omnipod® DASH

Pod shown without the necessary adhesive.

Insulet Corporation
100 Nagog Park
Acton, MA 01720
1-800-591-3455
omnipod.com

18296-ENG

POD IC: 8446A-SAW
POD IC: 8446A-529
POD IC: 8446A-ATLAS
PDM IC: 20782-NUUA1
PDM IC: 20782-NUUA1P
PDM IC: 20782-NUUA1P2

Model Number: PDM-USA1-D001-MG-USA1 18296-ENG-AW Rev. 13 02/25

Omnipod DASH® User Guide

omnipod® DASH
insulin management system

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

Patent: www.insulet.com/patents

18296-ENG-AW Rev 13 02/25

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Reference

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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

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, Lyumjev, 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.

Do not attempt to alter, modify, or disassemble any part of the Omnipod DASH System. Doing so may put your health and safety at risk.

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.

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

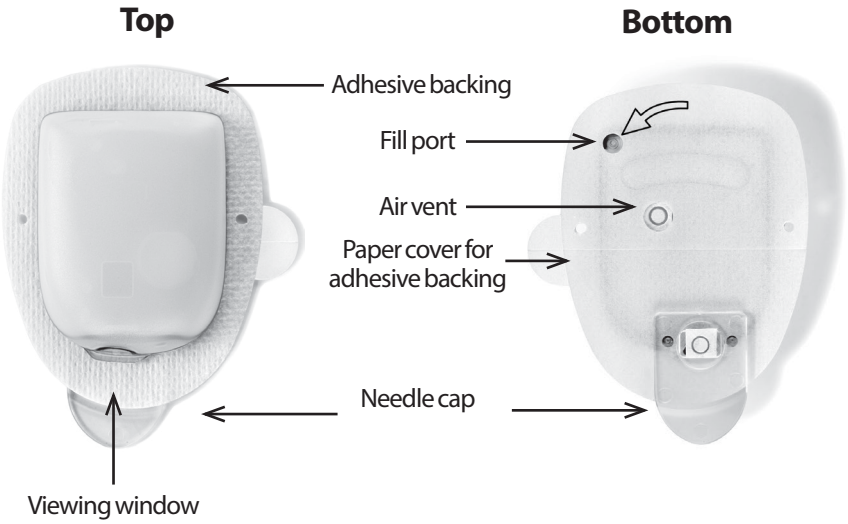
The Omnipod DASH System is made up of two primary parts: The Pod, which delivers insulin to your body, and the Personal Diabetes Manager (PDM), which lets you control the Pod.

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.



The Personal Diabetes Manager (PDM)

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

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.

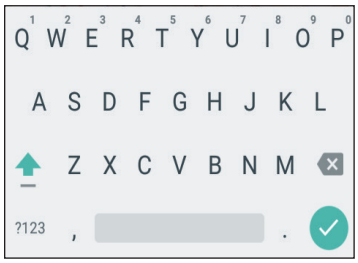
8 g ← Editable fields are underlined or framed by a box.

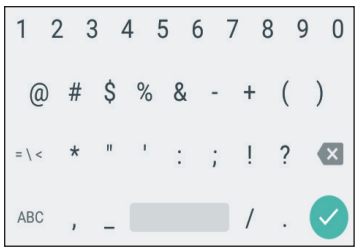
1 U ← Non-editable fields are not underlined or framed by a box.

Tapping blue and underlined text 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.

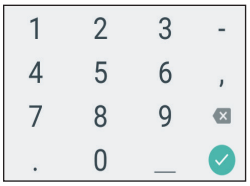
Tap the spacebar icon ( ) to add a space between characters.

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



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.

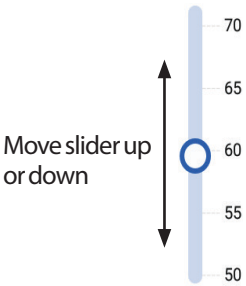
Using a scroll wheel

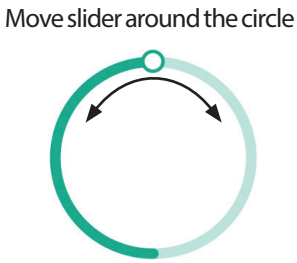
Place your finger on the scroll wheel. Move your finger up to select a smaller number and down to select a larger number. The faster you move your finger, the faster the wheel will scroll.

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.





Selecting, Adding, and Deleting Items

Toggles

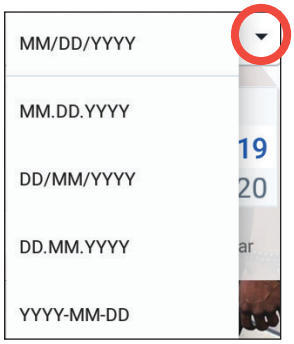
Tap a toggle to change the selection from one side to the other.

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."

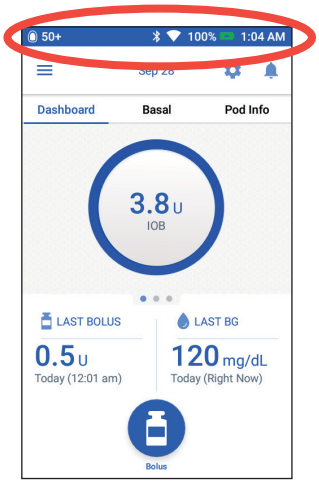
     When expanded, selections for the Notifications & Alarms history screen and the Insulin & BG History screen appear.
  3. Tap Insulin & BG History.

