iLet Bionic Pancreas System User Educational Resource Guide

Beta Bionics

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1. The iLet Bionic Pancreas System: what you might expect

The iLet Bionic Pancreas System

How is this different from my current diabetes care?

Right now, you and your physician must calculate	The iLet does all of this for you
Basal insulin Using long-acting insulin injections or basal rates in an insulin pump **High glucose correction insulin** Using correction factors	**Fully automated**
Meal insulin Using carb counting and carb-to-insulin ratios	**Meal Announcement** Requires that you announce the meal as Breakfast, Lunch, or Dinner, and provide an estimate of the carb content as Usual for me, More, or Less for that meal type.

The iLet makes insulin dosing decisions every five minutes using your CGM glucose level. It will respond to rising and falling CGM levels and will adjust insulin doses accordingly. You will still have highs and lows, and your CGM graph will not be flat or in range all the time when wearing the iLet.

The iLet automatically calculates how much insulin to give you for basal, for high CGM levels, and for meals.

You will not know what these calculations are and you will not be able to edit the doses, but you will be able to see how much insulin was dosed.

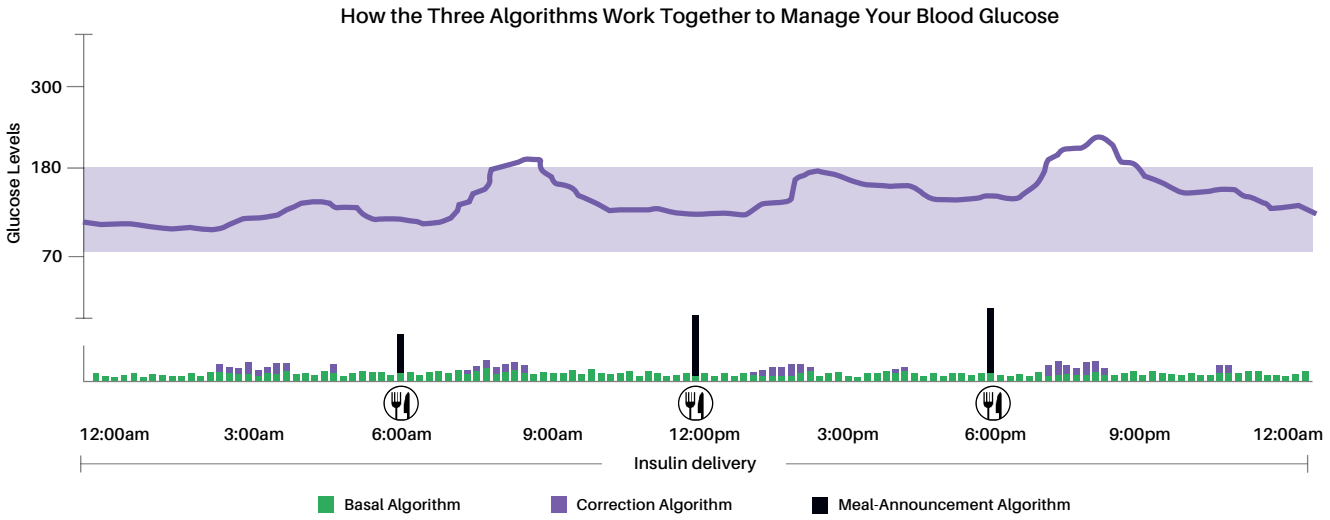
The three algorithms that make up the iLet Bionic Pancreas are:

Basal insulin algorithm: This algorithm calculates how much "baseline" insulin you should have. It calculates the basal dose needed based on your glucose profile from the previous 24 hours and increases or decreases that dose based on current CGM glucose and trend.

Bolus correction insulin algorithm: This algorithm makes adjustments or "corrections" that you might need above and beyond the basal insulin dose. It calculates the correction dose needed based on your glucose profile from the previous 24 hours, current CGM glucose and trend, and insulin on board.

Meal announcement insulin algorithm: This is specifically for making sure you have the right insulin dosing for meals. You will learn how to "announce" a meal to the system or tell the iLet that you are having a meal. This algorithm will then figure out how much insulin you need. This algorithm will learn and adapt as you announce meals over time.

The iLet never stops learning and is always adapting to your insulin needs. It will continue to adapt as your insulin needs change over time. Adaptation works best if you follow your usual routine in the first few days. Don't challenge the iLet right away - all it knows is the weight that was entered. It does not know anything else about your insulin needs yet, and starts out conservatively for most users.



There are still times with high blood glucose levels and low blood glucose levels while using the iLet due to food, activities, hormones, stress, etc.

- Even when you use the Meal Announcement, **your blood glucose levels could rise above 250 mg/dl** for a few hours. You'll need to be comfortable with letting the iLet regulate your blood glucose.
- **Your blood glucose levels could drop below 70 mg/dl or 54 mg/dl**, especially during or soon after exercise.

When wearing the iLet, you cannot:

- program any insulin settings (no basal rates, correction factors, or carb ratios).
- give a correction dose of insulin.
- enter carbohydrates into a bolus calculator or determine the amount of insulin to give for a meal.
- change how the iLet is automating insulin delivery.

2. Managing Highs & Lows

You will still experience high and low CGM glucose values that require your attention while using the iLet. Call your HCP if you have any questions or if you need assistance in managing your glucose levels while using the iLet.

General Tips

- It is important to be patient with the iLet as it adapts to your insulin needs and responds to your changing glucose levels. It is also critically important to maintain your iLet device properly and respond to all alerts promptly.
- Low glucose levels (hypoglycemia) require treatment with rapid- acting carbohydrates (juice, glucose tabs, etc). You may need to treat with fewer carbs than you are used to because your iLet will have likely already decreased and/or stopped insulin dosing.
- High glucose levels (hyperglycemia) may require you to replace your insulin infusion site or take other steps to resolve a problem with your device.
- It is recommended that you use the High and Low glucose alerts in the iLet. Whatever volume you choose, make sure you are able to hear and respond to these alerts.
- Not responding to glucose alerts quickly can cause low and high glucose events to become longer and more serious than they otherwise might have been.
- If you are feeling symptoms of high or low glucose levels that are not consistent with your CGM glucose, it is always a good idea to confirm with a fingerstick blood-glucose reading. If your CGM is very inaccurate compared to your fingerstick blood-glucose reading, calibrate your CGM according to the manufacturer's instructions.
- Make sure the iLet Connect Luer adapter is on straight and tightly attached to the tubing. If this connection is not tight, insulin can leak out causing hyperglycemia, or air can get in and push insulin into your body, causing hypoglycemia.

> **CAUTION:** Managing your BG using your iLet device is different from managing your BG on your own. Follow the instructions as provided in this training. Always ask your healthcare provider for additional guidance if you are unsure.

Symptoms of High Glucose (Hyperglycemia)

When your blood glucose is high, you may:

- feel very tired, thirsty, or hungry.
- have dry mouth.
- urinate more often than usual.

