Beta Bionics

Patient Management with the iLet Bionic Pancreas System

This guide covers the most common topics you will encounter after a patient starts the iLet Bionic Pancreas.

Best Practices for Personalized Learning

For best results, the user should follow these guidelines until meals adapt when they start using the iLet. These guidelines may need to be revisited if glycemic results aren't as expected.

- Eat meals that have the "Usual" amount of carbs for them for each meal type and announce them as "Usual." Being consistent with how they choose the meal type and size will help the iLet learn.
- 2. Announce right at the start of the meal. Users can announce up to 15 mins before or 30 mins after, but no earlier or later than that.
- Wait at least 4 hours before eating meals with carbs and announcing again. The system needs this time to learn if the dose should adapt up/ down.
- If the user needs to eat between meals while meals are still adapting, low-carb or carb-free foods are the best option. Examples include nuts, cheese, eggs, meat, or non-starchy vegetables.

Additional Learning Concepts:

- Review the user's carbohydrate awareness and meal sizes, re-educating as needed.
- Remind the user to respond to glucose alerts while meals adjust, as the system will automatically regulate insulin.
- Only treat with rapid-acting carbs when the iLet gives a hypoglycemia or predicted hypoglycemia alert.
- · Overtreating lows can increase the risk of future lows.
- Lowering the CGM target will recruit the corrections algorithm sooner, helping to reduce post-high hypoglycemia. The iLet allows two CGM target settings within 24 hours.

Adjustments to Improve Glycemic Outcomes

High % of "More" Meal Announcements

This is often done when the user is attempting to increase their insulin doses from the iLet in response to previous hyperglycemia. As a result of this action, the strength of the meal dose may decrease.

INTERVENTION

Return to Best Practices for Personalized Learning.

Educate user to only consider the carbs on the plate when announcing meals to the iLet. The system has already responded and will continue to respond to the glucose level with the basal and corrections algorithms.



Announcing Meals to Treat Hyperglycemia

Observed pattern of increased meal announcement frequency during periods of hyperglycemia at times when the user is not typically eating.

Stacked insulin may cause lows. Meals will adapt down and user will continue to have postprandial highs/increased risk of lows.

INTERVENTION

Review proper treatment of hyperglycemia.

Educate user that the system learns from high and low glucose and will adjust to the patient's needs accordingly.

Consider lowering the CGM target around meals to recruit the corrections algorithm earlier in the glycemic excursion.

REPORT



Adjustments to Improve Glycemic Outcomes

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High % of "Less" Meal Announcements

This is often done when the user is attempting to decrease the insulin doses from the iLet in response to previous hypoglycemia. As a result, their "Usual" meal adapts up in strength and will be double in size compared to "Less."

INTERVENTION

Return to Best Practices for Personalized Learning.

Consider Factory Reset if meal doses are deemed unsafe.

Be prepared to treat, but not overtreat, for hypoglycemia after meal announcement.

Review user's carbohydrate awareness and their assessments of meal sizes, and re-educate as needed

REPORT



Announcing Inappropriate Meal Size Based on the **Current Blood Glucose Level**

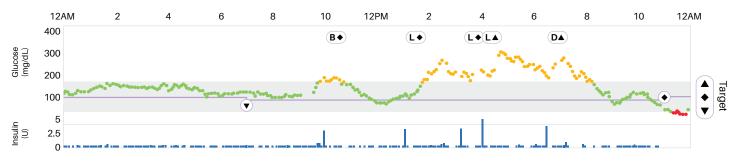
Observed pattern of meals being announced as More during periods of hyperglycemia and Less during periods of euglycemia or hypoglycemia. This can negatively impact meal adaptation, stack insulin and increase the risk of hypoglycemia.

INTERVENTION

Return to Best Practices for Personalized Learning.

Educate user to only consider the carbs on the plate when announcing meals to the iLet. The system has already responded and will continue to respond to the glucose level with the basal and corrections algorithms.

REPORT



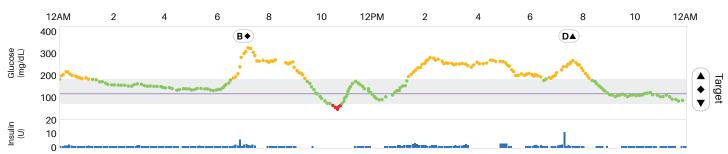
Late Meal Announcements

Initial glucose rise promotes corrective insulin and may lead to hypoglycemia when combined with a meal announcement.

