

omnipod[®]
INSULIN MANAGEMENT SYSTEM

INSULIN MANAGEMENT SYSTEM



CAREGIVER GUIDE

SIMPLE, NONSTOP INSULIN DELIVERY
DESIGNED SO KIDS CAN BE KIDS



KATIE R.

Podder[™]
SINCE 2015



GET TO KNOW THE OMNIPOD® SYSTEM.

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This guide is intended to be used in conjunction with the individual'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 www.myomnipod.ca or by calling the Omnipod® Customer Care Program.



Caution: Consult User Guide.

This guide is for PDM model CAT45E. The PDM model number is written on the back cover of each PDM.



WHAT'S DIFFERENT ABOUT THE POD? SIMPLE.

The Omnipod® Insulin Management System 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 the user 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 to start on the Omnipod® System.

Whether you're a school nurse, daycare provider, parent, grandparent, or other secondary caregiver for an individual 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 7.6 meters for 60 minutes.

The PDM is not waterproof.

Omnipod® Customer Care Program: 1.855.POD.INFO (1.855.763.4636)
From outside of Canada: 1.289.247.3534
www.myomnipod.ca

In an emergency you should call the individual'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

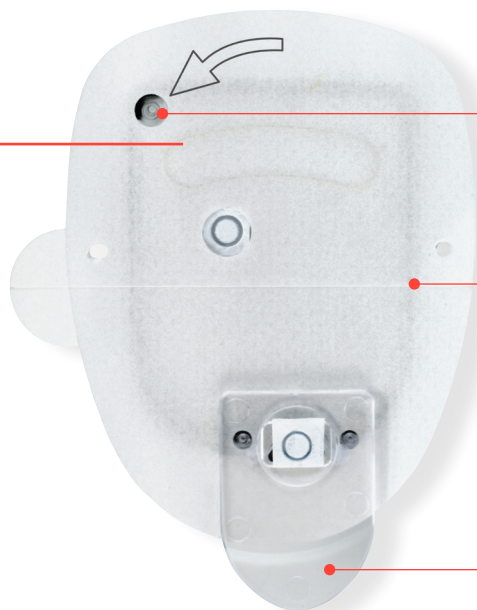
3.9 cm wide
5.2 cm long
1.45 cm high

Weight

25 g 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



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

Temp basal: Adjust insulin delivery for exercise or illness according to the individual'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

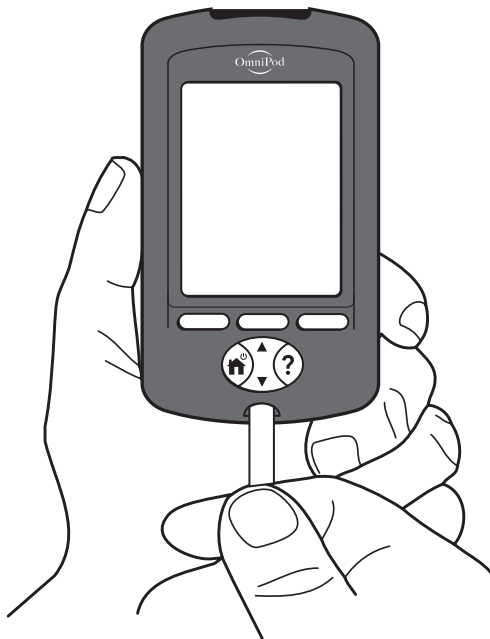
Suspend: Temporarily suspend, cancel, or resume insulin delivery programs

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 individual'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 individual's Diabetes Management Plan.

Because food intake can be unpredictable, consult the individual's Diabetes Management Plan or healthcare provider to determine the appropriate timing of insulin delivery.

1.



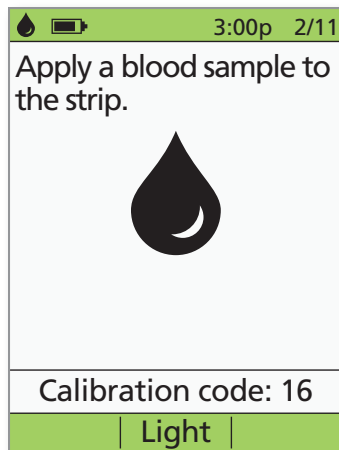
- + Insert FreeStyle or FreeStyle Lite test strip into strip port.
- + Check that the code on the vial of test strips matches the code on the PDM screen.
- + If the codes do not match, use the **Up/down controller** button to match the code on the PDM to the code on the vial.