More serious symptoms of high blood glucose and diabetic ketoacidosis (DKA) include:

- flushed or dry skin.

- rapid breathing or breath that smells fruity.
- abdominal pain, nausea, and vomiting.

Symptoms of Low Glucose (Hypoglycemia)

When your blood glucose is low, you may feel:

- nervous, anxious, or shaky.
- sweaty or confused.

More serious symptoms of low glucose include:

- seizure or loss of consciousness (passing out).

> **NOTE:** Remember, it is very important that you maintain your iLet device properly and respond to all alerts promptly!

When Your Glucose Level is High

Your iLet will automatically deliver insulin in response to rising and high CGM glucose levels to bring your glucose level safely back into range. This may take longer than you expect.

> **REMEMBER:** DO NOT take additional insulin via injections, inhaler, or another pump while using the iLet unless directed by your healthcare provider.

Always check to confirm that your iLet is working as it should. Make sure your iLet:

- is reading your CGM glucose level every five minutes and your CGM glucose level is consistent with your fingerstick BG level.
- is delivering insulin doses in response to your CGM glucose level.
- has enough battery power.
- has enough insulin in the cartridge. Change your insulin cartridge, iLet Connect , tubing, and infusion site if it has been more than 3 days since you last changed them.
- does not have an active alert that has stopped insulin dosing (i.e., occlusion, complete cartridge change process, empty cartridge, dosing stopped, etc.).
- is connected to the tubing and your infusion set. Make sure the Luer connector is on straight and tightly attached to the tubing. If this connection is not tight, insulin can leak out causing hyperglycemia, or air can get in and push insulin into your body, causing hypoglycemia.
- is not leaking insulin anywhere (make sure there is no wetness or smell of insulin along the tubing at the connector site, along the tubing, and at the infusion site).

If everything looks like it's working, give the iLet time to respond to your glucose levels. Continue to monitor your glucose until it returns to a normal range.

> **REMEMBER:** If you have the High Glucose alert turned on, the iLet will notify you if your CGM glucose has been above 300 mg/dl for 90 minutes.

Signs that the infusion site is not working include:

- The device is working properly (charged, has insulin, is reading CGM glucose levels), but CGM glucose levels continue to rise and/or stay high despite insulin dosing by the device
- CGM glucose is above 300 mg/dl for 90 minutes or more or above 400 mg/dl once
- Any evidence the site may be kinked, dislodge, or is leaking insulin (is wet, smells like insulin)
- Consider changing your insulin cartridge, tubing, and iLet Connect in addition to your infusion site if there is any suspicion of leaking in the cartridge area.

Occlusion Alerts

Occlusion alerts can potentially cause hyperglycemia, because insulin delivery will be suspended until you acknowledge the alert.

- Check for any obvious kink in tubing or other reason delivery is blocked.
- If occlusion alerts reoccur, change the infusion set and contact your study team as needed.
- When in doubt, change it out!

Change your insulin infusion site if you have any suspicion that it is not working. When in doubt, change it out!

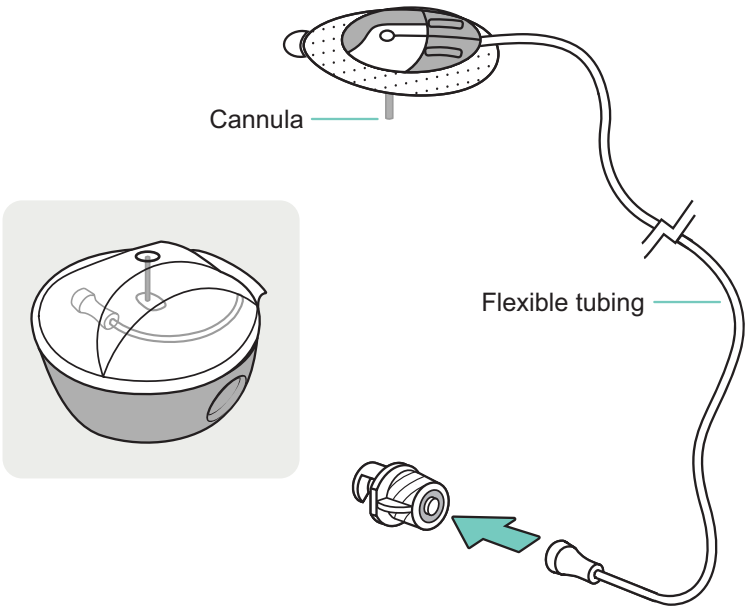


Figure A

Understanding Ketones

When blood glucose is high and your body does not have enough insulin, it cannot break down glucose for energy. Instead, your body will produce ketones. High ketone levels are toxic and cause diabetic ketoacidosis.

You can check for ketones with urine strips or a blood-ketone meter at any time. You should check for ketones when:

- CGM glucose has been greater than 300 mg/dl for 90 minutes.
- CGM glucose has been greater than 400 mg/dl once.
- you are vomiting, have an upset stomach or other signs of illness.
- you suspect your infusion set might not be working.

If your CGM glucose is above 300 mg/dl for 90 minutes or more:

Figure B

- Your iLet will alert for high glucose readings (see Figure B), and you should respond immediately! If your glucose level is this high for this long, it likely means that something is not working as it should.
- Check a fingerstick blood glucose reading to confirm your hyperglycemia.
- Check a fingerstick blood ketone level or urine ketone level as directed by your healthcare provider.
- Consult with your healthcare provider and your Ketone Action Plan.
- Change your infusion site if you have ketones or as directed by your healthcare provider.
- Pay attention to high BG levels and respond to this alert quickly. Prolonged high BGs can cause late correction insulin dosing, and may cause the iLet to temporarily be more aggressive with insulin dosing to try and bring your glucose level back down. This can lead to hypoglycemia later.
- Avoid long periods of high BGs by:
  - Announcing for meals with carbohydrates.
  - Maintaining the device so it always has enough insulin and battery.
  - Keeping the High Glucose alert turned on.

- Setting the volume to a level you can hear.
- Change the infusion set if you have any doubt it is not working.

REMEMBER: Unless specifically directed to do so by your healthcare provider, DO NOT take additional insulin that the iLet does not know about (via injections, inhaler, or another pump). This is dangerous and can result in severe hypoglycemia.

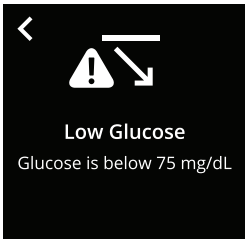
REMEMBER: NEVER use the Meal Announcement to correct a high blood glucose level. This is dangerous and can result in severe hypoglycemia. It will also affect your iLet's learning, causing future Meal Announcement doses to be less effective.

REMEMBER: WHEN IN DOUBT, CHANGE IT OUT!

When Your Glucose Level is Low

Your iLet will reduce or stop insulin dosing in response to low or falling CGM glucose levels. Always make sure to have rapid-acting carbohydrates and emergency glucagon available to respond to low glucose levels. Make sure your CGM alerts are turned on and you can hear them.

