

omnipod®

INSULIN MANAGEMENT SYSTEM



CAREGIVER GUIDE

SIMPLE, NONSTOP INSULIN DELIVERY
DESIGNED SO KIDS CAN BE KIDS



KATIE R.

Podder

SINCE 2015



GET TO KNOW OMNIPOD.®

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This guide is intended to be used in conjunction with the child's Diabetes Management Plan, input from the parents and/or healthcare provider and the OmniPod® Insulin Management System User Guide. PDM imagery is for illustrative purposes only and should not be considered suggestions for user settings.

Refer to the OmniPod® System User Guide for complete information on how to use the System, and for all related warnings and cautions. The User Guide is available online at myomnipod.com or by calling Customer Care.

 **Caution: Consult User Guide.**

This guide is for PDM model UST400. The PDM model number is written on the back cover of each PDM.



WHAT'S DIFFERENT ABOUT THE POD? SIMPLE.

OmniPod® provides up to 3 days of nonstop insulin delivery* so kids with diabetes can run, play, and move, all while staying in control of their insulin. The system is simply 2 parts—the tubeless Pod and the handheld Personal Diabetes Manager (PDM) that your child keeps nearby so you can both wirelessly program insulin delivery. The Pod is waterproof †, lightweight, and discreet, and can be worn anywhere you would give an injection. OmniPod® helps simplify insulin delivery, so kids can be kids and you can worry less. That's just part of what makes people so passionate about the Pod.

Preparing your child to start on OmniPod®.

Whether you're a school nurse, daycare provider, parent, grandparent, or other secondary caregiver for a child using the OmniPod® Insulin Management System, this guide will lead you through some of the key functions you may need to perform.

Have questions?

We're here to help with our 24/7 comprehensive customer support.

*Up to 72 hours of insulin delivery

†The Pod has a waterproof IPX8 rating for up to 25 feet for 60 minutes.

The PDM is not waterproof.

Customer Care: 800.591.3455
From outside the US: 978.600.7850
myomnipod.com

In an emergency you should call the child's healthcare provider as well as the parent or emergency contact.

 Healthcare provider name Healthcare provider number

 Parent name Parent number

 Emergency contact name Emergency contact number

THE POD

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

TOP



Pod shown at actual size

Dimensions
 1.53" wide
 2.05" long
 0.57" high

Weight
 0.88 oz without insulin

Viewing window

BOTTOM



Fill port

Adhesive Backing

Needle cap

THE PDM

A wireless Personal Diabetes Manager (PDM) that's simple to use.

PDM shown at actual size



USB port

Color LCD screen

Soft key labels

Soft keys

Home/power

User info/support

Up/down controller

Test strip port with light

MAIN MENU ITEMS

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

More actions:

- + Change the Pod
- + Add BG readings
- + Assign/Edit BG tags
- + Food library

Temp basal: Adjust insulin delivery for exercise or illness according to the child's Diabetes Management Plan. This menu item is present only if the Temp basal option is turned on.

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

Settings:

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

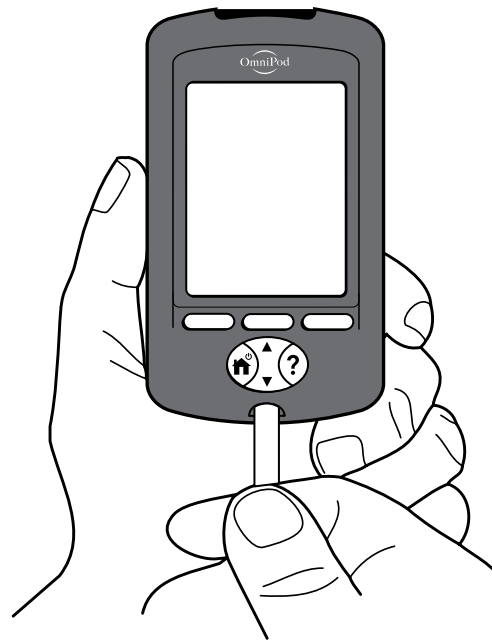
Suspend: Temporarily suspend, cancel, or resume insulin delivery programs

HOW TO CHECK BLOOD GLUCOSE AND DELIVER A BOLUS.