- 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

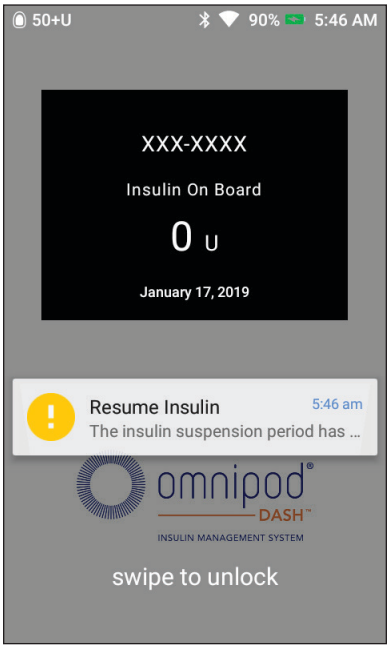
For charging instructions, see"Charge the battery" on page 22.

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?

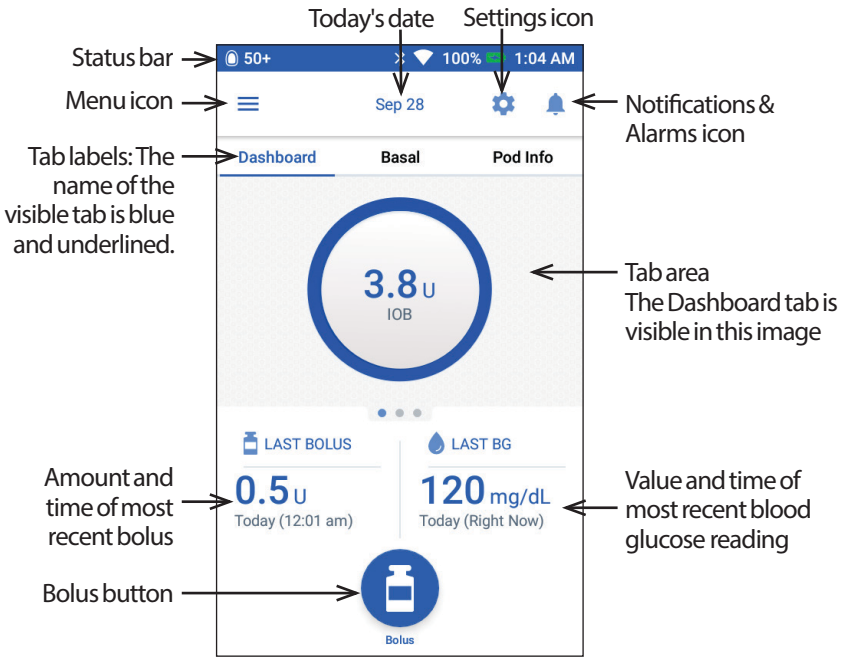
You can use the last four digits of the PDM's serial number as an alternate PIN:

1. Find the serial number next to the 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.



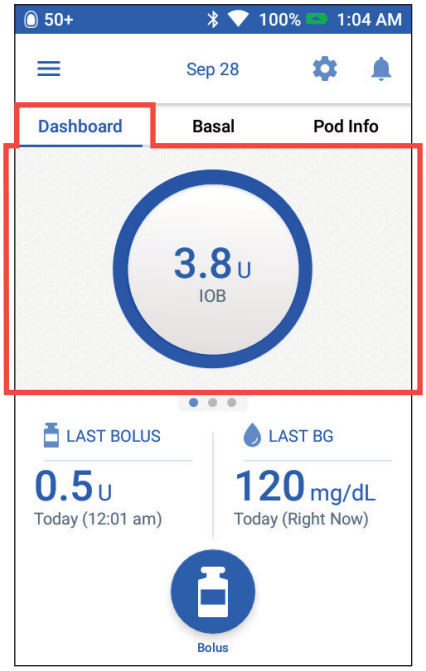
The tab area of the Home screen can display bolus information on the Dashboard, basal information, or Pod information. To change which information is displayed:

- 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 ⓘ 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).

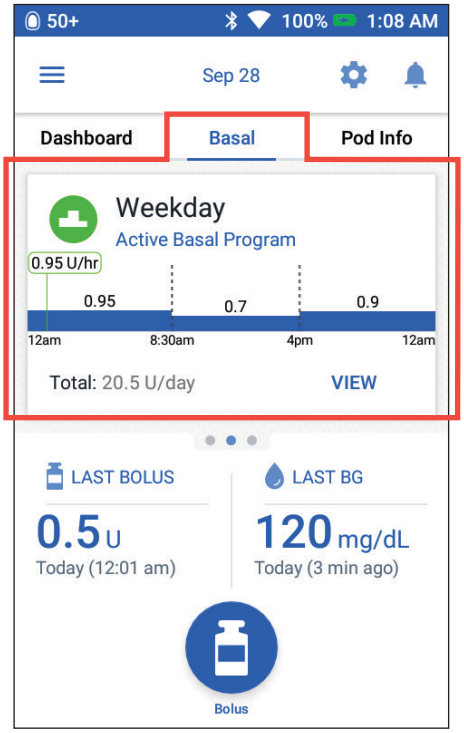
When the Bolus Calculator is off

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 150 for details.

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

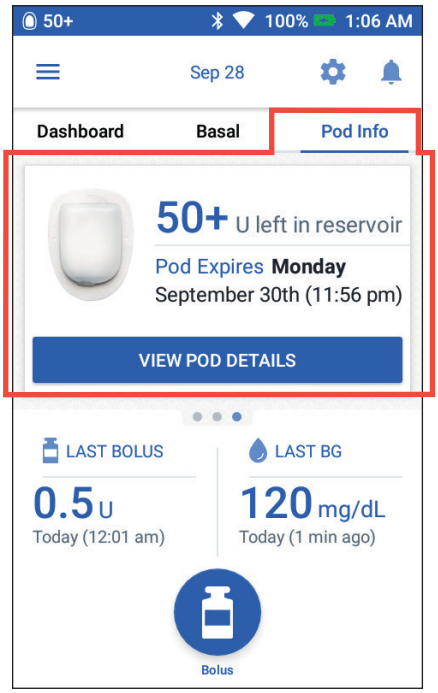
If there is no active Pod, the Pod Info tab says "No Active Pod." To set up a new Pod, see "Changing Your Pod" on page 37.

