

11 Taking Care of Your PDM and Pod

- Do not expose the battery or its charger to liquids, including water, rain, or snow, as this can cause malfunction. If the battery or charger is exposed to liquid, contact Customer Care.
- Do not allow anyone, including children and pets, to put the battery in their mouth. Doing so may result in damage or explosion.
- Do not place the PDM or battery on or in heating devices, such as microwave ovens, stoves, or radiators. The battery may explode if overheated.
- Do not drop the battery. If the battery is dropped, contact Customer Care.
- Only use an Insulet approved battery, charger, and cable to charge your PDM. Using unapproved batteries, chargers, or cables can cause the battery to explode or damage the PDM, and may void the warranty.
- If the battery is damaged so that fluid leaks from the battery, do not allow the leaked fluid to make direct contact with your skin or eyes. If this happens, immediately flush your skin or eyes with clean water and consult a doctor.
- If the battery is deformed or hot to the touch before you insert it into the PDM for the first time, do not use this battery in your PDM. Use of this battery may lead to battery leakage, fire, or explosion. Place the battery on a metal surface and leave it outside, if possible. Contact Customer Care for a new battery.
- If the battery deforms, changes color, or overheats while charging, during use, or in storage, do not handle the battery and do not continue use. Continued use may lead to battery leakage, fire, or explosion. Place the PDM on a metal surface and leave it outside, if possible. Contact Customer Care for further instructions.
- Inspect your PDM battery charger before each use. If the adapter for the charger falls in water or is cracked, do not use it.
- PDM is in Airplane mode. Keep PDM in Airplane mode for best battery life.

Contact Customer Care if you notice the following:

- Charging taking too long
- Battery discharging too quickly
- PDM too hot to touch
- Swelling of the PDM and/or battery
- Smell of gas coming from PDM and/or battery
- Wall charger getting too hot

PDM battery messages you may see

Battery message	What you should do
Incompatible Charger	Disconnect charger. Connect provided PDM charger and cable.
Battery Too Warm	Disconnect charger if connected. Allow the PDM to cool.
Battery Too Cold	The PDM is too cold to be charged. Allow the PDM to reach room temperature.
Charging Error	Disconnect the charger. Allow the PDM to reach room temperature.

Charging the PDM battery

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.

Under normal use, the battery should hold its charge for more than one day.

A PDM message alerts you when the battery charge is low. The battery icon in the status bar tracks the remaining charge in the battery (see "The Status Bar" on page 9). To charge the battery, see "Charge the battery" on page 22.

You can charge your battery many times, but all batteries have a limited lifespan. If you notice a significant deterioration in the duration of the PDM's battery charge, contact Customer Care.

Note: Charging times can vary depending on the surrounding temperature and the remaining battery level.

Tip: Develop a routine to charge the PDM battery at the same time every day. Do not wait for the low PDM battery message.

Warnings:

If the battery power becomes critically low, the PDM turns itself off to preserve the data in memory. At this point, you cannot use the PDM until you have plugged in the charger.

Note: If the PDM battery is critically low and the PDM has turned off, your Pod continues to deliver basal insulin according to the active Basal Program or temp basal. If you do not charge your PDM battery, this insulin delivery continues until the Pod expires.

Note: The history records stay in memory for 60 days even if the battery power is critically low.

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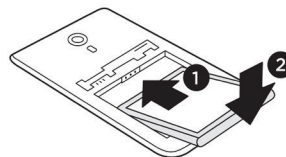
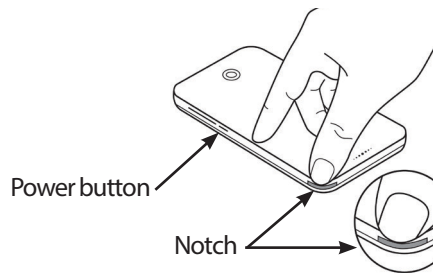
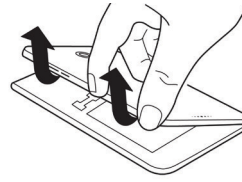
Inserting the PDM battery during first time setup

Caution: Use ONLY the rechargeable battery that came with your PDM. Contact Customer Care if you have questions.

Caution: Do not insert the PDM battery while the PDM is connected to external power (e.g. a wall outlet via the USB cable and charger).

To insert the PDM battery:

1. Ensure the USB cable is disconnected from the PDM.
2. If your PDM is on, turn it off by pressing the Power button, tapping Power off, and then tapping OK.
3. If the white pull tab is still on the PDM, remove the back cover using the pull tab as follows:
 - a. Hold the PDM with the back cover facing you.
 - b. Place two or more fingers of one hand between the pull tab and the PDM.
 - c. Brace the thumb of that hand against the back of the PDM.
 - d. Pull back on the pull tab and lift off the cover.
 - e. Skip to step 5.
4. If the white pull tab is no longer on the PDM, remove the back cover as follows:
 - a. Hold the PDM sideways and locate the notch in the PDM case. The notch is located in the corner below the Power button.
 - b. Holding the PDM firmly, place a fingernail into the notch and pull the front cover away from the back cover.
 - c. Slide your finger along the opening to completely separate the front from the back.
 - d. Lift off the back cover.
5. Orient the new battery so the three gold tabs on the battery line up with the three gold pins in the battery compartment. The "-" and "+" signs on the battery label should face you.



Caution: Do not remove the label from the battery.

Caution: Be careful not to damage any of the small metal parts inside the battery compartment.

6. Slide the battery into place. Gently push the bottom of the battery to fit it into place.
7. To replace the back cover of the PDM:
 - a. Line up the cover's edge along the side with the Sound/vibrate and Power buttons. Press down on this side first.
 - b. Press down along the back cover until the cover has clicked into place.

The PDM is now ready to use. If this is a new PDM, see "Initial PDM Setup" on page 21 for instructions for entering your settings.

Note: Do not attempt to replace the battery after first-time insertion. If you are experiencing battery or charging issues, contact Customer Care.

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CHAPTER 12

Understanding PDM and Pod Function

This chapter explains how the PDM and Pod interact, features such as basal and bolus insulin delivery, and how the Bolus Calculator works.

PDM and Pod Interactions

This section describes how the PDM controls the Pod, and what the Pod can do without input from the PDM.

Pod actions controlled by the PDM

The Pod requires input from the PDM in order to:

- Become activated or deactivated
- Change to a different Basal Program
- Start a bolus or temp basal
- Cancel a bolus or temp basal
- Suspend or resume insulin delivery

Pod activation

Pods are dormant until they are activated by a PDM. Once a PDM activates a Pod, that PDM and Pod are paired together, which means that they can only communicate with each other even if there are other Pods or PDMs within range. During Pod activation, the PDM transfers the active Basal Program details to the Pod.

The PDM's communication range is automatically reduced during activation. Therefore, the PDM should touch the Pod (in or out of its tray) during Pod activation. As an added precaution, do not activate your Pod in the same area that someone else is activating a Pod.

How close do the PDM and Pod need to be after activation?

After activation, the PDM should always be able to communicate with a Pod that is up to 5 feet (1.5 m) away. Depending on the surroundings, the PDM may be able to communicate with a Pod that is as much as 50 feet (15 meters) away. To ensure that you can deliver a bolus, change the basal rate, or receive status updates from the Pod, make sure the PDM is within 5 feet (1.5 m) of the Pod.

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When you are not actively using the PDM, store it in a nearby location, such as a shirt pocket or in a drawer, briefcase, or purse.

Status checks: How the PDM checks Pod function

The PDM periodically queries the Pod about its status, called a "status check." The PDM performs a status check:

- When you wake up the PDM.
- When you navigate to the Pod Info tab.
- Periodically, whether the PDM is awake or asleep.

Note: Following a sleeping status check, the PDM only wakes up and sounds an audible alarm if the Pod has a hazard alarm. If the Pod has an advisory alarm or a notification, the PDM remains asleep and silent.

During a status check, the PDM collects information from the Pod about bolus deliveries, the amount of remaining insulin, and any alarm situations. The PDM displays this information as follows:

- The Home screen displays information about the most recent bolus.
- The Pod icon on the status bar shows how much insulin remains in the Pod's reservoir (see "The Status Bar" on page 9).
- The Lock screen and a full screen message display information about Pod alarms.

Timing of alarms originating in the Pod

If the Pod is sounding a hazard alarm, the Pod broadcasts a signal to the PDM.

- If the PDM is in range and awake, within 25 seconds of the Pod's initial alarm sound, the PDM also sounds an alarm and displays the alarm message.
- If the PDM is in range but asleep, the Pod cannot wake it up. The PDM finds out about the Pod alarm when it does a 'sleeping status check.' In this case, there could be a delay of up to five minutes and 25 seconds between when the Pod sounds the alarm and when the PDM sounds the alarm.
- If the PDM is out of range of the Pod, the PDM cannot receive any communication from the Pod. Therefore, if you hear a Pod alarm or notification, bring the PDM in range of the Pod and wake the PDM up. Within 25 seconds, the PDM sounds the alarm and displays the alarm message.

When the PDM cannot communicate with the Pod

When the PDM attempts to communicate with an active Pod that is in range, communication usually occurs quickly.

The PDM cannot communicate with the Pod when:

- The PDM is, or has temporarily been, too far from the Pod; for example, when you attend a meeting, leaving your PDM back at your desk.
- The PDM's battery has run down.
- There is too much outside interference (see "Omnipod DASH System Notice Concerning Interference" on page 197).

For information about handling PDM-Pod communication problems, see "Communication Errors" on page 132.

Pod deactivation

Deactivation unpairs a PDM and Pod from each other. Deactivation:

- Stops the current Pod's insulin delivery.
- Permanently silences any alarms from that Pod.
- Frees the PDM to activate a new Pod.

Note: Deactivation does not occur automatically when the Pod expires or runs out of insulin. In these situations, you must still use the PDM to deactivate the current Pod before the PDM can activate a new Pod.

Discarding a Pod

When the PDM cannot resolve a communication error, the PDM is unable to deactivate the Pod. In this situation, the PDM asks if you want to "discard" the Pod. "Discarding" unpairs the PDM from that Pod but does not stop the Pod's insulin delivery. Therefore, if you tell the PDM to "discard" a Pod, be sure to remove and dispose of the old Pod before activating a new Pod. To prevent the "discarded" Pod from sounding an alarm at a later time, follow the instructions for silencing a Pod alarm on page 135. Otherwise, if a discarded Pod sounds an alarm, the alarm stops after 15 hours.

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What the Pod can do between PDM instructions

Once activated, the Pod can perform the following without input from the PDM:

- Deliver insulin according to the active Basal Program's schedule. The Pod has a built-in clock that allows it to track the timing of the Basal Program's segments.
- Stop delivery of a temp basal at the scheduled time and resume delivery of the active Basal Program.
- Once a bolus or an extended bolus is started, complete the delivery of the bolus.
- Track the amount of insulin remaining inside the Pod.
- Track the amount of time until Pod expiration. Stop delivering insulin once the Pod expires.
- Perform self-checks to verify that insulin delivery is occurring as expected. Sound an alarm if it is not.
- Send alarm and notification messages to the PDM, if it is in range.
- Stop insulin delivery if the Auto-off feature is enabled and you have not used the PDM within the specified period of time.

Auto-off

The optional Auto-off feature is useful if you are prone to hypoglycemia unawareness. When you enable the Auto-off feature, you define a length of time for an Auto-off countdown timer. The Pod and PDM will sound an alarm if you do not use your PDM within that amount of time. To change the Auto-off setting, see "Pod Auto-off" on page 109.

Resetting the Auto-off countdown timer

Any action you take that causes the PDM to communicate with the Pod resets the Auto-off countdown timer to the beginning. Therefore, if Auto-off is enabled, make sure the PDM is in range of the Pod, then wake up your PDM. This resets the timer and prevents the alarm from sounding.

Auto-off alarms

If you have not used your PDM within the amount of time specified by the Auto-off countdown timer, the Pod and PDM sound an advisory alarm every minute for 15 minutes. The PDM also displays an on-screen message.

If you do not use your PDM within 15 minutes of the onset of the Pod's Auto-off advisory alarm, the Pod stops delivering insulin and both the PDM and Pod sound a hazard alarm. Tap OK to silence the alarm and deactivate your Pod.

PDM and Paired BG Meter Interaction

The following actions occur whenever you sync your PDM with a paired BG meter:

- The PDM transmits its time, date and goal/target range information to the BG meter, overwriting the BG meter's time, date and goal/target range if they differ. This ensures that the time of blood glucose readings and boluses can be compared accurately.

Tip: *To keep your PDM and BG meter clocks in sync, always sync your BG meter immediately before and after a time or date change (see "Date and time, and language" on page 102).*

- The BG meter transmits all blood glucose readings taken since the last time it synced to the PDM.
- If the BG meter tagged a reading as a control solution reading, the PDM adds a control solution tag.

BG readings from a paired BG meter and the Bolus Calculator

When the Bolus Calculator imports a blood glucose value from a paired BG meter:

- The Bolus Calculator automatically displays a blood glucose reading that was taken within the past 10 minutes.
- If multiple readings were taken within the past 10 minutes, the Bolus Calculator uses the most recent reading.
- If the clocks on the BG meter and PDM differ by more than five minutes, the Bolus Calculator does not display any reading from the BG meter.

BG readings from a paired BG meter and the history records

The PDM history records store all blood glucose readings and control solution readings from a paired BG meter.

Exception: If the PDM and BG meter's clocks differ by more than five minutes, the history records do not display any of the new readings from the BG meter.

Basal Insulin Delivery

Even without eating, our bodies need a small, constant supply of insulin for normal daily living, which is referred to as "basal" insulin. In people without diabetes, the pancreas continuously delivers this basal insulin. For people using the Omnipod DASH System, the Pod mimics a pancreas of a person without diabetes by delivering basal insulin at the rate that you program into the PDM.

