpair it from the other PDM before you can pair it to your current PDM. Follow the on-screen instructions to unpair from a previous PDM.

    b. When you see the Successfully Paired message, tap OK.

    c. Verify that your BG meter is listed as paired.

6. To unpair a paired BG meter:

    a. Tap the Options icon (⋮) next to the BG meter's name.

    b. Tap Unpair Meter.

    c. If the BG meter is successfully unpaired, tap OK.

    d. If the BG meter is not successfully unpaired, check that the BG meter is turned on and tap TRY AGAIN to retry unpairing. Or tap REMOVE METER to remove the BG meter's name from the list of paired BG meters.

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

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

7. To rename a paired BG meter:

    a. Tap the Options icon (⋮) next to the paired BG meter's name.

    b. Tap Edit.

    c. Tap the Name field and enter the new name for the BG meter.

    d. Tap SAVE.

Note: If your paired BG meter does not appear on the list, move your PDM closer to your meter and tap SCAN AGAIN. If that doesn't work, tap RESET to turn Bluetooth® off and then on again.

Basal and Temp Basal Settings

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

Maximum Basal Rate

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

To change your Maximum Basal Rate:

1. Navigate to: Settings icon (⚙) > Basal & Temp Basal > Max Basal Rate.
2. Tap the Max Basal Rate field and enter the new value for your Maximum Basal Rate.
3. Tap SAVE.

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.

Temp basal

To turn on or off the ability to set temp basals:

1. Navigate to: Settings icon (⚙) > Basal & Temp Basal.
2. To enable or disable the ability to set temporary basal rates (temp basals), tap the toggle on or off.
3. To change between using percent (%) or flat rate (U/hr) temp basals:
    a. Tap Temp Basal.
    b. Select the desired method for setting a temp basal:
        *   Tap Percent (%) to modify the active Basal Program by a set percentage increase or decrease.
        *   Tap Flat Rate (U/hr) to replace the active Basal Program with a fixed basal rate for the specified duration.
    c. Tap SAVE.

Bolus Delivery Settings

These settings allow you to change your Maximum Bolus, extended bolus, and Bolus Calculator settings.

Maximum Bolus

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

Caution: Check with your healthcare provider before adjusting this setting.

To change your Maximum Bolus:

1.   Navigate to: Settings icon (⚙) > Bolus > Maximum Bolus.

2.   Tap the Max Bolus field and enter the new Maximum Bolus value.

3.   Tap SAVE.

Extended bolus

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.   Navigate to: Settings icon (⚙) > Bolus.

2.   Tap the toggle next to Extended Bolus to turn on or off the ability to extend a bolus.

Bolus Calculator settings

This section describes how to adjust the settings used by the Bolus Calculator to calculate meal and correction boluses.

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

9 Adjusting Settings

Turn the Bolus Calculator on or off

To turn the Bolus Calculator on or off:

1. Navigate to: Settings icon (⚙) > Bolus.

2. Tap the toggle on the Bolus Calculator row to turn it on or off.

3. If this is the first time you have turned the Bolus Calculator on, follow the screen's instructions or see "Target BG and Correct Above values" on page 33. The following sections tell you how to edit these settings.

Target BG and Correct Above

When calculating a correction bolus, the Bolus Calculator aims to bring your blood glucose to your Target BG value. However, the Bolus Calculator only calculates a correction bolus if your blood glucose is above your Correct Above setting. To edit Target BG or Correct Above values:

1. Write a list of all of the desired Target BG and Correct Above segments to guide you through re-entering the values for each segment.

   Tip: *You can write this list on the pages at the end of this User Guide.*

2. Navigate to: Settings icon (⚙) > Bolus > Target BG & Correct Above.

3. Tap NEXT.

4. To edit a segment, tap the row containing the segment you want to edit.

   a. Tap the End Time field to enter a new end time.

   b. Tap the Target BG field to enter a new Target BG value.

   c. Tap the Correct Above field to enter a new Correct Above value.

   d. Tap NEXT.

5. Repeat the previous step as needed for the remaining segments.

6. After confirming that all segments are correct, tap SAVE.

Note: You can add and delete segments by editing the existing segments.

Minimum BG for Calcs

Minimum BG for Calcs is a threshold that you set. If your blood glucose reading is below your Minimum BG for Calcs, the Bolus Calculator is disabled and does not calculate a bolus. To edit this value:

1. Navigate to: Settings icon (⚙) > Bolus > Min BG for Calcs.

2. Tap the Min BG for Calcs field and enter the desired value. Alternatively, touch the blue circle and slide your finger up or down the slider to select the Min BG for Calcs value.

3. Tap SAVE.

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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 158 for more details).

To turn Reverse Correction on or off:

1.   Navigate to: Settings icon (⚙) > Bolus.

2.   Tap the toggle on the Reverse Correction line to turn it on or off.

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. To edit this value:

1.   Navigate to: Settings icon (⚙) > Bolus > Duration of Insulin Action.

2.   Tap the Duration of Insulin Action field and enter the new value.

3.   Tap SAVE.

CHAPTER 10
Alarms, Notifications, and Communication Errors

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 to ensure appropriate insulin delivery.

The Omnipod DASH® System generates the following types of alarms and messages:

⚠️ **Hazard alarms** are high priority alarms that indicate a serious problem has occurred and you should remove your Pod.

⚠️ **Advisory alarms** are lower priority alarms that indicate that a situation exists that needs your attention.

🕐 **Notifications**, also called reminders, remind you about an action that you may want to perform.

• **Informational signals** inform you that the Pod is following your insulin delivery instructions. No action is required.

• **Communication error** messages display when the PDM is unable to communicate with the Pod.

For how to view the alarms and notifications history, see page 89.

Responding to Alarms

To respond to a hazard alarm or advisory alarm:

1. Wake up your PDM. The Lock screen shows an alarm message along with the hazard alarm (⚠️) icon or advisory alarm (❗) icon.

2. Unlock your PDM. After you enter your PIN, a full-screen alarm message appears.

   Note: If you are using your PDM when an alarm occurs, the alarm message appears as a full-screen message.

3. Follow the on-screen instructions or see the individual alarm details starting on page 125.

Note: You can use your PDM even if you do not address the cause of an advisory alarm immediately. However, you must acknowledge a hazard alarm before you can use your PDM for anything else.

Tip: *If you follow the PDM's instructions and are still not able to silence a hazard alarm, see "Silencing an Alarm" on page 135.*

Note: If a temp basal or extended bolus is running when a Pod hazard alarm occurs, the PDM informs you that it was canceled.

Responding to Notifications

Notifications remind you about actions you may want to perform.

Finding out about notifications

To alert you to a notification, the Pod sounds a tone and the PDM either sounds a tone or vibrates (see "Sounds and Vibrations" on page 124). When you hear a sound or feel a vibration, check your PDM for a message.

Note: Program reminders, confidence reminders, and some informational signals do not have an accompanying message.

If your PDM is asleep when you hear or feel a notification, wake up the PDM. The Lock screen shows the notification icon (🕐) and the notification message.

- If there are multiple messages, the most recent message is shown at the top of the list.

- If there are more messages than can be displayed on the Lock screen, a banner beneath the messages shows the number of additional messages.

If you are using your PDM when a notification is triggered, the notification message appears at the top of the screen. To remove the message from the screen:

- Do nothing. The message disappears after several seconds and is saved as a new message.

- Swipe up to remove the message immediately and save it as a new message.

- Swipe right to remove the message immediately and save it as an acknowledged message.

Acknowledging notifications

Note: Waking up and using your PDM does not automatically acknowledge, or silence, notifications.

All new notifications are included in the Notifications & Alarms count (🔔4) in the red circle in the upper right of most screens.

To acknowledge the notification:

1. Wake up your PDM.

2. Tap the bell icon (🔔4) to bring up the Notifications & Alarms screen.

3. Read any messages with blue notification icons (🕐). Scroll down the screen, if necessary, to see any additional notifications with blue icons (🕐).

4. Tap the back arrow (←) in the upper left of the screen to mark the notifications as acknowledged.

    Note: Putting the PDM to sleep by pressing the Power button does not mark the notifications as acknowledged. You must tap the back arrow (←) to acknowledge the notification.

Priority and Predictability of Alarms and Notifications

Hazard alarms take priority over advisory alarms. In general, only one hazard alarm can occur at a time. In the unlikely event that a Pod and PDM hazard alarm occur simultaneously, the PDM hazard alarm is displayed first.

Advisory alarms take priority over notifications. If multiple advisory alarms occur, the PDM displays the most recent message first. The following advisory alarms always precede a hazard alarm:

Advisory alarm	**Hazard alarm**
⚠ Pod Expired →	⚠ Pod Expired
⚠ Low Reservoir →	⚠ Empty Reservoir
⚠ Auto-Off Alert →	⚠ Auto-Off

You can prevent these hazard alarms by responding to their advisory alarm in a timely manner.

Note: As an extra alert, a Pod Expiration (⏰) notification precedes the Pod Expired advisory alarm.

Sounds and Vibrations

The Omnipod DASH® System uses sounds and vibrations to attract your attention to an alarm or notification.

Tip: *To test the sounds and vibrations, see "Check alarms" on page 105.*

Pod alarms

The Pod sounds an alarm tone when it detects a problem that can affect insulin delivery.

- Pod hazard alarm tones are continuous tones broken up periodically by a set of beeps.

- Pod advisory alarms and notifications tones are intermittent beeps, which repeat periodically until you acknowledge them.

PDM alarms

The PDM sounds an alarm tone in response to an internal problem or when it detects that a Pod alarm is occurring.

- PDM hazard alarms begin with a continuous vibration and, after approximately 1.5 minutes, add a continuous audible tone.

  For safety reasons, PDM alarms always progress to an audible alarm even if the Sound/vibrate mode is set to vibrate.

- PDM advisory alarms are intermittent tones, which repeat periodically until you acknowledge them.

- PDM notifications have intermittent vibrations or tones, which repeat periodically until you acknowledge them.

See "Timing of alarms originating in the Pod" on page 146 for more information.

The Sound/vibrate button

The PDM's Sound/vibrate button, located on the upper right edge of the PDM, controls whether the following reminders use vibrations or audible tones: Check BG after Pod change, Check BG after bolus, Missed bolus, No Pod, and Custom reminders.

*   To turn vibrations on, press and hold the lower end of the Sound/vibrate button until the vibrate icon ( ) appears on the indicator.

*   To turn sound on, press the upper end of the Sound/vibrate button until the bell icon ( ) appears on the indicator.

*   To increase or decrease the volume, press the upper or lower end of the Sound/vibrate button to move the round indicator. Move the round indicator to the left to decrease the volume. Move it to the right to increase the volume.

Hazard Alarm List

Hazard alarms make you aware of serious situations. Always respond to a hazard alarm immediately. Some alarm messages give you a unique number called a reference number. Give that number to Customer Care when you call about that alarm.

The individual hazard alarms are summarized here.

⚠️ **Pod Expired**—The Pod has reached the end of its operating life and insulin delivery has stopped. Both the Pod and PDM sound the alarm.

Message: Pod Expired. Insulin delivery stopped. Change Pod now.

What to do: Tap OK, DEACTIVATE POD NOW. Change your Pod. Check your blood glucose.

⚠️ **Empty Reservoir**—The Pod's insulin reservoir is empty and insulin delivery has stopped. Both the Pod and PDM sound the alarm.

Message: Empty Reservoir. Insulin delivery stopped. Change Pod now.

What to do: Tap OK, DEACTIVATE POD NOW. Change your Pod. Check your blood glucose.