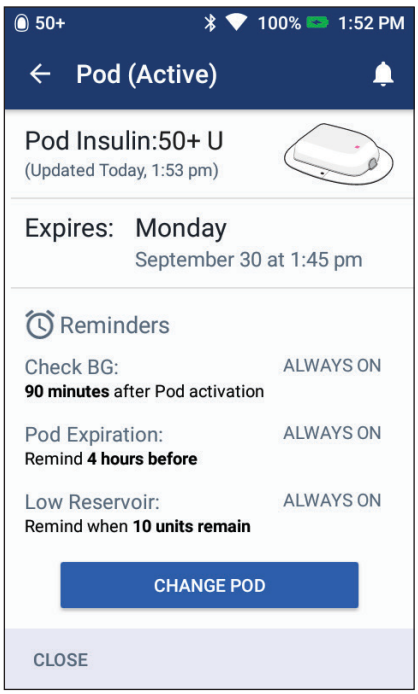
If there is an active Pod, tap VIEW POD DETAILS to bring up a screen that lets you deactivate or change your Pod.

The VIEW POD DETAILS screen shows:

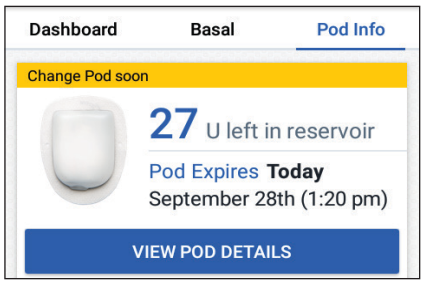
- Amount of insulin in the Pod.
- Time of the last successful communication between the PDM and Pod.
- Date and time of the Pod's expiration.
- Any active reminders.
- A CHANGE POD button.

  Tip: *You can also access this screen by tapping* Menu icon (☰) > Pod.

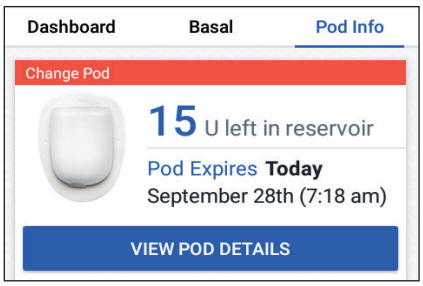




When your Pod will expire soon, a yellow Change Pod soon banner appears on the Pod Info tab. The yellow banner appears 12 hours before Pod expiration or at the time of your Pod expiration reminder, whichever is earlier.

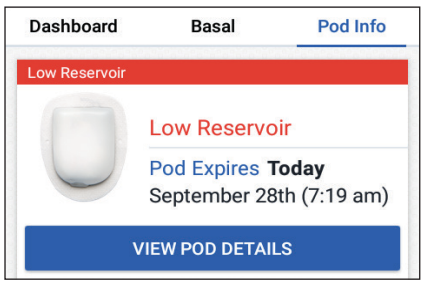


At six hours before Pod expiration, a red Change Pod banner appears on the Pod Info tab.



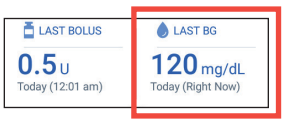
When less than five units of insulin remain in the Pod, a red Low Reservoir banner appears on the Pod Info tab. If the Pod will expire soon and there are less than five units of insulin in the Pod, the red Low Reservoir banner is displayed on the Pod Info tab.

Note: If you change the date or time, the Pod expiration date and time are adjusted to match the new date and time.



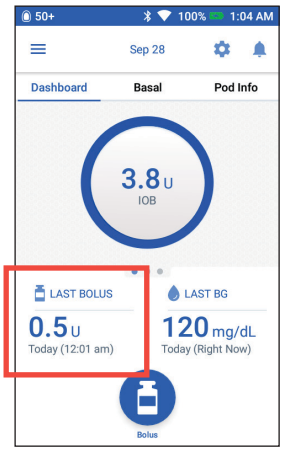
Last BG section

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.

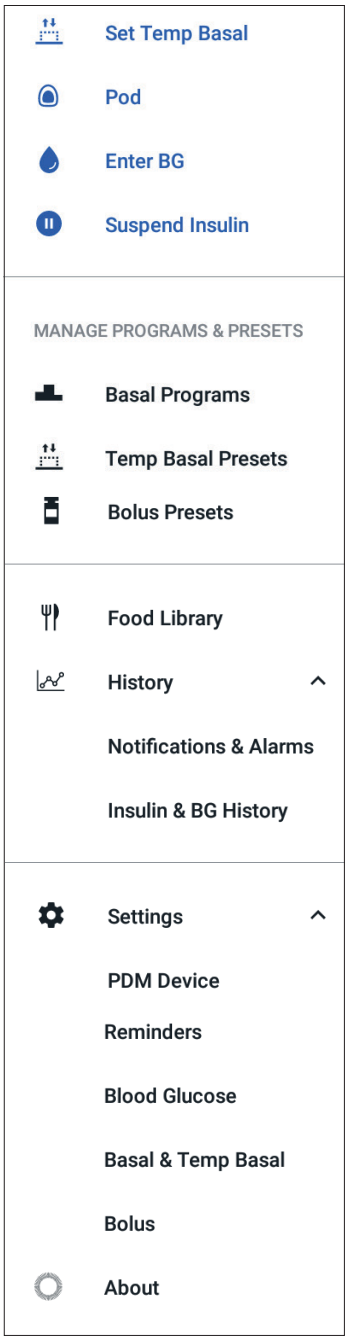
The Home Page's Menu

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.

