Bolus Calculator examples

For an explanation of IOB, see page 160. For an explanation of the correction and meal bolus equations, see page 162.

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

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

Correction Bolus **1 U** ← Your blood glucose is 50 mg/dL over your target. With your correction factor at 50 and no IOB adjustment, you will need a 1 U correction bolus.

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

Meal IOB adjustment

Meal IOB = 0 U
1 U - 0 U = 1 U ← No IOB, so no IOB adjustment.

Correction IOB adjustment

Correction IOB = 0 U
1 U - 0 U = 1 U ← No IOB, so no IOB adjustment.

Meal Bolus **3 U** ← You are eating 45g carbs. With your IC ratio at 15 and no IOB adjustment, you will need a 3 U meal bolus.

Carbs = 45 g, IC Ratio = 15 g/U
45 / 15 = 3 U

Correction IOB adjustment

Remaining correction IOB = 0 U
3 U - 0 U = 3 U ← No IOB, so no IOB adjustment.

Calculated Bolus **4 U** ← The calculated bolus is the sum of your correction bolus and meal bolus.

Your Adjustment 0 U ← Any adjustment you make to the calculated bolus is shown here. No adjustment was made.

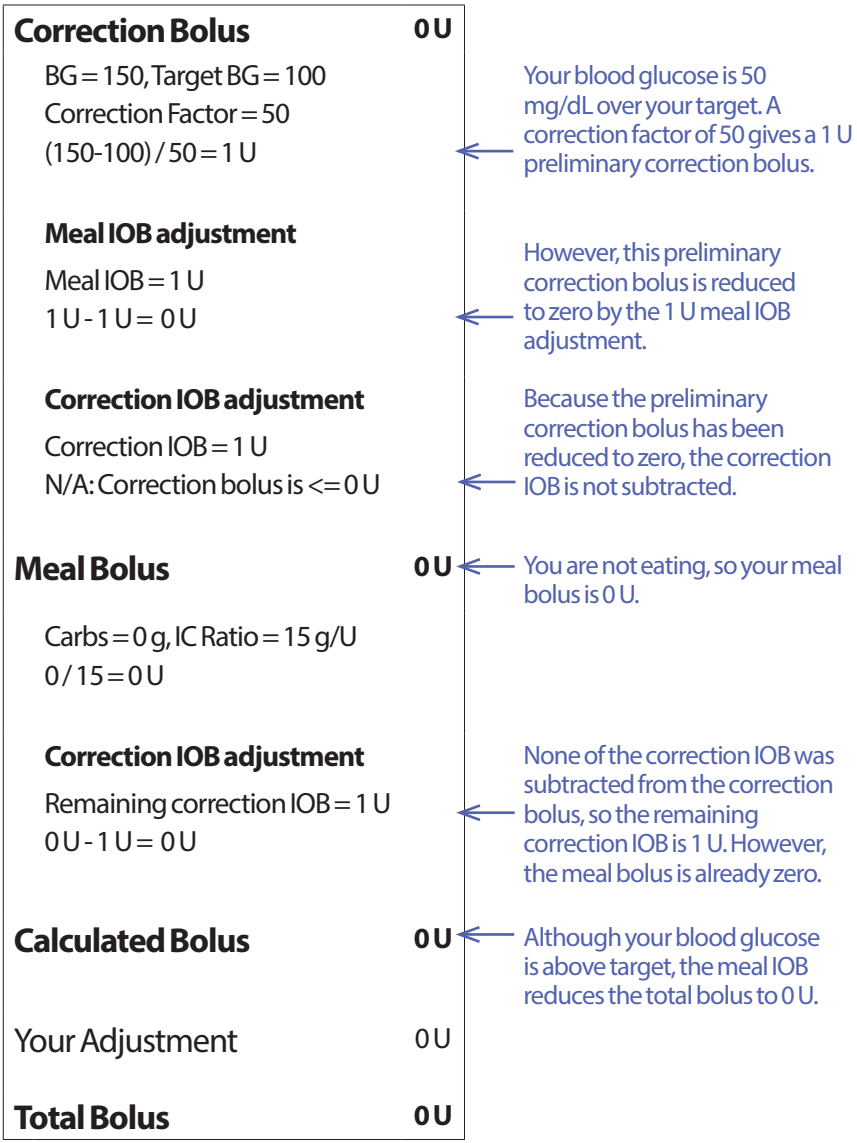
Total Bolus **4 U** ← The total bolus is the sum of the calculated bolus and any adjustment made by you.