⚠ **Auto-Off**—The Pod has stopped delivering insulin because you did not respond to the Auto-off advisory alarm. Both the Pod and PDM sound the alarm. To change the Auto-off setting, see "Pod Auto-off" on page 109. For more information about how Auto-off works, see "Auto-off" on page 148.

> Message: Auto-Off. Insulin delivery stopped. Your PDM and Pod have not communicated in the last <amount of time>. To resume insulin delivery, change your Pod.

> What to do: Tap OK, DEACTIVATE POD NOW. Change your Pod. Check your blood glucose.

⚠ **Occlusion**—The Pod's cannula is blocked, which has stopped insulin delivery. Both the Pod and PDM sound the alarm.

> Message: Occlusion Detected. Insulin delivery stopped. Change Pod now. Check your BG.

> What to do: Tap OK, DEACTIVATE POD NOW. Change your Pod. Check your blood glucose.

⚠ **Pod Error**—The Pod detects an unexpected error. Both the Pod and PDM sound the alarm.

> Message: Pod Error. Insulin delivery stopped. Change Pod now.

> What to do: Tap OK, DEACTIVATE POD NOW. Change your Pod. Check your blood glucose.

⚠ **Call Customer Care** —An unexpected error is detected in the Pod or PDM. The Pod, PDM, or both may sound the alarm.

> Message: Call Customer Care. Remove Pod now.
> Ref: <reference-number>.

> What to do: Tap OK to silence the alarm. Remove your Pod. Call Customer Care immediately. Check your blood glucose.

⚠ **System Error**—An unexpected error is detected in the Pod or PDM. The Pod, PDM, or both may sound the alarm.

> Message: System Error. Remove Pod now. Call Customer Care.
> Ref: <reference-number>.

> What to do: Tap OK, DEACTIVATE POD NOW. Remove your Pod. Call Customer Care immediately. Check your blood glucose.

⚠ **PDM Error**—An unexpected error is detected in the PDM. The PDM sounds the alarm.

Message: PDM Error. Remove Pod now. Call Customer Care.
Ref: <reference-number>.

What to do: Tap OK to silence the alarm. Remove your Pod. Call Customer Care immediately. Check your blood glucose.

⚠ **PDM Error**

Message: PDM Error. Tap "OK" to reset clock.

What to do: Tap OK. Reset the clock. Change your Pod. Check your blood glucose.

⚠ **Pod deactivation required**

Message: Pod deactivation required. Tap "OK" to deactivate.

What to do: Tap OK, DEACTIVATE POD NOW to deactivate your Pod. Remove your Pod.

⚠ **PDM Memory Corruption**

Message: PDM Memory Corruption. Remove Pod now. Call Customer Care. Tap OK to reset PDM and delete all user settings.

What to do: Tap OK to reset your PDM. This deletes all of your user settings, but does not delete your history records. The PDM guides you through reentering your user settings, and date and time, if necessary. Consult your healthcare provider if you do not know your user settings.

Advisory Alarm List

Advisory alarms inform you of a situation that needs your attention in the near future.

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

The individual advisory alarms are summarized here.

⚠️ **Pod Expired**—Your Pod will stop delivering insulin soon. This escalates to the Pod Expired hazard alarm if ignored. Both the Pod and PDM may sound the alarm.

> Vibration/tone: Periodically, until acknowledged.
>
> Message: Pod Expired. Change Pod now.
>
> What to do: Tap OK. Change your Pod.

⚠️ **Low Reservoir**—The volume of insulin in the Pod reservoir is below the specified value. This escalates to the Empty Reservoir hazard alarm if ignored. To change this value, see "Low reservoir level" on page 109. Both the Pod and PDM may sound the alarm.

> Vibration/tone: Once a minute for 3 minutes. Repeats every 60 minutes until acknowledged.
>
> Message: Low Reservoir. <x> U insulin or less remain in Pod. Change Pod soon.
>
> What to do: Tap OK. Change your Pod.

⚠️ **Auto-Off**—You have not used your PDM in the Auto-off countdown period that you specified. The Pod will stop delivering insulin soon if you do not respond to this alarm. To enable or disable the Auto-off feature or to change the countdown period, see "Pod Auto-off" on page 109. Both the Pod and PDM sound the alarm.

> Vibration/tone: Once a minute for 15 minutes.
>
> Message: Auto-Off alert. Your PDM and Pod have not communicated in the last <amount of time specified by you>. Tap OK to trigger a communication between your PDM and Pod.
>
> What to do: Tap OK to reset the Auto-off countdown timer to the beginning of the countdown period.

⚠️ **Resume Insulin**—The time period that you specified for insulin suspension has passed. If you do not resume insulin delivery, you could develop hyperglycemia. Both the Pod and PDM sound the alarm.

Vibration/tone: Once a minute for 3 minutes. Repeats every 15 minutes until insulin delivery is resumed.

Message on Lock screen: Resume Insulin. The insulin suspension period has ended.

Full screen message: Do you want to resume insulin delivery with the <name> Basal Program? The insulin suspension period has ended.

What to do: Tap RESUME INSULIN to restart the scheduled Basal Program or tap REMIND ME IN 15 MIN to keep insulin delivery suspended. This alarm recurs every 15 minutes until you resume insulin delivery.

⚠️ **Low PDM Battery**—The PDM battery charge has 15% or less remaining.

Vibration/tone: None. To preserve the battery, the PDM is silent.

Message: Low PDM Battery. PDM battery is getting low. Recharge battery soon.

What to do: Tap OK. Recharge your PDM battery as soon as possible.

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

Note: The battery icon in the status bar of most screens displays the remaining battery charge. When the charge is completely gone, the PDM powers off. You must recharge the PDM to use it again. You can use your PDM while it is charging.

Notifications List

Notifications, also called reminders, remind you about various actions you may want to perform. Some are generated automatically and others have settings that you control (see "Adjusting Settings" on page 99).

Tip: *Use the Sound/vibrate button on the right-side of the PDM to control whether the PDM's notification sounds a tone or vibrates (see "The Sound/vibrate button" on page 125).*

The notifications are:

🕐 **Pod Expiration**—Tells you how much time is left before the Pod expiration advisory alarm. To change the timing of this notification, see "Pod expiration" on page 109. Both the Pod and PDM sound the notification.

> Vibration/tone: A set of three beeps. Repeats periodically until acknowledged.

> Message: Pod Expiration. Pod expires at <time, date>.

> What to do: Acknowledge the message (see "Acknowledging notifications" on page 123). Change your Pod.

🕐 **No Active Pod**—The PDM reminds you to activate a new Pod to begin basal insulin delivery.

> Vibration/tone: Every 15 minutes.

> Message: No Active Pod. Activate a Pod to start insulin delivery.

> What to do: Unlock the PDM. Activate a new Pod.

🕐 **Check BG After Pod Change**—The PDM reminds you to check your blood glucose and the cannula infusion site 90 minutes after activating a new Pod.

> Vibration/tone: Every 5 minutes until acknowledged.

> Message: Check BG. Check BG and infusion site after Pod change.

> What to do: Acknowledge the message (see "Acknowledging notifications" on page 123). Check your blood glucose. Check the infusion site to see if the cannula is properly inserted.

🕐 **Check BG After Bolus**—The PDM reminds you to check your blood glucose after a bolus. To edit these reminders, see "Check BG after Bolus reminders" on page 110.

> Vibration/tone: Every 5 minutes until acknowledged.

> Message: Reminder: Check BG. <x> hours have passed since your bolus.

> What to do: Acknowledge the message (see "Acknowledging notifications" on page 123). Check your blood glucose.

🕐 **Missed Bolus**—The PDM reminds you that you have not delivered a bolus within the time period you have specified. To edit these reminders, see "Missed bolus reminders" on page 110.

> Vibration/tone: Every 15 min until acknowledged.

> Message: Missed Bolus. Meal bolus not delivered between <start time> - <end time>.

> What to do: Acknowledge the message (see "Acknowledging notifications" on page 123). Consider your meal schedule.

⏰ **Custom Reminder**—The PDM shows a message of your choice. To create or edit these reminders, see "Custom reminders" on page 112.

> Vibration/tone: Every 15 min until acknowledged.

> Message: <Your reminder text>.

> What to do: Acknowledge the message (see "Acknowledging notifications" on page 123).

⏰ **Wireless Update** (**Software Update**)—This message reminds you that a software update has been wirelessly downloaded but not yet installed.

> Message: Wireless Update. Download complete.

> What to do: Install the PDM software update as soon as possible (see "Software update (Wireless update)" on page 106). You must deactivate your Pod before installing the software update.

Informational Signals List

The Pod and PDM can provide informational tones or vibrations to let you know that normal PDM and Pod events are occurring as expected. You do not need to do anything in response to these signals. The PDM does not show an explanatory message.

Tip: *Use the Sound/vibrate button on the right-side of the PDM to control whether some of these signals sound an audible tone or vibrate (see "The Sound/vibrate button" on page 125).*

Confidence reminders—These tones or vibrations let you know that your temp basals and boluses are working as expected. These reminders are on by default. To turn them on or off, see "Confidence reminders" on page 112.

> PDM tones/vibrations: At the start of a temp basal, bolus, or extended bolus.

> Pod beeps: Once at the end of a temp basal, bolus, or extended bolus.

Program reminders—These beeps remind you that you have a temp basal or extended bolus running. These reminders are on by default. To turn them on or off, see "Program reminders" on page 112.

> Pod beeps: Once every 60 minutes while a temp basal or extended bolus is running.

Pod activation—These tones or vibrations occur at various times during the Pod activation process to indicate progress. You cannot turn these off.

> Pod beeps: Twice when it has been filled with the minimum amount of insulin needed for activation (see page 41).

> PDM tones/vibrations: When the Pod and PDM are successfully paired.

> Pod beeps: Beginning 10 minutes after the Pod is filled with insulin, the Pod beeps every five minutes until insulin delivery has started.

Pod deactivation—PDM sounds a tone or vibrates: Twice when the Pod is successfully deactivated.

Basal Program changes—These tones or vibrations inform you of changes to your Basal Program. You cannot turn these off.

> PDM tones/vibrations: When a Basal Program is activated, edited, suspended, or resumed.

> Pod beeps: Once every 15 minutes while insulin is suspended.

Canceling temp basals and boluses—Informs you that the temp basal or bolus has been successfully canceled.

> Pod beeps: Once when you cancel a temp basal, bolus, or extended bolus. You cannot turn these beeps off.

Communication Errors

When your PDM sends an instruction to your Pod, the communication usually succeeds quickly. If an error in communication occurs, the PDM displays the "no Pod communication" icon on the status bar (see "The Status Bar" on page 9). The PDM communicates with the DISPLAY® app only when the PDM is in sleep mode. PDM sleep mode starts up to one minute after the PDM screen turns black.

Communication can fail if:

- The PDM is, or has temporarily been, too far from the Pod—For successful communication, the PDM and Pod should be side by side during activation and within 5 ft (1.5 meters) after activation. Any insulin command will initiate a connection between the PDM and Pod.

- The PDM's Bluetooth communication system is temporarily in use—This could happen, for example, during communication with the Omnipod DISPLAY® app.

- Communication is disrupted by outside interference—See the "Omnipod DASH® System Notice Concerning Interference" on page 194.

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

Error when canceling a bolus

If you are trying to cancel a bolus when a communication error occurs, the PDM offers these options:

- CANCEL: Select this option to stop attempting to cancel the bolus. The Pod continues to deliver the bolus.