A bolus is an extra dose of insulin that helps manage the rapid natural rise in blood glucose (also known as blood sugar) that results when you eat carbohydrates (sugar or starch). Follow the steps below to check the child's blood glucose level, determine the appropriate bolus and deliver the bolus. These steps assume that the suggested bolus calculator has been turned on as part of the child's Diabetes Management Plan.

Because children's food intake is often unpredictable, consult the child's Diabetes Management Plan or healthcare provider to determine the appropriate timing of insulin delivery.

1.



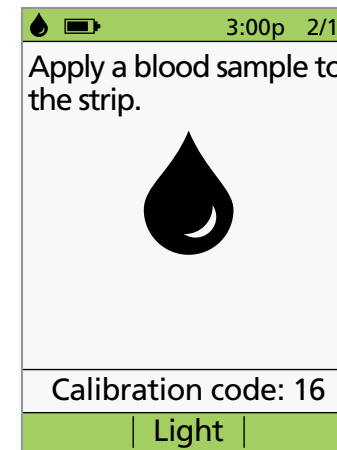
- + Insert FreeStyle® test strip into strip port.
- + Check that the code on the vial of test strips matches the code on the PDM screen.
- + If the codes do not match, use the **Up/down controller** button to match the code on the PDM to the code on the vial.



Caution: Consult User Guide.

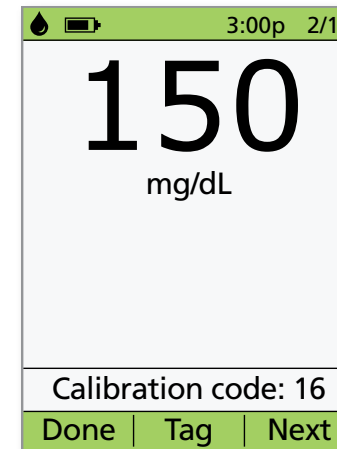
HOW TO CHECK BLOOD GLUCOSE AND DELIVER A BOLUS

2.



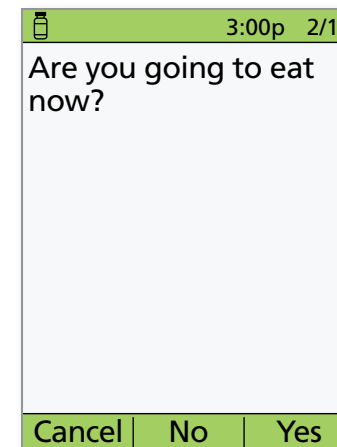
- + Wash the finger with soap and water or an alcohol wipe and dry it completely.
- + Prick finger with the lancing device.
- + Press **Light** to illuminate the test strip in low-light situations.
- + Apply blood sample to test strip.

3.



- + When blood glucose reading appears, press **Next** to continue.

4.



- + If eating now, press **Yes**.
- OR
- + If not eating, press **No**.

WARNING:

Measurements obtained from alternate site testing should not be used to calculate insulin doses with OmniPod Insulin Management System.

For more information about blood glucose testing, control solution testing, manual blood glucose test entry and the Suggested Bolus Calculator, see Chapter 7, Checking Your Blood Glucose, in your OmniPod® Insulin Management System User Guide.

HOW TO CHECK BLOOD GLUCOSE AND DELIVER A BOLUS

5.

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

6.

- + Review the BG and carb values to make sure they are correct, then press **Confirm**.

7.

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

HOW TO CHECK BLOOD GLUCOSE AND DELIVER A BOLUS

8.