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Approximately 50% of a person's total daily insulin dose typically comes from basal insulin delivery; the remaining 50% typically comes from bolus doses.

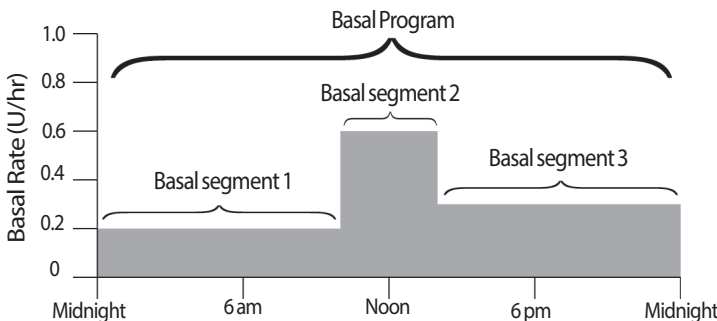
This section describes the Omnipod DASH System's two modes for delivering continuous basal insulin: Basal Programs and temp basals.

Basal Programs

A basal rate is the number of units of insulin delivered per hour.

A basal segment defines the time of day during which a given basal rate is delivered.

A collection of basal segments covering a midnight-to-midnight period is called a "Basal Program." In other words, a Basal Program describes the rate of insulin delivery throughout an entire 24-hour period.

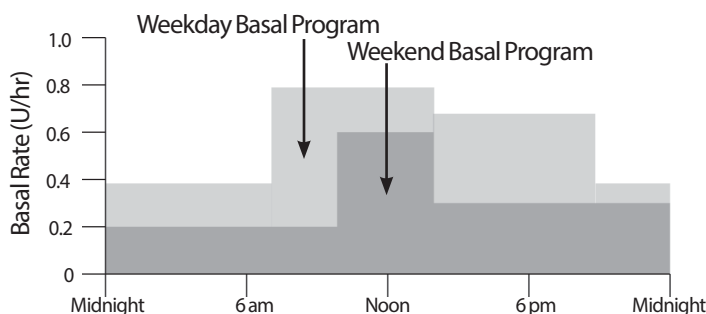


Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver more or less insulin at certain times of day. For example, you could deliver a lower rate of insulin during the night and a higher rate during the day. This figure shows a Basal Program with three basal segments.

To create the Basal Program shown in the preceding figure, the following basal segments are programmed into the PDM:

Segment	Basal rate	
1: Midnight–10:00 am	0.20 U/hr	Between midnight and 10:00 am, the Pod delivers 0.20 units of insulin per hour.
2: 10:00 am–2:00 pm	0.60 U/hr	Between 10:00 am and 2:00 pm, the Pod delivers 0.60 units of insulin per hour.
3: 2:00 pm–midnight	0.30 U/hr	Between 2:00 pm and midnight, the Pod delivers 0.30 units of insulin per hour.

You may have different routines on different days of the week; for example your weekend routine may differ from your weekday routine. To handle these predictable changes in your routine, you can create up to 12 different Basal Programs (see "Basal Programs" on page 81). This figure shows two possible Basal Programs, one for weekdays and the other for weekends.



Temporary basal rates

The ability to set temporary basal rates, also called "temp basals," is an important feature of the Omnipod DASH System. A temp basal lets you override the currently running Basal Program by setting a different basal rate for a predetermined period of time.

For example, if you are going cross-country skiing for several hours, you could set a temp basal to lower your basal rate during and after your exercise (see "Using Temporary Basal Rates" on page 75).

Temp basals can last from 30 minutes to 12 hours. At the end of the specified time, the Pod automatically reverts to the active Basal Program.

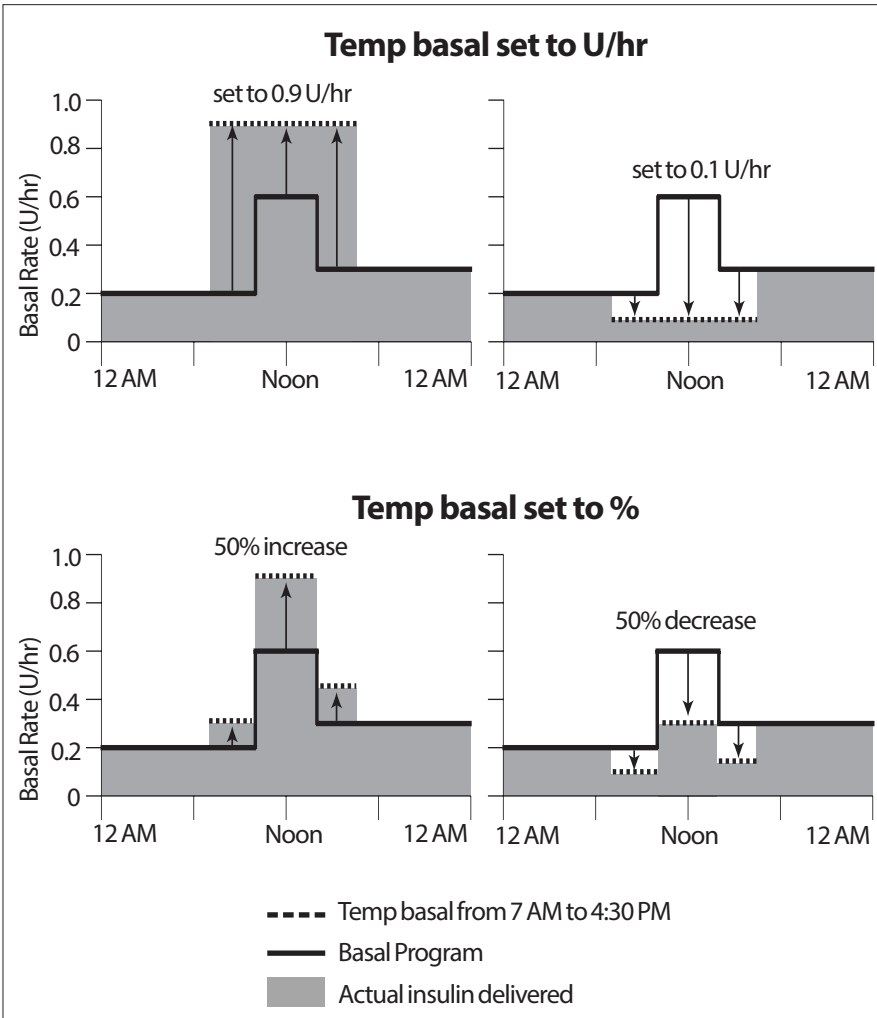
Temp basal settings: Units per hour (U/hr) or percent (%)

Temp basals can be set using percent (%) or units per hour (U/hr).

Setting temp basals to units per hour (U/hr) means that the Pod delivers insulin at a flat rate for the duration of the temp basal. In other words, the details of the currently scheduled Basal Program are ignored during these temp basals.

Setting temp basals to percent (%) means insulin delivery follows the pattern defined by the currently scheduled Basal Program, but increases or decreases the insulin delivery by the specified percentage. For example, a 50% increase raises the Basal Program's insulin delivery by 50%, while a 50% decrease lowers the Basal Program's insulin delivery by 50%.

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The calculations for the 50% increase temp basal in the preceding figure are:

Segment boundaries*	Basal rate of Basal Program (U/hr)	50% increase (U/hr)	Resulting temp basal rate: (U/hr)
Midnight–7:00 am	0.20		
7:00 am–10:00 am	0.20	$0.20 \times 50\% = 0.10$	$0.20 + 0.10 = 0.30$
10:00 am–2:00 pm	0.60	$0.60 \times 50\% = 0.30$	$0.60 + 0.30 = 0.90$
2:00 pm–4:30 pm	0.30	$0.30 \times 50\% = 0.15$	$0.30 + 0.15 = 0.45$
4:30 pm–midnight	0.30		

* Segments are defined by the currently scheduled Basal Program.

Temp basal limitations

Prohibited temp basals: You cannot set a temp basal of 0%, as there would be no change from the active Basal Program.

Maximum temp basal:

- When using percent (%), you can set the temp basal up to 95% more than your active Basal Program's rate with the following exception: You cannot set a temp basal that would go above your Maximum Basal Rate during any time segment covered by the temp basal duration.
- When using a flat rate (U/hr), you cannot set a temp basal above your Maximum Basal Rate.

Temp basals that turn off basal insulin delivery: When using percent (%), if you set a decrease that results in a flow of less than 0.05 U/hr for a segment, the PDM informs you that you will receive 0 U/hr of insulin for one or more segments.

If the temp basal is long enough, you will eventually receive some insulin. This is because the Pod delivers insulin in 0.05 U pulses.

For example, if the flow rate for a basal segment is 0.10 U/hr and you create a temp basal with a 60% decrease for:

- One hour, the resulting flow rate of 0.04 U/hr results in no insulin being delivered for the one hour duration of the temp basal.
- Two hours, the resulting flow rate of 0.04 U/hr results in a delivery of 0 U insulin in the first hour and 0.05 U insulin in the second hour.

You can set a temp basal to turn off basal insulin delivery for a set period of time by using a 100% decrease or a flat rate of 0 U/hr. The Pod beeps at the start and end of a temp basal period of no basal insulin. You can still deliver boluses when using a temp basal to turn off basal insulin delivery.

Tip: *Using a temp basal to turn off basal insulin delivery is useful if you want your Basal Program to automatically resume when the temp basal ends (see "Methods to temporarily stop insulin delivery" on page 156).*

Temp basal presets

Some temporary changes in your daily routine are easy to predict, and you may know from experience how they affect your insulin needs. For example, you might join a summer soccer league or attend an exercise class. For women, your monthly hormonal change can affect blood glucose in a predictable manner.

To handle predictable, short-term changes, you can define temp basal presets (see "Temp Basal Presets" on page 85). Once stored, a temp basal preset can be activated quickly at a later time (see "Activate a temp basal preset" on page 77).

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Methods to temporarily stop insulin delivery

There may be times when you want to stop all insulin delivery, or at least all basal insulin delivery, for a period of time. If you do not want to deactivate your current Pod, you can request a temporary halt of insulin delivery as follows:

- Suspend insulin delivery:
Menu icon (≡) > Suspend Insulin.
- Set a temp basal to turn off insulin delivery:
Menu icon (≡) > Set Temp Basal. Then select 100% decrease or 0 U/hr.

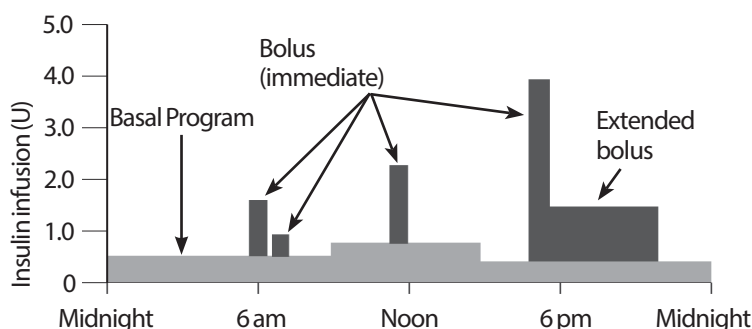
The following table compares these options for pausing insulin delivery.

	Suspend insulin	Temp basal of 0 U/hr
Effect on basal and bolus insulin delivery	No basal delivery No bolus delivery	No basal delivery Boluses allowed
Minimum duration for stopping insulin	30 min	30 min
Maximum duration for stopping insulin	2 hrs	12 hrs
Insulin delivery resumes automatically	No	Yes
Screen display at end of specified duration	"Resume insulin. The insulin suspension period has ended."	Middle tab of Home screen titled "Basal" (not "Temp Basal")
Beeps while insulin is stopped	Every 15 min	At beginning and every 60 min
Beeps at end of specified duration	Every 15 min until you tap Resume	One beep, then insulin resumes automatically
Must be used when	Editing an active Basal Program Changing the time or date Testing alarm and vibrate feature	Use is never required
How to cancel	Menu icon (≡) > Resume Insulin	Home:Temp Basal tab > CANCEL

Immediate and Extended Boluses

A bolus is an extra dose of insulin that is delivered in addition to the continuous basal rate of insulin delivery. Use boluses to bring down high blood glucose levels and to cover the carbohydrates (carbs) in a meal.

You have the option of delivering the entire bolus at once. This is referred to as an "immediate bolus" or, simply, a "bolus." Alternatively, you can spread out the delivery of all or part of a meal bolus so that it is delivered steadily over a specified period of time. This is referred to as an "extended bolus."



You may want to extend a bolus if your meal contains high-fat or high-protein foods. These foods slow down digestion and therefore slow down the post-meal rise in your blood glucose.

About Manually-Calculated Boluses

A manually-calculated bolus is a bolus that you have calculated without the help of the Bolus Calculator. You can use manually-calculated boluses when the Bolus Calculator is set to off or if the Bolus Calculator is disabled (see "Maximum Bolus" on page 158). Consult your healthcare provider for instructions about how to calculate a bolus.

You can extend some or all of a manually-calculated bolus.

If there is a bolus amount that you deliver frequently, you can create bolus presets (see "Bolus Presets" on page 87) that can be activated quickly at a later time.

Note: You can only use bolus presets if the Bolus Calculator is off.

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The Bolus Calculator

The PDM's Bolus Calculator can do a lot of the work of calculating a bolus for you. The Bolus Calculator uses your personal settings and also takes into account any insulin that remains from recent boluses (referred to as insulin on board or IOB).

Bolus Calculator boluses

When calculating a bolus, the Bolus Calculator considers a bolus to be made up of the following two components:

- **Correction bolus:** Used to lower blood glucose when it gets too high.
- **Meal bolus:** Used to cover carbs in a meal.