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

Duration of Insulin Action = 4 hours.

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

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



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

Duration of Insulin Action = 4 hours.

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

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

Correction Bolus **0 U** ← Blood glucose is at target, so the correction bolus is zero.

BG = 100, Target BG = 100
Correction Factor = 50
(100-100) / 50 = 0 U

Meal IOB adjustment

Meal IOB = 1 U
N/A: Correction bolus is <= 0 U ← The correction bolus is zero, so the meal IOB is not subtracted.

Correction IOB adjustment

Correction IOB = 0 U
N/A: Correction bolus is <= 0 U ← No IOB adjustment.

Meal Bolus **3 U**

Carbs = 45 g, IC Ratio = 15 g/U
45 / 15 = 3 U ← You are eating 45 g carbs. With your IC ratio at 15 and no correction IOB adjustment, the meal bolus is 3 U.

Correction IOB adjustment

Remaining correction IOB = 0 U
3 U - 0 U = 3 U ← No IOB adjustment is made. There is no correction IOB, and meal IOB is never subtracted from a meal bolus.

Calculated Bolus **3 U** ← Even though there was a 1 U meal IOB, it did not reduce the calculated bolus.

Your Adjustment 0 U

Total Bolus **3 U**

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

Duration of Insulin Action = 2 hours.

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

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

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

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

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

Correction Bolus **- 0.5 U** ← Your blood glucose is below your target, so a Reverse Correction is calculated.

BG = 75, Target BG = 100
Correction Factor = 50
(75 -100) / 50 = -0.5 U
(Reverse correction ON)

Meal IOB adjustment

Meal IOB = 0 U
N/A: Correction bolus is <= 0 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 <= 0 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 U

Correction IOB adjustment

Remaining correction IOB = 0 U
3 U - 0 U = 3 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	= Total number of BG readings in the day (or date range)
Highest BG	= Highest BG reading in the day (or date range)
Lowest BG	= Lowest BG reading in the day (or date range)

Insulin delivery summaries

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

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

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

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

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

Summary item	Calculation
Row 3 (see page 90)	
Total Insulin	= Sum of basal and bolus insulin delivered
Average Total Insulin	= $\frac{\text{Sum of basal and bolus insulin delivered}}{\text{Number of days}}$
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

Warnings:

If an infusion site shows signs of infection:

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

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

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

Check your blood glucose frequently

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

Check your blood glucose:

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

Prepare for Emergencies

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

> **Warning:** Keep an emergency kit with you at all times to quickly respond to any diabetes emergency.

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

- Several new, sealed Pods
- A vial of rapid-acting U-100 insulin (see "General Warnings" on page xii for insulins cleared for use in the Omnipod DASH™ System)
- Syringes or pens for injecting insulin
- Blood glucose test strips
- Blood glucose meter
- Ketone test strips
- Lancing device and lancets
- Glucose tablets or another fast-acting source of carbohydrate
- Alcohol prep swabs
- Instructions from your healthcare provider about how much insulin to inject if delivery from the Pod is interrupted
- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and the Omnipod DASH™ System
- Phone numbers for your healthcare provider and/or physician in case of an emergency
- Glucagon kit and written instructions for giving an injection if you are unconscious (see "Avoid Lows, Highs, and DKA" on page 178)

Traveling and Vacations

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

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

Keep supplies accessible

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

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

  Note: Generic medications may be easier to find than brand names outside your country.
- Snacks and hypoglycemia treatment, in case food is not available
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of your physician and of a physician at your final destination

Note: Keep your emergency kit with you during trips or vacations (see "Prepare for Emergencies" on page 175). As it may be difficult or impossible to get insulin or supplies in an unfamiliar place, take more supplies than you think you'll need.