Your iLet has four different alerts for low CGM glucose readings:

Alert	Meaning	Response
Urgent Low Glucose 	CGM glucose < 54 mg/dl	• Check a fingerstick blood glucose reading to confirm hypoglycemia. • Treat with up to 15 grams of rapid-acting carbohydrates. You may need to treat with fewer carbs than you are used to because your iLet will have likely already decreased and/or stopped insulin dosing. • Always wait and give your glucose level a chance to respond to the rapid-acting carbohydrates before treating again. • Check a fingerstick blood-glucose reading approximately 15 minutes after treating. Your fingerstick glucose reading may show a rise in glucose level before your CGM glucose rises. • Treat again with rapid-acting carbohydrates if your glucose level remains low. • Continue to monitor your glucose until it remains above 70 mg/dl.
Low Glucose 	CGM glucose < 75 mg/dl	

Alert	Meaning	Response
Glucose Falling Quickly 	CGM glucose < 100 mg/dl and falling 2 mg/dl/min or more (CGM glucose will be < 70 mg/dl within 15 minutes)	Treat with rapid-acting carbohydrates to prevent a hypoglycemic event from happening. You may not need the full amount of carbohydrates you would usually use to prevent this low glucose event from happening.
Urgent Low Soon 	CGM glucose will be < 54 mg/dl within 20 minutes	

If you see your CGM glucose level dropping, but your glucose is still above 100 mg/dl:

- do not treat with rapid-acting carbohydrates right away.
- monitor your CGM glucose levels and be patient.

> **REMEMBER**: If you have the Low Glucose alerts turned on, the iLet will notify you and you can treat with rapid-acting carbs as needed.

How to Treat Low Glucose Levels

- Make sure to treat low glucose levels with only rapid-acting carbohydrates. These include juice, glucose tablets, Skittles, fruit chews, etc. These will provide the quick rise in BG that you need and, if taken in moderation, will not cause your BG to go too high or stay high for a long time.
- Do not use slower acting carbohydrates to treat a low glucose level. These include things with more fat or protein, such as chocolate, peanut butter, crackers, etc. These types of foods will cause your BG to rise more slowly, leaving your BG too low for too long, and may cause higher BGs later when you don't need it.
- Do not take more carbohydrates than needed to treat a low glucose level. This can cause your glucose to respond too much, leading to a high glucose level and triggering more insulin dosing from the iLet. This may end up causing a "roller coaster" effect while your iLet responds to both rising and falling glucose levels.

- NEVER announce a meal for carbohydrates used to treat a low BG.
- If your BG is low before a meal, treat the low glucose with rapid-acting carbohydrates and allow the glucose to rise before you eat and announce for your meal. Once your glucose is within range, eat and announce the meal as planned. Choose the meal size based on the carbohydrate content of the meal, and do not consider the carbs used to treat the low.
  - Do not include carbs used to treat lows in your meal announcement size. This will cause additional hypoglycemia.
  - Do not announce your meal as smaller than what it actually is to get less insulin as a "reverse correction". This will cause hyperglycemia because you won't get enough insulin for the meal you are eating now. It may also cause the meal dose to adapt upwards, delivering too much insulin the next time you announce a meal and causing future hypoglycemia.

REMEMBER: Your CGM glucose may lag behind your blood glucose level when you are treating lows. Consider checking a fingerstick blood glucose level using a meter 15 minutes after treating and before deciding to treat again, as your glucose may have already returned to range.

To stay safe on your iLet, always:

- Keep CGM glucose alerts turned on.
- Keep the iLet volume set to a level you can hear. Use alerts on your smartphone in addition to the iLet.
- Respond to all alerts quickly.
- Make sure your iLet and infusion site are working whenever BG is high for a period of time.
- Change your infusion set if you have any suspicion that it is not working. When in doubt, change it out!
- Treat low BGs with up to 15 grams of rapid-acting carbs and wait 15 minutes before treating again if needed.
- Avoid taking carbs to treat low BGs too early and avoid over-treating.

3. Meal Announcement Guide

Why do I need to announce my meals?

- When you announce a meal the iLet will give you insulin to help limit the glucose rise after eating. The iLet may add more insulin if needed.

When do I announce?

- Announce a meal right when you start eating.
- You can announce a meal up to 30 minutes after you start eating. If you forget to meal announce, and more than 30 minutes have passed since you started eating, do not announce, otherwise you might cause insulin "stacking".

> **CAUTION:** Announcing more than 30 minutes after you have started eating can result in severe hypoglycemia.

- If you announce a meal and then decide to eat more, you can announce again for the additional carbohydrates (carbs). Only consider the amount of additional carbs you are eating when choosing the meal size, not the carbs you have already announced.

> **CAUTION:** If eating more and announcing again, do not include carbs that you have already announced when deciding the meal size. This could result in severe hypoglycemia.

What is the meal TYPE?

- Select the meal type based on what you consider to be breakfast, lunch, or dinner (see Figure C).
- You are free to decide the meal type based on carbohydrate content, time of day, or whatever you find works best for you.
- Being consistent with what you consider breakfast, lunch, and dinner will help the iLet learn how to treat your meals.

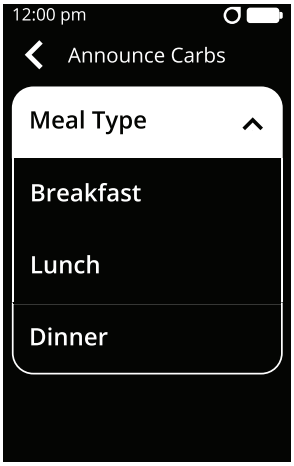


Figure C

What is the meal SIZE?

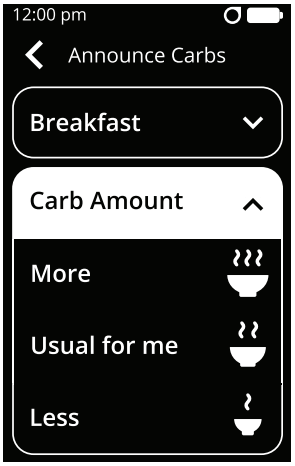


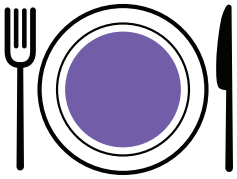
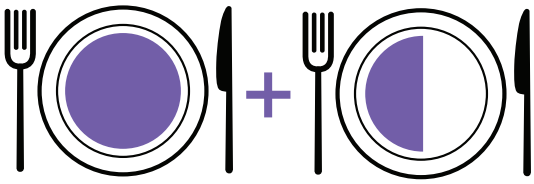
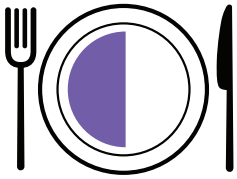
Figure D

- **It is important to choose your meal size based on the amount of carbs in the meal, NOT the total size of the meal or the amount of protein, fiber, or fat.**
- Although the iLet System does not require you to enter an exact carb amount to calculate and administer a meal bolus, it does require that you announce the meal as Breakfast, Lunch, or Dinner and provide an estimate of the carb content as Usual for me, More, or Less for that meal type (see Figure D). Choose the meal size compared to the usual amount of carbs you eat for the chosen meal type.
- You should be choosing Usual for me MOST of the time.
  - Use Less if your meal has around half the carbs of your Usual for me meal.
  - Use More if your meal has around 50% more carbs than your Usual for me meal.
- All that matters is what you consider to be Usual, More, or Less for yourself and for the chosen meal type.