Extended boluses

When using the Bolus Calculator, you can extend some or all of a meal bolus, but a correction bolus cannot be extended. A correction bolus is always delivered first. In the following example, three units of insulin are extended:

Total bolus = 5 units (1 unit correction bolus + 4 units meal bolus)

- Deliver now = 2 units (1 unit correction + 1 unit meal bolus)
- Extend = 3 units (3 units meal bolus)

Maximum Bolus

The PDM does not allow you to enter a bolus that is above your Maximum Bolus setting. If the Bolus Calculator calculates a bolus amount greater than your Maximum Bolus, you will only be able to deliver up to the Maximum Bolus amount. To adjust it, tap the Total Bolus field and enter a revised bolus.

Controlling the bolus amount

The Bolus Calculator is a useful tool, but you have the ultimate control over the amount of a bolus to be delivered. After the Bolus Calculator suggests a bolus amount, you can confirm the suggested bolus or increase or decrease it.

When the Bolus Calculator does not work

The Bolus Calculator does not work when it is disabled or when it is set to off. You control whether the Bolus Calculator is turned on or off, but the PDM controls when it is disabled.

If the Bolus Calculator is set to off, the PDM does not track IOB and does not suggest a bolus.

If the Bolus Calculator is set to on, the PDM may disable it in a few situations. Being disabled means that the Bolus Calculator is temporarily unable to calculate a suggested bolus.

Conditions that disable the Bolus Calculator:	The Bolus Calculator is disabled until:	While the Bolus Calculator is disabled:
Your blood glucose reading is below your Minimum BG for Calcs setting.	Ten minutes pass. or A new blood glucose reading is above your Minimum BG for Calcs setting.	IOB is displayed on the Home screen.
Your blood glucose reading is "HI."	Ten minutes pass. or A new blood glucose reading is lower than "HI."	IOB is displayed on the Home screen.
There is an unconfirmed bolus when you discard a Pod.	A complete Duration of Insulin Action period passes.	IOB is not displayed on the Home screen.
There is an internal clock reset.	8.5 hours pass.	IOB is not displayed on the Home screen.

Factors used in the Bolus Calculator's calculations

The Bolus Calculator accounts for the following when it calculates a bolus:

- Your current blood glucose level, Target BG, Correct Above threshold, and Correction Factor
- The carbs you are about to eat and your IC Ratio
- Your Duration of Insulin Action and insulin on board (IOB)
- Your Minimum BG for Calcs
- Reverse Correction, if it is enabled

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Target BG

When calculating a correction bolus, the Bolus Calculator aims to bring your blood glucose down to the Target BG.

Correct Above threshold

The Bolus Calculator only suggests a correction bolus if your blood glucose reading is above your Correct Above setting. This feature can prevent corrections to blood glucose values that are only slightly higher than your Target BG.

Insulin on board

Insulin on board (IOB) is the amount of insulin still active in your body from earlier boluses. IOB from previous correction boluses is referred to as correction IOB. IOB from previous meal boluses is referred to as meal IOB.

When calculating a new bolus, the Bolus Calculator may reduce the suggested bolus based on the IOB.

The Duration of Insulin Action setting represents the amount of time that insulin remains "on board" or "active" in your body.

Note: The Bolus Calculator only subtracts IOB from a suggested bolus if your current blood glucose is known. You should always test your blood glucose prior to delivering a bolus.

Duration of insulin action

The Bolus Calculator uses your Duration of Insulin Action setting to calculate the insulin on board from prior boluses.

Minimum BG for Calcs

The Bolus Calculator does not suggest a bolus if your blood glucose reading is below your Minimum BG for Calcs level.

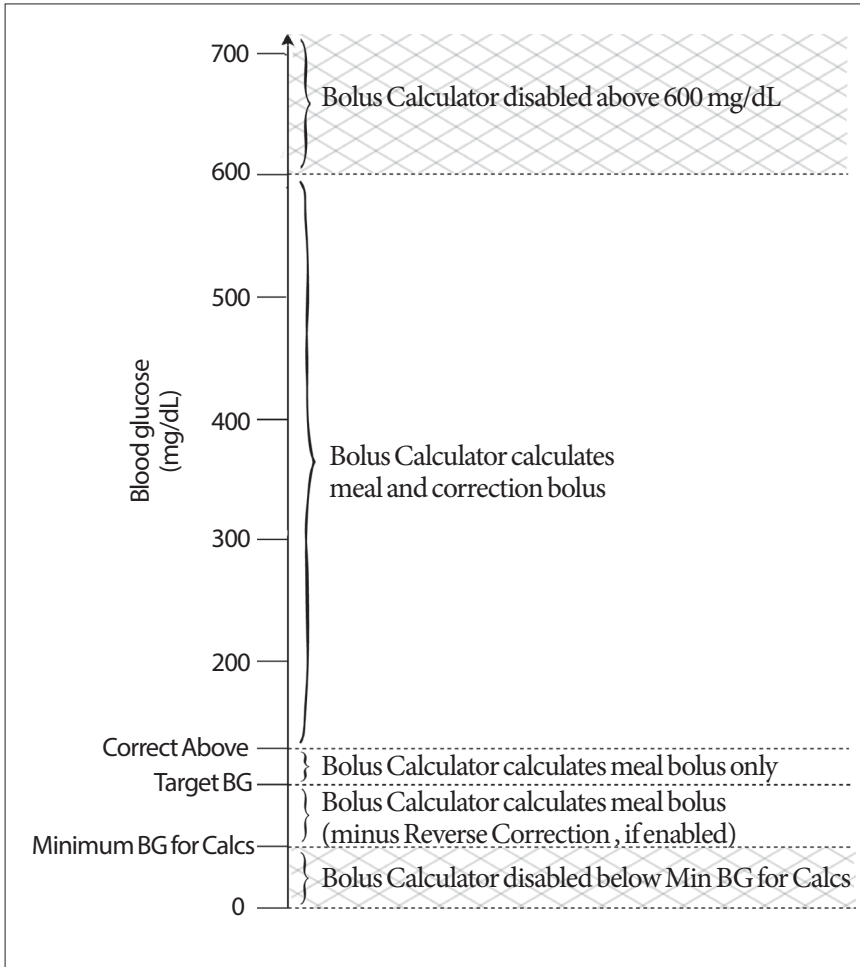
Reverse Correction

If the Reverse Correction setting is turned on and your blood glucose level is below your Target BG, the Bolus Calculator uses the calculated negative correction bolus to reduce the meal bolus. This allows part of the meal to be used to raise the low blood glucose level towards the Target BG.

If the Reverse Correction setting is turned off, the Bolus Calculator suggests the full meal bolus even if your blood glucose level is below your Target BG.

Boundaries of the Bolus Calculator suggestions

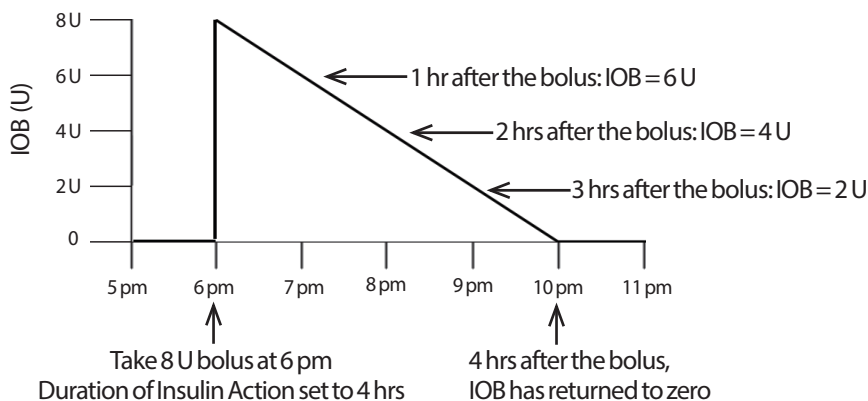
The following figure shows the boundaries between the types of calculations performed by the Bolus Calculator. For example, the Bolus Calculator suggests a meal bolus, but not a correction bolus, if your blood glucose reading is between your Target BG and your Correct Above settings. If your blood glucose is above the range of your BG meter or is above 600 mg/dL, the reading is recorded as "HI" and the Bolus Calculator cannot calculate a bolus.



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Insulin on board (IOB)

After a bolus is delivered, the amount of insulin that is active in the body decreases over several hours. The Bolus Calculator approximates this decrease in insulin by calculating an 'insulin on board' (IOB) value. The calculated IOB value decreases over time and reaches zero at the time set by the Duration of Insulin Action value. For example, if your Duration of Insulin Action is 4 hours and an 8 unit bolus is given at 6 pm, the IOB amount decreases steadily over time as shown in this graph.

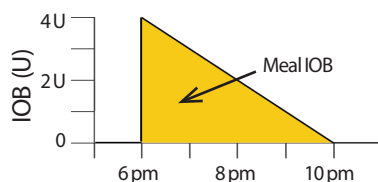


Types of IOB: meal IOB, correction IOB, or both

A bolus, and the IOB from that bolus, can be entirely meal, entirely correction, or both. The following graphs show how the IOB from a 4 U total bolus decreases over time with a Duration of Insulin Action of 4 hours.

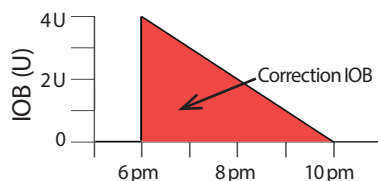
Entirely meal

A meal bolus is calculated when you are eating a meal and your blood glucose is less than your Correct Above value. The IOB from this bolus is entirely meal IOB.



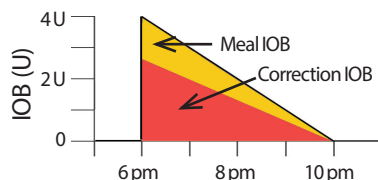
Entirely correction

A correction bolus is calculated when you are not eating and your blood glucose is above your Correct Above value. The IOB from this bolus is entirely correction IOB.



Both meal and correction

When you are eating and your blood glucose is above your Correct Above value, the total bolus includes a meal bolus and a correction bolus component. Likewise, the IOB from this bolus has a meal IOB and a correction IOB component.



Insulin on board (IOB) calculations

$$\frac{\text{Duration of insulin action} - \text{time since previous bolus}}{\text{Duration of insulin action}} \times \text{previous bolus}$$

IOB from a previous correction bolus is called a “correction IOB.”

IOB from a previous meal bolus is called a “meal IOB.”

Correction IOB example

Duration of insulin action: 3 hours

Time since previous correction bolus: 1 hour

Previous correction bolus: 3 U

$$\frac{3 \text{ hours} - 1 \text{ hour}}{3 \text{ hours}} \times 3 \text{ U} = 2 \text{ U correction IOB}$$

In other words, one hour after your previous correction bolus, your body has used up only 1 unit from the correction bolus. The remaining 2 units of insulin are still in your body working to correct your blood glucose level. Accounting for correction IOB in bolus calculations prevents the delivery of too much insulin when correcting a high BG or eating a meal.

Meal IOB example

Duration of insulin action: 3 hours

Time since previous meal bolus: 2 hours

Previous meal bolus: 4.5 U

$$\frac{3 \text{ hours} - 2 \text{ hours}}{3 \text{ hours}} \times 4.5 \text{ U} = 1.5 \text{ U meal IOB}$$

In other words, two hours after your previous meal bolus, your body has used up 3 units from the meal bolus. The remaining 1.5 units of insulin are still in your body working to cover your meal.

Meal IOB is only used to reduce a correction bolus; it does not reduce a new meal bolus. The correction bolus is only reduced until it becomes 0 units.

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Bolus Calculator equations

The Bolus Calculator first calculates a preliminary correction and meal bolus. It then adjusts these preliminary values for IOB, if applicable. The final suggested bolus is equal to the sum of the resulting correction bolus and meal bolus.

$$\text{Preliminary correction bolus} = \frac{\text{Current BG} - \text{Target BG}}{\text{Correction Factor}}$$

Example: Current BG: 200 mg/dL, Target BG: 100 mg/dL
Correction Factor (CF): 50

$$\frac{200 \text{ mg/dL} - 100 \text{ mg/dL}}{50} = 2 \text{ U prelim. correction bolus}$$

$$\text{Preliminary meal bolus} = \frac{\text{Carb intake}}{\text{Insulin-to-carb (IC) ratio}}$$

Example: Carb intake: 45 grams of carb, IC ratio: 15

$$\frac{45}{15} = 3 \text{ U prelim. meal bolus}$$

$$\text{Final correction bolus} = (\text{prelim. correction bolus} - \text{meal IOB}) - \text{correction IOB}$$

The meal IOB is subtracted first. If the preliminary correction bolus is still above zero, then the correction IOB is subtracted

Note: A correction bolus is never reduced below 0 U.

$$\text{Final meal bolus} = \text{prelim. meal bolus} - \text{remaining correction IOB}$$

Meal IOB is never subtracted from a meal bolus. Only a remaining correction IOB is subtracted from a meal bolus (see "Remaining correction IOB" on page 166).

Note: A meal bolus is never reduced below 0 U.

$$\text{Calculated bolus} = \text{final correction bolus} + \text{final meal bolus}$$

Reverse Correction bolus calculation: If the Reverse Correction feature is turned on and if your current blood glucose is below your Target BG but above your Minimum BG for Calcs, the Bolus Calculator subtracts a correction amount from the preliminary meal bolus.

$$\text{Meal bolus with Reverse Correction} = \text{Reverse Correction} + \text{prelim meal bolus}$$

Example: Current BG: 75 mg/dL, Target BG: 100 mg/dL
Correction Factor: 50, Preliminary meal bolus: 1.5 U

$$\frac{75 \text{ mg/dL} - 100 \text{ mg/dL}}{50} = -0.5 \text{ U Reverse Correction}$$

$$-0.5 \text{ U (Reverse Correction)} + 1.5 \text{ U (prelim meal bolus)} = 1.0 \text{ U meal bolus}$$

A Reverse Correction is only applied to the meal bolus. In this example, the meal bolus is reduced by 0.5 units.