Caution: Consult User Guide.

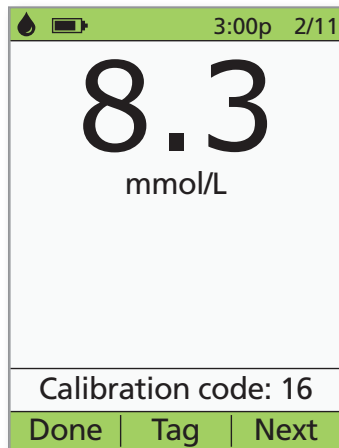
HOW TO CHECK BLOOD GLUCOSE AND DELIVER A BOLUS

2.



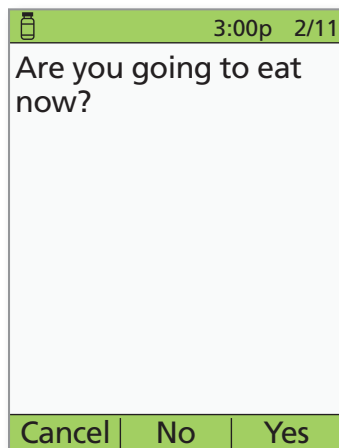
- + Wash the finger with soap and water or an alcohol wipe and dry it completely.
- + Prick finger with the lancing device.
- + Press **Light** to illuminate the test strip in low-light situations.
- + Apply blood sample to test strip.

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.

3:00p 2/11

Enter carbs.

0 g

Back | Enter

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

6.

3:00p 2/11

Suggested bolus: 5.00u
Carbs: 60 g
BG: 8.3 mmol/L

5.00 U

Back | Extend | Enter

- + Review the BG and carb values to make sure they are correct.

7.

3:00p 2/11

Suggested bolus: 5.00 U

Meal: (60/15) = 4.00 U
Correction:
(8.3 - 5.5)/2.8 = 1.00 U
Meal IOB:
(0.00 U) = -0.00 U
Correction IOB:
(0.00 U) = -0.00 U
Total = 5.00 U

5.00 U

Close

Back | Extend | Enter

- + 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.

Suggested bolus: 5.00u
Carbs: 60 g
BG: 8.3 mmol/L

5.00 U

Back | Extend | Enter

- + 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 individual's Diabetes Management Plan.*
- + If extended boluses are not part of the individual's Diabetes Management Plan, the **Extend** option will not appear on the screen.

9.

Start bolus?

Now: **5.00 U**

Ext: **0.00 U**
(0.0 hr)

Total: **5.00 U**

Back | Confirm

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


10.

Delivering bolus

5.00 U

Cancel

- + 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 individual 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.

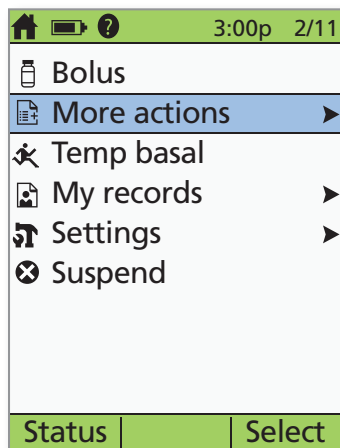
TIP  Patient **does not** need to stay within the communication distance of 1.5 meters during the entire bolus delivery process. As soon as the delivering bolus screen has shown up, the PDM can be put away since the bolus has begun to be delivered.

HOW TO CHANGE THE POD.

You may need to change the Pod:

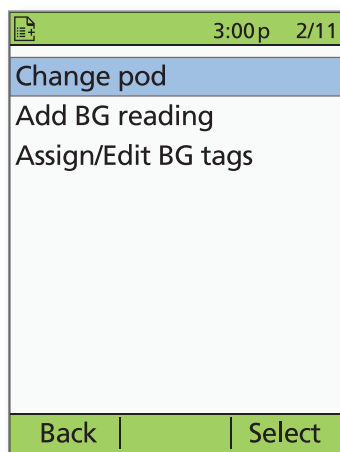
- + When the reservoir is low or empty, or the Pod is nearing expiration
- + In response to an alarm
- + If the Pod has become dislodged
- + If the individual has a blood glucose reading of 13.9 mmol/L or more and has moderate to large ketones
- + If you experience unexpected elevated blood glucose levels
- + 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.