Announce snacks the same way you would announce meals.

- If the snack you are eating has as many carbs as your meals for that meal type, then announce that snack as a meal.
- If your snack does not have as many carbs are your Less meal type, then you should not announce that snack as a meal.

Meal Size Guide:

Carb Amount	Example	
Usual for me Carb Amount		This is the usual amount of carbs you would typically eat for that meal type.
More Carb Amount		This is around 50% more carbs than your Usual for me meal (1.5 times as many carbs as your Usual for me meal).
Less Carb Amount		This is around half as many carbs than your Usual for me meal (50% of your Usual for me meal).
DO NOT ANNOUNCE		If the meal or snack you are eating has less than one quarter (25%) of the carbs in your Usual for me meal, you do not need to announce.

How can I help the iLet learn my meals?

- Be consistent with how you decide the meal type and size.
  - Only select Breakfast if you are eating your breakfast, Lunch for your lunch, and Dinner for your dinner.
  - Only think about the carbs in your meal when selecting the size, not the amount of fat, fiber, or protein.
- When the iLet is initially learning how much insulin you need for meals, the Less meal option is not available and cannot be selected in the meal size drop down list.
  - The Less option will be available once the iLet has learned how much insulin you need for your Usual for me meal. This will happen separately for Breakfast, Lunch and Dinner. This can happen after one meal announcement, or it may take several meal announcements. Once this happens, the Less option will no longer be marked as unavailable and you will be able to select this size in the drop-down list.
  - If the Less option is not yet available and you are eating less carbs than your Usual for me meal, do not announce that meal. The iLet will deliver insulin in response to your rising CGM glucose.

- In the first few days, try to eat meals that have carbs in the Usual for me range and wait at least 4 hours before eating and announcing again. This will help the iLet learn how much insulin you need for your Usual for me meal.

- If your BG is low before a meal, treat the low glucose with rapid-acting carbohydrates and allow the glucose to rise before you eat and announce for your meal. Once your glucose is within range, eat and announce the meal as planned. Choose the meal size based on the carbohydrate content of the meal, and do not consider the carbs used to treat the low.

  - Do not include carbs used to treat lows in your meal announcement size. This will cause additional hypoglycemia.

  - Do not announce your meal as smaller than what it actually is to get less insulin as a "reverse correction". This will cause hyperglycemia because you won't get enough insulin for the meal you are eating now. It may also cause the meal dose to adapt upwards, delivering too much insulin the next time you announce a meal and causing future hypoglycemia.

- If your BG is low after a meal:

  - Consider your glucose trend and the circumstances around when you announced the meal. The low BG may not be related to the meal announcement.

  - Consider the amount of carbs that were in the meal and whether you selected the correct meal type and size for what you ate.

    - If the low BG happened within an hour of the meal announcement, and without a period of high glucose levels after the meal, you may have overestimated the carb content of the meal.

    - If the low BG happened several hours after the meal announcement, and after an extended period of high glucose levels, you may have underestimated the carb content of the meal.

  - Do not over-treat the low. Taking too many carbs to treat this low will cause the BG to rise too much, leading to additional insulin dosing. This will prevent the iLet from learning that the initial meal dose was too big, so it might not adapt the dose downward.

- The iLet never stops learning and is always adapting to your insulin needs. It will continue to adapt your insulin dose sizes for meals as your insulin needs change.

To stay safe on your iLet, always:

- Be consistent with how you choose your meal size within each meal type.
- Announce snacks as meals if they have as many carbs as a meal.
- Only announce meals that have carbs. Do not consider protein or fat when choosing your meal size.
- It's best to announce meals and snacks right when you're about to eat (or no more than 15 minutes before or 30 minutes after you start to eat).
- Don't use meal announcements to correct highs, and do not announce for carbs used to treat lows.
- Avoid over-treating lows that occur after meals to help the iLet learn the meal dose was too big.

4. Exercise Management

When you exercise, your insulin needs can change significantly. Your iLet does not know that you are exercising. Your iLet will continue to increase or decrease insulin dosing in response to your changing CGM glucose levels as usual.

There are things you can do to help prevent hypoglycemia during and after exercise:

- Before exercise, make sure your CGM glucose is not low and not falling.
- Make sure your CGM alerts are turned on and the volume is set to a level that you can hear on your iLet, and your CGM app on your smartphone if applicable. Respond to CGM alerts immediately.
- Always make sure to have rapid-acting carbohydrates available to prevent or treat hypoglycemia. Carry emergency glucagon with you to treat severe hypoglycemia.

Can I eat carbohydrates in preparation for exercise while using the iLet?

- If you eat carbohydrates before exercising while still connected to the iLet, the iLet will automatically increase insulin delivery in response to your rising CGM glucose levels. This will cause you to have more insulin working in your body while you are exercising, increasing your risk of hypoglycemia during and after exercise – exactly what you were trying to avoid!
- If you want to "pre-load" with carbs, make sure to eat your carbohydrate meal or snack **AFTER DISCONNECTING** from the iLet. This way, the iLet cannot deliver insulin and your glucose will rise from the carbs in the meal or snack as you intended.

You have 2 options to consider when performing exercise that usually leads to falling glucose levels

OPTION 1 | Disconnect from the iLet

You and your healthcare team may decide to stop insulin dosing before, during, and/or after exercise. To stop insulin delivery, disconnect the iLet tubing from the infusion set base and set the device aside. Leave your infusion set base on your skin so that you can easily reconnect to the iLet when you are ready. You can pause insulin delivery while you are disconnected from the iLet to prevent insulin from being wasted. Remember to resume insulin delivery when you reconnect.

- Be sure to do this for all water related activities.
- Disconnect from your iLet up to 1 hour before exercise, or as recommended by your healthcare team.
- Make sure you can still monitor your CGM glucose and hear your CGM alerts using your CGM app on your smartphone. Keep your iLet device close by to hear the alerts if you do not have a smart phone.
- **DO NOT** "pre-load" with carbs **BEFORE** disconnecting from the iLet.
  - If you choose to "pre-load" with carbs, only do so **AFTER** disconnecting from the iLet.
- Remember to reconnect to the iLet and resume insulin delivery when you are finished exercising.
  - Staying disconnected for too long or forgetting to resume insulin after reconnecting can result in hyperglycemia and development of ketones. Consult with your healthcare team about how long you should be disconnected from the iLet and always remember to resume insulin delivery when reconnecting.