Bolus Calculator rules

The Bolus Calculator applies the following rules to the suggested bolus doses:

- Suggested bolus doses are rounded down to the nearest 0.05 U.
- If the total of the suggested bolus calculation (correction bolus plus meal bolus) is less than zero, the suggested bolus dose is 0.00 U.
- The Bolus Calculator does not suggest a bolus dose if your current blood glucose reading is below your Minimum BG for Calcs.
- The Bolus Calculator suggests a correction bolus only when your blood glucose reading is above your Correct Above threshold.
- Meal IOB, which is insulin on board from a previous meal bolus, is subtracted first from the current correction bolus, if any, until the correction bolus is zero. However, any remaining meal IOB is *never* subtracted from the current meal bolus.
- Correction IOB, which is insulin on board from a previous correction bolus, is then subtracted from the current correction bolus, if any remains, until the correction bolus is zero. At that point, any remaining correction IOB is subtracted from the current meal bolus.
- The calculated insulin on board is rounded up to the nearest 0.05 U.
- A Reverse Correction only occurs if the meal bolus is greater than 0.00 U.
- If your blood glucose value is below your Target BG value and Reverse Correction is on, the Reverse Correction bolus is subtracted from the suggested meal bolus. If Reverse Correction is off, the Bolus Calculator does not subtract insulin from the suggested meal bolus dose.

If you manually adjust the suggested bolus, the following rules apply:

- If you increase a suggested bolus, the increase is applied to the meal bolus unless there is no meal bolus, in which case it is applied to the correction bolus.
- If you decrease a suggested bolus, the decrease is applied to the meal bolus until it reaches zero; then it is applied to the correction bolus. If there is no meal bolus, the decrease is applied to the correction bolus.

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Overview of the Bolus Calculator CALCULATIONS screen

The Bolus Calculator's screen can be accessed by tapping VIEW BOLUS CALCULATIONS from the Insulin & BG history screen or by tapping CALCULATIONS from the Bolus Calculator screen.

The screenshot shows the 'Bolus Calculation' screen with the following content and annotations:

- Correction Bolus** 1 U
 - Annotation: "Your current blood glucose reading and Target BG setting are listed here." points to "BG = 150, Target BG = 100".
 - Annotation: "Your Correction Factor setting is listed here." points to "Correction Factor = 50".
 - Annotation: "A correction bolus is adjusted for meal IOB first..." points to "Meal IOB adjustment".
 - Annotation: "... then for correction IOB." points to "Correction IOB adjustment".
 - Annotation: "Correction IOB is subtracted from the correction bolus first..." points to "Correction IOB = 0 U".
- Meal Bolus** 4 U
 - Annotation: "The carbs in your meal and your IC Ratio are listed here." points to "Carbs = 60 g, IC Ratio = 15 g/U".
 - Annotation: "... and any remaining correction IOB is subtracted from the meal bolus." points to "Correction IOB adjustment".

At the bottom of the screen is a 'CLOSE' button.

You need to scroll down to see the total bolus and any adjustments you may have made to the calculated bolus.

The blood glucose units on the Calculations screen are mg/dL.

Note: IOB adjustments are only made if you have entered a blood glucose reading.

Remaining correction IOB

A calculated bolus amount can never be less than zero. If a correction IOB is greater than the preliminary correction bolus, subtracting only part of the correction IOB from the preliminary bolus brings the correction bolus to zero.

The 'remaining correction IOB' is the amount of the correction IOB that was not needed to bring the preliminary correction bolus to zero. This remaining amount is then used to reduce the meal bolus, if there is a meal bolus.

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The preliminary and final boluses in the CALCULATIONS screen

The Bolus Calculation screen shows the calculations for a preliminary bolus first (correction and meal bolus), and then shows the IOB adjustments that produce the final correction bolus and final meal bolus. See "Bolus Calculator equations" on page 164 for a step-by-step description of these calculations.

The preliminary correction bolus calculations and where the preliminary correction boluses appear on the Calculations screen, as well as which numbers represent the final correction bolus, are identified here:

The screenshot shows the 'Bolus Calculation' screen with the following content:

- Correction Bolus** 1 U
BG = 150, Target BG = 100
Correction Factor = 50
 $(150 - 100) / 50 \approx 1 \text{ U}$
- Meal IOB adjustment**
Meal IOB = 0 U
 $1 \text{ U} - 0 \text{ U} = 1 \text{ U}$
- Correction IOB adjustment**
Correction IOB = 0 U
 $1 \text{ U} - 0 \text{ U} \approx 1 \text{ U}$
- Meal Bolus** 4 U
Carbs = 60 g, IC Ratio = 15 g/U
 $60 / 15 \approx 4 \text{ U}$
- Correction IOB adjustment**
Remaining correction IOB = 0 U
 $4 \text{ U} - 0 \text{ U} \approx 4 \text{ U}$
- Calculated Bolus** 5 U
- Total Bolus** = 5 U
- Correct Above: 110 mg/dL
- CLOSE

Final correction bolus
(rounded down to the
nearest 0.05 U)

Final meal bolus

The following pages show examples of the Calculations screen with various blood glucose, meal, and IOB scenarios.

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Bolus Calculator examples

For an explanation of IOB, see page 162. For an explanation of the correction and meal bolus equations, see page 164.

Example 1: Eating 45 g carbs, BG of 150 mg/dL is above target, no IOB

Duration of Insulin Action = 4 hours. You have not delivered a bolus in the past 4 hours, so there is no IOB (no meal IOB, no correction IOB).

Correction Bolus	1 U	← Your blood glucose is 50 mg/dL over your target. With your correction factor at 50 and no IOB adjustment, you will need a 1 U correction bolus.
BG = 150, Target BG = 100		
Correction Factor = 50		
$(150 - 100) / 50 = 1 \text{ U}$		
Meal IOB adjustment		
Meal IOB = 0 U		
$1 \text{ U} - 0 \text{ U} = 1 \text{ U}$		← No IOB, so no IOB adjustment.
Correction IOB adjustment		
Correction IOB = 0 U		
$1 \text{ U} - 0 \text{ U} = 1 \text{ U}$		← No IOB, so no IOB adjustment.
Meal Bolus	3 U	← You are eating 45g carbs. With your IC ratio at 15 and no IOB adjustment, you will need a 3 U meal bolus.
Carbs = 45 g, IC Ratio = 15 g/U		
$45 / 15 = 3 \text{ U}$		
Correction IOB adjustment		
Remaining correction IOB = 0 U		← No IOB, so no IOB adjustment.
$3 \text{ U} - 0 \text{ U} = 3 \text{ U}$		
Calculated Bolus	4 U	← The calculated bolus is the sum of your correction bolus and meal bolus.
Your Adjustment	0 U	← Any adjustment you make to the calculated bolus is shown here. No adjustment was made.
Total Bolus	4 U	← The total bolus is the sum of the calculated bolus and any adjustment made by you.

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Example 2: Not eating, BG of 150 mg/dL is above target, 1 U meal IOB, 1 U correction IOB

Duration of Insulin Action = 4 hours.

Three hours ago, you delivered an 8 U bolus (4 U meal bolus, 4 U correction bolus) because you were eating and had a high blood glucose reading.

Now, three hours after the 8 U bolus, there are 2 U of IOB left (1 U meal IOB, 1 U correction IOB).

Correction Bolus BG = 150, Target BG = 100 Correction Factor = 50 $(150 - 100) / 50 = 1 \text{ U}$ Meal IOB adjustment Meal IOB = 1 U $1 \text{ U} - 1 \text{ U} = 0 \text{ U}$ Correction IOB adjustment Correction IOB = 1 U N/A: Correction bolus is $\leq 0 \text{ U}$	0 U	Your blood glucose is 50 mg/dL over your target. A correction factor of 50 gives a 1 U preliminary correction bolus. ← However, this preliminary correction bolus is reduced to zero by the 1 U meal IOB adjustment. ← Because the preliminary correction bolus has been reduced to zero, the correction IOB is not subtracted. ←
Meal Bolus Carbs = 0 g, IC Ratio = 15 g/U $0 / 15 = 0 \text{ U}$ Correction IOB adjustment Remaining correction IOB = 1 U $0 \text{ U} - 1 \text{ U} = 0 \text{ U}$	0 U	← You are not eating, so your meal bolus is 0 U. None of the correction IOB was subtracted from the correction bolus, so the remaining correction IOB is 1 U. However, the meal bolus is already zero. ←
Calculated Bolus Your Adjustment Total Bolus	0 U 0 U 0 U	← Although your blood glucose is above target, the meal IOB reduces the total bolus to 0 U.

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Example 3: Eating 45 g carbs, BG of 100 mg/dL is at target, 1 U meal IOB

Duration of Insulin Action = 4 hours.

Three hours ago, you delivered a 4 U bolus (4 U meal bolus) because you were eating. There was no correction bolus because your blood glucose was at your Target BG.

Now, three hours later and just before your next meal, there is 1 U of IOB from the previous meal, which is a 1 U meal IOB. There is no correction IOB because the earlier bolus had no correction component.

Correction Bolus	0 U	← Blood glucose is at target, so the correction bolus is zero.
BG = 100, Target BG = 100		
Correction Factor = 50		
$(100-100) / 50 = 0 \text{ U}$		
Meal IOB adjustment		
Meal IOB = 1 U		
N/A: Correction bolus is $\leq 0 \text{ U}$	←	The correction bolus is zero, so the meal IOB is not subtracted.
Correction IOB adjustment		
Correction IOB = 0 U		
N/A: Correction bolus is $\leq 0 \text{ U}$	←	No IOB adjustment.
Meal Bolus	3 U	
Carbs = 45 g, IC Ratio = 15 g/U		
$45 / 15 = 3 \text{ U}$		
Correction IOB adjustment		
Remaining correction IOB = 0 U		
$3 \text{ U} - 0 \text{ U} = 3 \text{ U}$		
Calculated Bolus	3 U	← Even though there was a 1 U meal IOB, it did not reduce the calculated bolus.
Your Adjustment	0 U	
Total Bolus	3 U	

Example 4: Eating 60 g carbs, BG of 150 mg/dL is above target, 1 U correction IOB

Duration of Insulin Action = 2 hours.

One hour ago, you delivered a 2 U bolus to correct a high blood glucose. Because you were not eating at that time and did not enter a carbohydrate value into the Bolus Calculator, this was a 2 U correction bolus.

Now, one hour later, you are about to eat. There is a 1 U correction IOB from the earlier bolus, and no meal IOB because you did not eat at the time of your last bolus.

Correction Bolus	0 U	
BG = 150, Target BG = 100		
Correction Factor = 50		
$(150 - 100) / 50 = 1 \text{ U}$		← Your blood glucose is 50 mg/dL over your target. A correction factor of 50 gives a 1 U preliminary correction bolus.
Meal IOB adjustment		
Meal IOB = 0 U		
$1 \text{ U} - 0 \text{ U} = 1 \text{ U}$		← No meal IOB, so no meal IOB adjustment.
Correction IOB adjustment		
Correction IOB = 1 U		
$1 \text{ U} - 1 \text{ U} = 0 \text{ U}$		← The 1 U correction IOB reduces the correction bolus to zero.
Meal Bolus	4 U	
Carbs = 60 g, IC Ratio = 15 g/U		
$60 / 15 = 4 \text{ U}$		← You are eating 60 g carbs. An IC ratio of 15 gives a 4 U preliminary meal bolus.
Correction IOB adjustment		
Remaining correction IOB = 0 U		
$4 \text{ U} - 0 \text{ U} = 4 \text{ U}$		← The entire correction IOB was used to reduce the correction bolus to zero, so no correction IOB remains. The meal bolus remains at 4 U.
Calculated Bolus	4 U	
Your Adjustment	0 U	← The calculated bolus is entirely a meal bolus. Even though your blood glucose is above target, the correction IOB reduced the correction bolus to zero.
Total Bolus	4 U	

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Example 5: Reverse correction on, eating 45 g carbs, BG of 75 mg/dL is below target, no IOB

Duration of Insulin Action = 2 hours. You have not given yourself a bolus in the past 2 hours, so there is no IOB (no meal IOB, no correction IOB).

Correction Bolus	- 0.5 U	← Your blood glucose is below your target, so a Reverse Correction is calculated.
BG = 75, Target BG = 100		
Correction Factor = 50		
$(75 - 100) / 50 = -0.5 \text{ U}$		
(Reverse correction ON)		
Meal IOB adjustment		
Meal IOB = 0 U		
N/A: Correction bolus is $\leq 0 \text{ U}$		← No change in the reverse correction bolus for two reasons: IOB is zero, and IOB is never subtracted from a reverse correction.
Correction IOB adjustment		
Correction IOB = 0 U		
N/A: Correction bolus is $\leq 0 \text{ U}$		← No change in the reverse correction bolus for two reasons: IOB is zero, and IOB is never subtracted from a reverse correction.
Meal Bolus	3 U	← You are eating 45 g carbs. With your IC ratio at 15 and no correction IOB adjustment, the meal bolus is 3 U.
Carbs = 45 g, IC Ratio = 15 g/U		
$45 / 15 = 3 \text{ U}$		
Correction IOB adjustment		
Remaining correction IOB = 0 U		
$3 \text{ U} - 0 \text{ U} = 3 \text{ U}$		← No IOB, so no IOB adjustment.
Calculated Bolus	2.50 U	← The negative reverse correction bolus reduces the meal bolus.
Your Adjustment	0 U	
Total Bolus	2.50 U	← With Reverse Correction set to On and a blood glucose below your target, the meal bolus is reduced to allow some of the meal carbs to increase your blood glucose towards your target.

Calculations for History Summaries

This section lists the calculations for the summary data shown on the one day and multiple day history screens.