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*  *) 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

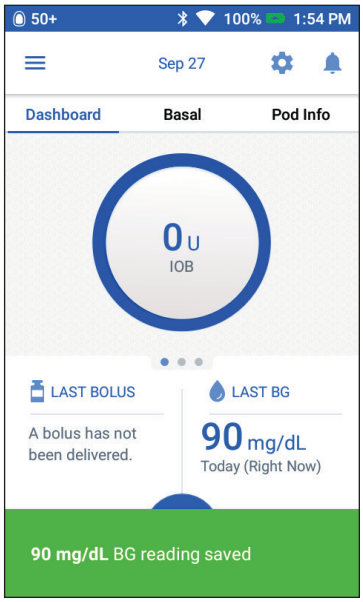
Notifications ( ) remind you about actions you may want to perform (see "Notifications List" on page 129). For example, you can set a reminder to tell you to measure your blood glucose after a specified amount of time.

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 177).

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 the PDM battery during first time setup" on page 144).
2. Assemble the charger by plugging the charger cable's USB Type A plug into the charger's wall adapter.

   Caution: Use ONLY the Insulet-provided micro-USB charger to charge your PDM. Using unapproved chargers can cause the battery to explode or damage the PDM and may void the warranty.
3. Plug the charger into a wall outlet. Select an outlet that you can access easily and unplug the charger from easily when necessary.
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: Use ONLY the rechargeable battery that came with your PDM. 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 189.

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.

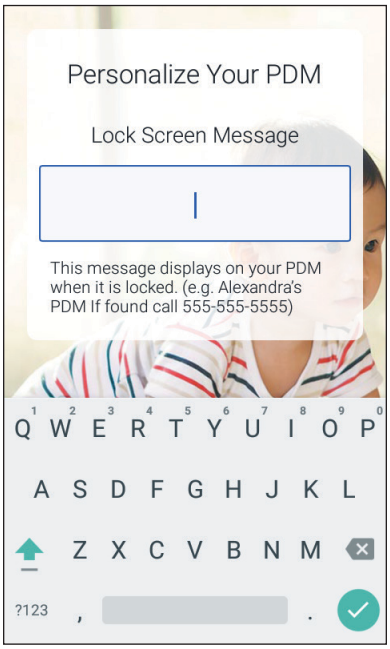
   Note: You must enter at least one character.

   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.



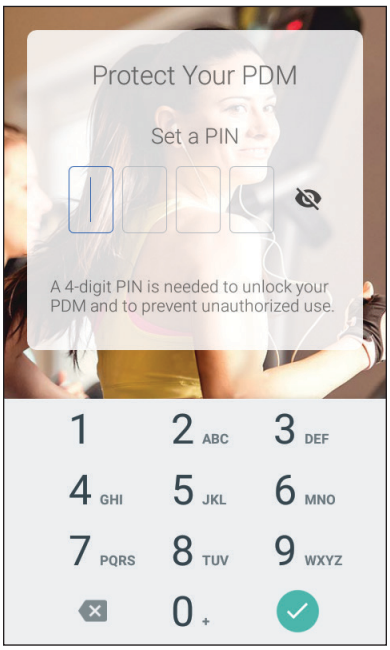
Note: When you wake up your PDM, you will see your personalized screen message and background image. Always confirm that the PDM is yours before using it.

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.*



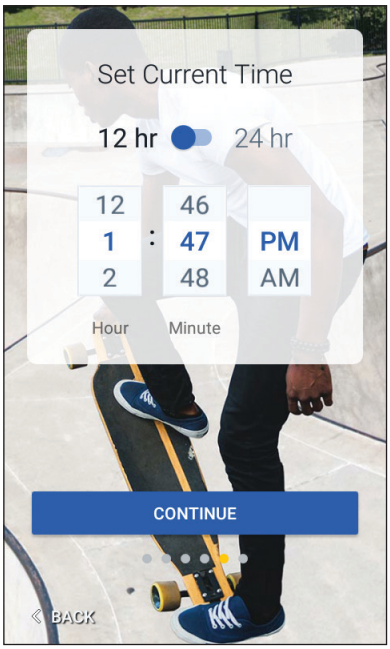
2. On the number pad, tap each number of your PIN. Then tap the checkmark.
3. Enter the same four numbers again to confirm your PIN. Tap the checkmark.

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.

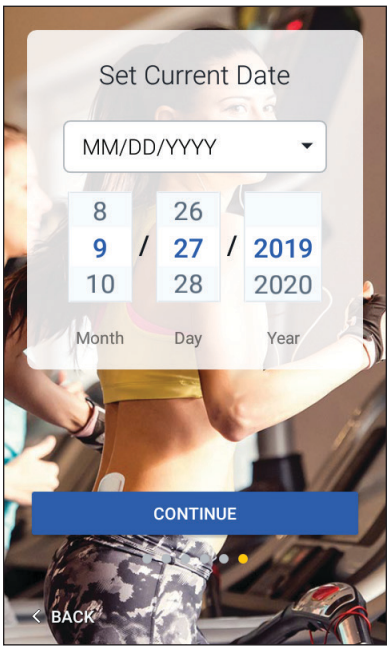


Caution: Check that you have set the time correctly. The time setting affects the operation of several Omnipod DASH System features and can impact your insulin delivery.

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.