  Note: If the 'cancel bolus' instruction has already been sent, this CANCEL option is not available.

- TRY AGAIN: Move to a new location, then select this option to tell the PDM to continue attempting to communicate with the Pod.

- DEACTIVATE POD: Select this option and follow the PDM's instructions for replacing your Pod.

If the 'cancel bolus' instruction has already been sent from the PDM when a communication error occurs, the PDM offers these options:

- CHECK STATUS: Select this option to attempt to re-establish communication with the pod and obtain the current status of the 'cancel bolus' command

- DEACTIVATE POD: Select this option to deactivate the pod when CHECK STATUS is unsuccessful.

Error when sending insulin instructions to the Pod

A communication error may occur when the PDM attempts to send the following insulin delivery instructions to the Pod—suspending or resuming insulin, activating a new Basal Program, starting or canceling a temp basal, or starting a bolus.

If a communication error occurs when the PDM attempts to send an insulin delivery instruction, the PDM offers you different options. The options offered depend on whether the PDM has sent the Pod the instruction and hasn't received confirmation that it was carried out, or whether the PDM hasn't sent the instruction.

If the PDM has sent the Pod the instruction and hasn't received confirmation that it was carried out, the PDM offers these options:

- CHECK STATUS: Move to a new location, then select this option to recheck for confirmation that the instruction was carried out.

- DEACTIVATE POD: Select this option and follow the PDM's instructions for replacing your Pod.

If the PDM has *not* sent the Pod the instruction, the PDM tells you to move to a new location and tap TRY AGAIN to reattempt communication. After you tap TRY AGAIN, if the next communication attempt fails, the PDM offers these options:

- CANCEL: Select this option to cancel sending the instruction. In this case, the Pod continues with its prior insulin delivery mode. You can try to send the instruction later.

- TRY AGAIN: Move to a new location, then select this option to tell the PDM to reattempt to send the instruction to the Pod.

- DEACTIVATE POD: Select this option and follow the PDM's instructions for replacing your Pod.

Note: At any point, if the PDM receives confirmation from the Pod that the instruction was successfully received, a green banner appears informing you that the instruction has been carried out.

Error when activating a Pod

If a communication error occurs during Pod activation, the PDM offers these options:

- DISCARD POD: Select this option to stop attempting to use this Pod.

- TRY AGAIN: Select this option to attempt to reestablish communication.

Error when deactivating a Pod

If a communication error occurs during Pod deactivation, the PDM offers these options:

- DISCARD POD: Select this option to tell your PDM to unpair from that Pod. The PDM instructs you to remove your Pod and tap CONTINUE.

- TRY AGAIN: Select this option to attempt to reestablish communication.

Note: After selecting the discard option, you can prevent future alarms from the discarded Pod by following the instructions in "Silencing an Alarm" on page 135.

Note: If there is an unconfirmed bolus when you discard a Pod, the PDM does not know how much of the bolus was delivered. Therefore, the PDM temporarily disables the Bolus Calculator. If you tap the Bolus button while the Bolus Calculator is disabled, the PDM displays a message that says "Bolus Calculator

temporarily disabled." You can deliver a manually-calculated bolus when the Bolus Calculator is disabled.

Silencing an Alarm

You can usually silence Pod or PDM alarms by tapping a button on the alarm screen. If the alarm continues, or if you are discarding a Pod and want to prevent a future alarm, follow the directions in this section.

Pod alarm

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.

4. Firmly press a paper clip or similar item straight down into the alarm shut-off port. If an alarm is sounding, the alarm stops. You need to apply enough force to break a thin layer of plastic.

Press down *firmly*.

Alarm shut-off port

Gold circle

Fill port
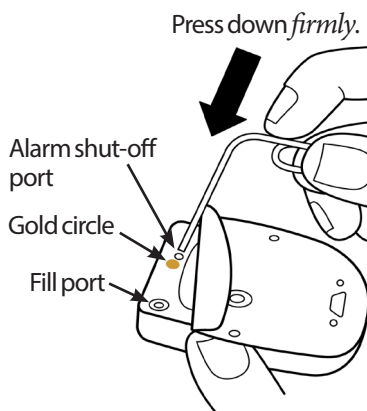
PDM alarm

If a PDM alarm is not silenced when you tap the alarm screen's button:

1. Press and hold the Power button, then tap Power off.

2. Take out and reinsert the PDM's battery. For instructions on removing and replacing the PDM battery, see "Inserting or replacing the PDM battery" on page 143.

3. Press and hold the Power button to turn the PDM back on.

This action silences the PDM's alarm. Your history records and personal settings are preserved. However, you may have to reset the time and date and change your Pod. After you reset the time, the Bolus Calculator is temporarily disabled. A PDM message tells you when the Bolus Calculator can be used again. You can deliver a manually-calculated bolus when the Bolus Calculator is disabled.

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CHAPTER 11
Taking Care of Your PDM and Pod

The Omnipod DASH® Insulin Management System has no user-serviceable parts. If you require assistance operating or maintaining the Omnipod DASH® System, call Customer Care.

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

Pod and Insulin Care

This section describes proper care of your Pod. To order all Omnipod DASH® 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 the insulin's expiration date.

Pods and the environment

Avoid extreme temperatures

The Pod's operating temperature is between 73°F and 98.6°F (between 23°C and 37°C). Under normal circumstances, your body temperature keeps the Pod well within this range.

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

> **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 if you will not use a 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.

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 does not kink and the Pod does not detach from your skin.

PDM Care

This section describes proper care of your PDM.

> **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.

PDM storage

When you are not using your PDM, store it in a convenient, nearby location that is cool and dry.

If the PDM is not safe from children or others who may press the buttons by accident, do not share your PDM's PIN number with anyone. Also, store the PDM in a safe place.

Long term storage of the PDM

If you are not going to use your PDM for an extended period of time, allow your battery to reach approximately 50% charge. Then press and hold the Power button to turn the PDM off, and remove the PDM battery (see "Inserting or replacing the PDM battery" on page 143).

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

Note: When you reinsert your battery into the PDM, you will need to reset date and time, but your user settings will be retained.

PDM and the environment

Avoid extreme temperatures

Extreme operating temperatures can affect the PDM's battery and interfere with Omnipod DASH® System operation. Avoid using the PDM in temperatures below 41°F (5°C) or above 104°F (40°C).

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

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 battery, and dry the battery with a clean, lint-free cloth.

    Note: For detailed instructions for removing and replacing the battery, see "Inserting or replacing the PDM battery" on page 143.

3. Gently absorb any water in the battery compartment with a clean, lint-free cloth.

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

4. Leave the battery compartment door open until the PDM is thoroughly dry.

5. After the PDM has thoroughly air-dried, replace the battery and replace the door to the battery compartment.

6. Turn on the PDM to see if it is working.

7. If the PDM is not working, call Customer Care.

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 by moving to a new location (for more information, see "Communication Errors" on page 132).

USB cable

When you use a USB cable to upload your PDM records to another device or to charge your PDM, disconnect the USB cable as soon as you are finished.

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

Note: You can use the PDM while it is charging or transferring data.

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

Cleaning your PDM

Always keep your PDM USB port free of debris and liquids. Dirt, dust, and liquids can impair the functionality of your PDM or damage it.

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

To clean your PDM:

1. Press the Power button briefly to put your PDM to sleep.

2. Wipe the outer surface of the PDM with a damp, lint-free cloth. If necessary, use a solution of a mild detergent mixed in warm water.

3. Dry the outer surface with a dry, lint-free cloth.

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

Every time you clean your PDM, 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 you notice any signs of deterioration, stop using the PDM. Call Customer Care if you have questions or for information about PDM replacement.

If you drop the PDM

Shock or a severe impact can damage your PDM. 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 Power button to see whether the PDM turns on and the Lock screen appears.

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

PDM Battery Care

The PDM uses a rechargeable lithium ion battery. If there is a problem with your battery or charger, contact Customer Care for information about replacements.

Safe use of the PDM battery

> **Warnings:**
>
> Do not expose your battery to high heat. Do not puncture, crush, or apply pressure to your battery. Failure to follow these instructions could result in an explosion, fire, electric shock, damage to the PDM or battery, or battery leakage.
>
> Do not incinerate a battery. Dispose of an old battery in accordance with local waste disposal regulations.

To safely use the rechargeable battery:

- To prolong battery life, store and charge it in a cool, dry place out of direct sunlight. Avoid leaving the battery in a car where temperature extremes can permanently damage the battery.

- Your PDM may become warm after prolonged use or when exposed to high temperatures. If your PDM or battery become hot to the touch, unplug the USB cable if it is plugged in, and avoid prolonged skin contact. Place your PDM in a cool location and allow it to cool down to room temperature.

- Do not connect the battery poles with pieces of metal, such as keys or jewelry. Doing so may short-circuit the battery and cause injuries or burns.

- Do not expose the battery or its charger to liquids, including water, rain, or snow, as this can cause malfunction. If the battery or charger is exposed to liquid, allow it to dry.

- Do not allow anyone, including children and pets, to put the battery in their mouth. Doing so may result in damage or explosion.

- Do not place the PDM or battery on or in heating devices, such as microwave ovens, stoves, or radiators. The battery may explode if overheated.

- Do not drop the battery.

- Only use an Insulet approved battery, charger, and cable to charge your PDM. Using unapproved batteries, chargers, or cables can cause the battery to explode or damage the PDM, and may void the warranty.

- If the battery is damaged so that fluid leaks from the battery, do not allow the leaked fluid to make direct contact with your skin or eyes. If this happens, immediately flush your skin or eyes with clean water and consult a doctor.

- If the battery deforms, changes color, or overheats while charging, during use, or in storage, immediately remove the battery. Continued use may lead to battery leakage, fire, or explosion.

- Inspect your PDM battery charger before each use. If the adapter for the charger falls in water or is cracked, do not use it.

Charging the PDM battery

Under normal use, the battery should hold its charge for more than one day.

A PDM message alerts you when the battery charge is low. The battery icon in the status bar tracks the remaining charge in the battery (see "The Status Bar" on page 9). To charge the battery, see "Charge the battery" on page 22.

You can charge your battery many times, but all batteries have a limited lifespan. If you notice a significant deterioration in the duration of the PDM's battery charge, contact Customer Care about replacing your battery.

Note: Charging times can vary depending on the surrounding temperature and the remaining battery level.

Tip: *Develop a routine to charge the PDM battery at the same time every day. Do not wait for the low PDM battery message.*

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

Note: If the PDM battery is critically low and the PDM has turned off, your Pod continues to deliver basal insulin according to the active Basal Program or temp basal. If you do not charge your PDM battery, this insulin delivery continues until the Pod expires.

Note: The history records stay in memory for 60 days even if the battery power is critically low or the battery is removed.

Inserting or replacing the PDM battery

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

To insert or replace the PDM battery:

1. If your PDM is on, turn it off by pressing the Power button, tapping Power off, and then tapping OK.

2. If the white pull tab is still on the PDM, remove the back cover using the pull tab as follows:

    a. Hold the PDM with the back cover facing you.

    b. Place two or more fingers of one hand between the pull tab and the PDM.

    c. Brace the thumb of that hand against the back of the PDM.

    d. Pull back on the pull tab and lift off the cover.

    e. Skip to step 4.

3. If the white pull tab is no longer on the PDM, remove the back cover as follows:

    a. Hold the PDM sideways and locate the notch in the PDM case. The notch is located in the corner below the Power button.