Blood glucose summaries

The calculations used for the blood glucose summaries include readings from a paired BG meter and manually-entered readings, with the exception that they do not include control solution records. The calculations do include any HI and LO readings unless otherwise noted. The multi-day calculations include all days in the time period.

Summary item	Calculation
Row 1 (see page 90)	
Average BG	$= \frac{\text{Sum of all BG readings}}{\text{Total number of BG readings}}$ Note: The sum and the total do not include HI or LO blood glucose readings.
BG in Range	$= \frac{\text{Number of BG readings within BG Goal Range}}{\text{Total number of BG readings}} \times 100$
BGs Above	$= \frac{\text{Number of BG readings above BG Goal Range upper limit}}{\text{Total number of BG readings}} \times 100$
BGs Below	$= \frac{\text{Number of BG readings below BG Goal Range lower limit}}{\text{Total number of BG readings}} \times 100$
Row 2 (see page 90)	
Avg Readings per Day	$= \frac{\text{Number of BG readings}}{\text{Number of days}}$ Note: This appears in the multiple day view only.
Number of BG Readings	$= \text{Total number of BG readings in the day (or date range)}$
Highest BG	$= \text{Highest BG reading in the day (or date range)}$
Lowest BG	$= \text{Lowest BG reading in the day (or date range)}$

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Insulin delivery summaries

Bolus insulin calculations include Bolus Calculator boluses and manually-calculated boluses. If you cancel an immediate or extended bolus before it completes, only the amount actually delivered is included in the calculation.

Basal insulin calculations includes insulin delivered according to the active Basal Program adjusted for periods when a temp basal was running, insulin was suspended, or there was no active Pod.

When the PDM has not received confirmation from the Pod about actual insulin delivery, the insulin delivery calculations are estimates based on the scheduled insulin delivery (see page 97).

For calculations of insulin delivery over multiple days, the number of days in the time period does not include days in which no insulin (either basal or bolus) was delivered.

For calculations of total carbohydrates over multiple days, the number of days in the time period does not include days in which no carbohydrates were entered into the Bolus Calculator.

Summary item	Calculation
Row 3 (see page 90)	
Total Insulin	= Sum of basal and bolus insulin delivered
Average Total Insulin	= $\frac{\text{Sum of basal and bolus insulin delivered}}{\text{Number of days}}$
Basal Insulin	= Amount of basal insulin delivered
Average Basal Insulin	= $\frac{\text{Amount of basal insulin delivered}}{\text{Number of days}}$
Bolus Insulin	= Amount of bolus insulin delivered
Average Bolus Insulin	= $\frac{\text{Amount of bolus insulin delivered}}{\text{Number of days}}$
Total Carbs	= Total grams of carbs entered into the Bolus Calculator
Average Total Carbs	= $\frac{\text{Total grams of carbs entered into the Bolus Calculator}}{\text{Number of days}}$

CHAPTER 13

Living with Diabetes

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

Before deciding on the Omnipod DASH System, you and your healthcare provider discussed the benefits of the Omnipod DASH System, as well as the responsibilities that come with insulin pump therapy. Remember: safe use begins and ends with you. If you have questions or doubts about being able to safely use the Omnipod DASH System at any time, consult your healthcare provider immediately.

Daily Activities

To ensure proper Omnipod DASH System operation and your continued good health, check your infusion site, your PDM messages, and your blood glucose frequently.

Infusion site checks

At least once a day, use the Pod's viewing window to inspect the infusion site. Check the site for:

- Leakage or scent of insulin, which may indicate the cannula has dislodged
- Signs of infection, such as pain, swelling, redness, discharge, or heat

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Warnings:

If an infusion site shows signs of infection:

- Immediately remove the Pod and apply a new Pod at a different infusion site.
- Contact your healthcare provider. Treat the infection according to instructions from your healthcare provider.

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

Tip: Consider making infusion site checks a part of your daily routine, like showering or brushing your teeth.

Check your blood glucose frequently

When you routinely check your blood glucose level, you can identify and treat high or low blood glucose before it becomes a problem.

Check your blood glucose:

- At least 4 to 6 times a day: when you wake up, before every meal, and before going to bed
- Whenever you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low, or if you suspect that your blood glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

Prepare for Emergencies

Tip: Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.

Warning: ALWAYS keep an emergency kit with you to quickly respond to any diabetes emergency or in the case that your Omnipod DASH System stops working. Always carry supplies to perform a Pod change should you need to replace your Pod at any time.

Prepare an emergency kit to keep with you at all times. The kit should include:

- Several new, sealed Pods
- A vial of rapid-acting U-100 insulin (see "General Warnings" on page xii for insulins cleared for use in the Omnipod DASH System)
- Syringes or pens for injecting insulin
- Blood glucose test strips
- Blood glucose meter
- Ketone test strips
- Lancing device and lancets
- Glucose tablets or another fast-acting source of carbohydrate
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod DASH System
- Phone numbers for your healthcare provider and/or physician in case of an emergency
- Glucagon kit and written instructions for giving an injection if you are unconscious (see "Avoid Lows, Highs, and DKA" on page 180)

Traveling and Vacations

It is important that you check your blood glucose more frequently while you are traveling. Changes in time zones, activity levels, and meal times can all affect your blood glucose levels.

Proper preparation is important when traveling. The following sections will help you prepare for your travels.

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Keep supplies accessible

On airplanes, trains, and buses, keep these items with you, rather than checking them:

- Personal Diabetes Manager (PDM)
- Extra Pods
- An emergency kit
- Vials of insulin (cargo area temperatures may affect insulin)
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod DASH System
- Prescriptions for all medications
- Medications and supplies with their original prescription label

Note: Generic medications may be easier to find than brand names outside your country.

- Snacks and hypoglycemia treatment, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of your physician and of a physician at your final destination

Note: Keep your emergency kit with you during trips or vacations (see "Prepare for Emergencies" on page 177). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

Tip: *When you travel outside the country or for long periods of time, be sure to take extra Pod supplies. Prior to departure, call Customer Care to inquire about additional Omnipod DASH System supplies for your trip.*

Plan for changing time zones

If you're planning a vacation or business trip to a different time zone, you may need to adjust your Basal Programs. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct Basal Program can be more challenging. Your healthcare provider can help with these adjustments.

Airports and flying

Before traveling by plane, familiarize yourself with the airport's security procedures and prepare your diabetes supplies for the security process and flight.

Airport security

Prepare for your travel:

- Airport security checks and screening procedures may change, so review the airport website and the TSA website for travel updates before your trip.
- Arrive at the airport 2-3 hours before your flight.
- Have your insulin management supplies easily accessible to ensure that airport security checks run smoothly.

Airport security offers the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. You must request this before the screening process begins. Your medical supplies should be in a separate bag when you approach the security officer.

To prevent contamination or damage to your supplies, you should be asked at the security checkpoint to display, handle, and repack your own supplies during the visual inspection process. Any medication and/or associated supplies that cannot be cleared visually must be submitted for X-ray screening.

If you are concerned about going through the walk-through metal detector, notify the security officer that you're wearing an insulin pump. You should advise the security officer that the insulin pump cannot be removed because it is inserted with a catheter (tubing) under the skin.

Visit the TSA Contact Center if you have any further questions or concerns.

Note: Pods and PDMs can safely pass through airport X-ray machines (see the "Omnipod DASH System Notice Concerning Interference" on page 197).

Flying and Airplane mode

Warning: The atmospheric pressure in an airplane cabin can change during flight, which may affect the Pod's insulin delivery. Check your blood glucose frequently while flying. If needed, follow your healthcare provider's treatment instructions.

Caution: ALWAYS keep your PDM in Airplane mode to save battery power. If you turn Airplane mode off, your battery could run out much faster. The PDM does not require a cellular network connection to communicate with the Pod.

The PDM controls the Pod using Bluetooth wireless technology. Before flying, check your airline's policy regarding the use of Personal Medical Electronic Devices that communicate using Bluetooth technology.

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Note: The Omnipod DASH System is safe to use at atmospheric pressures typically found in airplane cabins during flight. The Omnipod DASH System can be used at atmospheric pressures as low as 700 hPA, which is lower than the typical pressure in airplane cabins.

Avoid Lows, Highs, and DKA

Act promptly at the first sign of hypoglycemia, hyperglycemia, or diabetic ketoacidosis. The easiest and most reliable way to avoid these conditions is to check your blood glucose often.

General precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme highs or lows, or if highs or lows are occurring more often than usual.
- If you have technical problems with your Omnipod DASH System and cannot resolve them, call Customer Care immediately.

Hypoglycemia (low blood glucose)

Hypoglycemia can occur even when a Pod is working properly. Never ignore the signs of low blood glucose, no matter how mild. If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness. If you suspect that your blood glucose level is low, check your blood glucose level to confirm.

Symptoms of hypoglycemia (low blood glucose)

Never ignore the following symptoms, as they could be signs of hypoglycemia:

- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion

- Tingling in the lips or tongue
- Anxiety
- Irritability

Tip: *Hypoglycemia unawareness is a condition in which you do not realize when your blood glucose level is low. If you are prone to hypoglycemia unawareness, you may want to use the PDM's blood glucose reminder and check your blood glucose more frequently (see "Check BG after Bolus reminders" on page 109).*

Tip: *Make sure your blood glucose is at least 100 mg/dL before driving or working with dangerous machinery or equipment. Hypoglycemia may cause you to lose control of a car or dangerous equipment. Also, when you focus intently on a task, you may miss the symptoms of hypoglycemia.*

Tip: *Even if you cannot check your blood glucose, do NOT wait to treat symptoms of hypoglycemia, especially if you are alone. Waiting to treat symptoms could lead to severe hypoglycemia, which can quickly lead to shock, coma, or death.*

Tip: *Teach people you trust (like family members and close friends) how to give a glucagon injection. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.*

To avoid hypoglycemia (low blood glucose)

- Work with your healthcare provider to establish individualized BG Targets and guidelines.
- Keep a fast-acting carbohydrate with you at all times to respond quickly to low blood glucose. Examples of fast-acting carbs are glucose tablets, hard candies, or juice.
- Teach your friends, family members, and colleagues to recognize the signs of hypoglycemia, so they can help if you develop hypoglycemia unawareness or a severe adverse reaction.
- Keep a glucagon injection kit with your emergency supplies. Teach friends and family members how to give a glucagon injection in case you have severe hypoglycemia and become unconscious.

Periodically check the expiration date of your glucagon kit to make sure it has not expired.

Note: Always carry medical identification (such as an emergency wallet card) and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

Again, **frequent blood glucose checks are the key to avoiding potential problems.** Detecting low blood glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in any and all areas listed above.

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To treat hypoglycemia (low blood glucose)

Any time your blood glucose is low, treat it immediately according to your healthcare provider's instructions. Check your blood glucose every 15 minutes while you are treating, to make sure you don't overtreat the condition and cause blood glucose levels to rise too high. Contact your healthcare provider as needed for guidance.

Possible causes of hypoglycemia	Suggested action
Incorrect Basal Program	Confirm that the correct Basal Program is active. Confirm that the PDM time is set correctly. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too large	Take bolus with food. Check blood glucose before giving a meal bolus. If necessary, adjust the bolus. Check the bolus size and timing. Do not overcorrect for post-meal glucose levels. Check carb intake. Consult your healthcare provider for guidance.
Incorrect Target BG level or incorrect Correction Factor or incorrect IC Ratio	Consult your healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia or hypoglycemia unawareness	Consult your healthcare provider about hypoglycemia unawareness and about raising Target BG levels.
Unplanned physical activity	Consult your healthcare provider about using a temp basal (temporary basal rate).

Possible causes of hypoglycemia	Suggested action
Prolonged or intense exercise	Adjust insulin delivery as instructed by your healthcare provider. Check blood glucose before, during, and after activity and treat as necessary. Note: Effects of exercise can last several hours—even a full day—after activity ends. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Low carbohydrate intake prior to activity	Check blood glucose before activity. Consult your healthcare provider for guidance.
Alcohol consumption	Check blood glucose frequently, especially before going to bed. Consult your healthcare provider for guidance.

Hyperglycemia (high blood glucose)

Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If an occlusion (interruption of insulin delivery from the Pod) occurs, your blood glucose can rise rapidly.

Warning: An occlusion may result from a blockage, Pod malfunction, or from using old or inactive insulin (see "Occlusion detection" on page 194). If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.

Tip: *Hyperglycemia symptoms can be confusing. Always check your blood glucose before you treat for hyperglycemia.*

Symptoms of hyperglycemia (high blood glucose)

Never ignore the following symptoms, as they could be a sign of hyperglycemia:

- Fatigue
- Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

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To avoid hyperglycemia (high blood glucose)

Check your blood glucose:

- At least 4–6 times a day (when you wake up, before each meal, and before going to bed)
- If you feel nauseated or sick
- Before driving a car
- Whenever your blood glucose has been running unusually high or low
- If you suspect that your blood glucose is high or low
- Before, during, and after exercise
- As directed by your healthcare provider

To treat hyperglycemia (high blood glucose)

Always check your blood glucose levels frequently while treating hyperglycemia. You don't want to over-treat the condition and cause your blood glucose level to drop too far.

1. Check your blood glucose level. The result will help you to find out how much insulin is needed to return your blood glucose to your blood glucose goal.
2. If your blood glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check blood glucose again after 2 hours.
5. If blood glucose levels have not decreased, do both of the following:
 - Take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.
 - Replace the Pod. Use a new vial of insulin to fill the new Pod. Then contact your healthcare provider for guidance
6. If you feel nauseated at any point, check for ketones and contact your healthcare provider immediately (see "Diabetic ketoacidosis (DKA)" on page 186).