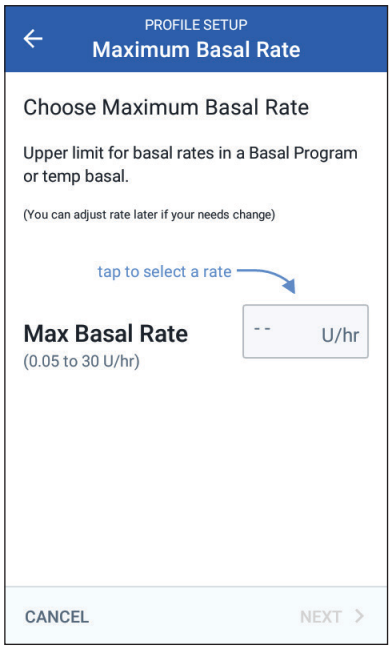
Basal Insulin Settings

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

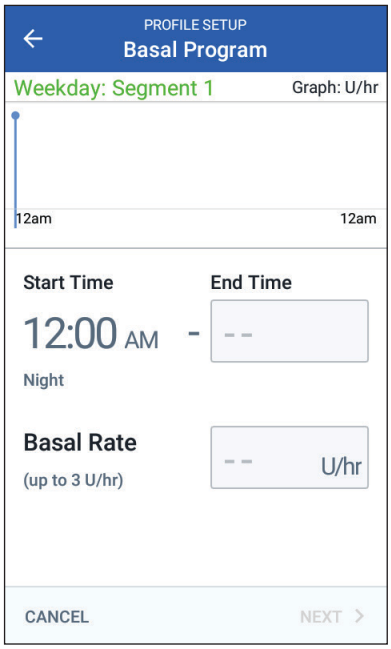
The next step is to define a Basal Program. For a description of basal rates, basal segments, and Basal Programs, see "Basal Insulin Delivery" on page 151.

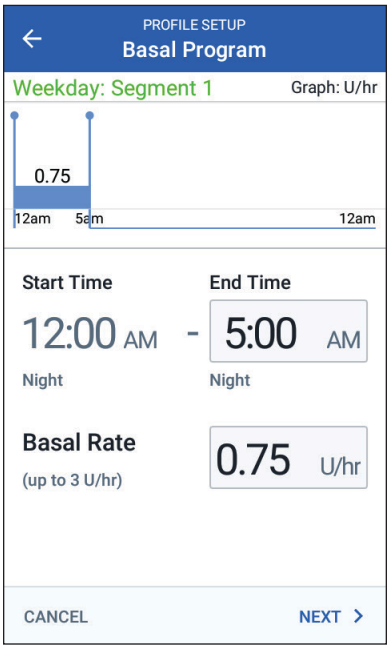
Name and tag the Basal Program

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.





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.

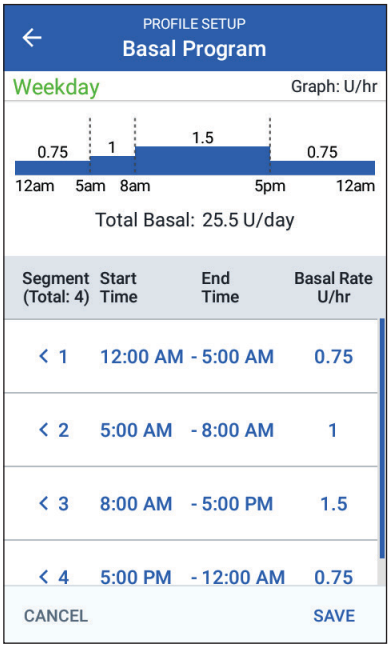
After specifying a basal rate for the final segment, your Basal Program is complete.

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.



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 153.

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 115.
2. Tap NEXT.

Blood Glucose Settings

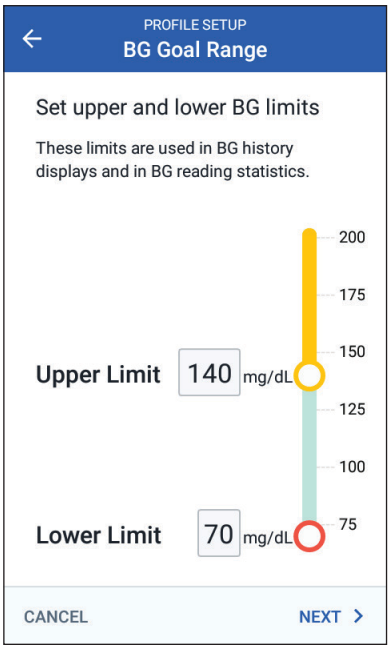
The blood glucose settings define what blood glucose readings are considered in range and allow you to pair to a CONTOUR®NEXT ONE BG meter.

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.



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

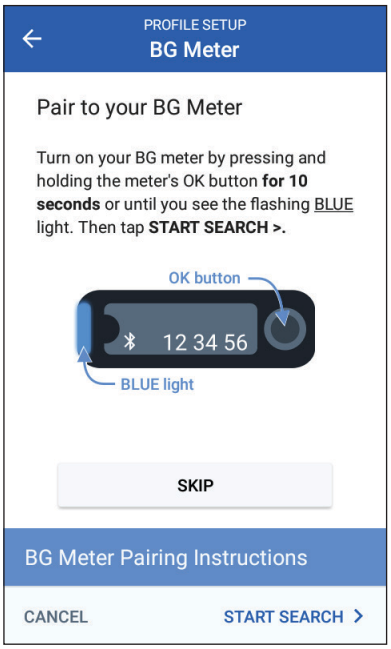
To pair a BG meter:

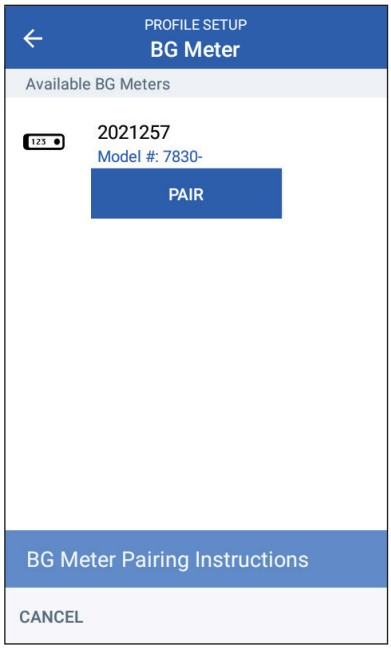
1. Turn off your BG meter, and place it within six feet of your PDM.
2. Turn on the blue light on your BG meter. To do so, press and hold the OK button on the BG meter until its white light changes to a flashing blue light.
3. On the PDM, tap START SEARCH.

   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 158).

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.

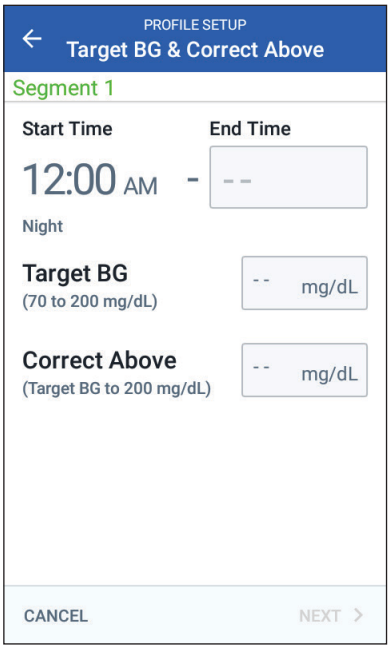
Target BG and Correct Above values

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

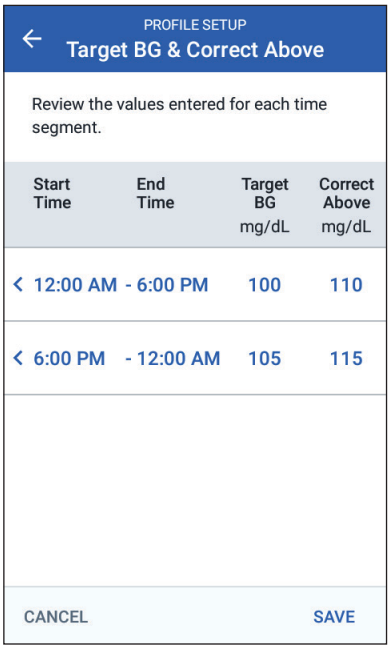
Setting values for each segment follows the same pattern that you used to create your Basal Program:

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.



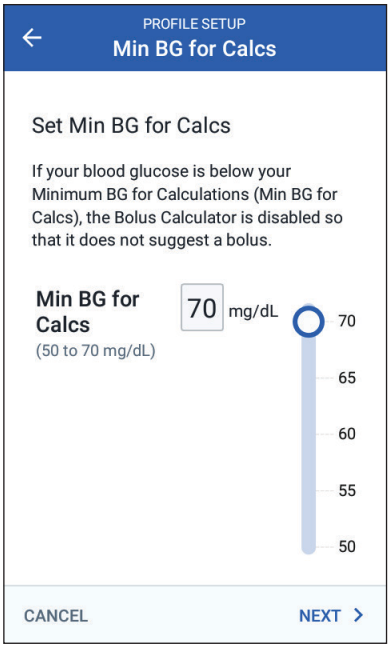
Minimum BG for Calcs

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 158).

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.*

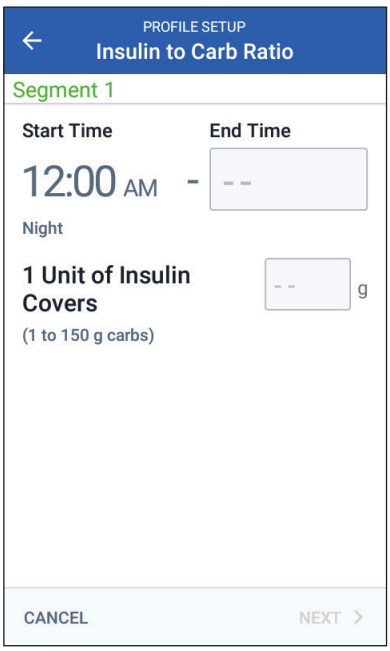
2. Tap NEXT.



Insulin to Carb Ratio

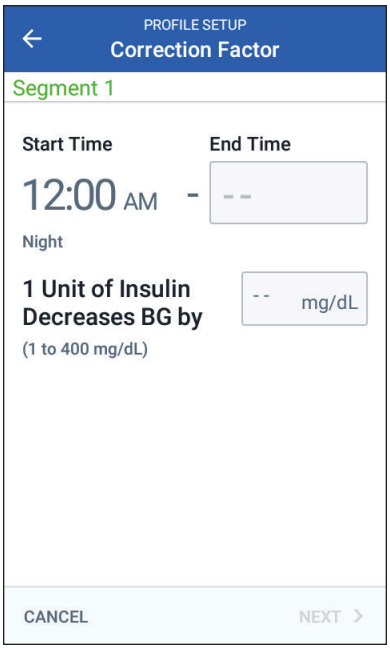
Your Insulin to Carbohydrate Ratio, or "IC Ratio," defines how many carbohydrates are covered by one unit of insulin. The Bolus Calculator uses the IC Ratio to calculate the meal portion of a suggested bolus. You can create up to eight IC Ratio segments per day.