    Power button

    Notch

    b. Holding the PDM firmly, place a fingernail into the notch and pull the front cover away from the back cover.

    c. Slide your finger along the opening to completely separate the front from the back.

    d. Lift off the back cover.
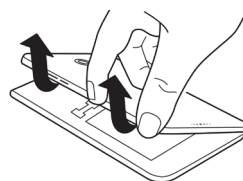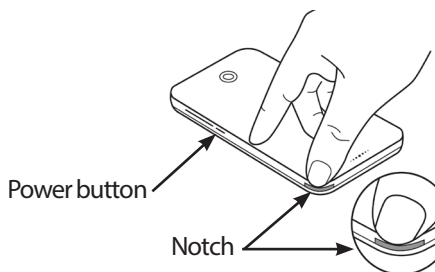
4. If a battery is in place, put your fingernail in the slot just below the battery on the right-hand side and lift out the battery.

5. Orient the new battery so the three gold tabs on the battery line up with the three gold pins in the battery compartment. The "-" and "+" signs on the battery label should face you.

    Caution: Do not remove the label from the battery.

    Caution: Be careful not to damage any of the small metal parts inside the battery compartment.
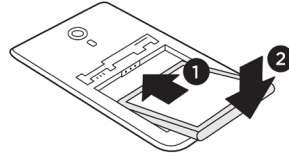
6. Slide the battery into place. Gently push the bottom of the battery to fit it into place.

7. To replace the back cover of the PDM:

    a. Line up the cover's edge along the side with the Sound/vibrate and Power buttons. Press down on this side first.

    b. Press down along the back cover until the cover has clicked into place.

The PDM is now ready to use. If this is a new PDM, see "Initial PDM Setup" on page 21 for instructions for entering your settings.

Note: If you replaced the battery in your current PDM, you must reset the time and date (see "Date and time, and language" on page 102). Your history records and personal settings will be saved.

CHAPTER 12
Understanding PDM and Pod Function

This chapter explains how the PDM and Pod interact, features such as basal and bolus insulin delivery, and how the Bolus Calculator works.

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 a PDM activates a Pod, that PDM and Pod are paired together, which means that they can only communicate with each other even if there are other Pods or PDMs within range. During Pod activation, the PDM transfers the active Basal Program details to the Pod.

The PDM's communication range is automatically 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 should always be able to communicate with a Pod that is up to 5 feet (1.5 m) away. Depending on the surroundings, the PDM may be able to communicate with a Pod that is as much as 50 feet (15 meters) away. To ensure that you can deliver a bolus, change the basal rate, or receive status updates from the Pod, make sure the PDM is within 5 feet (1.5 m) of the Pod.

When you are not actively using the PDM, store it in a nearby location, such as a shirt pocket or in a drawer, briefcase, or purse.

Status checks: How the PDM checks Pod function

The PDM periodically queries the Pod about its status, called a "status check." The PDM performs a status check:

- When you wake up the PDM.

- When you navigate to the Pod Info tab.

- Periodically, whether the PDM is awake or asleep.

  Note: Following a sleeping status check, the PDM only wakes up and sounds an audible alarm if the Pod has a hazard alarm. If the Pod has an advisory alarm or a notification, the PDM remains asleep and silent.

During a status check, the PDM collects information from the Pod about bolus deliveries, the amount of remaining insulin, and any alarm situations. The PDM displays this information as follows:

- The Home screen displays information about the most recent bolus.

- The Pod icon on the status bar shows how much insulin remains in the Pod's reservoir (see "The Status Bar" on page 9).

- The Lock screen and a full screen message display information about Pod alarms.

Timing of alarms originating in the Pod

If the Pod is sounding a hazard alarm, the Pod broadcasts a signal to the PDM.

- If the PDM is in range and awake, within 25 seconds of the Pod's initial alarm sound, the PDM also sounds an alarm and displays the alarm message.

- If the PDM is in range but asleep, the Pod cannot wake it up. The PDM finds out about the Pod alarm when it does a 'sleeping status check.' In this case, there could be a delay of up to five minutes and 25 seconds between when the Pod sounds the alarm and when the PDM sounds the alarm.

- If the PDM is out of range of the Pod, the PDM cannot receive any communication from the Pod. Therefore, if you hear a Pod alarm or notification, bring the PDM in range of the Pod and wake the PDM up. Within 25 seconds, the PDM sounds the alarm and displays the alarm message.

When the PDM cannot communicate with the Pod

When the PDM attempts to communicate with an active Pod that is in range, communication usually occurs quickly.

The PDM cannot communicate with the Pod when:

- The PDM is, or has temporarily been, too far from the Pod; for example, when you attend a meeting, leaving your PDM back at your desk.

- The PDM's battery has run down.

- There is too much outside interference (see "Omnipod DASH® System Notice Concerning Interference" on page 194).

For information about handling PDM-Pod communication problems, see "Communication Errors" on page 132.

Pod deactivation

Deactivation unpairs a PDM and Pod from each other. Deactivation:

- Stops the current Pod's insulin delivery.

- Permanently silences any alarms from that Pod.

- 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

When the PDM cannot resolve a communication error, the PDM is unable to deactivate the Pod. In this situation, the PDM asks if you want to "discard" the Pod. "Discarding" unpairs the PDM from that Pod but does not stop the Pod's insulin delivery. Therefore, if you tell the PDM to "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 a Pod alarm on page 135. Otherwise, if a discarded Pod sounds an alarm, the alarm stops 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's segments.

- Stop delivery of a temp basal at the scheduled time and resume delivery of the active Basal Program.

- Once a bolus or an extended bolus is started, complete the delivery of the bolus.

- Track the amount of insulin remaining inside the Pod.

- Track the amount of time until Pod expiration. Stop delivering insulin once the Pod expires.

- Perform self-checks to verify that insulin delivery is occurring as expected. Sound an alarm if it is not.

- Send alarm and notification messages to the PDM, if it is in range.

- Stop insulin delivery if the Auto-off feature is enabled and you have not used the PDM within the specified period of time.

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. The Pod and PDM will sound an alarm if you do not use your PDM within that amount of time. To change the Auto-off setting, see "Pod Auto-off" on page 109.

Resetting the Auto-off countdown timer

Any action you take that causes the PDM to communicate with the Pod resets the Auto-off countdown timer to the beginning. Therefore, if Auto-off is enabled, make sure the PDM is in range of the Pod, then wake up your PDM. This resets the timer and prevents the alarm from sounding.

Auto-off alarms

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.

If you do not use your PDM within 15 minutes of the onset of the Pod's Auto-off advisory alarm, the Pod stops delivering insulin and both the PDM and Pod sound a hazard alarm. Tap OK to silence the alarm and deactivate your Pod.

PDM and Paired BG Meter Interaction

The following actions occur whenever you sync your PDM with a paired BG meter:

- The PDM transmits its time, date and goal/target range information to the BG meter, overwriting the BG meter's time, date and goal/target range if they differ. This ensures that the time of blood glucose readings and boluses can be compared accurately.

  Tip: *To keep your PDM and BG meter clocks in sync, always sync your BG meter immediately before and after a time or date change (see "Date and time, and language" on page 102).*

- The BG meter transmits all blood glucose readings taken since the last time it synced to the PDM.

- If the BG meter tagged a reading as a control solution reading, the PDM adds a control solution tag.

BG readings from a paired BG meter and the Bolus Calculator

When the Bolus Calculator imports a blood glucose value from a paired BG meter:

- The Bolus Calculator automatically displays a blood glucose reading that was taken within the past 10 minutes.

- If multiple readings were taken within the past 10 minutes, the Bolus Calculator uses the most recent reading.

- If the clocks on the BG meter and PDM differ by more than five minutes, the Bolus Calculator does not display any reading from the BG meter.

BG readings from a paired BG meter and the history records

The PDM history records store all blood glucose readings and control solution readings from a paired BG meter.

Exception: If the PDM and BG meter's clocks differ by more than five minutes, the history records do not display any of the new readings from the BG meter.

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 DASH® 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 DASH® 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.
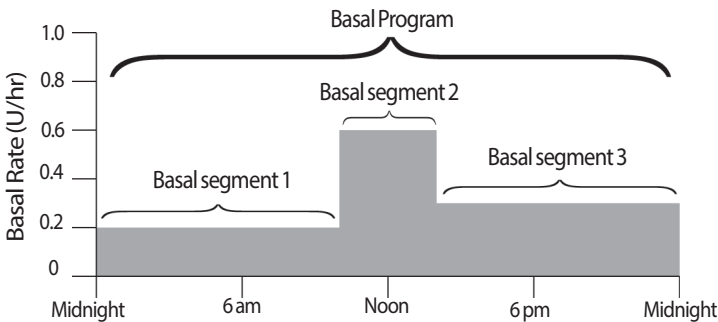
Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver more or less insulin at certain times of day. For example, you could deliver a lower rate of insulin during the night and a higher rate during the day. This figure shows a Basal Program with three basal segments.

To create the Basal Program shown in the preceding figure, the following basal segments are programmed into the PDM:

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 12 different Basal Programs (see "Basal Programs" on page 81). This figure shows two possible Basal Programs, one for weekdays and the other for weekends.
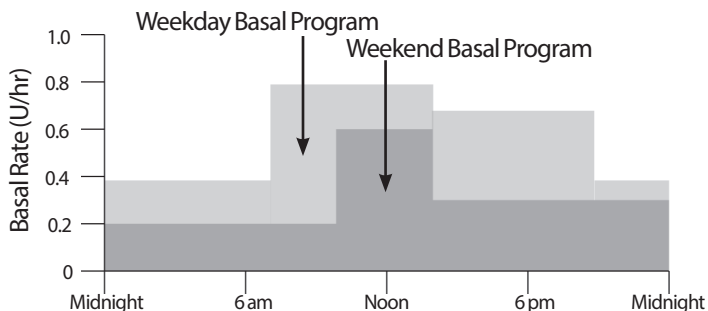
Temporary basal rates

The ability to set temporary basal rates, also called "temp basals," is an important feature of the Omnipod DASH® 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 75).

Temp basals can last from 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.

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, 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%.