OPTION 2 | Stay Connected to the iLet

You may wish to remain connected to the your iLet during exercise. The iLet will continue to increase or decrease insulin dosing in response to your CGM glucose levels.

- **DO NOT** "pre-load" with carbs.
- ALWAYS make sure to have rapid acting carbohydrates available to treat hypoglycemia. Carry emergency glucagon with you to treat severe hypoglycemia.
- If your CGM glucose is low or is dropping fast during or after exercise, treat with rapid acting carbs as needed. Continue to monitor your blood glucose until it remains above 70 mg/dl.
- **DO NOT** take more carbohydrates than needed to treat a low glucose level. This can lead to a high glucose level triggering more insulin dosing from the iLet. This may end up causing a "roller coaster" effect while your iLet responds to both rising and falling glucose levels.

REMEMBER

Always make sure to have rapid-acting carbohydrates available to prevent or treat hypoglycemia. Carry emergency glucagon with you to treat severe hypoglycemia.

Make sure your CGM alarms are turned on and the volume is set to a level that you can hear.

DO NOT pre-load with carbs while still connected to the iLet.

5. BG - Run Mode

> **WARNING:** The iLet is intended to dose insulin based on CGM data. In the events where CGM stops providing glucose data to the iLet, BG-run mode will serve to continue a safe level of insulin delivery, but it will not provide the same level of glucose control as the iLet with CGM. BG-run use SHOULD BE TEMPORARY and always for the shortest duration possible with the goal to resume CGM-guided iLet insulin dosing AS SOON AS POSSIBLE.

Your iLet needs to be receiving glucose values from a CGM sensor to give you insulin. If your iLet is not displaying a CGM value, it is in BG-run mode.

In BG-run mode:

- Your iLet will continue dosing basal insulin based on its previously learned basal rates as long as you enter the required fingerstick BG values.
- If you enter a BG that is low, the iLet will shut off your basal insulin for an hour, or until you enter a BG that is not low.
- If you enter a BG that is high, the iLet may give you correction insulin.
- You can continue to announce meals and the iLet will give you insulin for your meal type and size.

However, you will need to enter BG values frequently or all insulin dosing will be stopped. If you are unable to enter the required blood glucose values, you will need to switch to your backup therapy plan as prescribed by your healthcare provider.

> **CAUTION:** If your CGM is offline for an extended period of time, dosing will stop and you should switch to alternative therapy until you are able to reconnect to a CGM sensor. A countdown timer will appear before dosing would stop.

Reasons your iLet might go into BG-run mode:

- Failed CGM sensor or transmitter, if applicable
- Sensor is offline or disconnected (e.g., connectivity with sensor is lost, warming up a new sensor, etc.)

When the iLet enters BG-run mode, you have two choices:

1. Respond to the iLet alerts by entering a fingerstick BG value with each alert. This will allow the iLet to continue dosing insulin until CGM values are available again (within the time limits explained below).

   OR

2. Switch to a backup therapy plan prescribed by your healthcare provider until CGM values are available again. You may want to do this if you think it will take longer than 48 hours to restart your CGM.

Duration of BG-run mode

If you have been using the iLet for 7 days or less, BG-run mode will last up to **48 hours**.
If you have been using the iLet for more than 7 days, BG-run mode will last up to **72 hours**.

After the maximum period of 48 or 72 hours, all insulin dosing will stop and a CGM value is required to restart dosing (see Figure E). The iLet will not start dosing any insulin again until it receives a CGM value. If your iLet will not be receiving a CGM value soon, you will need to switch to your backup therapy plan as advised by your healthcare provider.

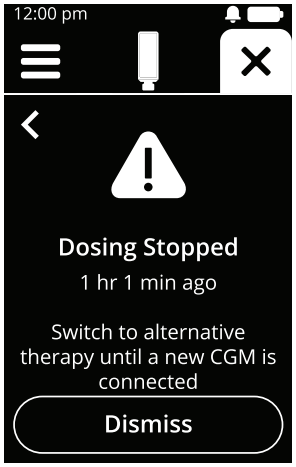


Figure E

Insulin suspension during and after BG-run mode

During BG-run mode:

- The iLet will alarm to request a BG entry every 4 hours until CGM is restored. If no BG is entered within 4 hours of the alert, insulin delivery will stop (see Figure D).
- You MUST enter a BG, resume CGM, or switch to backup insulin delivery.
- Insulin suspension can occur at any time during the day or night.
- After 72 consecutive hours with no CGM, BG-run mode will end and ALL insulin dosing will stop.
  - You MUST resume CGM or switch to backup insulin delivery. The iLet will not deliver any insulin until a CGM value is received.

BG-run mode operates slightly differently during the first 7 days of iLet use:

- The iLet will alert to request a BG every 1 hour until CGM is restored, not 4 hours. If no BG is entered within 1 hour of the alert, insulin delivery will stop (see Figure F).
- Insulin suspension will never start between 12-4 am. If suspension was indicated during this time, it will suspend immediately at 4 am.
- BG-run mode will only last 48 consecutive hours, not 72. After 48 consecutive hours with no CGM, BG-run mode will end and ALL insulin dosing will stop.
  - You MUST resume CGM or switch to backup insulin delivery. The iLet will not deliver any insulin until a CGM value is received.

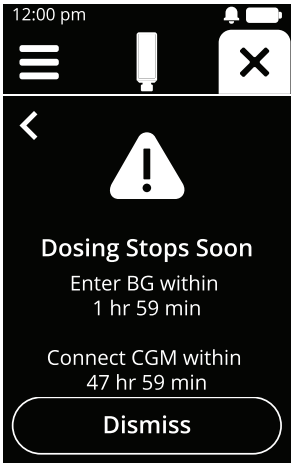


Figure F

Entering a blood glucose value during BG-run mode

The iLet will alert you to enter fingerstick BG values:

If you enter BG-run mode in the first 7 days of using the iLet:	Enter BGs every hour until CGM is restarted.
If you enter BG-run mode after 7 days of using the iLet:	Enter BGs every 4 hours until CGM is restarted.

To help keep your glucose in good control while your CGM is not on, it is recommended that you check and enter BG values at the following times:

- When you wake up
- Before each meal
- 2 hours after a meal
- Before bed
- Before, during, and after exercise
- If you are feeling high or low

The iLet will alert whenever a BG value is **required** to continue insulin dosing.

Enter BG

If the CGM sensor is online, you do not need to enter BG values for autonomous dosing. You may enter a BG to calibrate your CGM sensor. Refer to the your CGM manufacturer's instructions for calibration guidance.

a. Use a BG meter to check your BG.
b. From the Home screen, tap the Menu icon in the upper left corner (see Figure G).
c. Tap the Enter BG icon (see Figure H).
d. Type in a BG value. Tap Next to continue (see Figure I).
e. Check if the BG entered is correct. Tap Confirm to proceed.