Warning: If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

7. Investigate possible causes for hyperglycemia to avoid similar problems in the future (see the following table).

Possible causes of hyperglycemia	Suggested action
Expired insulin or insulin exposed to extreme temperatures	Deactivate and remove the used Pod. Apply a new Pod filled from a new vial of insulin.
Infusion site in or near a scar or mole	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Infected infusion site	Deactivate and remove the used Pod. Apply a new Pod in a different location and consult your healthcare provider.
Dislodged cannula	Deactivate and remove the used Pod. Apply a new Pod in a different location. Note: Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.
Empty Pod	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Incorrect Basal Program	Confirm that the correct Basal Program is active. Confirm that the PDM time is set correctly. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too small	Check carb intake. Take bolus with food. Check blood glucose before giving meal bolus. If necessary, adjust bolus. Consult your healthcare provider for guidance.
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type. Consult your healthcare provider about using the extended bolus option.
Less activity than normal	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Blood glucose value greater than 250 mg/dL (with ketones present) before exercise	Do not exercise when ketones are present. Note: Blood glucose increases with exercise when ketones are present. Consult your healthcare provider for guidance.

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Possible causes of hyperglycemia	Suggested action
Infection or illness or medication change	See "Sick days" on page 187. Consult your healthcare provider about sick day guidelines and about medication changes.
Weight loss or gain or menstrual cycle or pregnancy	Consult your healthcare provider for guidance.

Diabetic ketoacidosis (DKA)

Pods use rapid-acting insulin, so you have no long-acting insulin in your body. If insulin delivery from the Pod is interrupted (an occlusion), your blood glucose can rise rapidly and lead to diabetic ketoacidosis (DKA). DKA is a serious—but preventable—emergency that can occur if you ignore high blood glucose levels.

Warnings:

If left untreated, DKA can cause breathing difficulties, shock, coma, and eventually death.

If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do not drive yourself.

Symptoms of DKA

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose and check for ketones to rule out DKA.

To avoid DKA

The easiest and most reliable way to avoid DKA is by checking your blood glucose at least 4–6 times a day. Routine checks allow you to identify and treat high blood glucose before DKA develops.

To treat DKA

- Once you have begun treatment for high blood glucose, check for ketones. Check for ketones any time your blood glucose is 250 mg/dL or above.
- If ketones are negative or trace, continue treating for high blood glucose.
- If ketones are positive and you are feeling nauseated or ill, immediately contact your healthcare provider for guidance.
- If ketones are positive but you are not feeling nauseated or ill, replace the Pod, using a new vial of insulin.
- Check blood glucose again after 2 hours. If blood glucose level has not declined, immediately contact your healthcare provider for guidance.

Handling Special Situations

Sick days

Any physical stress can cause your blood glucose to rise, and illness is a physical stress. Your healthcare provider can help you make a plan for sick days. The following are only general guidelines.

When you are ill, check your blood glucose more often to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose to rule out DKA (see "Diabetic ketoacidosis (DKA)" on page 186).

To handle sick days:

- Treat the underlying illness to promote faster recovery.
- Eat as normally as you can.
- Adjust bolus doses, if necessary, to match changes in meals and snacks.
- Always continue your basal insulin, even if you are unable to eat. Contact your healthcare provider for suggested basal rate adjustments during sick days.
- Check your blood glucose every 2 hours and keep careful records of results.
- Check for ketones when blood glucose is 250 mg/dL or higher.
- Follow your healthcare provider's guidelines for taking additional insulin on sick days.
- Drink plenty of fluids to avoid dehydration.
- Contact your healthcare provider if symptoms persist.

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Exercising, playing sports, or working hard

Check your blood glucose levels before, during, and after exercising, playing sports, or doing unusually hard physical labor.

The Pod's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare provider about these products.

Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

For some contact sports, if the Pod is in a location where it is likely to be knocked off, consider removing the Pod and placing a new one in a more protected location.

Be sure to check your blood glucose levels before removing the Pod and after applying a new one. Pods are designed for one-time use. Do not attempt to reapply a Pod that has been removed.

Tip: *If possible, plan removal times to coincide with a scheduled Pod replacement.*

If you will need to remove the Pod for more than one hour, ask your healthcare provider to recommend appropriate guidelines.

X-rays, MRIs, and CT scans

The Pod and PDM can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

Warning: The Pod and PDM may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove and dispose of your Pod and place your PDM outside the treatment area. Check with your healthcare provider on Pod removal guidelines.

Surgery or hospitalization

For scheduled surgeries or hospitalization, you should tell the physician/surgeon or hospital staff about your Pod. It may be necessary to remove it for certain procedures or treatments. Remember to replace the basal insulin that was missed while the Pod was removed. Your healthcare provider can help you prepare for these situations.

Appendix

Troubleshooting PDM Startup

While unlikely to happen with normal use, certain button press combinations during PDM startup can cause the PDM to display Boot Mode or Safe Mode.

Even when the PDM is in Boot Mode, the Pod continues delivering insulin according to the instructions it was given. Safe Mode does not affect PDM or Pod functionality.

Return to normal PDM operation as follows:

Boot Mode

If your PDM screen displays, "Select Boot Mode", then do the following:

1. Press the Sound/Vibrate UP (VOLUME_UP) button as needed to move the arrow (<<==) until it points to [**Recovery Mode**]. Then, press the Sound/Vibrate DOWN (VOLUME_DOWN) button to select [**Recovery Mode**].

Caution: Do not select the [Fastboot Mode] because it will stop the PDM from responding. If the PDM stops responding, contact Customer Care.

2. From the Android Recovery screen, press the Sound/Vibrate (VOLUME_UP/VOLUME_DOWN) button to highlight **Reboot system now**. Then, press the Power button to select it.

The PDM restarts.

Safe Mode

If your PDM screen displays, "Safe Mode" in the lower left corner, then restart the PDM and remove the "Safe Mode" text from the screen as follows:

1. Press and hold the Power Button, then tap Power off.
2. Tap OK to confirm.
3. Press and hold the Power button to turn the PDM back on.

Appendix

Summary of Settings and Options

The options for the various Omnipod DASH Insulin Management System settings are:

Time format	12-hour or 24-hour clock.
Time zones	GMT-11:00 to GMT+13.00.
Date format	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9.
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
Temp basal	%, units/hr, or Off. Default is Off. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Temp basal presets	Maximum of 12.
BG Goal Range for blood glucose history	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments.
BG reminder	On or Off. Default is Off. Maximum of 4 active at one time. Reminder can occur between 30 min to 4 hrs after bolus is started. Set in 30-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, Off.
Bolus Calculator	On or Off. Default is On.
Target BG value	Maximum of 8 segments; 70 to 200 mg/dL in 1 mg/dL increments.
Correct Above threshold	Maximum of 8 segments; Target BG to 200 mg/dL in 1 mg/dL increments.
Minimum BG for Calcs	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.

Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.
Reverse Correction	On or Off. Default is On.
Duration of insulin action	2 to 6 hours in 30-minute increments. Default is 4 hours.
Maximum Bolus size	0.05-30 U.
Extended bolus	%, Units, or Off. Default is Off. 30 minutes to 8 hours in 30-minute increments.
Bolus preset	Maximum of 7. Cannot exceed the Maximum Bolus.
MY FOODS list	Maximum of 50 items.
Custom foods	Range: 0-225 g carbohydrates.
Suspend	30 minutes to 2 hours.
Low reservoir volume advisory	10 to 50 units in 1-unit increments. Default is 10.0 U.
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours.
Auto-off timer	Off, or 1 to 24 hours in 1-hour increments. Default is Off.
History screen display	Rolling 90-day period.
Language	English, Spanish. Default is English.

Pod Specifications

Size: 1.53" wide x 2.05" long x 0.57" high (3.9cm x 5.2cm x 1.45cm)

Weight (without insulin): 0.92 oz (26 grams)

Operating temperature range: Pod operating environment of 41°F to 104°F (5°C to 40°C).

Note: The Pod temperature equilibrates from 73°F to 98.6°F (23°C to 37°C) when worn on the body.

Startup temperature: above 50°F (10°C)

Storage temperature range: 32°F to 86°F (0°C to 30°C)

Warm-up time (0°C to 20°C): 7 minutes

Cooldown time: No time is required for cooldown from maximum storage temperature (30°C) to operating temperature.

Reservoir volume (deliverable): 200 units

Cannula insertion depth: 0.16-0.28 in (4-7 mm)

Depth of insulin infusion: ≥ 0.16 in (4 mm)

Waterproof rating: IP28 (25 feet (7.6 meters) for up to 60 minutes)

Insulin concentration: U-100

Alarm type: Audible. Output: ≥ 45 db(A) at 1 meter

Sterilizing agent: sterilized using ethylene oxide

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Operating relative humidity range: 20 to 85%, non-condensing

Storage relative humidity range: 20 to 85%, non-condensing

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.5 U

Flow Capability:

Prime rate: 0.05 unit per second

Basal: Programmable by the user in 0.05U increments up to 30.0 U per hour

Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

Delivery accuracy (tested per IEC 60601-2-24):

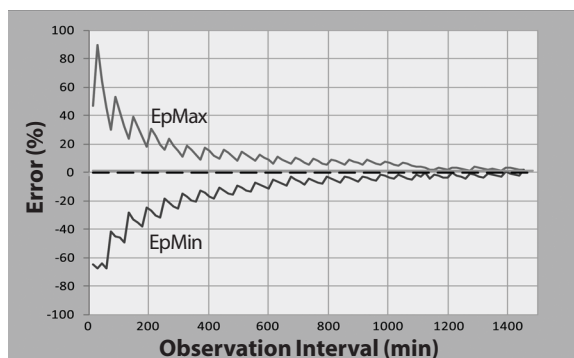
Basal: $\pm 5\%$ at rates ≥ 0.05 U/hr

Bolus: $\pm 5\%$ for amounts ≥ 1.0 unit

± 0.05 units for amounts < 1.0 unit

Note: The user should consider bolus dose accuracy when setting a bolus dose. When using the lowest bolus dose allowable (0.05 units), the actual bolus delivered may be as low as 0.00 units or as high as 0.10 units.

Accuracy test results: The following graph shows the flow accuracy of the Pod against given time periods. The measurements were made using a Pod with a basal rate of 0.5 $\mu\text{l/h}$ (which delivers 0.05 U/h of U-100 insulin) at a high operating temperature. The overall mean percentage flow error was 1.40%.



PDM Specifications

Size: 2.52" wide x 4.79" long x 0.39" high (6.4cm x 12.2cm x 1.0cm)

Weight: 3.74 oz (106 grams)

Screen active area: 4.0" diagonal $\pm 5\%$ (10.2 cm $\pm 5\%$)

Operating temperature range: 41°F to 104°F (5°C to 40°C)

Charging temperature range: 41°F to 104°F (5°C to 40°C)

Storage temperature range: 32°F to 86°F (0°C to 30°C)

Operating relative humidity range: 20% to 90%, non-condensing

Storage relative humidity range: 20% to 90%, non-condensing

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The PDM and Pod should be

- At startup: Adjacent and touching, either in or out of tray, to ensure proper communication during priming.
- During normal operation: Within 5 feet (1.5 m) of each other. Depending on the location, the communication distance may handle separations up to 50 feet (15 meters) away.

Waterproof rating: IP22 when used with outer case (avoid liquid)

Note: The IP22 rating applies ONLY when your PDM is used with the provided outer case (gel skin). The risk of water ingress into the PDM is greater without the outer case. Contact Customer Care about purchasing additional outer cases, if needed.

Alarm type: Audible. Output: ≥ 45 db(A) at 1 meter

Notification type: Audible and vibratory

PDM Service Life: 5 years

Battery life: Full charge covers approximately 1.5 days of typical use after 2 years of typical use

Battery charger operating line voltage: 100 to 240 VAC, 50/60 Hz

Use only the Insulet-provided charger to charge your PDM. Using unapproved chargers can cause the battery to explode or damage the PDM and may void the warranty.

Battery charger service life: 10,000 operating hours

Protection from Over-infusion or Under-infusion

The Pod software monitors the infusion rate. If an error that would result in over- or under-infusion is detected and cannot be corrected, insulin delivery stops, and an alarm sounds.

Occlusion detection

An occlusion is a blockage or interruption in insulin delivery from the Pod. If the Omnipod DASH System detects an occlusion, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

An occlusion hazard alarm sounds when an average of 3 units to 5 units of missed insulin occurs. The following table depicts occlusion detection for three different situations when using U-100 insulin. For example, if the Pod’s cannula becomes occluded when delivering a 5 U bolus, 35 minutes may pass before the Pod sounds a hazard alarm.

	Time between occlusion and Pod alarm	
	Typical time	Maximum time
5.00 U bolus	33 minutes	35 minutes
1.00 U/hr basal	3.0 hr	5.5 hr
0.05 U/hr basal	51 hr	80 hr (Pod expiration)

If an occlusion spontaneously clears up, a volume of insulin could be released. That volume would not exceed the volume of the programmed insulin intended for delivery.

If an occlusion is detected during an immediate bolus, the Pod sounds a hazard alarm at the conclusion of the immediate bolus.

Warning: At very low basal flow rates, checking your blood glucose frequently may give you an early indication of an occlusion. Occlusions can result in hyperglycemia.