- + Press **Enter** to accept the suggested bolus.
OR
- + Press **Extend** and follow on-screen instructions to deliver a portion/percentage of the bolus immediately and the rest over a set period of time. *Only use the **Extend** option when required by the child's Diabetes Management Plan.*
- + If extended boluses are not part of the child's Diabetes Management Plan, the **Extend** option will not appear on the screen.

9.

- + Press **Confirm** to start the bolus.

10.

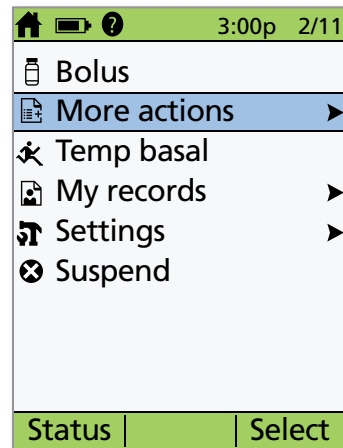
- + The PDM screen will indicate when bolus delivery has begun. If necessary, you may press **Cancel** to stop a bolus while it is being delivered.
- + The child does not need to remain near the PDM during delivery. Delivery time varies based on the size of the bolus dose.
- + Once bolus delivery begins,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

HOW TO CHANGE THE POD.

You may need to change the Pod:

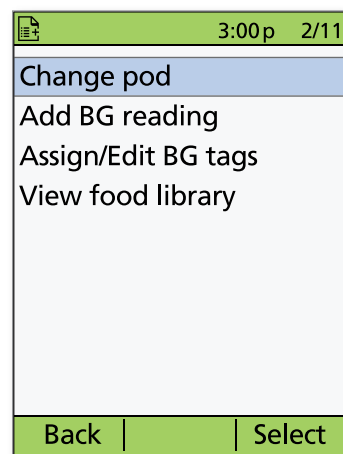
- + When the reservoir is low or empty, or the Pod is nearing expiration
- + In response to an alarm
- + If the Pod has become dislodged
- + If the child has a blood glucose reading of 250 mg/dL or more and has moderate to large ketones
- + If you experience unexpected elevated blood glucose levels
- + As directed by your healthcare provider
- + If a Pod is active and fails to beep

1.



- + Turn on the PDM.
- + Press the **Home/power** button, then select **More actions**.

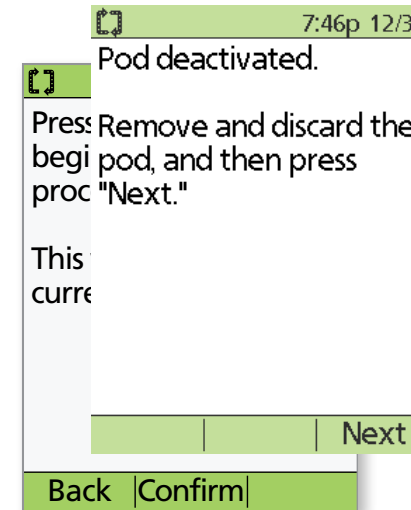
2.



- + Select **Change pod**.

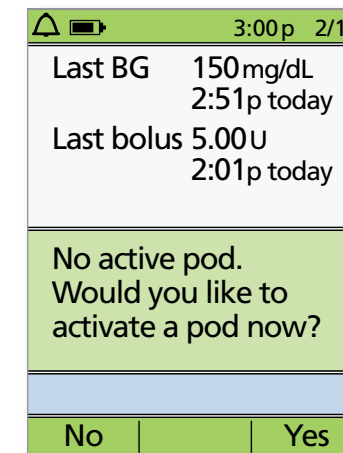
HOW TO CHANGE THE POD

3.



- + Press **Confirm** to deactivate Pod.
- + Gently remove the deactivated Pod by slowly peeling back the adhesive. (Our users have reported commercial solvent or baby oil can be helpful to soften the adhesive if necessary.)

4.



- + Press **Yes** to activate a new Pod.
- + Follow the steps on pages 11 and 12 to fill a new Pod with insulin. As you proceed, if the PDM screen times out, press and hold the **Home/power** button to turn it back on.