Temp basal set to U/hr

Temp basal set to %

- - - - Temp basal from 7 AM to 4:30 PM
——— Basal Program
▓ Actual insulin delivered
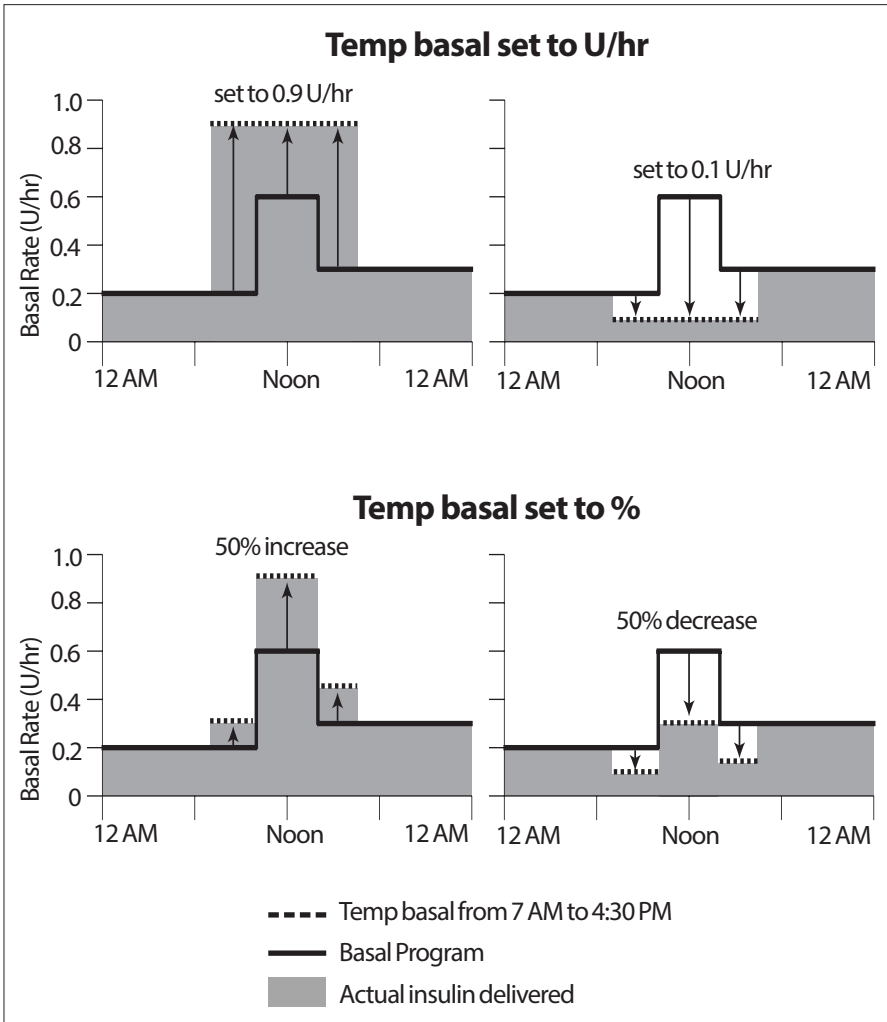
The calculations for the 50% increase temp basal in the preceding figure are:

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		

* Segments are defined by the currently scheduled Basal Program.

Temp basal limitations

Prohibited temp basals: 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.

- When using a flat rate (U/hr), you cannot set a temp basal above your Maximum Basal Rate.

Temp basals that turn off basal insulin delivery: When using percent (%), if you set a decrease that results in a flow of less than 0.05 U/hr for a segment, the PDM informs you that you will receive 0 U/hr of insulin for one or more segments.

If the temp basal is long enough, you will eventually receive some insulin. This is because the Pod delivers insulin in 0.05 U pulses.

For example, if the flow rate for a basal segment is 0.10 U/hr and you create a temp basal with a 60% decrease for:

- One hour, the resulting flow rate of 0.04 U/hr results in no insulin being delivered for the one hour duration of the temp basal.

- Two hours, the resulting flow rate of 0.04 U/hr results in a delivery of 0 U insulin in the first hour and 0.05 U insulin in the second hour.

You can set a temp basal to turn off basal insulin delivery for a set period of time by using a 100% decrease or a flat rate of 0 U/hr. 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: *Using a temp basal to turn off basal insulin delivery 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 154).*

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 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 85). Once stored, a temp basal preset can be activated quickly at a later time (see "Activate a temp basal preset" on page 77).

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 deactivate your current Pod, you can request a temporary halt of insulin delivery as follows:

- Suspend insulin delivery:

  Menu icon (≡) > Suspend Insulin.

- Set a temp basal to turn off insulin delivery:

  Menu icon (≡) > Set Temp Basal. Then select 100% decrease or 0 U/hr.

The following table compares these options for pausing insulin delivery.

	Suspend insulin	Temp basal of 0 U/hr
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	"Resume insulin. The insulin suspension period has ended."	Middle tab of Home screen titled "Basal" (not "Temp Basal")
Beeps while insulin is stopped	Every 15 min	At beginning and every 60 min
Beeps at end of specified duration	Every 15 min until you tap 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	Menu icon (≡) > Resume Insulin	Home: Temp Basal tab > 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. Use boluses to bring down high blood glucose levels and to cover the carbohydrates (carbs) in a meal.

You have the option of delivering the entire bolus at once. This is referred to as an "immediate bolus" or, simply, a "bolus." Alternatively, you can spread out the delivery of all or part of a meal bolus so that it is delivered steadily over a specified period of time. This is referred to as an "extended bolus."
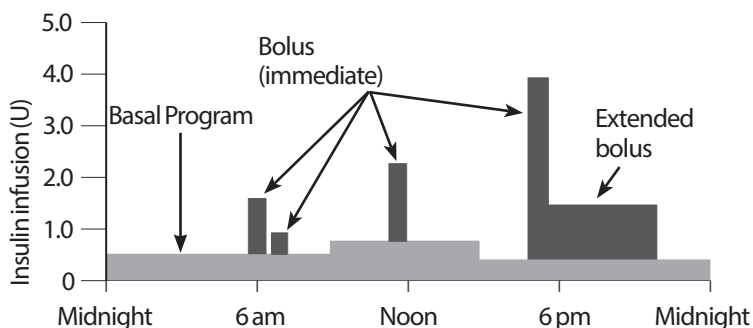
You may want to extend a bolus if your meal contains high-fat or high-protein foods. These foods slow down digestion and therefore slow down the post-meal rise in your blood glucose.

About Manually-Calculated Boluses

A manually-calculated bolus is a bolus that you have calculated without the help of the Bolus Calculator. You can use manually-calculated boluses when the Bolus Calculator is set to off or if the Bolus Calculator is disabled (see "Maximum Bolus" on page 156). 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 87) that 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 cover 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. A 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 enter a bolus that is above your Maximum Bolus setting. If the Bolus Calculator calculates a bolus amount greater than your Maximum Bolus, you will only be able to deliver up to the Maximum Bolus amount. To adjust it, tap the Total Bolus field and enter a revised bolus.

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 set to off. You control whether the Bolus Calculator is turned on or off, but the PDM controls when it is disabled.

If the Bolus Calculator is set to off, the PDM does not track IOB and does not suggest a bolus.

If the Bolus Calculator is set to 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.

Conditions that disable the Bolus Calculator:	The Bolus Calculator is disabled until:	While the Bolus Calculator is disabled:
Your blood glucose reading is below your Minimum BG for Calcs setting.	Ten minutes pass. or A new blood glucose reading is above your Minimum BG for Calcs setting.	IOB is displayed on the Home screen.
Your blood glucose reading is "HI."	Ten minutes pass. or A new blood glucose reading is lower than "HI."	IOB is displayed on the Home screen.
There is an unconfirmed bolus when you discard a Pod.	A complete Duration of Insulin Action period passes.	IOB is not displayed on the Home screen.
There is an internal clock reset.	8.5 hours pass.	IOB is not displayed on the Home screen.

Factors used in the Bolus Calculator's calculations

The Bolus Calculator accounts for the following when it calculates a bolus:

* Your current blood glucose level, Target BG, Correct Above threshold, and Correction Factor

* The carbs 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 earlier 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 Duration of Insulin Action setting represents the amount of time that insulin remains "on board" or "active" in your body.

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 uses the calculated negative correction bolus to reduce the meal bolus. This allows part of the meal to be used to raise the low blood glucose level towards the Target BG.

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 the range of your BG meter or is above 600 mg/dL, the reading is recorded as "HI" and the Bolus Calculator cannot calculate a bolus.
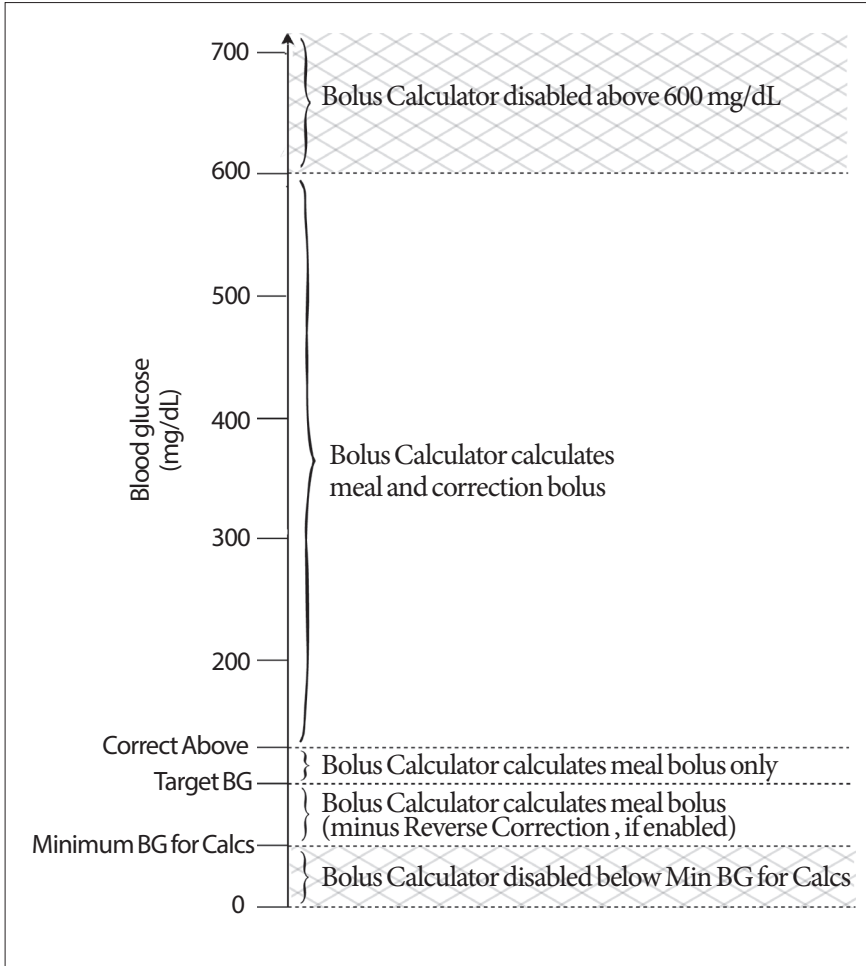
Insulin on board (IOB)

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.
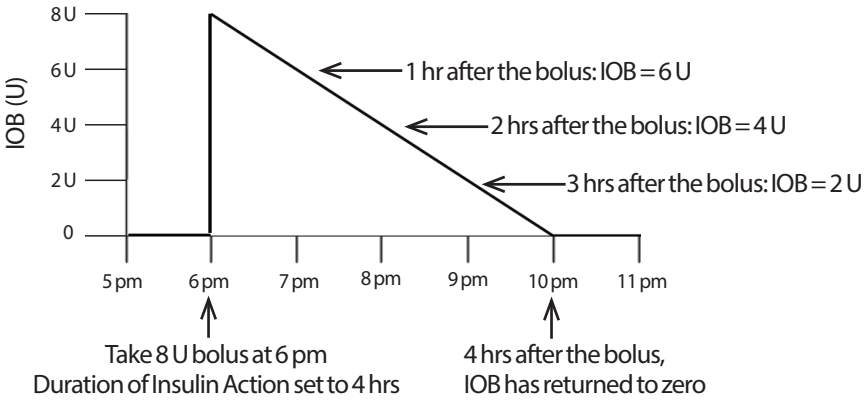
Types of IOB: meal IOB, correction IOB, or both

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.
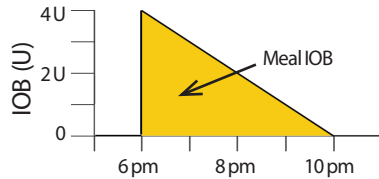
Entirely correction

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.
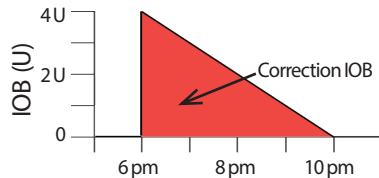
Both meal and correction

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.
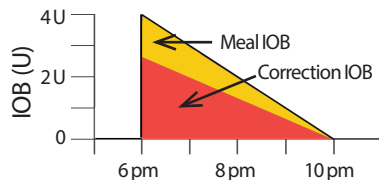
Insulin on board (IOB) calculations

$$\frac{\text{Duration of insulin action} - \text{time since previous bolus}}{\text{Duration of insulin action}} \times \text{previous bolus}$$

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

$$\frac{3\text{ hours} - 1\text{ hour}}{3\text{ hours}} \times 3\text{ U} = 2\text{ U correction IOB}$$

In other words, one hour after your previous correction bolus, your body has used up only 1 unit from the correction bolus. The remaining 2 units of insulin are still in your body working to correct your blood glucose level. Accounting for correction 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

$$\frac{3\text{ hours} - 2\text{ hours}}{3\text{ hours}} \times 4.5\text{ U} = 1.5\text{ U meal IOB}$$

In other words, two hours after your previous meal bolus, your body has used up 3 units from 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 does not reduce a new meal bolus. The correction bolus is only reduced until it becomes 0 units.