INTERVENTION

Educate user to announce meals at the start of their meal or no more than 30 minutes after they start eating. Use daily reports to show insulin doses administered by the iLet in response to rising glucose levels prior to the announced meals.

REPORT



Adjustments to Improve Glycemic Outcomes

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Drifting Hypoglycemia

Hypoglycemia observed unrelated to meal or correction insulin.

INTERVENTION

To prevent the iLet from determining the baseline insulin need is higher than it actually is, educate patient to:

- · Ensure they announce any snacks that contain enough carbs that they require a meal announcement.
- · Avoid overtreating lows.

Consider changing CGM glucose target one step higher starting a few hours prior to the hypoglycemia trend.





Excessive Glucose Variability

Observed pattern of glucose variability, with lows following highs and highs following lows. This is often related to missed meal announcements or over-treating lows and may result in the system improperly adapting to the user's needs.

INTERVENTION

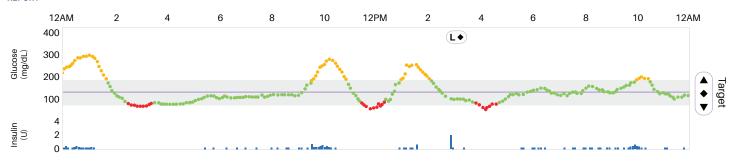
If not announcing meals, return to Best Practices for Personalized Learning.

Review proper treatment of hypoglycemia.

They may need to treat with fewer carbs than they are used to because the iLet will have already decreased and/or stopped insulin dosing.

Although it may seem counterintuitive, consider lowering the CGM target around meals to recruit the corrections algorithm earlier in the glycemic excursion.

REPORT



Treating For Hypoglycemia When Euglycemic

System may improperly adapt to user's needs. Observed pattern of sharp increases in glucose following periods when glucose was trending down, but still in range.

INTERVENTION

Educate user:

- · That the system will learn from trends and adapt quickly and appropriately.
- To wait for a low alert from the iLet before treating with rapid-acting carbs.
- To avoid overtreating hypoglycemia.
- To make sure alerts on other devices outside of iLet match the iLet.

Use report to show that insulin doses are decreased and suspended in response to falling glucose levels, decreasing the amount of rapid-acting carbs needed to treat hypoglycemia.

REPORT



Considerations for Common Patient Scenarios

Scenario Considerations If eating very low carb meals, a meal announcement may not be required. If the user chooses not to announce meals with more significant carb content, the system will rely heavily on correction insulin. This could put the user at risk for hypoglycemia. Lowering the CGM target by one step could help to reduce this risk as it will deliver correction insulin earlier in the glycemic excursion, however **Skipping Meal** it's always recommended that the user appropriately announce meals. **Announcements** If a snack has as many carbs as any meal type or size, the user should announce the snack as the meal type and size it most closely resembles. Snacks The user should always have rapid-acting carbohydrates with them during exercise. Option 1: Disconnect from the iLet for Exercise • The user can consider disconnecting from the iLet up to 30 minutes prior to exercise at the discretion of healthcare team. · The user can pause insulin when disconnected from the iLet. Pausing insulin when they are disconnected helps prevent insulin from being wasted. · If the user plans to "pre-load" with carbs, the user should do so after disconnecting from the iLet. · The user should reconnect to the iLet after activity. Staying disconnected for too long could result in Exercise hyperglycemia and ketone production, which should be discussed with the healthcare team. Option 2: Stay Connected to the iLet during Exercise · The iLet will continue to increase or decrease insulin in response to CGM levels. The user should not "pre-load" with carbs while staying connected. The iLet adapts autonomously and continuously to the user's insulin needs. Therefore, in most cases, there is no need to make any adjustment to the iLet. If the user experiences hyper/hypoglycemia during an illness, an adjustment to the CGM target can be considered. The target should be returned to the initial setting once the user has returned to baseline. **Physiological**

Reminder

Changes

The iLet user must keep their CGM alerts turned on at a volume they can hear, respond to alerts promptly, and maintain the device.

Resources

HCP Resources:

- Healthcare Provider User Guide: www.betabionics.com/hcp/hcp-resources/
- · Recorded Webinars: www.betabionics.com/hcp/hcp-webinars/

Patient Resources:

- Educational Guide, User Guide with indications for use and warnings, updated instructions, and additional resources: https://www.betabionics.com/user-resources/
- 24/7 Beta Bionics Customer Support: Call 855-745-3800 or email support@betabionics.com
- Dexcom Customer Support: Call 888-738-3646
- Abbott Libre Customer Support: Call 888-963-8038

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