NOTES

If the PDM screen times out during the process, press and hold the **Home/power** button to continue.



Caution: Consult User Guide.

HOW TO CHANGE THE POD

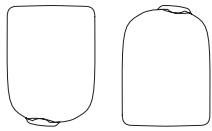
POD PLACEMENT OPTIONS

The Pod may be placed over any subcutaneous tissue in most places one would deliver an insulin injection. Please note the recommended positioning for each body area. The child's Diabetes Management Plan or healthcare provider should indicate any preferred sites.

POD POSITIONING

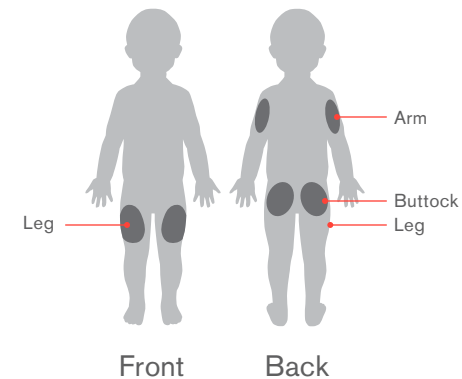
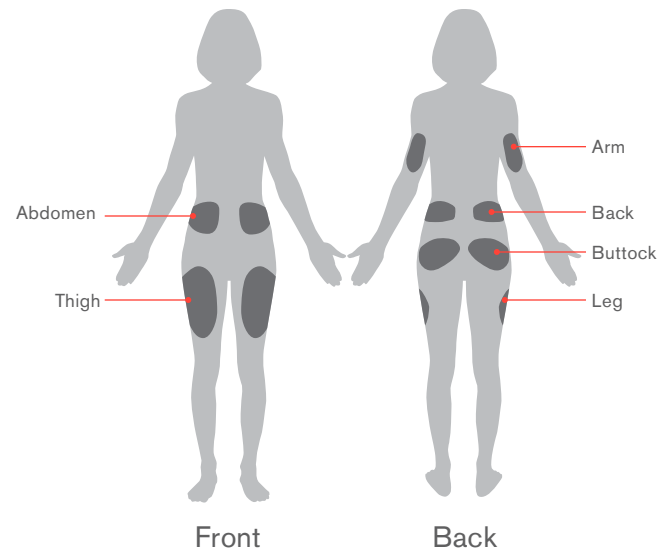
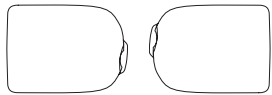
Arm and Leg:

Position the Pod *vertically* or at a slight angle.



Back, Abdomen, and Buttocks:

Position the Pod *horizontally* or at a slight angle.



SITE SELECTION

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

OPTIMAL ADHESION

Always clean the site thoroughly with an alcohol swab to remove all body oils and lotions, which may loosen the Pod's adhesive. Let the site air-dry completely; do not blow on the site to dry it.

HOW TO CHANGE THE POD

ACTIVATE A NEW POD



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

STEP 1: FILL THE POD

1.1



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

1.2



- + Remove the protective cap.



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

If the PDM screen times out during the process, press and hold the **Home/power** button to continue.

HOW TO CHANGE THE POD

1.3



- + Draw air into the fill syringe equal to the amount of insulin indicated in the child's Diabetes Management Plan.
- + Depress air into the vial of insulin.
- + Turn the vial and syringe upside down.
- + Withdraw insulin from the vial and fill the syringe with the amount of insulin indicated in the child's Diabetes Management Plan; fill at least to the MIN line.
- + Remove any air bubbles from the syringe.