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 157.

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 111.

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

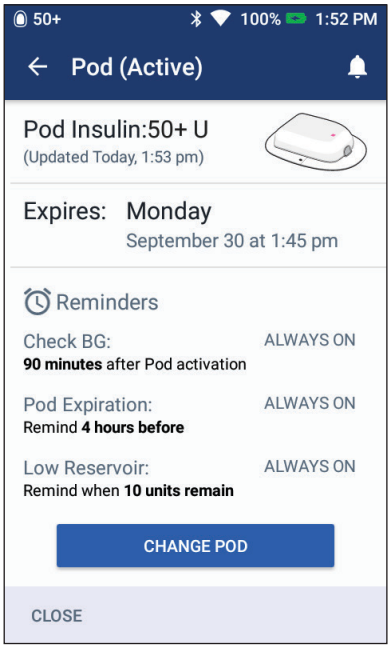
   or

   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.

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

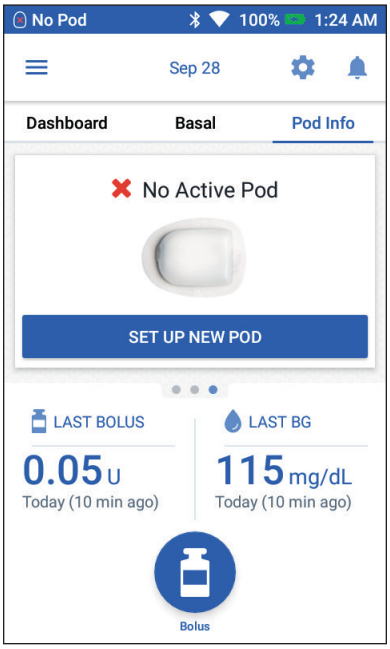
If you have no active Pod and are ready to activate a new Pod:

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 deliver insulin accurately or otherwise work properly.

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

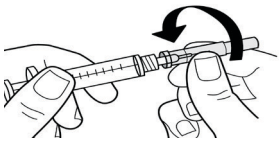
To minimize the possibility of site infection, do NOT apply a Pod without first using aseptic technique. This means to:

- 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.

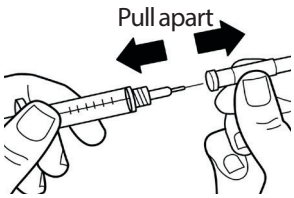
1. Gather the necessary supplies:
   - A vial of rapid-acting U-100 insulin cleared for use in the Omnipod DASH System
   - An unopened DASH Pod (look for the Omnipod DASH logo on the Pod tray lid)
   - Alcohol prep swabs
   - Your Omnipod DASH PDM
2. Wash your hands before starting and keep them clean 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:



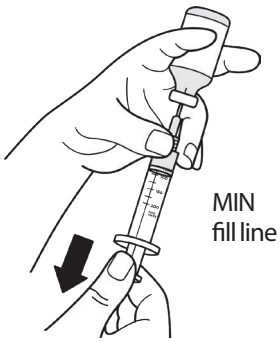
1. Use an alcohol prep swab to clean the top of the insulin vial.
2. Securely twist the fill needle onto the fill syringe.
3. Pull outward to remove the protective cap from the needle. Save the cap; you will need it later.



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.



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, move away from any other Pods being activated in range of your PDM.

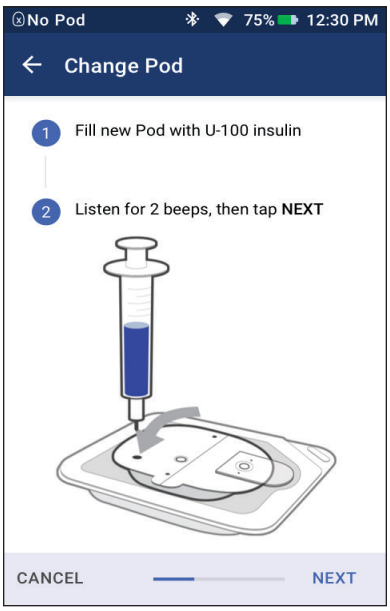
Caution: Be sure to insert the fill syringe into the fill port and not any other location on the Pod. Do not insert the fill syringe more than once into the fill port. Only use the fill syringe and needle that came with your Pod. The fill syringe is intended for single use only and should only be used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

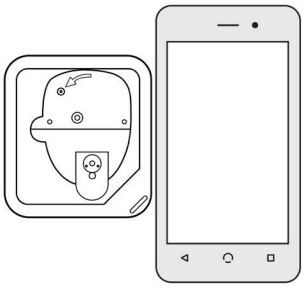
NEVER use a Pod if you feel resistance when you depress the plunger. This condition can result in interrupted insulin delivery.

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 2):



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 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.

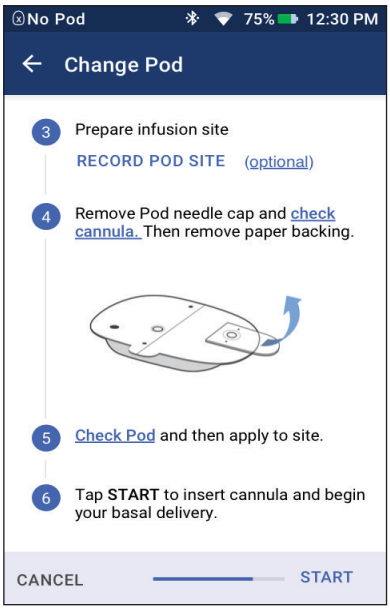
Note: After pairing, the PDM should always be able to communicate with a Pod that is up to 5 feet (1.5 m) away. Depending on the location, the PDM may be able to communicate with a Pod that is as much as 50 feet (15 meters) away.