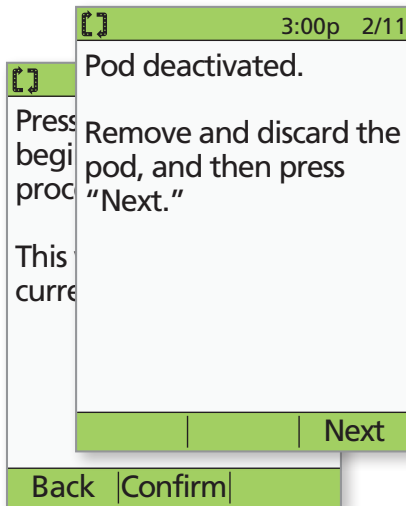
- + Select **Change pod**.



Caution: Consult User Guide.

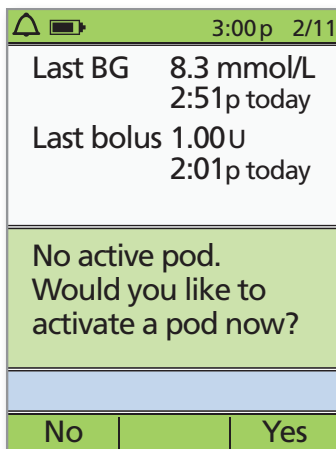
HOW TO CHANGE THE POD

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.

HOW TO CHANGE THE POD

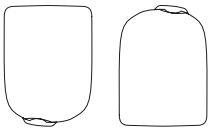
POD PLACEMENT OPTIONS

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 individual's Diabetes Management Plan or healthcare provider should indicate any preferred sites.

POD POSITIONING

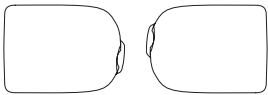
Arm and Leg:

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



Back, Abdomen, and Buttocks:

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

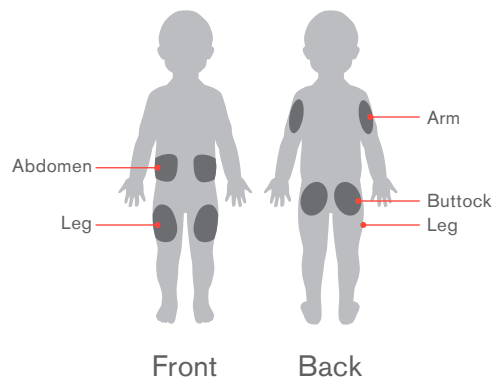
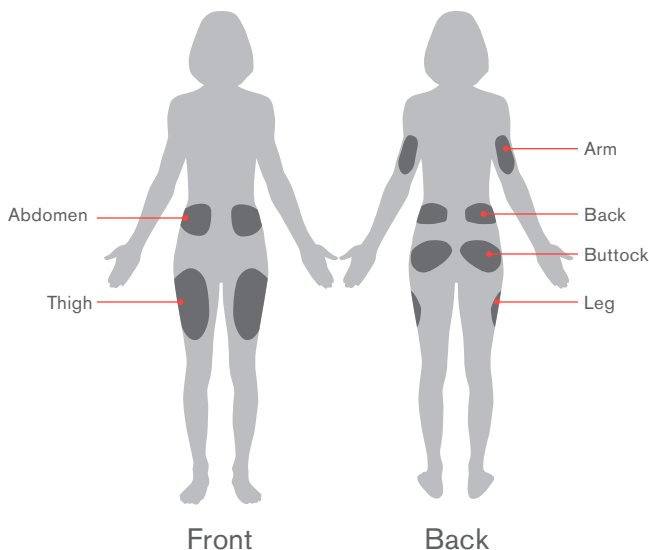


SITE SELECTION

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 2.5 cm away from the previous site, 5 cm 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 individual'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 individual'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.



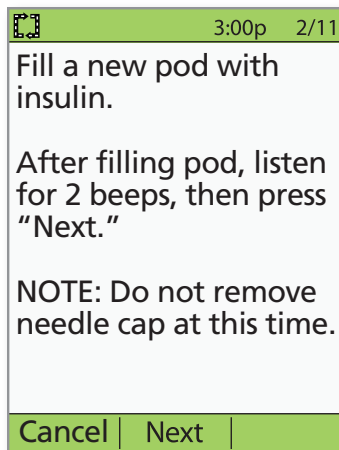
WARNING: NEVER inject air into the fill port.
Doing so may result in unintended or interrupted insulin delivery.