1.4



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



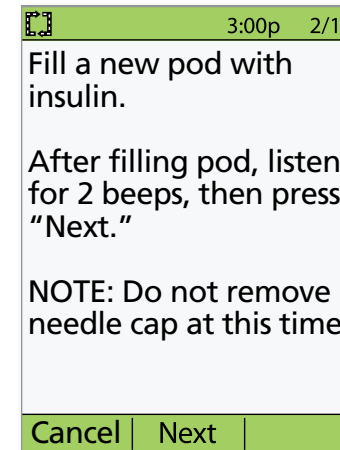
WARNING: NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.



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

HOW TO CHANGE THE POD

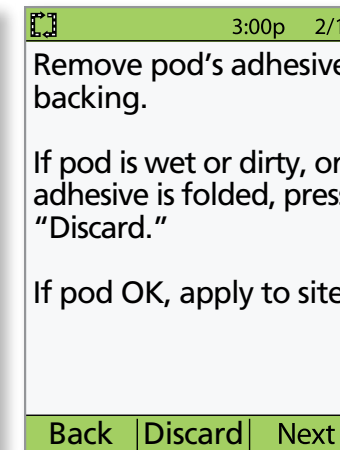
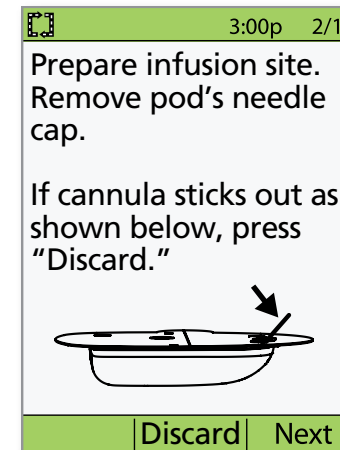
1.5



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

STEP 2: APPLY THE POD

2.1



- + Select the infusion site, being careful to avoid areas where the Pod will be affected by folds of skin. Refer to the figures on page 10 for recommended sites and placement tips.

2.2



- + For optimal adhesion, always clean the site thoroughly with an alcohol swab to remove all body oils and lotions, which may loosen the Pod's adhesive. Let the site air-dry completely; do not blow on the site to dry it.

If the PDM screen times out during the process, press and hold the **Home/power** button to continue.

HOW TO CHANGE THE POD

2.3



- + Remove the needle cap.

2.4



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

2.5

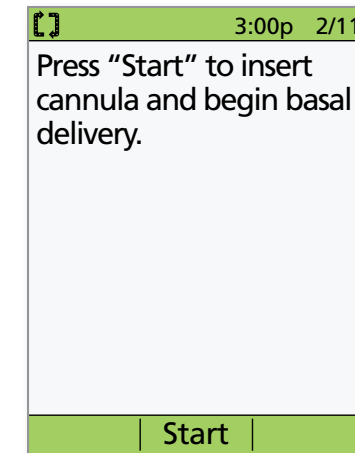


- + Apply the Pod to the selected site.
- + Run your finger around the adhesive to secure it.
- + Press **Next** on the PDM.
- + To facilitate insertion, place one hand over the Pod and make a wide pinch around the skin surrounding the viewing window; this step is critical if the insertion site does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

HOW TO CHANGE THE POD

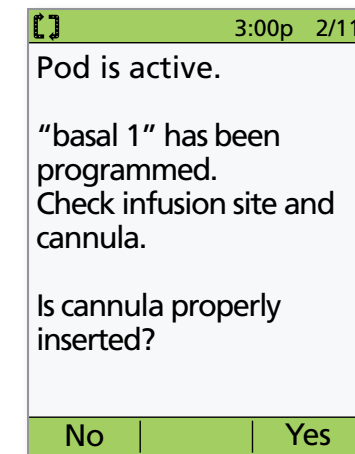
STEP 3: PRESS START

3.1



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

3.2

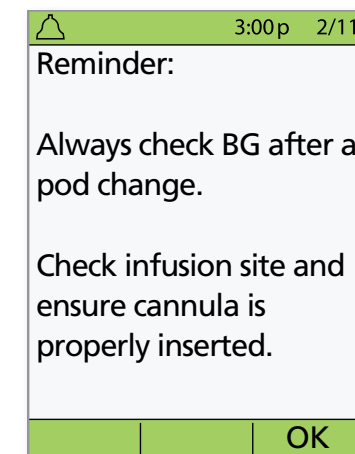


- + Once complete, the PDM indicates that the Pod is active and asks you to check the infusion site.
- + Look through the Pod's viewing window to check that the cannula is properly inserted, then press **Yes**.