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):



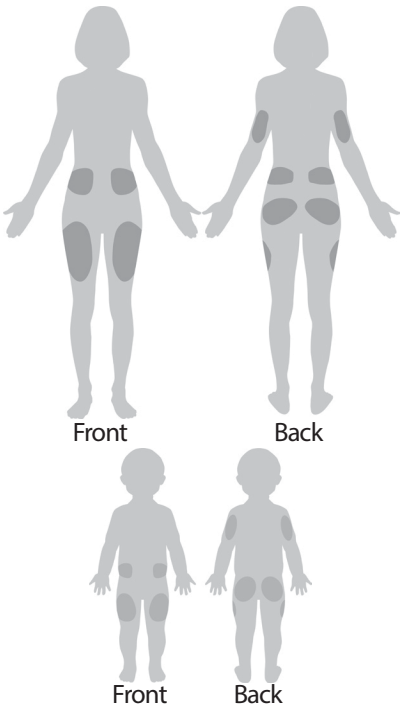
Guidelines for Pod site selection

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

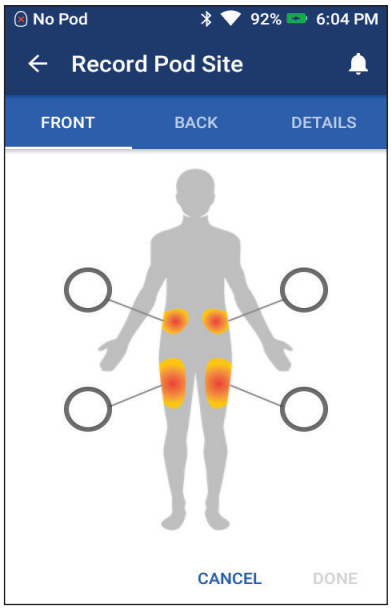
- Ideal sites have a layer of fatty tissue.
- Ideal sites offer easy access and viewing.
- The site should be at least 1 inch (2.5 cm) away from the previous site to avoid skin irritation.
- The site should be at least two inches (5 cm) away from your navel.
- Avoid sites where belts, waistbands, or 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.

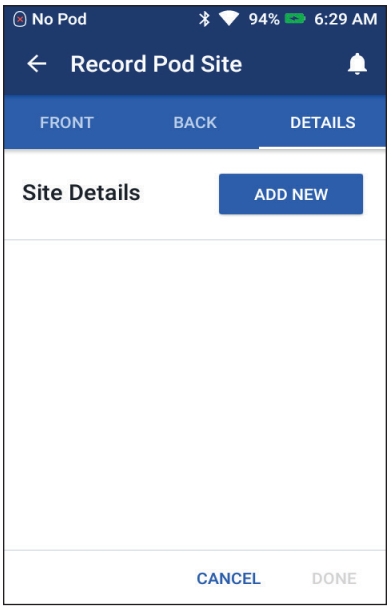
Pod site map (optional)

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).



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.

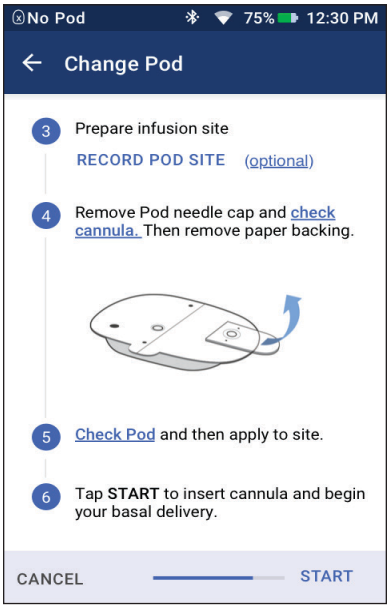
Prepare the infusion site

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.

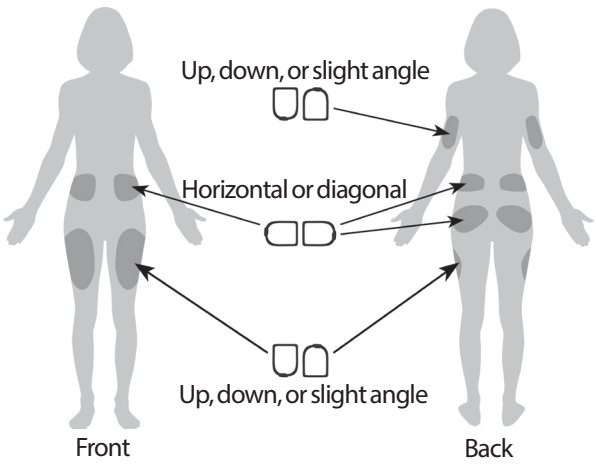
   When you remove the cap, a drop of insulin may be visible at the end of the cannula or in the well.
3. If any of the following apply, tap CANCEL, and then dispose of the Pod and begin again with a new Pod:
   - The Pod is accidentally dropped, as this may compromise sterility.
   - The Pod or its adhesive 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.

   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.

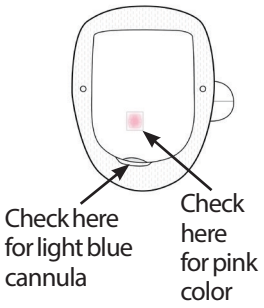
The cannula can be inserted only once with each Pod.

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.



> **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.
>
> **Warning:** If you see blood in the cannula, check your blood glucose more frequently to ensure insulin delivery has not been affected. If you experience unexpected elevated blood glucose levels, change your Pod.

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 Unresolved 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 147.

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