Omnipod DASH System Label Symbols Glossary

The following symbols appear on the Omnipod DASH System or its packaging:

Symbol	Meaning	Symbol	Meaning
	Compatible with		Refer to instruction manual/booklet
	Do not re-use		MR unsafe
	Date of manufacture		Manufacturer
	Country of Manufacture – United States of America		Country of Manufacture – Malaysia
	Country of Manufacture – China		Sterilized using ethylene oxide
	Batch code		Keep dry
	Use-by date		Temperature limit
	Atmospheric pressure limitation		Humidity limitation
	Serial number		Catalogue number
	Discard electrical and electronic equipment separately from standard waste.		Do not use if package is damaged and consult instructions for use
	Importer		Type BF applied part
	Non-pyrogenic fluid path		Marking of conformity
	Medical device		UK Conformity Assessed
	Charging cable		Charging adapter
	Fill Syringe and Needle Assembly		Pod
	Switzerland Authorized Representative		Compatible with U-100 insulin only

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IP22	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; avoid liquid	IP28	Protects persons against access to hazardous parts with fingers and protects against solid foreign object ingress of diameter 12.5 mm or greater; Submersible: Waterproof to 7.6 meters (25 feet) for up to 60 minutes
FCCID:	Federal Communication Commission Identifier with number	Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
IC:	Complies with ISED Canada Radio Standards Specifications	HVIN:	Hardware version identification number
	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Recycling		Single sterile barrier system
	Australian Regulatory Compliance Mark		Single patient multiple use
	Toll free number		Local number
	Email address		PDM battery
	Omnipod® carry case		PDM skin
	PDM		Intertek Authorized Product Certification Mark
	(France) The Triman indicates that the product must be sorted or returned to a collection point.		(France) Packaging intended for recycling

	(France) This product must be separated from conventional perforating DASTRI for recycling.		(France) This pictogram means that the product contains a piercing object.
	(France) Electronic perforating waste must be stored in the secure DASTRI purple box. These purple boxes are distributed free of charge in pharmacies.		(France) The puncture waste must be placed in a DASTRI needle box. These needle boxes are distributed by pharmacies.
	(France) All pharmacies distribute and collect DASTRI needle boxes free of charge from self-treatment patients.		

Omnipod DASH System Notice Concerning Interference

The Omnipod DASH Insulin Management System (both the Pod and the PDM) complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

Caution: Changes or modifications not expressly approved by Insulet Corporation could void the user's authority to operate the equipment.

Both the Pod and the PDM generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications of other devices. There are no guarantees that interference will not occur in a particular installation. If the Omnipod DASH System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

- Move or relocate the Omnipod DASH System.
- Increase the distance between the Omnipod DASH System and the other device that is emitting or receiving interference.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod DASH System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod DASH System fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

Caution: Cables and accessories not specified within the instructions for use are not authorized. Using other cables or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the Omnipod DASH System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod DASH System should be observed to verify normal operation in this setting.

The Omnipod DASH System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod DASH System communicates with the following characteristics:

Frequency: 2.402-2.480 GHz, digitally modulated, with an effective radiated power of 0.89 mW

The Omnipod DASH System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2:2014+AMD1:2020.

The Omnipod DASH System has demonstrated immunity to both radio-frequency identification (RFID) systems and Electronic Article Surveillance (EAS) systems. Testing has been performed in accordance with AIM 7351731 to demonstrate this immunity.

Caution: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the Omnipod DASH System. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions		
This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.		
Emissions	Emissions according to	Electromagnetic environment
RF Emissions (CISPR 11)	Group 1	The Pod, Controller, and Transmitter emit low-level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected. The System is suitable for use in all establishments, including domestic establishments.
CISPR B Emissions Classification	Class B	
Harmonic Emissions (IEC 61000-3-2)	Class A	
Voltage Fluctuations/ Flicker Emissions (IEC 61000-3-3)	$P_{st} \leq 1.0$ $P_L \leq 0.65$ $d_c \leq 3.3\%$ $d_{max} \leq 4\%$ $d_{(t)} \geq 200\text{ ms}$ during a voltage change should be $\leq 3\%$	

Appendix

Electromagnetic Immunity

The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	contact discharge: ± 8 kV air discharge: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz – 2.7 GHz	10 V/m at 80 MHz – 2.7 GHz	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod DASH® System.
Proximity fields from RF wireless communications equipment	450, 810, 930, 1720, 1845, 1970, and 2450 MHz at 28 V/m	450, 810, 930, 1720, 1845, 1970, and 2450 MHz at 28 V/m	
	385 MHz at 27 V/m	385 MHz at 27 V/m	
	710, 745, 780, 5240, 5500, 5785 MHz at 9 V/m	710, 745, 780, 5240, 5500, 5785 MHz at 9 V/m	
Electrical Fast Transient/burst (IEC 61000-4-4)	± 2 kV power supply line ± 1 kV input/output lines	± 2 kV power supply line ± 1 kV input/output lines	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Conducted Disturbances induced by RF fields (IEC 61000-4-6)	3Vrms 150 KHz-80 MHz 6Vrms in ISM and amateur radio bands between 150 KHz and 80 MHz	3Vrms 150 KHz-80 MHz 6Vrms in ISM and amateur radio bands between 150 KHz and 80 MHz	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod DASH® System.

Electromagnetic Immunity			
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field.
Voltage Dips, Short Interruptions, Voltage Variations on Power Supply input lines (IEC 61000-4-11)	70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT (100% dip in UT) for 250 cycles	70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 1 cycle at 0 degrees 0% UT (100% dip in UT) for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% UT (100% dip in UT) for 250 cycles	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user requires continued operation during power mains interruption, it may be necessary to use an uninterruptible power supply or a battery.
Proximity Magnetic Fields (IEC 61000-4-39)	30 kHz at 8 A/m, 134.2 kHz at 65 A/m, 13.56 MHz at 7.5 A/m	30 kHz at 8 A/m, 134.2 kHz at 65 A/m, 13.56 MHz at 7.5 A/m	RFID equipment should be used no closer to any part of the device, including cables, than the recommended 15 cm separation distance.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Appendix

Customer's Bill of Rights

Mission Statement

Insulet Corporation is dedicated to designing, developing, and distributing products that provide superior treatment options and lifelong health benefits for people with diabetes.

Scope of Services

Insulet Corporation's scope of services is limited to providing the Omnipod DASH Insulin Management System. The Omnipod DASH System consists of the Pod and the handheld, wireless Personal Diabetes Manager (PDM), which programs the Pod with insulin delivery instructions.

Compliance

The Omnipod DASH Insulin Management System is manufactured and distributed by Insulet Corporation. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact us at 1-800-591-3455 (from outside the United States, 1-978-600-7850).

Inquiries

Representatives are available to answer product-related inquiries 24 hours per day at our toll free number, 1-800-591-3455 (from outside the United States, 1-978-600-7850). For all other questions, concerns, or complaints, please contact us between the hours of 8:30am and 6:00pm Eastern Time, Monday through Friday, at 1-800-591-3455 (from outside the United States, 1-978-600-7850). We will respond immediately whenever possible; some issues may take up to 14 days to resolve.

CHAP Accredited

Insulet Corporation has been accredited by the Community Health Accreditation Program (CHAP) since 2007. To learn more about CHAP or to communicate concerns that you have been unable to resolve directly with the company, please visit www.chapinc.org or call CHAP at 1-800-656-9656.

Customer's Bill of Rights and Responsibilities

You have the right to:

1. Receive considerate and respectful service.
2. Receive service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.
3. Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice later in this section.
4. Receive a timely response to your request for service.

5. Receive continued service.
6. Select the medical equipment supplier of your choice.
7. Make informed decisions regarding your care planning.
8. Understand what services will be provided to you.
9. Obtain an explanation of charges, including policy for payment.
10. Agree to or refuse any part of the plan of service or plan of care.
11. Voice complaints without fear of termination of service or other reprisals.
12. Have your communication needs met.

You have the responsibility to:

1. Ask questions about any part of the plan of service or plan of care that you do not understand.
2. Use the equipment for the purpose for which it was prescribed, following instructions provided for use, handling care, safety and cleaning.
3. Supply Insulet Corporation with insurance information necessary to obtain payment for services.
4. Be accountable for charges not covered by your insurance. You are responsible for settlement in full of your account.
5. Notify us immediately of:
 - a. Equipment failure, damage or need of supplies.
 - b. Any change in your prescription or physician.
 - c. Any change or loss in insurance coverage.
 - d. Any change of address or telephone number, whether permanent or temporary.

Limited Express Warranty, Disclaimer, and Limitation of Remedies for the PDM and Pods

LIMITED EXPRESS WARRANTY, DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES FOR THE Omnipod DASH INSULIN MANAGEMENT SYSTEM PERSONAL DIABETES MANAGER AND PODS (United States of America)

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod DASH System Personal Diabetes Manager

Subject to the terms and conditions stated herein ("Limited Express Warranty"), Insulet Corporation warrants to you, the original purchaser of the Omnipod DASH Insulin Management System ("Omnipod DASH System"), that, if Insulet Corporation determines, during the period of four (4) years from the date of purchase, that the Omnipod DASH System Personal Diabetes Manager ("PDM") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet Corporation will either repair or replace, at its sole option, the PDM. If Insulet Corporation chooses to repair the PDM, Insulet Corporation may choose to do so by implementing a software update, including an over-the-air software update, without further notice to the original purchaser. If Insulet Corporation chooses to replace the PDM, Insulet Corporation may choose to do so by replacing the PDM with an updated PDM.

This four-year (4) warranty period applies only to new PDMs, and in the event the PDM is repaired or replaced, the warranty period shall not be extended or reset. Thus, if Insulet Corporation replaces a PDM under this Limited Express Warranty, the warranty coverage for the replacement PDM shall expire four (4) years from the date of purchase of the original PDM.

Limited Warranty Coverage for the Omnipod DASH System Pods

Subject to this Limited Express Warranty, Insulet Corporation warrants to you, the original purchaser of the Omnipod DASH System, that, if Insulet Corporation determines, during the period of twenty-four (24) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod DASH System Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet Corporation will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e. the activation must occur on or before the expiration date printed on the label with a manufacture date no more than twenty-four (24) months before, and within seventy-two (72) hours of the time that you notify Insulet Corporation of the claim).

This twenty-four (24) month and seventy-two (72) hour warranty period applies only to new Pods, and in the event a Pod is replaced, the warranty period shall not be extended or reset. Thus, if Insulet Corporation replaces a Pod under this Limited Express Warranty, the warranty coverage for the replacement Pod shall expire either twenty-four (24) months from the manufacture date of the original Pod or seventy-two (72) hours from the time of activation of the original Pod, whichever occurs first.

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

Claim Procedure

To be eligible for this Limited Express Warranty, you must notify Insulet Corporation of the claimed defect with the PDM or the Pod within the applicable warranty periods by calling Customer Care at 1-800-591-3455 (from outside the USA: 1-978-600-7850). For a claim involving the PDM, you must provide the PDM serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the PDM and/or

the Pod, the manufacture date of the Pod, and the time of activation of the Pod. Your failure to follow any of the above steps may result in the denial of coverage under this Limited Express Warranty. Unless Insulet Corporation elects to repair the PDM (which may include, but is not limited to, a repair kit, replacement part(s) Insulet Corporation may provide, or an over-the-air software update) or refers you to a third party, you must obtain a prior authorization and return the PDM or the Pod to Insulet Corporation. The PDM or Pod must be properly packaged and returned to Insulet Corporation according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit. With a prior authorization, Insulet Corporation will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the PDM or Pod to Insulet Corporation under this Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet Corporation, except those performed or provided by third parties to which you were explicitly referred by Insulet Corporation.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, Insulet Corporation may require that you provide a valid proof of purchase, manufacture or activation. Your failure to provide a valid proof of purchase, manufacture or activation, as determined by Insulet Corporation, may result in the denial of coverage under this Limited Express Warranty.

Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental, or other transfer of the PDM or of the Pod to any other person or entity.

This Limited Express Warranty will apply only if the PDM or the Pod at issue has been used in accordance with the Omnipod DASH System User Guide and/or other written instructions provided by Insulet Corporation. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE PDM OR THE POD HAVE BEEN:

- Altered, changed or modified by any person or entity other than Insulet Corporation;
- Opened, serviced or repaired by any person or entity other than Insulet Corporation;
- Damaged by an act of God or other “force majeure” like event;
- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care, or storage; or
- Damaged by wear and tear; causes unrelated to defective materials or workmanship or other circumstances outside of the reasonable control of Insulet Corporation.

This Limited Express Warranty does not apply to test strips, batteries that are not provided by Insulet Corporation, other accessories, or related products provided by third parties (e.g., data management tools, CGMs).

This Limited Express Warranty does not extend to design defects (i.e. claims that the PDM or the Pod should have been designed in a different way).

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

REPAIR OR REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE PDM OR THE POD IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF INSULET CORPORATION. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE SO LONG AS INSULET CORPORATION IS WILLING AND ABLE TO REPAIR OR REPLACE A PDM

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OR A POD WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER PRESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL INSULET CORPORATION, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN THE PDM OR A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT, OR OTHERWISE.

Important Additional Provisions

INSULET CORPORATION DOES NOT WARRANT THE SUITABILITY OF THE PDM, THE POD, OR THE Omnipod DASH SYSTEM FOR ANY SPECIFIC PERSON AS HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction. The above Limited Express Warranty applies only to PDMs and the Pods that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. INSULET CORPORATION'S LIABILITY IN SUCH JURISDICTIONS SHALL BE LIMITED TO THE MAXIMUM EXTENT PERMITTED BY LAW. SUCH LIMITATIONS SHALL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING: ANY IMPLIED WARRANTIES THAT CANNOT BE DISCLAIMED UNDER THE LAW OF A PARTICULAR JURISDICTION ARE LIMITED, TO THE EXTENT ALLOWED BY LAW, TO THE TIME PERIOD COVERED BY THE ABOVE LIMITED EXPRESS WARRANTY, OR TO THE APPLICABLE TIME PERIOD PROVIDED BY LAW, WHICHEVER PERIOD IS SHORTER.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet Corporation and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between Insulet Corporation and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a PDM, a Pod, or an Omnipod DASH System. No employee, agent or other representative of Insulet Corporation, or any other party is authorized to make any product warranty or agreement applicable to a PDM, a Pod, or an Omnipod DASH System in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the Omnipod DASH System, please return any Omnipod DASH System products (including any PDM and Pods) to Insulet Corporation in exchange for a full refund. Failure to return such Omnipod DASH System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Rev: January 15, 2018

HIPAA Privacy Notice

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

This notice of privacy practices (the “HIPAA Privacy Notice”) describes how we may use and disclose your Medical Information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act, and all regulations issued thereunder (“HIPAA”). It also describes your rights to access and control your Medical Information. As used herein, “Medical Information” is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. Most uses or disclosures of your Medical Information constituting psychotherapy notes will be made only after receiving your written authorization. We will not use or disclose your Medical Information for purposes of marketing, except as permitted by law and/or outlined in this HIPAA Privacy Notice. We will not sell your Medical Information, without first obtaining your written authorization. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations where we may use or disclose your Medical Information without your prior written authorization, as described further below:

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided By Us

Treatment, Payment and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

Appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

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Family, Friends and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities, or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.