WARNING: NEVER inject insulin (or anything else) into the fill port while the Pod is on the child's body. Doing so may result in unintended or interrupted insulin delivery.

3.3



WARNING: The PDM will generate an automatic reminder to check the child's blood glucose 1.5 hours after each Pod change. If the cannula is not properly inserted, hyperglycemia may result. Verify there is no wetness or scent of insulin, which may indicate the cannula has dislodged.

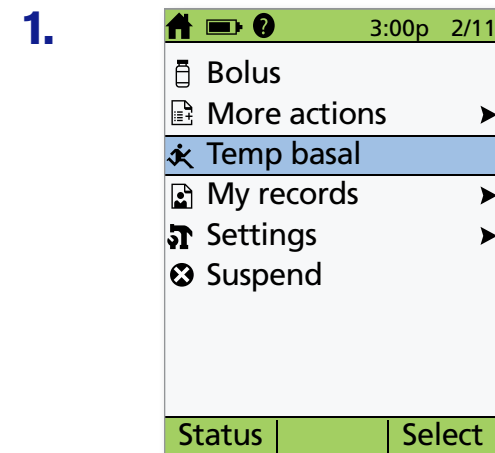
If the PDM screen times out during the process, press and hold the **Home/power** button to continue.

HOW TO ENTER A TEMPORARY BASAL RATE.

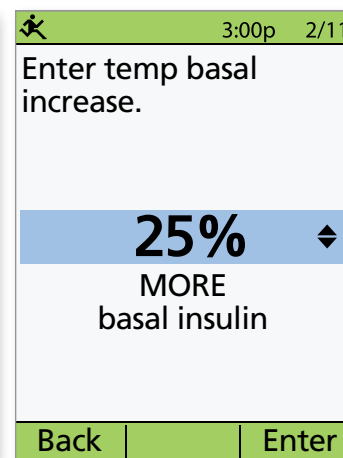
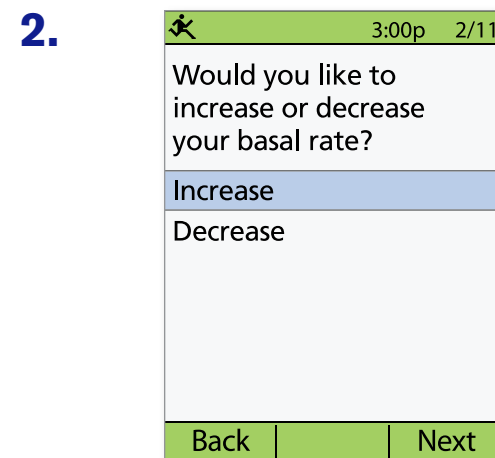
The basal rate refers to the steady dose of insulin the child receives at all times. You may need to:

- + Temporarily increase the basal rate in response to high blood sugar if, for instance, the child is ill or insulin delivery has been interrupted.
- + Temporarily decrease the basal rate prior to increased physical activity (physical education or organized sports) or in response to low blood sugar that does not respond to oral carbohydrates or other efforts.

The child's Diabetes Management Plan or healthcare provider should provide the appropriate temp basal rates.