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

Plan for changing time zones

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

Airports and flying

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

Airport security

Prepare for your travel:

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

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

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

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

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

Note: Pods and PDMs can safely pass through airport X-ray machines (see the "Omnipod DASH™ System Notice Concerning Interference" on page 194).

Flying and airplane mode

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

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

If use of a Personal Electronic Device using Bluetooth® technology is allowed, set your PDM to airplane mode while on the airplane (see "Airplane mode" on page 99). The Bluetooth® setting remains enabled in the PDM's airplane mode so you can communicate with your Pod and BG meter. Airplane mode turns off your PDM's Wi-Fi connectivity.

Note: The Omnipod DASH™ System is safe to use at atmospheric pressures typically found in airplane cabins during flight. The Omnipod DASH™ System

can be used at atmospheric pressures as low as 700 hPA, which is lower than the typical pressure in airplane cabins.

Avoid Lows, Highs, and DKA

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

General precautions

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

Hypoglycemia (low blood glucose)

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

Symptoms of hypoglycemia (low blood glucose)

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

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

Tip: *Hypoglycemia unawareness is a condition in which you do not realize when your blood glucose level is low. If you are prone to hypoglycemia unawareness, you may want to use the PDM's blood glucose reminder and check your blood glucose more frequently (see "Check BG after Bolus reminders" on page 110).*

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

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

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

To avoid hypoglycemia (low blood glucose)

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

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

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

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

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

To treat hypoglycemia (low blood glucose)

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

blood glucose levels to rise too high. Contact your healthcare provider as needed for guidance.

Possible causes of hypoglycemia	Suggested action
Incorrect Basal Program	Confirm that the correct Basal Program is active. Confirm that the PDM time is set correctly. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too large	Take bolus with food. Check blood glucose before giving a meal bolus. If necessary, adjust the bolus. Check the bolus size and timing. Do not overcorrect for post-meal glucose levels. Check carb intake. Consult your healthcare provider for guidance.
Incorrect Target BG level or incorrect Correction Factor or incorrect IC Ratio	Consult your healthcare provider about refining these settings as needed.
Prone to severe hypoglycemia or hypoglycemia unawareness	Consult your healthcare provider about hypoglycemia unawareness and about raising Target BG levels.
Unplanned physical activity	Consult your healthcare provider about using a temp basal (temporary basal rate).
Prolonged or intense exercise	Adjust insulin delivery as instructed by your healthcare provider. Check blood glucose before, during, and after activity and treat as necessary. **Note:** Effects of exercise can last several hours—even a full day—after activity ends. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Low carbohydrate intake prior to activity	Check blood glucose before activity. Consult your healthcare provider for guidance.

Possible causes of hypoglycemia	Suggested action
Alcohol consumption	Check blood glucose frequently, especially before going to bed. Consult your healthcare provider for guidance.

Hyperglycemia (high blood glucose)

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

> **Warning:** An occlusion may result from a blockage, Pod malfunction, or from using old or inactive insulin (see "Occlusion detection" on page 192). If insulin delivery is interrupted by an occlusion, check your blood glucose level and follow the treatment guidelines established by your healthcare provider. Hyperglycemia could result if appropriate actions are not taken.

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

Symptoms of hyperglycemia (high blood glucose)

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

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

To avoid hyperglycemia (high blood glucose)

Check your blood glucose:

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

- Before, during, and after exercise
- As directed by your healthcare provider

To treat hyperglycemia (high blood glucose)

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

1. Check your blood glucose level. The result will help you to find out how much insulin is needed to return your blood glucose to your blood glucose goal.
2. If your blood glucose is 250 mg/dL or above, check for ketones. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check blood glucose again after 2 hours.
5. If blood glucose levels have not decreased, do both of the following:
   - Take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.
   - Replace the Pod. Use a new vial of insulin to fill the new Pod. Then contact your healthcare provider for guidance
6. If you feel nauseated at any point, check for ketones and contact your healthcare provider immediately (see "Diabetic ketoacidosis (DKA)" on page 184).