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

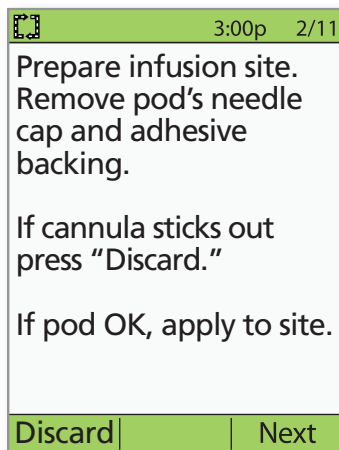
1.5



- + 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. The new site should be at least 2.5 cm away from the previous site, 5 cm away from the navel, and not over a mole or scar. 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

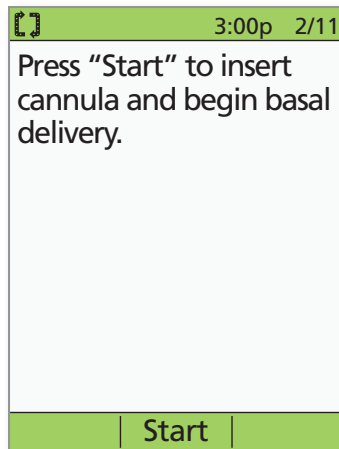


- + Apply the Pod to the selected site.
- + Run your finger around the adhesive to secure it.
- + Press **Next** on the PDM.
- + To facilitate insertion, place one hand over the Pod and make a wide pinch around the skin surrounding the viewing window; this step is critical if the insertion site does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

HOW TO CHANGE THE POD

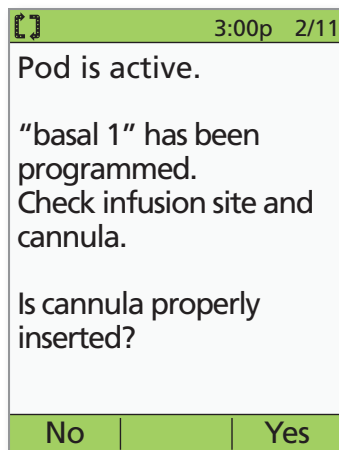
STEP 3: PRESS START

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. When you see the pink slide insert in this position, it means that the cannula is inserted (see image below). Then press **Yes**.



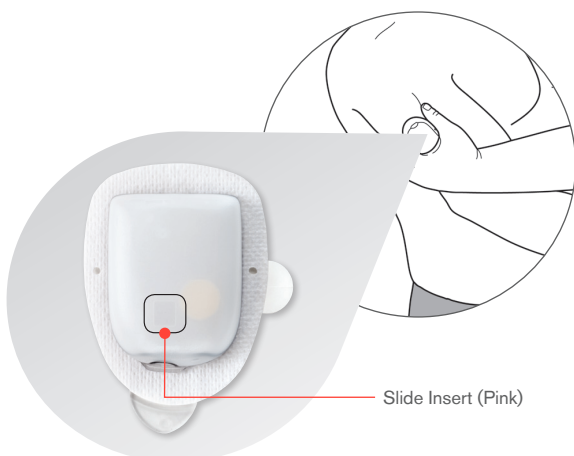
WARNINGS: NEVER inject insulin (or anything else) into the fill port while the Pod is on the individual's body. Doing so may result in unintended or interrupted insulin delivery.

If you observe blood in the cannula, check the individual's blood glucose more frequently to ensure insulin delivery has not been affected. If you observe unexpected elevated blood glucose levels, change the Pod.

Check the infusion site after insertion to ensure that the cannula was properly inserted. The individual should check their blood glucose 1.5 to 2 hours after each Pod change and check the infusion site periodically. 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.

At least once a day, use the Pod's viewing window to check the site for signs of infection and to confirm that the soft cannula is securely in place.

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



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

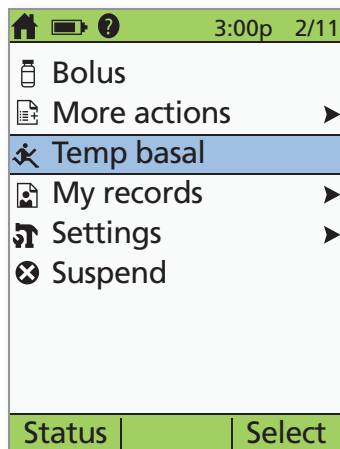
HOW TO ENTER A TEMPORARY BASAL RATE.

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

- + Temporarily increase the basal rate in response to high blood sugar if, for instance, the individual 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.