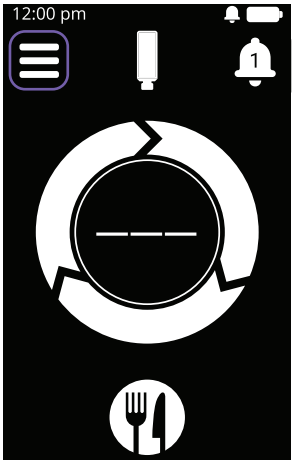


Figure G

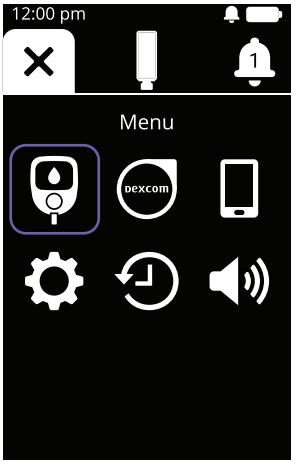


Figure H

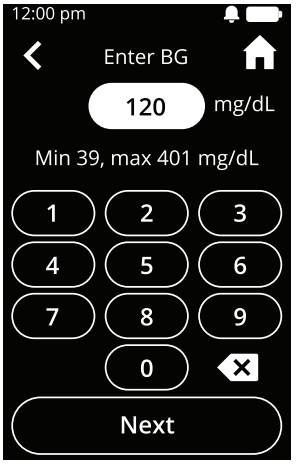


Figure I

Preparing for BG-run mode

ALWAYS make sure to have sufficient CGM supplies to avoid going into BG-run mode.

- ALWAYS request a replacement from Dexcom if a sensor fails or falls off early, or if the transmitter fails.

  Website: https://dexcom.custhelp.com/app/webform

  If you can't use the website, you can call Dexcom's customer support at 1-888-738-3646

- ALWAYS order supplies and obtain the required paperwork (prior authorization, etc.) as soon as possible to avoid running out.

- Contact Beta Bionics customer service with any issues or questions about BG-run mode or obtaining supplies.

  Phone: 1-855-745-3800

- Have your iLet mobile app running on your phone.
  - This will allow your HCP to have the most up to date insulin dosing information to help guide your care if needed.
  - This will also help Beta Bionics provide customer service and support when it comes to troubleshooting issues with your device.

Switching to your backup therapy plan

Contact your HCP right away to discuss your backup therapy plan. Your HCP will prescribe an insulin dosing regimen for you to follow until your iLet is receiving CGM values again.

Always disconnect from the iLet before starting your backup therapy plan.

Obtain the supplies you need. This may include:

- BG testing supplies (meter, strips, meter batteries, QC solution)
- Long-acting insulin pen & pen needles or syringes & vial
- Rapid-acting insulin pen & pen needles or syringes & vial
- Insulin dosing regimen

It is important that you always have a backup therapy plan and the necessary supplies when using the iLet. You must be able to switch to your backup therapy plan if necessary.

6. Maintaining your iLet

Take care of your iLet

- Keep it filled with insulin.
- Charge it.
- Make sure it is reading your CGM glucose.
- Do not let the iLet battery run out. It cannot dose insulin if it does not have power.

Cartridge, Tubing & Infusion set reminders:

- Change your insulin cartridge, iLet Connect, and tubing at least every 3 days or if there is a problem.
- Change your infusion site at least every 2 (Contact detach) or 3 days (Inset) or if there is a problem.
- Always replace your insulin cartridge, iLet Connect, and tubing together! You can change your insulin infusion site separately if you need to.

When changing the cartridge:

- Always disconnect from the iLet at your infusion site base when replacing your iLet cartridge and tubing. Stay disconnected until you have finished the change process to avoid unintentional insulin delivery.
- Do not re-use insulin cartridges, iLet Connects, tubing, or infusion sites.
- When filling the cartridge, be careful not to manipulate the needle while it is inserted into the cartridge or inset the needle too many times.
- Do not overfill the cartridge.
- Always rewind the iLet before installing the cartridge.
- Always put the filled cartridge into the iLet BEFORE the iLet Connect.

If you don't follow these steps, the cartridge can be damaged. This can cause leaking of insulin between the cartridge and the iLet Connect, leading to high BGs.

When wearing your iLet:

- Make sure the connection between your iLet Connect and tubing is straight and tight. If this connection is not tight, insulin can leak out causing hyperglycemia, or air can get in and push insulin into your body, causing hypoglycemia.
- Always disconnect from the iLet and tubing at your infusion site base on your body. Never disconnect from the iLet by removing the cartridge from the device while staying connected to the tubing or unscrewing the tubing from the iLet Connect and staying connected to the tubing.
- DO NOT let your iLet run out of insulin or leave an empty cartridge in for too long! This will cause hyperglycemia, as the iLet will not be able to dose insulin in response to your rising CGM glucose levels. This may cause hypoglycemia later, because the iLet will have to deliver correction insulin once it is able to again. Consider putting a reminder in your calendar or your smartphone to remind you to change your infusion set and replace your insulin cartridge.

Respond to alerts:

- Keep your CGM glucose alerts turned on.
- Respond quickly to all glucose related alerts to prevent events from becoming more serious.
- Set the volume to a level you can hear.
- Use CGM alerts on your smartphone to help you hear alerts.
- Always read, respond to, and dismiss active alerts on the iLet. Acknowledging the alerts may be required to resume insulin dosing.

Ask your healthcare provider:

- Do not change the body weight in your iLet without consulting HCP.
- Do not change the CGM glucose target in your iLet without consulting HCP.
- Do not take any insulin outside of the iLet without consulting with HCP.

CGM Maintenance

Replace your CGM sensor (and transmitter, if applicable) according to your CGM manufacturer's instructions. Always use FDA approved insertion sites.

The Dexcom G6 and Dexcom G7 CGM sensors need to be replaced every 10 days. The Dexcom G6 has a transmitter that needs to be replaced every 90 days. Always request a replacement from Dexcom if a sensor fails or falls off early, or if the transmitter fails.

Avoid replacing your CGM sensor (and transmitter, if applicable) before bed, or any other time when you will not be able to pay attention to your blood glucose. You will not have CGM values while the sensor warms up, so it will be important to check a fingerstick blood glucose whenever needed.

CGM Connectivity

Your iLet communicates with your CGM sensor using Bluetooth. Sometimes, they may lose communication with each other. If this loss of communication is brief and resolves on its own, this is normal and doesn't require action.

If your iLet is losing communication with the CGM sensor for long periods of time and/or very frequently, make sure:

- the iLet and CGM sensor are close enough together.
- the sensor (and transmitter, if applicable) is securely in place.
- the transmitter serial number or sensor pairing code in your iLet device are correct.

