PANTHERTOOL® for

iLet

Automated Insulin Delivery System

INSTRUCTIONS FOR USE

1 Use Beta Bionics app to sync user's device with the Beta Bionics Portal.

2 Access reports from the Beta Bionics Portal. Generate reports for the previous 14 days.

3 Follow this Tool for step-by-step guidance on clinical assessment and education.

STEP 1 **BIG PICTURE** (PATTERNS)

→ STEP 2 **SMALL PICTURE** (REASONS)

→ STEP 3 **PLAN** (SOLUTIONS)

OVERVIEW using C|A|R|E|S Framework

C | How it **CALCULATES**

- The iLet automates ALL insulin doses, including basal rates, meal and correction doses. Insulin automation is initialized by entering the user's weight, and over time insulin delivery adapts based on the iLet's analysis of daily glucose profiles.
- The iLet delivers a meal bolus when the user enters a meal announcement where the user indicates the meal type (breakfast, lunch, dinner) and estimate of carbohydrate content (Usual for me, More, Less).

A | What you can **ADJUST**

- The CGM Target is the only adjustable setting in the iLet; There are 3 options: Usual, Lower, Higher. Can set 2 CGM Targets throughout a 24-hour day
- Users cannot give a manual bolus and cannot adjust any of the insulin doses given by the iLet.

R | When it **REVERTS** to manual mode

- The iLet does not have a manual mode option as there are no pump settings programmed (basal rates, carb ratios, correction factor).
- If the iLet loses connection with the CGM, the system will enter BG-Run Mode for up to 72 hours. In BG-Run, the user must enter BG values periodically for the iLet to continue insulin delivery. After 72 hours, a CGM value is required to continue insulin delivery.

E | How to **EDUCATE**

- Announce all meals at the start of the meal. Announce snacks only if they have a similar carbohydrate content as a meal.
- Do not use meal announcements to try to get more insulin from the iLet or correct hyperglycemia. This will disrupt the iLet's adaptation and increase the chance of a low glucose level.
- Treat mild hypoglycemia with 5-10g carbohydrate to avoid rebound hyperglycemia.
- Always carry a BG meter/test strips so the system can operate in BG run mode if CGM connectivity is lost, or unexpected sensor failure occurs.
- Check ketones and replace the infusion set if there is unexplained hyperglycemia that lasts longer than 90 minutes.

S | **SENSOR**/**SHARE** characteristics

- Compatible with Dexcom G6 and G7. Use of Dexcom G6 or G7 mobile app is optional, cannot use Dexcom receiver.
- Can use Dexcom Share for remote CGM data sharing if using G6 or G7 mobile app.
- iLet mobile app permits auto-uploads to the Beta Bionics portal.

PANTHERPOINTERS® FOR CLINICIANS

1. Avoid overthinking the insulin delivery from the iLet. Focus on overall Time in Range (TIR), and user behaviors (use of meal announcements, wearing CGM, exercise management, nutrition, etc.) to optimize outcomes with the iLet.
2. Compare meal announcement behavior (meal type & size) with the user's diet and eating patterns. The Meal announcements should be entered at the start of the meal and based on carbohydrate content only and not on total calories, protein, fat or fiber content.
3. The CGM Target is the only adjustable setting in the iLet and can be set to "Usual", "Lower" or "Higher". You can set up to 2 targets in a 24-hr period to help optimize outcomes and reduce hyperglycemia or hypoglycemia.

PANTHER® Diabetes Technology. Deciphered. | danatech DIABETES TECHNOLOGY @ ADCES

This **PANTHER Program®** tool for **iLet Bionic Pancreas** was created with the support of **danatech**.

Glucose and Insulin Overview Report to assess system use, glycemic metrics and identify glucose patterns

A Is the person using the CGM?

% Time CGM is connected to the iLet: _____

If <90%, discuss why:

- Problems accessing supplies/sensors not lasting 10 days?
  → Contact Dexcom for replacement sensors.
- Skin problems or difficulty keeping sensor on?
  →Rotate sensor insertion sites (arms, hips, buttocks, abdomen)
  →Use barrier preps, tackifiers, overtapes, or adhesive remover wipes as necessary

SCAN TO VIEW:
pantherprogram.org/skin-solutions

B Is the user announcing meals?

Number of meal announcements/day: _____

- User should announce all meals (and snacks if of similar carb content as a meal) at the start of each meal

What is the distribution of Less, Usual and More sized meals for each meal type?

If "Usual" meals are < 50% of meal announcements, discuss why (see STEP 3 for additional guidance).

- User may need to reconsider how they define Usual and/or may need to re-set their meal adaptation.

If "Less" meals are >30% of meal announcements, discuss why.

- User may eat a lot of snacks throughout the day, which explains high frequency of less meals OR or may be afraid of hypoglycemia and trying to under dose for meals.

If "More" meals are >30% of meal announcements, discuss why.

- User may need to reconsider how they define Usual, may need to re-set their meal adaptation or may be using the meal announcement to get additional insulin.

Breakfast: More _____ % Usual _____ % Less _____ %

Lunch: More _____ % Usual _____ % Less _____ %

Dinner: More _____ % Usual _____ % Less _____ %

PANTHERPOINTERS® FOR CLINICIANS

1. The goal of this therapy review is to increase Time in Range (70-180 mg/dL) while minimizing Time Below Range (<70 mg/dL).
2. Is the Time Below Range **more** than 4%?
   If **YES**, focus on reducing **hypoglycemia** first.
   If **NO**, focus on reducing **hyperglycemia**.

C Is the user meeting Glycemic Targets?