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 correction bolus $= \dfrac{\text{Current BG - Target BG}}{\text{Correction Factor}}$

Example: Current BG: 200 mg/dL, Target BG: 100 mg/dL
Correction Factor (CF): 50

$\dfrac{200\,\text{mg/dL} - 100\,\text{mg/dL}}{50} = 2\,\text{U prelim. correction bolus}$

Preliminary meal bolus $= \dfrac{\text{Carb intake}}{\text{Insulin-to-carb (IC) ratio}}$

Example: Carb intake: 45 grams of carb, IC ratio: 15

$\dfrac{45}{15} = 3\,\text{U prelim. meal bolus}$

Final correction bolus = (prelim. correction bolus - meal IOB) - correction IOB

The meal IOB is subtracted first. If the preliminary correction bolus is still above zero, then the correction IOB is subtracted

Note: A correction bolus is never reduced below 0 U.

Final meal bolus = prelim. meal bolus - remaining correction IOB

Meal IOB is never subtracted from a meal bolus. Only a remaining correction IOB is subtracted from a meal bolus (see "Remaining correction IOB" on page 164).

Note: A meal bolus is never reduced below 0 U.

Calculated bolus = final correction bolus + final meal bolus

Reverse Correction bolus calculation: If the Reverse Correction feature is turned on and if your current blood glucose 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: Current BG: 75 mg/dL, Target BG: 100 mg/dL
Correction Factor: 50, Preliminary meal bolus: 1.5 U

$\dfrac{75\,\text{mg/dL} - 100\,\text{mg/dL}}{50} = -0.5\,\text{U Reverse Correction}$

- 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. In this example, the meal bolus is reduced by 0.5 units.

Bolus Calculator rules

The Bolus Calculator applies the following rules to the suggested bolus doses:

- Suggested bolus doses are rounded down to the nearest 0.05 U.

- If the total of the suggested bolus calculation (correction bolus plus meal bolus) is less than zero, the suggested bolus dose is 0.00 U.

- The Bolus Calculator does not suggest a bolus dose if your current blood glucose reading is below your Minimum BG for Calcs.

- The Bolus Calculator suggests a correction bolus only when your blood glucose 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 0.05 U.

- A Reverse Correction only occurs if the meal bolus is greater than 0.00 U.

- 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 adjust 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.

Overview of the Bolus Calculator CALCULATIONS screen

The Bolus Calculator's screen can be accessed by tapping VIEW BOLUS CALCULATIONS from the Insulin & BG history screen or by tapping CALCULATIONS from the Bolus Calculator screen.

Your current blood glucose reading and Target BG setting are listed here.

Your Correction Factor setting is listed here.

A correction bolus is adjusted for meal IOB first ...

... then for correction IOB.

Correction IOB is subtracted from the correction bolus first ...

The carbs in your meal and your IC Ratio are listed here.

... and any remaining correction IOB is subtracted from the meal bolus.

Bolus Calculation — 50+U — 90% — 5:47 AM

Correction Bolus — 1 U
BG = 150, Target BG = 100
Correction Factor = 50
(150-100) / 50 ≈ 1 U
Meal IOB adjustment
Meal IOB = 0 U
1 U - 0 U = 1 U
Correction IOB adjustment
Correction IOB = 0 U
1 U - 0 U ≈ 1 U

Meal Bolus — 4 U
Carbs = 60 g, IC Ratio = 15 g/U
60 / 15 ≈ 4 U
Correction IOB adjustment

CLOSE

You need to scroll down to see the total bolus and any adjustments you may have made to the calculated bolus.

The blood glucose units on the Calculations screen are mg/dL.

Note: IOB adjustments are only made if you have entered a blood glucose reading.

Remaining correction IOB

A calculated bolus amount can never be less than zero. If a correction IOB is greater than the preliminary correction bolus, subtracting only part of the correction IOB from the preliminary bolus brings the correction bolus to zero.

The 'remaining correction IOB' is the amount of the correction IOB that was not needed to bring the preliminary correction bolus to zero. This remaining amount is then used to reduce the meal bolus, if there is a meal bolus.

The preliminary and final boluses in the CALCULATIONS screen

The Bolus Calculation screen shows the calculations for a preliminary bolus first (correction and meal bolus), and then shows the IOB adjustments that produce the final correction bolus and final meal bolus. See "Bolus Calculator equations" on page 162 for a step-by-step description of these calculations.

The preliminary correction bolus calculations and where the preliminary correction boluses appear on the Calculations screen, as well as which numbers represent the final correction bolus, are identified here:

Bolus Calculation		
Correction Bolus	1 U	Final correction bolus (rounded down to the nearest 0.05 U)
BG = 150, Target BG = 100		
Correction Factor = 50		
(150-100) / 50 ≈ 1 U		
Meal IOB adjustment		
Meal IOB = 0 U		
1 U - 0 U = 1 U		
Correction IOB adjustment		
Correction IOB = 0 U		
1 U - 0 U ≈ 1 U		
Meal Bolus	4 U	Final meal bolus
Carbs = 60 g, IC Ratio = 15 g/U		
60 / 15 ≈ 4 U		
Correction IOB adjustment		
Remaining correction IOB = 0 U		
4 U - 0 U ≈ 4 U		
Calculated Bolus	5 U	
Total Bolus =	5 U	
Correct Above: 110 mg/dL		
CLOSE		

The following pages show examples of the Calculations screen with various blood glucose, meal, and IOB scenarios.

Bolus Calculator examples

For an explanation of IOB, see page 160. For an explanation of the correction and meal bolus equations, see page 162.

Example 1: Eating 45 g carbs, BG of 150 mg/dL is above target, no IOB

Duration of Insulin Action = 4 hours. You have not delivered a bolus in the past 4 hours, so there is no IOB (no meal IOB, no correction IOB).

Correction Bolus   **1 U** ← Your blood glucose is 50 mg/dL over your target. With your correction factor at 50 and no IOB adjustment, you will need a 1 U correction bolus.

BG = 150, Target BG = 100
Correction Factor = 50
(150-100) / 50 = 1 U

Meal IOB adjustment
Meal IOB = 0 U
1 U - 0 U = 1 U ← No IOB, so no IOB adjustment.

Correction IOB adjustment
Correction IOB = 0 U
1 U - 0 U = 1 U ← No IOB, so no IOB adjustment.

Meal Bolus   **3 U** ← You are eating 45g carbs. With your IC ratio at 15 and no IOB adjustment, you will need a 3 U meal bolus.

Carbs = 45 g, IC Ratio = 15 g/U
45 / 15 = 3 U
Correction IOB adjustment
Remaining correction IOB = 0 U
3 U - 0 U = 3 U ← No IOB, so no IOB adjustment.

Calculated Bolus   **4 U** ← The calculated bolus is the sum of your correction bolus and meal bolus.

Your Adjustment   0 U ← Any adjustment you make to the calculated bolus is shown here. No adjustment was made.

Total Bolus   **4 U** ← The total bolus is the sum of the calculated bolus and any adjustment made by you.

Example 2: Not eating, BG of 150 mg/dL is above target, 1 U meal IOB, 1 U correction IOB

Duration of Insulin Action = 4 hours.

Three hours ago, you delivered an 8 U bolus (4 U meal bolus, 4 U correction bolus) because you were eating and had a high blood glucose reading.

Now, three hours after the 8 U bolus, there are 2 U of IOB left (1 U meal IOB, 1 U correction IOB).

Correction Bolus 0 U	
BG = 150, Target BG = 100 Correction Factor = 50 (150-100) / 50 = 1 U	Your blood glucose is 50 mg/dL over your target. A correction factor of 50 gives a 1 U preliminary correction bolus.
Meal IOB adjustment Meal IOB = 1 U 1 U - 1 U = 0 U	However, this preliminary correction bolus is reduced to zero by the 1 U meal IOB adjustment.
Correction IOB adjustment Correction IOB = 1 U N/A: Correction bolus is <= 0 U	Because the preliminary correction bolus has been reduced to zero, the correction IOB is not subtracted.
Meal Bolus 0 U	You are not eating, so your meal bolus is 0 U.
Carbs = 0 g, IC Ratio = 15 g/U 0 / 15 = 0 U	
Correction IOB adjustment Remaining correction IOB = 1 U 0 U - 1 U = 0 U	None of the correction IOB was subtracted from the correction bolus, so the remaining correction IOB is 1 U. However, the meal bolus is already zero.
Calculated Bolus 0 U	Although your blood glucose is above target, the meal IOB reduces the total bolus to 0 U.
Your Adjustment 0 U	
Total Bolus 0 U	

Example 3: Eating 45 g carbs, BG of 100 mg/dL is at target, 1 U meal IOB

Duration of Insulin Action = 4 hours.

Three hours ago, you delivered a 4 U bolus (4 U meal bolus) because you were eating. There was no correction bolus because your blood glucose was at your Target BG.

Now, three hours later and just before your next meal, there is 1 U of IOB from the previous meal, which is a 1 U meal IOB. There is no correction IOB because the earlier bolus had no correction component.

Correction Bolus	**0 U**	Blood glucose is at target, so the correction bolus is zero.
BG = 100, Target BG = 100 Correction Factor = 50 (100-100) / 50 = 0 U		
Meal IOB adjustment		
Meal IOB = 1 U N/A: Correction bolus is <= 0 U		The correction bolus is zero, so the meal IOB is not subtracted.
Correction IOB adjustment		
Correction IOB = 0 U N/A: Correction bolus is <= 0 U		No IOB adjustment.
Meal Bolus	**3 U**	
Carbs = 45 g, IC Ratio = 15 g/U 45 / 15 = 3 U		You are eating 45 g carbs. With your IC ratio at 15 and no correction IOB adjustment, the meal bolus is 3 U.
Correction IOB adjustment		
Remaining correction IOB = 0 U 3 U - 0 U = 3 U		No IOB adjustment is made. There is no correction IOB, and meal IOB is never subtracted from a meal bolus.
Calculated Bolus	**3 U**	Even though there was a 1 U meal IOB, it did not reduce the calculated bolus.
Your Adjustment	0 U	
Total Bolus	**3 U**	

Example 4: Eating 60 g carbs, BG of 150 mg/dL is above target, 1 U correction IOB

Duration of Insulin Action = 2 hours.

One hour ago, you delivered a 2 U bolus to correct a high blood glucose. Because you were not eating at that time and did not enter a carbohydrate value into the Bolus Calculator, this was a 2 U correction bolus.

Now, one hour later, you are about to eat. There is a 1 U correction IOB from the earlier bolus, and no meal IOB because you did not eat at the time of your last bolus.