CGM Accuracy

CGM sensors measure the glucose level in your interstitial fluid (the fluid in the spaces between your blood vessels), not blood. Your glucose meter measures the glucose level in your blood. Your CGM glucose level and your blood glucose level will usually be different but should be close to each other.

Your iLet is dosing all your insulin based on your CGM glucose readings. If your CGM is inaccurate, you may get too much or too little insulin, causing hypoglycemia or hyperglycemia. It's important to make sure your CGM is accurate, and to resolve any CGM issues that come up.

You may need to calibrate your CGM using a fingerstick blood glucose level. However, calibrating your CGM at the wrong time can make accuracy worse; follow the guidance below to decide if a calibration is needed.

If you are concerned about your CGM accuracy, follow these five steps:

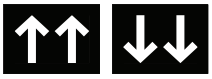
Step One: Check on your CGM sensor & glucose trend.

1. Make sure your CGM sensor is in place on your body.
2. Relieve any pressure on your CGM sensor (i.e., lying on your sensor).
3. Look at your glucose trend. If you have trend arrows that are straight up or straight down, your blood glucose level and CGM glucose level will likely be very different, and you need to give your CGM glucose level a chance to catch up.

Step Two: check a fingerstick blood glucose level using your glucose meter.

1. Make sure your hands are clean. Wash your hands with soap and water and dry them well.
2. Use only your fingers to check your blood glucose level, not an alternative site.
3. Make sure your glucose test strips are not expired and have been stored properly.

Glucose Trend Arrows

Icon	Description
	Glucose is steady, and changing less than 1 mg/dL each minute. Glucose may change up to 15 mg/dL in 15 minutes.
	Glucose is slowly rising or falling, and changing 1 - 2 mg/dL each minute. Glucose may change up to 30 mg/dL in 15 minutes.
	Glucose is rising or falling, and changing 2 - 3 mg/dL each minute. Glucose may change up to 45 mg/dL in 15 minutes.
	Glucose is rapidly rising or falling, and changing more than 3 mg/dL each minute. Glucose may change by more than 45 mg/dL in 15 minutes.
None	System can't calculate the speed and direction of your glucose change.

Step Three: compare your blood glucose and CGM glucose levels.

Look at how far apart your blood glucose value and CGM glucose value are.

Use the following reference table to determine if the two values are too far apart. Find the BG meter reading that is closest to your fingerstick BG and look at the Dexcom reading in the next column. If your current CGM glucose is within the range in that column, you do not need to calibrate. If your current CGM glucose is outside of the range in that column, you may need to calibrate.

BG Meter Reading (mg/dl)	Dexcom Reading (mg/dl)
40	20(LOW)-60
50	30(LOW)-70
60	40-80
70	G7: 56-84 G6: 50-90
80	64-96
90	72-108
100	80-120
110	88-132
120	96-144
130	104-156
140	112-168
150	120-180
160	128-192
170	136-204
180	144-216
190	152-228
200	160-240
210	168-252

BG Meter Reading (mg/dl)	Dexcom Reading (mg/dl)
220	176-264
230	184-276
240	192-288
250	200-300
260	208-312
270	216-324
280	224-336
290	232-348
300	240-360
310	248-372
320	256-384
330	264-396
340	272-408(HIGH)
350	280-420(HIGH)
360	288-432(HIGH)
370	296-444(HIGH)
380	304-456(HIGH)
390	312-468(HIGH)
400	320-480(HIGH)

This table provides sensor readings that are within ± 20% of the BG meter value for BG meter values greater than or equal to 70 mg/dl for the G7 or 80 mg/dl for the G6 and within 20 mg/dl of the BG meter value for BG meter values less than 70 for the G7 or less than 80 for the G6.

If you want to do the math yourself, you can use the following formula:

Current fingerstick BG is 70 mg/dl (or 80 mg/dl if using the Dexcom G6) or higher:

- Find 20% of your current fingerstick BG (Current fingerstick BG x 0.20).
  - To get the lower limit for your Dexcom reading, subtract this number from your current fingerstick BG.
  - To get the upper limit for your Dexcom reading, add this number to your current fingerstick BG.
- Look at your current CGM glucose to determine if it is within those limits. If not, a calibration may be needed.

Current fingerstick BG is less than 70 mg/dl (or 80 mg/dl if using the Dexcom G6):

- To get the lower limit for your Dexcom reading, subtract 20 mg/dl from your current fingerstick BG.
- To get the upper limit for your Dexcom reading, add 20 mg/dl to your current fingerstick BG.
- Look at your current CGM glucose to determine if it is within those limits. If not, a calibration may be indicated.

You only need to calibrate if they are more than 20% different from each other, or 20 mg/dl different if your blood glucose value is low.

Step Four: look at your current CGM glucose trend.

Look at your glucose trend. Did you just eat a meal, or treat a low glucose level? If your trend arrow is straight up or straight down, do not calibrate. Calibrating your CGM when your glucose level is changing can actually make accuracy worse. Glucose levels in interstitial fluid often lag behind glucose levels in blood. This is why your glucose levels on the two devices may be different if your glucose is changing rapidly.

Wait until your trend arrow is flat or diagonal. Then check another fingerstick glucose level and decide if a calibration is needed at that time.

Step Five: calibrate your CGM if needed.

Calibrate your CGM by entering a BG into your iLet. You can also calibrate your CGM by entering a BG into your CGM app on your smartphone. Do not calibrate in both places; you only need to do this on one device.

You must enter the glucose value within 5 minutes of taking the fingerstick. Do not use your fingerstick BG value to calibrate if it is more than 5 minutes old.

Examples and practice:

Example 1

Using these two numbers, find the number in the first column that is closest to 189 mg/dl. That would be 190 mg/dl. The Dexcom reading column in that row has a range of 152 to 228 mg/dl. The current CGM glucose of 215 mg/dl is within that range, so no calibration is needed.

Example 2

Using these two numbers, find the number in the first column that is closest to 244 mg/dl. That would be 240 mg/dl. The Dexcom reading column in that row has a range of 192-288 mg/dl. The current CGM glucose of 145 mg/dl is not within that range, so calibration may be needed.

However, the current CGM trend arrow is going straight up, meaning the glucose is changing rapidly. Do not calibrate at this time. Wait for glucose to stabilize and start the process again.

Example 2

Using these two numbers, find the number in the first column that is closest to 62 mg/dl. That would be 60 mg/dl. The Dexcom reading column in that row has a range of 40-80 mg/dl. The current CGM glucose of 93 mg/dl is not within that range, so calibration may be needed.

The current CGM trend arrow is flat, meaning the glucose is not rapidly changing. This is a good time to calibrate the CGM.

Now it's your turn!

Example 4

Is a calibration needed here? *Answer on the next page.*

The correct answer is yes!
For a fingerstick BG of 91 mg/dl, the Dexcom reading should be within 72-108 mg/dl. The current CGM glucose of 144 mg/dl is not within that range. Since the trend arrow is only diagonal, it is a good time to calibrate.