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

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

Possible causes of hyperglycemia	Suggested action
Expired insulin or insulin exposed to extreme temperatures	Deactivate and remove the used Pod. Apply a new Pod filled from a new vial of insulin.
Infusion site in or near a scar or mole	Deactivate and remove the used Pod. Apply a new Pod in a different location.

Possible causes of hyperglycemia	Suggested action
Infected infusion site	Deactivate and remove the used Pod. Apply a new Pod in a different location and consult your healthcare provider.
Dislodged cannula	Deactivate and remove the used Pod. Apply a new Pod in a different location. **Note:** Avoid sites near a waistband, belt, or other areas where friction may dislodge the cannula.
Empty Pod	Deactivate and remove the used Pod. Apply a new Pod in a different location.
Incorrect Basal Program	Confirm that the correct Basal Program is active. Confirm that the PDM time is set correctly. Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Incorrect bolus timing or bolus too small	Check carb intake. Take bolus with food. Check blood glucose before giving meal bolus. If necessary, adjust bolus. Consult your healthcare provider for guidance.
High-protein or high-fat meal	Calculate protein/fat intake and account for it in your bolus timing and bolus type. Consult your healthcare provider about using the extended bolus option.
Less activity than normal	Consult your healthcare provider about adjusting your Basal Programs or using a temp basal.
Blood glucose value greater than 250 mg/dL (with ketones present) before exercise	Do not exercise when ketones are present. **Note:** Blood glucose increases with exercise when ketones are present. Consult your healthcare provider for guidance.
Infection or illness or medication change	See "Sick days" on page 185. Consult your healthcare provider about sick day guidelines and about medication changes.

Possible causes of hyperglycemia	Suggested action
Weight loss or gain or menstrual cycle or pregnancy	Consult your healthcare provider for guidance.

Diabetic ketoacidosis (DKA)

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

Warnings:

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

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

Symptoms of DKA

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

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

To avoid DKA

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

To treat DKA

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

Handling Special Situations

Sick days

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

When you are ill, check your blood glucose more often to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose to rule out DKA (see "Diabetic ketoacidosis (DKA)" on page 184).

To handle sick days:

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

Exercising, playing sports, or working hard

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

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

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

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

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

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

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

X-rays, MRIs, and CT scans

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

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

Surgery or hospitalization

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

Appendix

Troubleshooting PDM Startup

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

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

Return to normal PDM operation as follows:

Boot Mode

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

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

   Caution: Do not select the [Fastboot Mode] because it will stop the PDM from responding. If the PDM stops responding, remove the battery, reinsert it, and restart the PDM to return to normal operation.

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

   The PDM restarts.

Safe Mode

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

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

Summary of Settings and Options

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

Time format	12-hour or 24-hour clock.
Time zones	GMT-11:00 to GMT+13.00.
Date format	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Screen time-out	30, 60, 120 seconds. Default is 30 seconds.
PIN	4 digits from 0 to 9.
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr.
Basal rate	Units/hr. Range: 0 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	Maximum of 12.
Basal rate segments	24 per Basal Program.
Temp basal	%, units/hr, or Off. Default is Off. Duration: 30 min to 12 hrs in 30-min increments.
Temp basal (set to %)	Range: 100% decrease (0 U/hr) to 95% increase from current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 U/hr to Maximum Basal Rate in increments of 0.05 U/hr.
Temp basal presets	Maximum of 12.
BG Goal Range for blood glucose history	Lower and upper limits: 70 to 200 mg/dL in 1 mg/dL increments .
BG reminder	On or Off. Default is Off. Maximum of 4 active at one time. Reminder can occur between 30 min to 4 hrs after bolus is started. Set in 30-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, Off.
Bolus Calculator	On or Off. Default is On.
Target BG value	Maximum of 8 segments; 70 to 200 mg/dL in 1 mg/dL increments.
Correct Above threshold	Maximum of 8 segments; Target BG to 200 mg/dL in 1 mg/dL increments.
Minimum BG for Calcs	50 to 70 mg/dL in 1 mg/dL increments Default is 70 mg/dL.
Insulin-to-carb (IC) ratio	Maximum of 8 segments; 1 to 150 g carb/U in 0.1 g carb/U increments.
Correction (sensitivity) factor	Maximum of 8 segments; 1 to 400 mg/dL in 1 mg/dL increments. Default is 50 mg/dL.