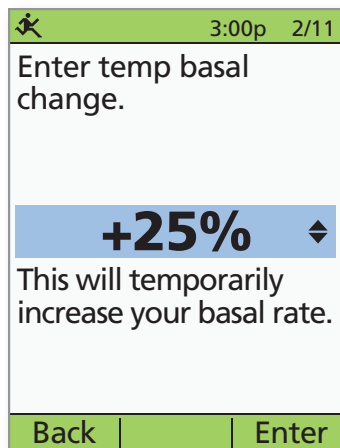
The individual's Diabetes Management Plan or healthcare provider should provide the appropriate temp basal rates.

1.



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

2.



- + 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).



Caution: Consult User Guide.

HOW TO ENTER A TEMPORARY BASAL RATE

3.

3:00p 2/11

Enter duration for temp basal.

Change: +25%

0.5 hr

Back | Enter

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

4.

3:00p 2/11

Start temp basal increase?

+25%

0.5 hr

Back | Confirm

- + 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.

5.

50+U 3:00p 2/11

Last BG 12 mmol/L
12:28p today

Last bolus 1.00U
12:28p today

Temp basal
+25% 0:30 remains

Pod exp 6:28a 2/14

Home

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

HOW TO SUSPEND INSULIN DELIVERY.

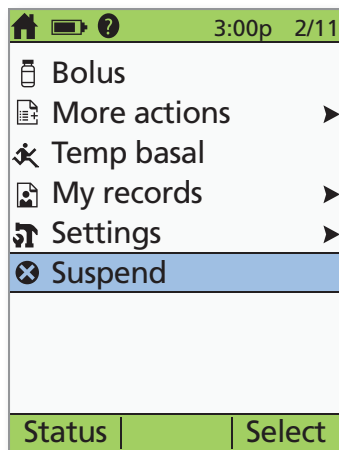
If the individual has severe low blood sugar you may need to suspend insulin delivery.

Never ignore the signs of low blood sugar (no matter how mild). Any time the individual's blood glucose is low, treat immediately. If blood glucose is below 3.9 mmol/L, provide the individual with 15 grams of fast-acting carbohydrates, such as glucose tablets, juice, or hard candy. Check it every 15 minutes while you are treating, to make sure you don't cause blood glucose levels to rise too high. If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness.

Symptoms of hypoglycemia. Never ignore these symptoms:

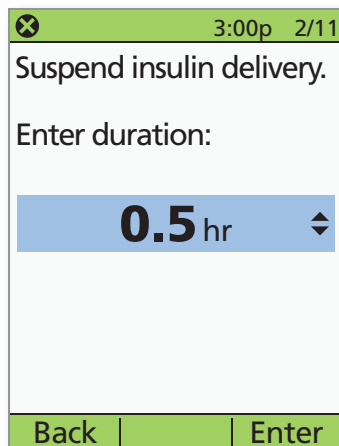
- + Shakiness
- + Fatigue
- + Unexplained sweating
- + Cold, clammy skin
- + Weakness
- + Blurred vision or a headache
- + Sudden hunger
- + Rapid heart rate
- + Confusion
- + Tingling in the lips or tongue
- + Anxiety

1.



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

2.



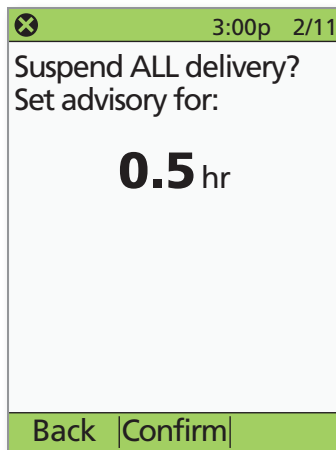
- + Enter the length of time the suspension should last (minimum 0.5 hour, maximum 2.0 hours), then press **Enter**.



Caution: Consult User Guide.

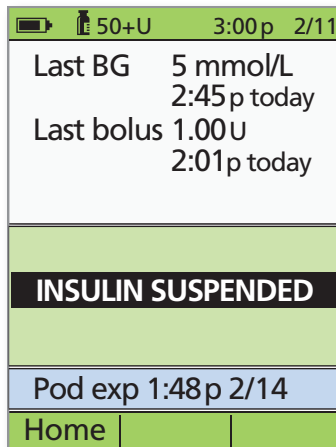
HOW TO SUSPEND INSULIN DELIVERY

3.