REMEMBER

Always check a fingerstick glucose level to confirm your CGM is accurate.

If your symptoms match your fingerstick BG reading but not your CGM, treat to your symptoms and glucose meter.

Calibrate your CGM sensor if it is needed, but DO NOT calibrate your CGM sensor if it is not needed, as this can make your CGM sensor less accurate.

Replace your CGM sensor if it continues to be inaccurate and contact your CGM manufacturer for assistance and replacement supplies.

Reference:
https://www.dexcom.com/en-us/faqs/bg-meter-vs-cgm-reading
https://www.dexcom.com/en-us/faqs/is-my-dexcom-sensor-accurate

Back up supplies to keep with you

Always be prepared to respond to an issue with your device or your blood glucose levels. Remember, your iLet cannot dose insulin if it doesn't have any insulin in the cartridge, any battery power left, or if you have gone too long without a CGM sensor!

Carry the following supplies with you all the time when using the iLet Bionic Pancreas System:

- Back up insulin therapy (syringes/vials or pens/pen needles)
- BG meter and strips to monitor BG in case of CGM malfunction
- Ketone testing supplies (blood ketone meter and strips or urine strips)
- Hypoglycemia treatment (rapid acting carbohydrates, emergency glucagon)
- CGM sensor (and transmitter, if applicable)
- Insulin cartridge, syringe and needle to fill the cartridge, iLet Connect, infusion set and tubing
- iLet charger
- Ketone action plan
- Emergency contact information

7. Frequently Asked Questions

How can I best succeed while using the iLet?

The iLet is different from any other insulin delivery device, as you cannot program any insulin settings or control any of the insulin dosing. The iLet can take a few days to learn how to best take care of your diabetes. The iLet will work best if you let it do the work for you. We recommend that you avoid overthinking what the iLet is doing.

Will I have to treat low blood glucose levels with the iLet?

Yes. You may still have low blood glucose levels (hypoglycemia) that you will need to treat with fast- acting sugar. The iLet will reduce or stop insulin dosing automatically in response to low CGM levels. You will still need to treat low blood glucose levels while using the iLet.

Do I need to correct high blood glucose levels with the iLet?

No. You cannot give additional insulin boluses when your blood glucose levels are high (hyperglycemia). The iLet automatically tries to give you insulin to bring your blood glucose down (this may take longer than you expect). You may need to change your infusion set or tubing and cartridge if you think your high blood glucose levels could be due to a problem with your insulin, tubing, or set. When in doubt, change it out!

How do I take insulin for meals?

When you eat meals, you should enter a Meal Announcement into the iLet. There is no need to count carbohydrates, and the iLet does not use a carbohydrate-to-insulin ratio. Instead, you tell the iLet if the amount of carbs you are eating is Usual for you, More than usual, or Less than usual. The iLet will use this information to determine how much insulin to give you. You cannot choose the exact dose of insulin (this has made some people uncomfortable in clinical studies).

What happens if I do not announce my meals?

The iLet will automatically give you insulin as your blood glucose rises, but it will not be able to track and learn from your meals. Your blood glucose may go higher and stay higher for longer than if you had announced the meal.

> **CAUTION**: This may lead to hypoglycemia later due to the correction algorithm adding more insulin than it would have if you had announced the meal.

What if I forget to announce a meal?

You can announce a meal up to 30 minutes after you start eating. If you forget to announce your meal, and more than 30 minutes have passed since you started eating, do not announce the meal. If you forget to announce your meal, the iLet will automatically deliver insulin in response to your rising CGM levels. Your blood glucose levels may go higher and stay higher for longer than if you had used the Meal Announcement feature. Having a low blood glucose later is also more likely.

> **CAUTION:** After 30 minutes your glucose is already rising and the iLet has already dosed insulin according to your rising CGM levels, even without a meal announcement. If you announce a meal during this time, you will "stack" insulin and be at risk for severe hypoglycemia. This will also confuse the iLet, causing future meal doses to be less effective.

I ate or drank carbohydrates to treat a low blood glucose. Should I announce those carbohydrates as a meal?

No. Do not announce a meal for carbohydrates used to treat low blood glucose.

> **CAUTION:** This could cause additional hypoglycemia and is dangerous.

Can I change how much insulin the iLet is giving me?

No. You cannot change insulin doses with the iLet. All insulin doses are automatically calculated by three separate algorithms which are continuously learning. The only action you can take to influence insulin delivery is to issue a Meal Announcement before eating a meal, or to disconnect from the iLet temporarily. Blood glucose control will worsen if you try to trick the system.

I usually have a snack before bed to keep my blood sugar in range overnight. Do I need to do this while using the iLet? If so, should I announce my bedtime snack?

You do not need to eat a bedtime snack to keep your blood glucose in range overnight while using the iLet. If you chose to eat before bed, you should announce it to the iLet the same as you would during the day. This will give you insulin upfront and help prevent additional dosing in response to the rise in glucose after you eat. This will reduce the risk of hypoglycemia during the night.

I do not eat foods with carbohydrates and if I do, they are very low carb. Should I still announce my meals?

No. If you eat a very low carb diet or no carbs at all, you should not announce meals.

Can I use the meal announcement to bring my glucose level down if I am not eating?

No. This can be dangerous.

> **CAUTION:** It could lead to severe hypoglycemia and confuse the iLet, causing future meal doses to be less effective.

If my glucose is high and I am about to eat, should I announce a meal that is larger than my actual meal to get more insulin correction up front?

No. Do not announce a meal that is larger than the actual meal size to correct high glucose levels. The iLet will have already delivered correction insulin in response to your high glucose.

> **CAUTION:** Announcing a larger meal than the actual size could lead to severe hypoglycemia and confuse the iLet, causing future meal doses to be less effective.

I am used to counting carbohydrates. I saw how much insulin the iLet gave me for my last meal. Should I work backwards to figure out my meal size based on my old insulin-to- carbohydrate ratio?

No. The iLet does not use insulin to carbohydrate ratios to dose insulin for meals.

Do not calculate the amount of carbohydrates you need based on the insulin dose your iLet gave you. This will affect the iLet's ability to learn about your insulin needs and confuse the iLet, causing future meal doses to be less effective.

I think the iLet has not learned my meal dose(s) because my glucose is high after meal(s). Is there anything I can do?

You may need to take a few days and focus on helping the iLet learn about your meals.

Be consistent with how you decide the meal type and size.

- Only select Breakfast if you are eating your breakfast, Lunch for your lunch, and Dinner for your dinner.
- Only think about the carbs in your meal when selecting the size, not the amount of fat or protein.

Try to eat meals that have carbs in the Usual for me range and wait at least 4 hours before eating and announcing again.

Avoid over-treating any lows that occur after meals to help the iLet learn if meal doses are too big.

After a few days, your meal dose(s) should adapt. Refer to the Meal Announcement Guide for more information on meal announcements and helping the iLet adapt.

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