Inmates: We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and good order of the correctional institution.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Non-identifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please submit a request at

<https://www.omnipod.com/privacyrequest>

We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a request to review your Medical Information, please submit a request at

<https://www.omnipod.com/privacyrequest>

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment,

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payment or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. Except as otherwise provided in this HIPAA Privacy Notice, we are not required to agree to a restriction that you may request. We are required to agree to your request to restrict disclosure of your Medical Information to a health plan if (i) the disclosure is to carry out payment or healthcare operations and is not otherwise required by law; and (ii) your Medical Information pertains solely to a healthcare item or service for which you or someone (other than the health plan) on your behalf, has paid us in full. If we agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please submit a request at

<https://www.omnipod.com/privacyrequest>

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications From Us By Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer at

<https://www.omnipod.com/privacyrequest>

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, for notification purposes, for national security or intelligence purposes, to correctional institutions or law enforcement officials, or as part of a limited data set. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under applicable law. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please submit a request at

<https://www.omnipod.com/privacyrequest>

We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

You Have The Right to Obtain a Copy of this HIPAA Privacy Notice: You have the right to obtain a paper copy of this HIPAA Privacy Notice from us, upon request, even if you have agreed to accept this notice electronically. If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request at

<https://www.omnipod.com/privacyrequest>

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our legal duties and privacy practices with respect to Medical Information, and to notify you if there is a breach resulting in disclosure of your unsecured Medical Information.

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the “Revised HIPAA Privacy Notice”). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our website at

<https://www.omnipod.com>.

If you would like to request a paper copy of this HIPAA Privacy Notice, please submit a request at

<https://www.omnipod.com/privacyrequest>

What To Do If You Have a Problem or Question

If you are unable to use the online privacy request form, you may obtain assistance by calling our toll-free number: 1-800-591-3455.

If you have any further questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us in writing or by phone at:

Insulet Corporation
Attn: Privacy Officer
Email: privacy@insulet.com

(866) 941-0155

Our mailing address is:

100 Nagog Park
Acton, MA 01720

Furthermore, if you believe that Insulet has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling (877) 696-6775. Insulet will not retaliate against you for filing such a complaint.

Effective Date: August 11, 2004

Revision Dates: April 1, 2009, September 20, 2013, April 22, 2014, September 2, 2014, and September 15, 2022.

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Glossary

A1c (see Hemoglobin A1c)

Activation: The process of waking up a Pod and pairing it to a PDM so that the Pod only responds to commands from that PDM.

Advisory alarm: Intermittent vibrations or beeps accompanied by a message advising about an action that you may want to take to prevent a serious problem.

Aseptic technique: A method for maintaining sterilization and preventing contamination.

Basal Program: A daily schedule for continuous insulin delivery. It consists of one or more segments, each defining a basal rate, that together cover the 24-hour period from midnight to midnight.

Basal rate: A small amount of insulin that is delivered continuously over a period of time. Basal rates are specified in units per hour (U/hr).

Basal segment: The time period during which a specific basal rate is delivered.

BG Goal Range: A user-defined range of desired blood glucose values. This range is used in the history records to show which blood glucose values fall within this range.

Blood glucose / Blood glucose level: The amount of glucose, or sugar, in the blood.

Blood glucose meter: A device used to check blood glucose level.

Bluetooth (see wireless communication)

Bolus Calculator: A feature that suggests meal and correction bolus doses based on your current blood glucose, the amount of carbohydrates you are about to eat, the insulin-on-board, and several user-specific settings.

Bolus dose: A dose of insulin taken to correct an elevated blood glucose level (a correction bolus) or to cover carbohydrates in a meal or snack (a meal bolus).

Bolus preset: A bolus dose of insulin that is assigned a custom name and stored by the PDM for later use.

Calorie: A unit of measurement used to express the energy value of food. Calories come from the carbohydrate, protein, and fat in food and drink.

Cannula: A small, thin tube inserted below the skin, which serves to introduce a liquid medication into the body.

DRAFT

Glossary

Carbohydrate bolus (see meal bolus)

Carbohydrate (carbs): One of the three main energy sources in food. (The other two are protein and fat.) Foods that contain carbohydrates include starches, sugars, vegetables, fruits, and dairy products.

Correction bolus: An amount of insulin taken to compensate for high blood glucose levels.

Correct Above threshold: The blood glucose level above which you would like to take insulin to reduce an elevated blood glucose.

Correction Factor (also known as sensitivity factor): A value that indicates how much one unit of insulin will lower your blood glucose. For example, if your Correction Factor is 50, one unit of insulin lowers your blood glucose by 50 mg/dL.

Custom food: An entry in the Food Library's MY FOODS list that states the number of carbohydrates contained in a favorite food item, snack, or entire meal. It is assigned a custom name and stored by the Food Library for later use.

Deactivate: Preferred method for unpairing the PDM from the active Pod. Deactivation turns off insulin delivery in the Pod and then unpairs the PDM from that Pod.

Diabetes, diabetes mellitus: A condition characterized by hyperglycemia (high blood glucose) resulting from the body's inability to use blood glucose for energy. In type 1 diabetes, the pancreas no longer makes insulin and therefore blood glucose cannot enter many cell types to be used for energy. In type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly.

Diabetic ketoacidosis (DKA): A serious condition in which extremely high blood glucose levels and a severe lack of insulin cause the body to break down fat and protein for energy. The breakdown of fat or protein releases ketones into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.

Discard Pod: The DISCARD POD option is offered if the PDM is unable to reestablish communication with the Pod after a communication error. This option allows the PDM to abandon that Pod and activate a new Pod. Note: A 'discarded' Pod may still be delivering insulin. Always remove a 'discarded' Pod from your body.

Duration of insulin action: The length of time that insulin remains active and available in your body after a bolus. This duration can vary greatly depending on the type of insulin you take.

Estimated bolus: After you confirm the amount of bolus that you want delivered, a bolus instruction is sent to the Pod. If the Pod is unable to send back confirmation of the amount of bolus actually delivered, the PDM estimates the amount delivered. This estimate is based on the expected delivery schedule. As soon as confirmation is received from the Pod, the PDM displays the actual (not estimated) bolus amount.

Extended bolus: The delivery of a meal bolus dose steadily over an extended period of time.

Fat: One of the three main energy sources in food. (The other two are carbohydrate and protein.) Fat contains 9 calories per gram. Foods high in fat include oils, margarine, salad dressings, red meat, and whole-milk dairy foods.

Fiber: The indigestible part of plant foods. Foods that are high in fiber include broccoli, beans, raspberries, squash, whole-grain bread, and bran cereal. Fiber is a type of carbohydrate, but it does not raise blood glucose levels as other carbohydrates do.

Food Library: A reference library of thousands of common food items showing each item's carbohydrate, fat, protein, fiber, and calories for a single portion.

Glucose: A simple sugar (also known as dextrose) used by the body for energy. Without insulin, many cells in the body cannot use glucose for energy.

Hazard alarm: A continuous sound and a screen message from the PDM or Pod indicating that an error has occurred or that insulin delivery has stopped. Alarms require your immediate attention.

Healthcare provider: A professional who practices medicine or teaches people how to manage their health.

Hemoglobin A1c (HbA1c): A test that measures a person's average blood glucose level over the past two to three months. Also called glycosylated hemoglobin, the test measures the amount of glucose that sticks to hemoglobin in red blood cells, which is proportional to the average amount of glucose in the blood over an extended time period.

Hyperglycemia (high blood glucose): A higher-than-normal level of glucose in the blood; generally above 250 mg/dL.

Hypoglycemia (low blood glucose): A lower-than-normal level of glucose in the blood; generally below 70 mg/dL.

Hypoglycemia unawareness: A condition in which a person does not feel or recognize the symptoms of hypoglycemia.

Infusing: Introducing a liquid substance under the skin into the body.

Infusion site: A place on the body where a Pod's cannula is inserted.

Insulin: A hormone that helps the body use glucose for energy. Insulin is made by cells in the pancreas called beta cells.

Glossary

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

Insulin on board (IOB) (active insulin): The amount of insulin that is still “active” in the body from a previous bolus dose. The Bolus Calculator tracks IOB for you. The amount of time insulin remains “on board” or “active” depends on your Duration of Insulin Action setting.

Ketoacidosis (see diabetic ketoacidosis)

Ketones: Acidic by-products that result from the breakdown of fat for energy. The presence of ketones indicates that the body is using stored fat and muscle (instead of glucose) for energy.

Manually-calculated bolus: A bolus amount of insulin chosen by you (not calculated by the Bolus Calculator).

Maximum Basal Rate: Upper limit for basal rates in a Basal Program or temp basal.

Maximum Bolus: The largest bolus that you can request from the PDM. The Bolus Calculator informs you if it calculates a bolus that is over this amount.

Minimum BG for Calcs: The minimum blood glucose reading at which the Bolus Calculator calculates a meal bolus. The Bolus Calculator is disabled below this value. “For Calcs” means “for use in the Bolus Calculator’s calculations.”

Meal bolus (also known as carbohydrate bolus): An amount of insulin administered before a meal or snack to ensure that blood glucose levels stay within the desired BG Goal Range after a meal.

Notifications: An on-screen reminder or informational message.

Occlusion: A blockage or interruption in insulin delivery.

Pairing: Linking two devices so that they can communicate wirelessly with each other. After a PDM and blood glucose meter are paired, they are referred to as “paired devices.” See also *sync*.

Podders: People with diabetes or caregivers of people with diabetes who use the Omnipod® system to manage their daily insulin needs.

Preset: A preset allows you to quickly enter a value that you use often.

Protein: One of the three main energy sources in food. (The other two are carbohydrate and fat.) Protein contains 4 calories per gram. Foods high in protein include meat, poultry, fish, legumes, and dairy products.

Reverse Correction (negative correction): If your blood glucose level is below your Target BG, the Bolus Calculator uses your Correction Factor to reduce a portion of a meal bolus dose. This is an optional feature, which should be turned on or off according to the advice of your healthcare provider.

Segments: Defined periods of time during a 24-hour day. Segments are used to define basal segments in a Basal Program, and also to define Target BG segments, IC Ratio segments, and Correction Factor segments.

Sensitivity factor (see Correction Factor)

Sync: The act of transferring information between two paired devices. For example, when the PDM syncs with a paired blood glucose meter, the meter transfers any recent blood glucose readings to the PDM.

Target BG: The blood glucose level that the Bolus Calculator tries to achieve. You can define different Target BGs for different time periods. For example, you can have one Target BG before meals, a different one after meals, and yet another at night.

Temp basal: A temporary basal rate that is used to cover predictable, short-term changes in basal insulin need. Temp basals are often used during exercise and for sick-day insulin adjustments.

Temp basal preset: An adjustment in a basal rate, in either % or U/hr, that can be assigned a custom name and stored by the PDM for later use.

Time segment (see segment)

Unconfirmed bolus: Occurs when you select the DISCARD POD option following a communication error during a bolus. In this case, the Pod was unable to send a confirmation to the PDM about how much of a bolus was actually delivered.

Wireless communication: Transfer of information without a physical connection between two devices. The PDM and Pod, and the PDM and selected blood glucose meters, communicate over short distances using radio waves, which is referred to as wireless communication.

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My PDM Settings

Use these pages to keep track of your important PDM settings. Remember to update your information if you change or add PDM settings.

Basal Program 1		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Basal Program 2		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Basal Program 3		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Basal Program 4		
Name		Basal rate
midnight	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr
	to	U/hr

Target BG		
Time segment	Target BG: Bolus Calculator aims for this value	Correct Above: Suggest correction if BG is above
midnight to	mg/dL	mg/dL
to	mg/dL	mg/dL
to	mg/dL	mg/dL
to	mg/dL	mg/dL
to	mg/dL	mg/dL
to	mg/dL	mg/dL
to	mg/dL	mg/dL
to	mg/dL	mg/dL

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My PDM Settings

Correction Factor			Insulin-to-Carbohydrate Ratio (IC Ratio)		
Correction Factor for each time segment		1 unit of insulin decreases BG by	IC Ratio for each time segment		1 unit of insulin covers
midnight	to	mg/dL	midnight	to	g carb
	to	mg/dL		to	g carb
	to	mg/dL		to	g carb
	to	mg/dL		to	g carb
	to	mg/dL		to	g carb
	to	mg/dL		to	g carb
	to	mg/dL		to	g carb
	to	mg/dL		to	g carb

Duration of Insulin Action	
Time that insulin remains “active” in the body after a bolus	hrs

Temp Basal Presets		
Name	Rate	(circle measurement)
		U/hr or %
		U/hr or %
		U/hr or %
		U/hr or %
		U/hr or %
		U/hr or %
		U/hr or %

Bolus Presets		Favorite Foods	
Name	Units	Name	Grams of carbohydrates
	U		g carb
	U		g carb
	U		g carb
	U		g carb
	U		g carb
	U		g carb
	U		g carb

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My Notes

DIWAMI

DRAFT

My Notes

DIWMI