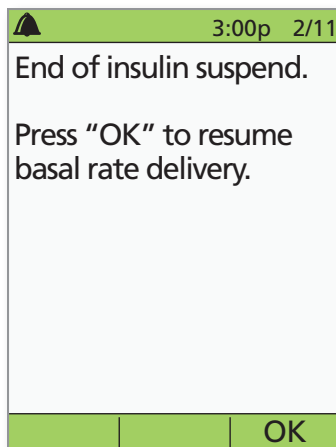
+ Press **Confirm**.

4.



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

5.



+ 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, the individual could develop hyperglycemia (high blood glucose).

SUPPLIES

You should have the following supplies on hand at all times:

- + Several new, sealed Pods
- + Extra new PDM batteries (at least two AAA alkaline)
- + A vial of rapid-acting U-100 insulin
- + Syringes or pens/needles for injecting insulin
- + Instructions from the individual's healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- + Blood glucose test strips
- + Ketone test strips
- + Lancing device and lancets
- + Glucose tablets or another fast-acting source of carbohydrate
- + Alcohol prep swabs
- + If traveling, a copy of a letter from the individual's healthcare provider for airline security
- + Phone numbers for the individual's parents, healthcare provider, and emergency contact
- + Glucagon emergency kit and written instructions for giving an injection



Caution: Consult User Guide.



PDM PERSONAL SETTINGS

Use this section to record the individual's most recent PDM settings, as provided by your healthcare provider.

1. MAX BASAL

- Select > Settings
 - > System setup
 - > Bolus/basal/calcs
 - > Max basal

Write down the **Max basal** value.

_____ U/hr

2. BASAL RATE

- Select > Settings
 - > Basal programs
 - Choose a program*
 - > View
 - > List

Write down each of the **Basal rate** settings.

Segment		Basal rate U/hr
12:00a	–	_____
	–	_____
	–	_____
	–	_____

3. TEMP BASAL SETTINGS

- Select > Settings
 - > System setup
 - > Bolus/basal/calcs
 - > Temp basal

Check the box below that matches the **Temp basal** setting.

% U/hr Off

4. BG SOUND

- Select > Settings
 - > System setup
 - > BG meter
 - > BG sound

Check the box below that matches the **BG sound** setting.

On Off

PDM PERSONAL SETTINGS

9. INSULIN TO CARB RATIO

- Select > Settings
 - > System setup
 - > Bolus/basal/calcs
 - > Ratios/factors/targets
 - > IC ratio

Write down the settings for **Insulin to carb (IC) ratio.**

Segment		IC ratio g carb/U
12:00a	—	_____
	—	_____
	—	_____
	—	_____

10. CORRECTION FACTOR

- Select > Settings
 - > System setup
 - > Bolus/basal/calcs
 - > Ratios/factors/targets
 - > Correction factor

Write down the settings for **Correction factor.**

Segment		Correction factor mmol/L per U
12:00a	—	_____
	—	_____
	—	_____
	—	_____

11. REVERSE CORRECTION

- Select > Settings
 - > System setup
 - > Bolus/basal/calcs
 - > Ratios/factors/targets
 - > Reverse correction

Check the box below that matches the **Reverse correction** setting.

On Off

12. INSULIN ACTION

- Select > Settings
 - > System setup
 - > Bolus/basal/calcs
 - > Ratios/factors/targets
 - > Insulin action

Write down the value for **Insulin action.**

_____ hr

PDM PERSONAL SETTINGS

13. BOLUS INCREMENT

- Select > Settings
> System setup
> Bolus/basal/calcs
> Bolus increment

Check the box that matches the **Bolus increment** value.

- 0.05 U 0.10 U
 0.50 U 1.00 U

14. MAX BOLUS

- Select > Settings
> System setup
> Bolus/basal/calcs
> Max bolus

Write down the value for **Max bolus** setting.

_____ U

15. EXTENDED

- Select > Settings
> System setup
> Bolus/basal/calcs
> Extended

Check the box below that matches the **Extended** setting.

- % Units Off

16. LOW RESERVOIR

- Select > Settings
> System setup
> Alerts/reminders
> Low reservoir

Write down the value for **Low reservoir**.

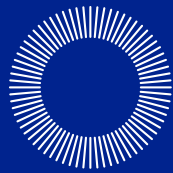
_____ U

17. EXPIRATION

- Select > Settings
> System setup
> Alerts/reminders
> Expiration

Write down the value for **Expiration**.

_____ hr



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PDM screens may vary based on model or user settings.

Model: CAT45E

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