Correction Bolus	**0 U**
BG = 150, Target BG = 100 Correction Factor = 50 (150-100) / 50 = 1 U	Your blood glucose is 50 mg/dL over your target. A correction factor of 50 gives a 1 U preliminary correction bolus.
Meal IOB adjustment Meal IOB = 0 U 1 U - 0 U = 1 U	No meal IOB, so no meal IOB adjustment.
Correction IOB adjustment Correction IOB = 1 U 1 U - 1 U = 0 U	The 1 U correction IOB reduces the correction bolus to zero.
Meal Bolus **4 U**	
Carbs = 60 g, IC Ratio = 15 g/U 60 / 15 = 4 U	You are eating 60 g carbs. An IC ratio of 15 gives a 4 U preliminary meal bolus.
Correction IOB adjustment Remaining correction IOB = 0 U 4 U - 0 U = 4 U	The entire correction IOB was used to reduce the correction bolus to zero, so no correction IOB remains. The meal bolus remains at 4 U.
Calculated Bolus **4 U**	The calculated bolus is entirely a meal bolus. Even though your blood glucose is above target, the correction IOB reduced the correction bolus to zero.
Your Adjustment **0 U**	
Total Bolus **4 U**	

Example 5: Reverse correction on, eating 45 g carbs, BG of 75 mg/dL is below target, no IOB

Duration of Insulin Action = 2 hours. You have not given yourself a bolus in the past 2 hours, so there is no IOB (no meal IOB, no correction IOB).

Correction Bolus	**- 0.5 U**	Your blood glucose is below your target, so a Reverse Correction is calculated.
BG = 75, Target BG = 100		
Correction Factor = 50		
(75 -100) / 50 = - 0.5 U		
(Reverse correction ON)		
Meal IOB adjustment		No change in the reverse correction bolus for two reasons: IOB is zero, and IOB is never subtracted from a reverse correction.
Meal IOB = 0 U		
N/A: Correction bolus is <= 0 U		
Correction IOB adjustment		No change in the reverse correction bolus for two reasons: IOB is zero, and IOB is never subtracted from a reverse correction.
Correction IOB = 0 U		
N/A: Correction bolus is <= 0 U		
Meal Bolus	**3 U**	You are eating 45 g carbs. With your IC ratio at 15 and no correction IOB adjustment, the meal bolus is 3 U.
Carbs = 45 g, IC Ratio = 15 g/U		
45 / 15 = 3 U		
Correction IOB adjustment		
Remaining correction IOB = 0 U		No IOB, so no IOB adjustment.
3 U - 0 U = 3 U		
Calculated Bolus	**2.50 U**	The negative reverse correction bolus reduces the meal bolus.
Your Adjustment	0 U	With Reverse Correction set to On and a blood glucose below your target, the meal bolus is reduced to allow some of the meal carbs to increase your blood glucose towards your target.
Total Bolus	**2.50 U**	

Calculations for History Summaries

This section lists the calculations for the summary data shown on the one day and multiple day history screens.

Blood glucose summaries

The calculations used for the blood glucose summaries include readings from a paired BG meter and manually-entered readings, with the exception that they do not include control solution records. The calculations do include any HI and LO readings unless otherwise noted. The multi-day calculations include all days in the time period.

Summary item	Calculation
Row 1 (see page 90)	
Average BG	$= \dfrac{\text{Sum of all BG readings}}{\text{Total number of BG readings}}$ **Note:** The sum and the total do not include HI or LO blood glucose readings.
BG in Range	$= \dfrac{\text{Number of BG readings within BG Goal Range}}{\text{Total number of BG readings}} \times 100$
BGs Above	$= \dfrac{\text{Number of BG readings above BG Goal Range upper limit}}{\text{Total number of BG readings}} \times 100$
BGs Below	$= \dfrac{\text{Number of BG readings below BG Goal Range lower limit}}{\text{Total number of BG readings}} \times 100$
Row 2 (see page 90)	
Avg Readings per Day	$= \dfrac{\text{Number of BG readings}}{\text{Number of days}}$ **Note:** This appears in the multiple day view only.
Number of BG Readings	$=$ Total number of BG readings in the day (or date range)
Highest BG	$=$ Highest BG reading in the day (or date range)
Lowest BG	$=$ Lowest BG reading in the day (or date range)

Insulin delivery summaries

Bolus insulin calculations include Bolus Calculator boluses and manually-calculated boluses. If you cancel an immediate or extended bolus before it completes, only the amount actually delivered is included in the calculation.

Basal insulin calculations includes insulin delivered according to the active Basal Program adjusted for periods when a temp basal was running, insulin was suspended, or there was no active Pod.

When the PDM has not received confirmation from the Pod about actual insulin delivery, the insulin delivery calculations are estimates based on the scheduled insulin delivery (see page 97).

For calculations of insulin delivery over multiple days, the number of days in the time period does not include days in which no insulin (either basal or bolus) was delivered.

For calculations of total carbohydrates over multiple days, the number of days in the time period does not include days in which no carbohydrates were entered into the Bolus Calculator.

Summary item	Calculation
Row 3 (see page 90)	
Total Insulin	= Sum of basal and bolus insulin delivered
Average Total Insulin	$= \dfrac{\text{Sum of basal and bolus insulin delivered}}{\text{Number of days}}$
Basal Insulin	= Amount of basal insulin delivered
Average Basal Insulin	$= \dfrac{\text{Amount of basal insulin delivered}}{\text{Number of days}}$
Bolus Insulin	= Amount of bolus insulin delivered
Average Bolus Insulin	$= \dfrac{\text{Amount of bolus insulin delivered}}{\text{Number of days}}$
Total Carbs	= Total grams of carbs entered into the Bolus Calculator
Average Total Carbs	$= \dfrac{\text{Total grams of carbs entered into the Bolus Calculator}}{\text{Number of days}}$

CHAPTER 13
Living with Diabetes

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

Before deciding on the Omnipod DASH® System, you and your healthcare provider discussed the benefits of the Omnipod DASH® 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 DASH® System at any time, consult your healthcare provider immediately.

Daily Activities

To ensure proper Omnipod DASH® System operation and your continued good health, check your infusion 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 an infusion site shows signs of infection:
>
> - Immediately remove the Pod and apply a new Pod at a different infusion site.
> - Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.
>
> 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 times. The kit should include:

- Several new, sealed Pods
- A vial of rapid-acting U-100 insulin (see "General Warnings" on page xii for insulins cleared for use in the Omnipod DASH® System)
- Syringes or pens for injecting insulin
- Blood glucose test strips
- 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 that you need to carry insulin supplies and the Omnipod DASH® System
- 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 178)

Traveling and Vacations

It is important that you check your blood glucose more frequently while you are traveling. Changes in time zones, activity levels, and meal times can all affect your blood glucose levels.

Proper preparation is important when traveling. The following sections will help you prepare for your travels.

Keep supplies accessible

On airplanes, trains, and buses, keep these items with you, rather than checking them:

- Personal Diabetes Manager (PDM)

- Extra Pods

- An emergency kit

- Vials of insulin (cargo area temperatures may affect insulin)

- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod DASH® System

- Prescriptions for all medications

- Medications and supplies with their original prescription label

    Note: Generic medications may be easier to find than brand names outside your country.

- Snacks and hypoglycemia treatment, in case food is not available

- Bottled water (especially on planes) to prevent dehydration

- The name and phone number of your physician and of a physician at your final destination

Note: Keep your emergency kit with you during trips or vacations (see "Prepare for Emergencies" on page 175). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

Tip: *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 DASH® System supplies for your trip.*

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.

Airports and flying

Before traveling by plane, familiarize yourself with the airport's security procedures and prepare your diabetes supplies for the security process and flight.

Airport security

Prepare for your travel:

- Airport security checks and screening procedures may change, so review the airport website and the TSA website for travel updates before your trip.

- Arrive at the airport 2-3 hours before your flight.

- Have your insulin management supplies easily accessible to ensure that airport security checks run smoothly.

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 an insulin 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 DASH® System Notice Concerning Interference" on page 194).

Flying and airplane mode

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

The PDM controls the Pod using Bluetooth® wireless technology. Before flying, check your airline's policy regarding the use of Personal Medical Electronic Devices that communicate using Bluetooth® technology.

If use of a Personal Electronic Device using Bluetooth® technology is allowed, set your PDM to airplane mode while on the airplane (see "Airplane mode" on page 99). The Bluetooth® setting remains enabled in the PDM's airplane mode so you can communicate with your Pod and BG meter. Airplane mode turns off your PDM's Wi-Fi connectivity.

Note: The Omnipod DASH® System is safe to use at atmospheric pressures typically found in airplane cabins during flight. The Omnipod DASH® System

can be used at atmospheric pressures as low as 700 hPA, which is lower than the typical pressure in airplane cabins.

Avoid Lows, Highs, and DKA

Act 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 DASH® System and cannot resolve them, call Customer Care immediately.

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 signs 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

Tip: *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 "Check BG after Bolus reminders" on page 110).*

Tip: *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.*

Tip: *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.*

Tip: *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.
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.

Possible causes of hypoglycemia	Suggested action
Alcohol consumption	Check blood glucose frequently, especially 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.

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

Tip: *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, do both of the following:

    - 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.

    - Replace the Pod. Use a new vial of insulin to fill the new Pod. Then contact your healthcare provider for guidance

6. If you feel nauseated at any point, check for ketones and contact your healthcare provider immediately (see "Diabetic ketoacidosis (DKA)" on page 184).

> **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.

7. 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.

Possible causes of hyperglycemia	Suggested action
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.
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 185.
	Consult your healthcare provider about sick day guidelines and about medication changes.

Possible causes of hyperglycemia	Suggested action
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 positive and you are feeling nauseated or ill, immediately contact 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 contact 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 184).

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.

- Contact 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, if the Pod is in a location where it is likely to be knocked off, consider removing the Pod and placing a new one in a more protected location.

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.

Appendix

Troubleshooting PDM Startup

While unlikely to happen with normal use, certain button press combinations during PDM startup can cause the PDM to display Boot Mode or Safe Mode.

Even when the PDM is in Boot Mode, the Pod continues delivering insulin according to the instructions it was given. Safe Mode does not affect PDM or Pod functionality.

Return to normal PDM operation as follows:

Boot Mode

If your PDM screen displays, "Select Boot Mode", then do the following:

1. Press the Sound/Vibrate UP (VOLUME_UP) button as needed to move the arrow (<<==) until it points to **[Recovery   Mode]**. Then, press the Sound/Vibrate DOWN (VOLUME_DOWN) button to select **[Recovery   Mode]**.

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

2. From the Android Recovery screen, press the Sound/Vibrate (VOLUME_UP/VOLUME_DOWN) button to highlight **Reboot system now**. Then, press the Power button to select it.

    The PDM restarts.

Safe Mode

If your PDM screen displays, "Safe Mode" in the lower left corner, then restart the PDM and remove the "Safe Mode" text from the screen as follows:

1. Press and hold the Power Button, then tap Power off.

2. Tap OK to confirm.

3. Press and hold the Power button to turn the PDM back on.

Summary of Settings and Options

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

Time format	12-hour or 24-hour clock.
Time zones	GMT-11:00 to GMT+13.00.
Date format	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9.
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
Temp basal	%, units/hr, or Off. Default is Off. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Temp basal presets	Maximum of 12.
BG Goal Range for blood glucose history	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments .
BG reminder	On or Off. Default is Off. Maximum of 4 active at one time. Reminder can occur between 30 min to 4 hrs after bolus is started. Set in 30-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, Off.
Bolus Calculator	On or Off. Default is On.
Target BG value	Maximum of 8 segments; 70 to 200 mg/dL in 1 mg/dL increments.
Correct Above threshold	Maximum of 8 segments; Target BG to 200 mg/dL in 1 mg/dL increments.
Minimum BG for Calcs	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.