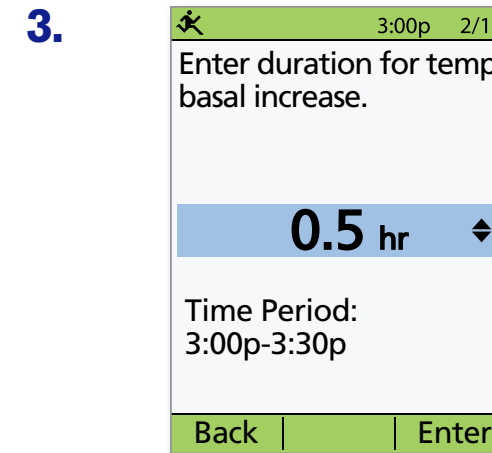


- + Turn on the PDM.
- + Press the **Home/power** button, then select **Temp basal**.
- + If temporary basal rates are not part of the child's Diabetes Management Plan, the **Temp basal** option will not appear on the screen.

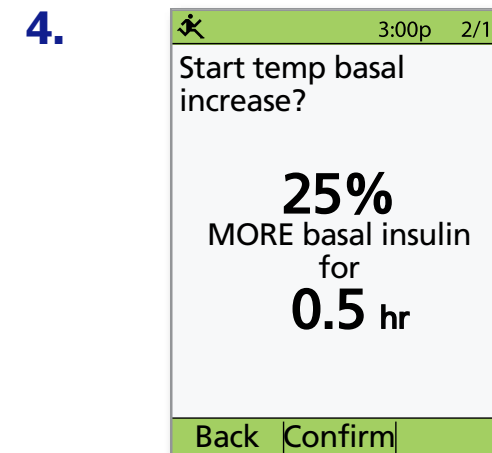


- + Choose **Increase** or **Decrease** basal rate, then press **Next**.
- + Enter % change (or temp basal rate), then press **Enter** (Shown here is an example of a temporary basal increase. In this example, 25% MORE insulin will be delivered).

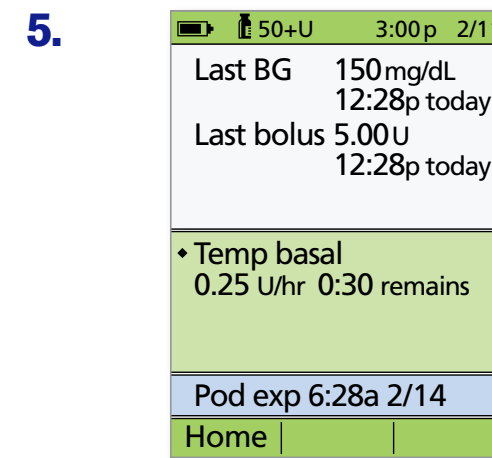
HOW TO ENTER A TEMPORARY BASAL RATE



- + Enter the length of time the temp basal should be delivered (in half-hour increments), then press **Enter**.



- + Press **Confirm** to start the temporary basal rate shown on the screen (In this example, 25% more basal insulin will be delivered for 0.5 hours). The Pod beeps to indicate that the temporary basal rate is running.

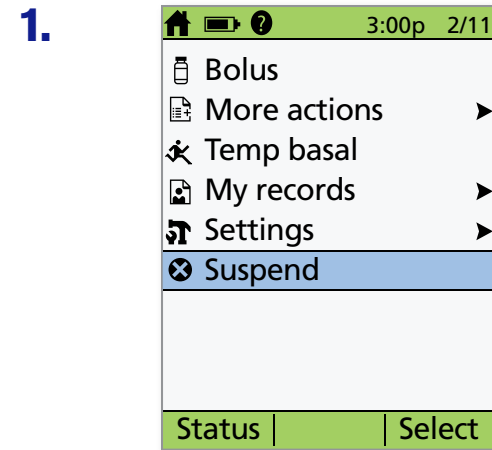


- + The **Status** screen indicates the temp basal rate and the remaining delivery time.