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

Pod Specifications

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

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

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

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

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

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

Reservoir volume (deliverable): 200 units

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

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

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

Insulin concentration: U-100

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

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

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

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.0 U

Flow Capability:

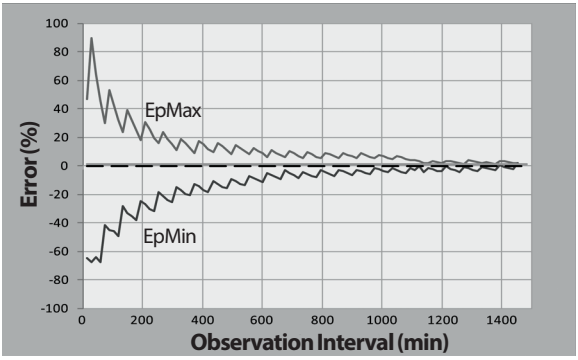
Basal: Programmable by the user in 0.05U increments up to 30.0 U per hour
Bolus Rate: 1.5 units per minute. Dose range from 0.05 to 30.0 units

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

Basal: ± 5% at rates ≥ 0.05 U/hr
Bolus: ± 5% for amounts ≥ 1.0 unit
± 0.05 units for amounts < 1.0 unit

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

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



PDM Specifications

Size: 2.48" wide x 5.1" long x 0.39" high (6.3 cm x 13.0 cm x 1.0 cm)

Weight: 6.17 oz (175 grams)

Screen active area: 4.0" diagonal ± 5% (10.2 cm ± 5%)

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

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

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

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

Operating atmospheric pressure: 700 hPA to 1060 hPA

Storage atmospheric pressure: 700 hPA to 1060 hPA

Communication distance: The PDM and Pod should be

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

Waterproof rating: IP22 (avoid liquid)

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

Notification type: Audible and vibratory

Battery: Rechargeable Li-ion battery, 3.7V, 1300 mAh

Only use the NUU mobile Li-Ion battery Model NUBA1 (Insulet PN 18363) with the PDM.

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

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

Only use the NUU mobile Switching Adapter Model HJ-0501000E1-US (Insulet PN 18401) with the PDM.

Protection from Over-infusion or Under-infusion

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

Occlusion detection

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

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

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

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

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

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

Omnipod DASH™ System Label Symbols

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

Symbol	Meaning
	Single use only
	Consult accompanying documents
STERILE EO	Sterilized using ethylene oxide
	Date of manufacture
LOT	Batch code
	Use by date
REF	Reference number
SN	Serial number
IP28	Submersible: Waterproof to 25 feet (7.6 meters) for up to 60 minutes
IP22	Avoid liquid
	Do not dispose with household waste

Symbol	Meaning
	MR unsafe
	Do not use if package is damaged
	Type BF applied part
	Manufacturer
	Keep dry
	Storage temperature, Operational temperature
	Storage relative humidity, Operational relative humidity
	Storage atmospheric pressure, Operational atmospheric pressure
	Non-pyrogenic fluid path
Rx ONLY	Prescription only
RoHS	RoHS compliant
	Pod

Omnipod DASH™ System Notice Concerning Interference

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

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

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

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

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

Electromagnetic Compatibility

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

General Notes

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

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

Caution: Cables and accessories not specified within the instructions for use are not authorized. Using other cables or accessories may adversely impact

safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

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

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

The Omnipod DASH™ System communicates with the following characteristics:

Frequency: 2.400-2.480 GHz, digitally modulated, with an effective radiated power of 1.14mW

The Omnipod DASH™ System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

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

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

Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
RF Emissions (CISPR 11)	Group 2	The Pod and the PDM emit low level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity

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

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 8 kV air discharge: ± 15 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	30 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	10 V/m at 80 MHz–2.7 GHz	10 V/m	Suitable for most environments. Keep portable RF communications equipment at least 12 inches (30 cm) away from the Omnipod DASH™ System.