Reverse Correction	On or Off. Default is On.
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Maximum Bolus size	0.05-30 U.
Extended bolus	%, Units, or Off. Default is Off. 30 minutes to 8 hours in 30-minute increments.
Bolus preset	Maximum of 7. Cannot exceed the Maximum Bolus.
MY FOODS list	Maximum of 50 items.
Custom foods	Range: 0-225 g carbohydrates.
Suspend	30 minutes to 2 hours.
Low reservoir volume advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Auto-off timer	Off, or 1 to 24 hours in 1-hour increments. Default is Off.
History screen display	Rolling 90-day period.
Language	English, Spanish. Default is English.

Pod Specifications

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

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

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

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

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

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

Reservoir volume (deliverable): 200 units

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

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

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

Insulin concentration: U-100

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

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

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

Operating atmospheric pressure: 700 hPA to 1060 hPA

Appendix

Storage atmospheric pressure: 700 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.0 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 0.05 U/h of U-100 insulin) at a high operating temperature. The overall mean percentage flow error was 1.40%.
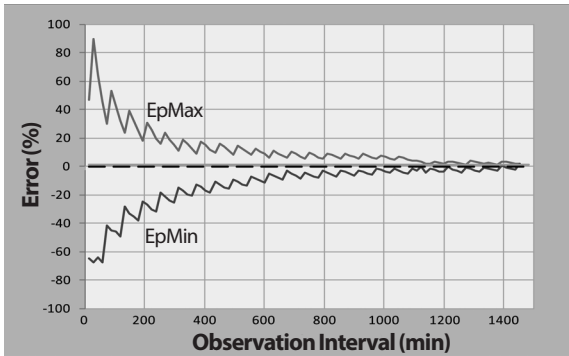
PDM Specifications

Size: 2.48" wide x 5.1" long x 0.39" high (6.3 cm x 13.0 cm x 1.0 cm)

Weight: 3.74 oz (106 grams)

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

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

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

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

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

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The PDM and Pod should be

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

Waterproof rating: IP22 (avoid liquid)

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

Notification type: Audible and vibratory

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

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

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

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

Only use the NUU mobile Switching Adapter Model HJ-0501000E1-US (Insulet PN 18401) with the PDM.

Protection from Over-infusion or Under-infusion

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

Occlusion detection

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

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

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

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

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

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

Omnipod DASH® System Label Symbols

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

Symbol	Meaning	Symbol	Meaning
⊘	Single use only	(MR)	MR unsafe
👆	Consult accompanying documents	⊗	Do not use if package is damaged
STERILE EO	Sterilized using ethylene oxide	👤	Type BF applied part
◰	Date of manufacture	▲	Manufacturer
LOT	Batch code	☂	Keep dry
⧖	Use by date	⌇	Storage temperature, Operational temperature
REF	Reference number	⊘	Storage relative humidity, Operational relative humidity
SN	Serial number	⊙	Storage atmospheric pressure, Operational atmospheric pressure
IP28	Submersible: Waterproof to 25 feet (7.6 meters) for up to 60 minutes	⊠	Non-pyrogenic fluid path
IP22	Avoid liquid	Rx ONLY	Prescription only
⌦	Do not dispose with household waste	RoHS	RoHS compliant
		⎕	Pod

Omnipod DASH® System Notice Concerning Interference

The Omnipod DASH® 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.

Caution: 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 DASH® 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 DASH® System.

- Increase the distance between the Omnipod DASH® 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 DASH® 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 DASH® 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.

Caution: Cables and accessories not specified within the instructions for use are not authorized. Using other cables or accessories may adversely impact

safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the Omnipod DASH® System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod DASH® System should be observed to verify normal operation in this setting.

The Omnipod DASH® 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 DASH® System communicates with the following characteristics:

Frequency: 2.400-2.480 GHz, digitally modulated, with an effective radiated power of 1.14mW

The Omnipod DASH® System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

The Omnipod DASH® System has demonstrated immunity to both radio-frequency identification (RFID) systems and Electronic Article Surveillance (EAS) systems. Testing has been performed in accordance with AIM 7351731 to demonstrate this immunity.

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

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.		
Emissions	**Compliance according to**	**Electromagnetic environment**
RF Emissions (CISPR 11)	Group 2	The Pod and the PDM emit low level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments including domestic establishments.

Appendix

Electromagnetic Immunity			
The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.			
Immunity against	**IEC 60601-1-2 test level**	**Compliance level (of this device)**	**Electromagnetic environment**
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz– 2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod DASH® System.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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 DASH® Insulin Management System. The Omnipod DASH® System consists of the Pod and the handheld, wireless Personal Diabetes Manager (PDM), which programs the Pod with insulin delivery instructions.

Compliance

The Omnipod DASH® 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).

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.

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 DASH® INSULIN MANAGEMENT SYSTEM PERSONAL DIABETES MANAGER AND PODS (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod DASH® System Personal Diabetes Manager

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Insulet Corporation warrants to you, the original purchaser of the Omnipod DASH® Insulin Management System ("Omnipod DASH® System"), that, if Insulet Corporation determines, during the period of four (4) years from the date of purchase, that the Omnipod DASH® 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. If Insulet Corporation chooses to repair the PDM, Insulet Corporation may choose to do so by implementing a software update, including an over-the-air software update, without further notice to the original purchaser. If Insulet Corporation chooses to replace the PDM, Insulet Corporation may choose to do so by replacing the PDM with an updated 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.

Limited Warranty Coverage for the Omnipod DASH® System Pods

Subject to this Limited Express Warranty, Insulet Corporation warrants to you, the original purchaser of the Omnipod DASH® 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 DASH® 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. the activation must occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before, and within seventy-two (72) hours of the time that 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

Claim Procedure

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

Appendix

Warranty. Unless Insulet Corporation elects to repair the PDM (which may include, but is not limited to, a repair kit, replacement part(s) Insulet Corporation may provide, or an over-the-air software update) 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 DASH® 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; or
- 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 that are not provided by Insulet Corporation, 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, THE POD, OR THE OMNIPOD DASH® 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 DASH® 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 DASH® 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 DASH® System, please return any Omnipod DASH® System products (including any PDM and Pods) to Insulet Corporation in exchange for a full refund. Failure to return such Omnipod DASH® System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Rev: January 15, 2018

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.

<u>Family, Friends and Emergencies</u>: 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.

<u>Marketing</u>: 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

<u>Required By Law</u>: 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.

<u>Public Health</u>: 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.

<u>Communicable Diseases</u>: 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.

<u>Health Oversight</u>: 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.

<u>Food and Drug Administration</u>: 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.

<u>Legal Proceedings</u>: 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.

<u>Law Enforcement</u>: 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.

<u>Research</u>: 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.omnipod.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.omnipod.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.

<u>You Have the Right to Request a Restriction of Your Medical Information</u>: 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.omnipod.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.

<u>You Have the Right to Request to Receive Confidential Communications from Us by Alternative Means or at an Alternative Location</u>: 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.

<u>You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information</u>: 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.omnipod.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.

<u>You Have The Right to Obtain a Copy of this HIPAA Privacy Notice</u>: 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

https://www.omnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

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.omnipod.com. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at

https://www.omnipod.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, September 2, 2014, and June 1, 2019

Glossary

A1c (see Hemoglobin A1c)

Activation: The process of waking up a Pod and pairing it to a PDM so that the Pod only responds to commands from that PDM.

Advisory alarm: Intermittent vibrations or beeps accompanied by a message 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 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 show 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 level.

Bluetooth® (see wireless communication)

Bolus Calculator: A feature that suggests meal and correction bolus doses based on your current blood glucose, the amount of carbohydrates you are about to eat, the 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 bolus dose of insulin that is assigned a custom name and stored by the PDM for later use.

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.

Carbohydrate bolus (see meal bolus)

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.

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.

Custom food: An entry in the Food Library's MY FOODS list that states the number of carbohydrates contained in a favorite food item, snack, or entire meal. It is assigned a custom name and stored by the Food Library for later use.

Deactivate: Preferred method for unpairing the PDM from the active Pod. Deactivation turns off insulin delivery in the Pod and then unpairs 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.

Discard Pod: The DISCARD POD option is offered if the PDM is unable to reestablish communication with the Pod after a communication error. This option allows the PDM to abandon that Pod and activate a new Pod. Note: A 'discarded' Pod may still be delivering insulin. Always remove a 'discarded' Pod from your body.

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.

Estimated bolus: After you confirm the amount of bolus that you want delivered, a bolus instruction is sent to the Pod. If the Pod is unable to send back confirmation of the amount of bolus actually delivered, the PDM estimates the amount delivered. This estimate is based on the expected delivery schedule. As

soon as confirmation is received from the Pod, the PDM displays the actual (not estimated) bolus amount.

Extended bolus: The delivery of a meal bolus dose steadily over an extended period of time.

Fat: One of the three main energy sources in food. (The other two are carbohydrate and protein.) Fat contains 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 thousands of 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 to 15, then you need to deliver one unit of insulin to cover every fifteen grams of carbohydrate you eat.

Glossary

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.

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 informs 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.

Notifications: An on-screen reminder or informational message.

Occlusion: A blockage or interruption in insulin delivery.

Pairing: Linking two devices so that they can communicate wirelessly with each other. After a PDM and blood glucose meter are paired, they are referred to as "paired devices." See also *sync*.

Podders: People with diabetes or caregivers of people with diabetes who use the Omnipod® system to manage their daily insulin needs.

Preset: A preset allows you to quickly enter a value that you use 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.

Segments: Defined periods of time during a 24-hour day. 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.

Sensitivity factor (see Correction Factor)

Sync: The act of transferring information between two paired devices. For example, when the PDM syncs with a paired blood glucose meter, the meter transfers any recent blood glucose readings to the PDM.

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 later use.

Time segment (see segment)

Unconfirmed bolus: Occurs when you select the DISCARD POD option following a communication error during a bolus. In this case, the Pod was unable to send a confirmation to the PDM about how much of a bolus was actually delivered.

Wireless communication: Transfer of information without a physical connection between two devices. The PDM and Pod, and the PDM and selected blood glucose meters, communicate over short distances using radio waves, which is referred to as wireless communication.

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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 PDM 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

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

Favorite Foods

Name	Grams of carbohydrates
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

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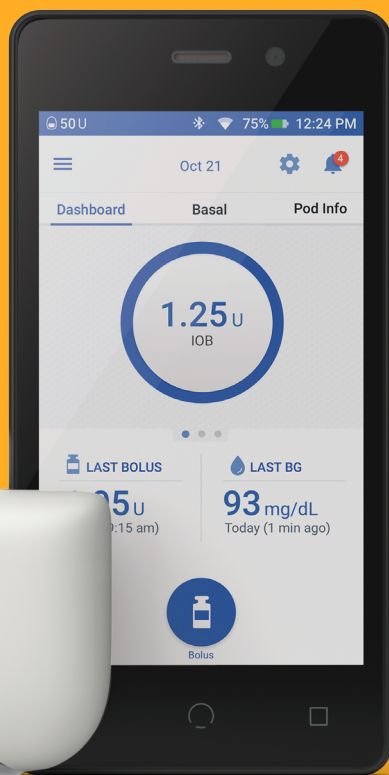
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