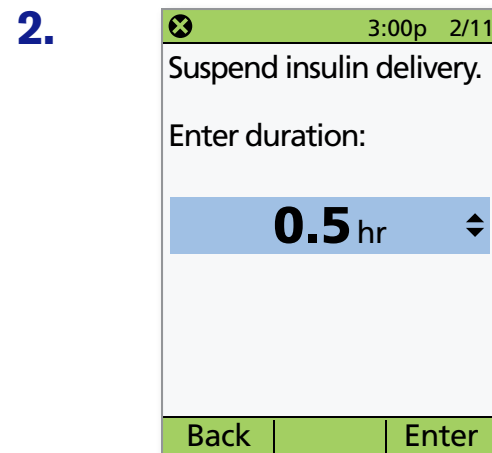
Caution: Consult User Guide.

HOW TO SUSPEND INSULIN DELIVERY.

If the child has severe low blood sugar you may need to suspend insulin delivery.

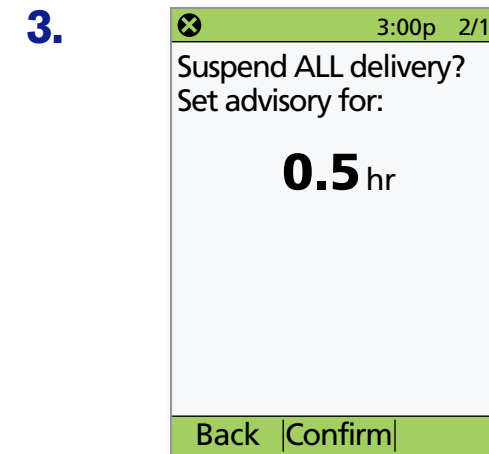


- + Turn on the PDM.
- + Press the **Home/power** button, then select **Suspend**.

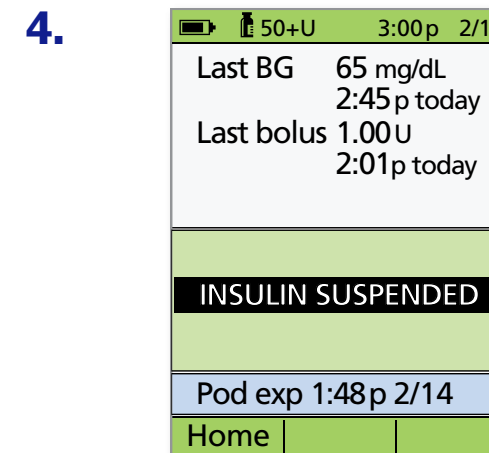


- + Enter the length of time the suspension should last (minimum 0.5 hour, maximum 2.0 hours), then press **Enter**.

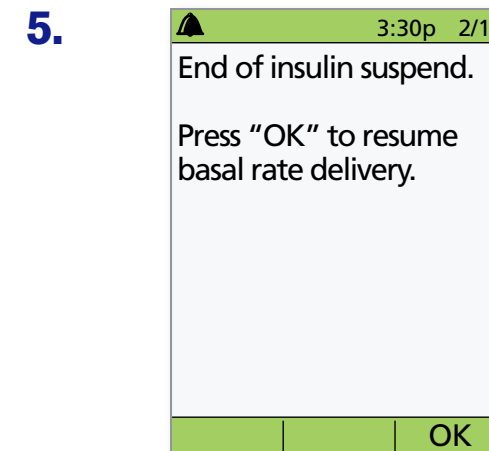
HOW TO SUSPEND INSULIN DELIVERY



- + Press **Confirm**.



- + The **Status** screen indicates that insulin delivery has been suspended.



- + The Pod will beep every 15 minutes until the end of the suspension period. At the end of the suspension period, a Pod advisory alarm will occur. At this time, turn the PDM on and press **OK** to resume the active basal program.



WARNING: Insulin delivery will not resume until you press OK. If you do not press OK to resume insulin delivery, you could develop hyperglycemia (high blood glucose).



omnipod®

3 DAYS*
NONSTOP
INSULIN

myomnipod.com

*Up to 72 hours
of insulin delivery

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PDM screens may vary based on model or user settings.

Model: UST400
17595 Rev. B 05/16