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

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

Customer's Bill of Rights

Mission Statement

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

Scope of Services

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

Compliance

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

Inquiries

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

CHAP Accredited

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

Customer's Bill of Rights and Responsibilities

You have the right to:

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

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

You have the responsibility to:

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

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

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

LIMITED EXPRESS WARRANTY COVERAGE

Limited Warranty Coverage for the Omnipod DASH™ System Personal Diabetes Manager

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

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

Limited Warranty Coverage for the Omnipod DASH™ System Pods

Subject to this Limited Express Warranty, Insulet Corporation warrants to you, the original purchaser of the Omnipod DASH™ System, that, if Insulet Corporation determines, during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, that an unexpired Omnipod DASH™ System Pod ("Pod") included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, Insulet Corporation will replace the Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e. the activation must occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before, and within seventy-two (72) hours of the time that you notify Insulet Corporation of the claim).

This eighteen (18) month and seventy-two (72) hour warranty period applies only to new Pods, and in the event a Pod is replaced, the warranty period shall not be extended or reset. Thus, if Insulet Corporation replaces a Pod under this Limited Express Warranty, the warranty coverage for the replacement Pod shall expire either eighteen (18) months from the manufacture date of the original Pod or seventy-two (72) hours from the time of activation of the original Pod, whichever occurs first.

LIMITED EXPRESS WARRANTY TERMS AND CONDITIONS

Claim Procedure

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

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

Proof of Purchase

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

Exclusions

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

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

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

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

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

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

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

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

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

Important Additional Provisions

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

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

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

No Other Warranty or Agreement

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

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

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

Rev: January 15, 2018

HIPAA Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

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

Uses and Disclosures of Medical Information

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

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

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

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

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

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

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

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

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 download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

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

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

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an amendment to your Medical Information.

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

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

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

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.

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 download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

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

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 download our Request form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

Our Duties

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

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our Website at www.myomnipod.com. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at

https://www.myomnipod.com/images/upload/HIPAA_Privacy_Notice_Request_Form.pdf

and follow the directions included on that form.

What To Do If You Have a Problem or Question

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

Insulet Corporation
Attn: Privacy Officer
100 Nagog Park
Acton, MA 01720
(866) 941-0155

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

Effective Date: August 11, 2004

Revision Dates: April 1, 2009, September 20, 2013, April 22, 2014, September 2, 2014, and June 1, 2019

Glossary

A1c (see Hemoglobin A1c)

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

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

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

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

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

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

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

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

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

Bluetooth® (see wireless communication)

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

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

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

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

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

Carbohydrate bolus (see meal bolus)

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

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

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

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

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

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

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

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

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

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

Estimated bolus: After you confirm the amount of bolus that you want delivered, a bolus instruction is sent to the Pod. If the Pod is unable to send back confirmation of the amount of bolus actually delivered, the PDM estimates the amount delivered. This estimate is based on the expected delivery schedule. As

soon as confirmation is received from the Pod, the PDM displays the actual (not estimated) bolus amount.

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

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

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

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

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

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

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

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

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

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

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

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

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

Insulin: A hormone that helps the body use glucose for energy. The beta cells of a healthy pancreas make insulin.

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

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

My PDM Settings

Correction Factor

Correction Factor for each time segment			1 unit of insulin decreases BG by
midnight	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL
_____	to	_____	_____ mg/dL

Insulin-to-Carbohydrate Ratio (IC Ratio)

IC Ratio for each time segment			1 unit of insulin covers
midnight	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb
_____	to	_____	_____ g carb

Duration of Insulin Action

Time that insulin remains "active" in the body after a bolus _____ hrs

Temp Basal Presets

Name	Rate	(circle measurement)
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %
_____	_____	U/hr or %

Bolus Presets

Name	Units
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U
_____	_____ U

Favorite Foods

Name	Grams of carbohydrates
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb
_____	_____ g carb

My Notes

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