Time in Range (TIR)
70-180 mg/dL _____ Goal is >70%

Time Below Range (TBR)
<70 mg/dL "Low" + "Very Low" _____ Goal is <4%

Time Above Range (TAR)
>180 mg/dL "High" + "Very High" _____ Goal is <25%

D What are the patterns of hyperglycemia and/or hypoglycemia?

The Glucose Overview compiles all data from reporting period into one day; shows median glucose throughout the day with the blue line, and variability around the median with the shaded bars. Wider ribbon = more glycemic variability. Identify the overall patterns by primarily focusing on the blue shaded area.

Hyperglycemia patterns:

_____

_____

Hypoglycemia patterns:

_____

_____

Use the **Daily Report** and discussion with the user to identify the reasons for the glycemic patterns identified in STEP 1 (hypoglycemia and/or hyperglycemia). Discuss the person's daily meal and exercise routines and how those routines relate to the glycemic patterns observed.

Identify the predominant 1-2 causes of hypo- or hyperglycemia patterns:

Is the **hypoglycemia** occurring:

- ☐ Fasting / Overnight?
- ☐ Around mealtime? (1-3 hours after meals)
- ☐ Where low glucose levels follow high glucose levels?
- ☐ Around or after exercise?

Is the **hyperglycemia** occurring:

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Hypoglycemia SOLUTION	PATTERN	Hyperglycemia SOLUTION
Increase CGM Target setting one step for period of hypoglycemia (e.g., Change from Usual to Higher) If overnight hypoglycemia is preceded by hyperglycemia, discuss evening/bedtime behaviors. Unannounced snacks, high carb/high fat meals, and alcohol use can cause hypoglycemia several hours later.	**Fasting / Overnight**	Decrease CGM Target setting one step for period of hyperglycemia. (e.g., Change from Usual to Lower) Discuss evening/bedtime behaviors. Review dinner meal composition and announcement behavior. Assess for any missed meal announcements at bedtime.
Review timing of meal announcements: Meal announcements should be at the start of the meal and no more than 15 min. before the start. If >30minutes after meal start, do not announce the meal as this increases risk for hypoglycemia. **Review meal composition:** Meal size is based only on carbohydrate content (not fat, protein or caloric intake). Educate to announce “Less” if meal has ~50% fewer carbs than their “Usual” meal and "More" if meal has ~50% more carbs than “Usual” meal. Consider raising CGM Target by one step (e.g., Change from Lower to Usual) around mealtimes.	**Around Mealtime** (1-3 hours after a meal/snack) * See next page for additional guidance around meals	**Assess for missed meal announcements:** All meals (and snacks with similar carb content as a meal) should be announced at the start of the meal. **Review meal composition:** Discuss how Usual meals are identified. Most meals should be announced Usual for me. Educate to announce “More” if meal has ~50% more carbs than a “Usual” Meal and “Less” if meal has ~50% less carbs than a“Usual” meal. User can do more than 1 announcement for meals larger than “More” or coursed meals. Consider lowering the CGM Target by one step (e.g., Change from Usual to Lower) around mealtimes.
Assess use of meal announcements and if user may be giving false meal announcements to try to get more insulin from the iLet, which increases the risk of hypoglycemia. Educate to only use meal announcements for meals.	**Low glucose follows High glucose** **High glucose follows Low glucose**	Educate to treat mild hypoglycemia with fewer grams of carbs (5-10g) & Wait 15 min. before any additional treatment Educate to treat predicted hypoglycemia as soon as a predictive alarm sounds so that there is time for the smaller amount of carbs to work before hypoglycemia occurs.
Assess exercise routines and snacks before, during or after exercise. Avoid large carb snacks prior to aerobic exercise as this will result in a large spike in glucose levels and increased insulin delivery from the iLet, increasing risk of hypoglycemia. Consider consuming small quantities of carbs throughout exercise instead of a large pre-exercise snack. Consider disconnecting from the iLet if a large pre-exercise snack is needed (do not stay disconnected for more than 1 hour).	**Around or after exercise**	Assess exercise routines and snacks before, during or after exercise. Hyperglycemia during exercise is more common with anaerobic exercise (e.g., sprinting, weight lifting). Recommend staying connected to the iLet during exercise if the user had been disconnecting.

GENERAL TIPS

- Meal size is based **solely** on carbohydrate content; **NOT** on protein or fat content and **NOT** on the quantity of food or calories in a meal
- Although carb counting is not necessary, users need basic skills to ***estimate*** carbohydrate content and should understand the following:
  - o Which foods contain carbohydrates and which do not
  - o How to estimate the quantity of carbohydrates in a meal, relative to their eating habits, to identify a "Usual for Me", "Less", and "More" meal size for each meal type (breakfast, lunch, dinner)
- The iLet adapts "More" and "Less" meals relative to the "Usual for me" meal doses.
  - o The dose for a "Less" meal will be 0.5x the "Usual for me" dose
  - o The dose for a "More" meal will be 1.5x the "Usual for me" dose

EDUCATION TIP

Identify "Usual for Me" meals first

- Review diet history with the user to identify the meals they eat most often for each meal type (breakfast, lunch, dinner). These are their "Usual for Me" meals. The iLet adapts to each meal type independently, therefore "Usual" carbohydrate content may vary for each meal type.
- Once you have identified "Usual for me" meals, Identify "More" and "Less" meals for that individual
  - o "More" meals have ~50% more carbohydrates than their Usual meal
  - o "Less" meals have ~50% less carbohydrates (or half the amount) than their Usual meal

KEY CONCEPTS

- Meal Size is relative to each user and their eating habits. The carbohydrate content in a "Usual for me" meal will vary from person to person.
- Consistency is the key! Be consistent in which meals are considered "Usual for me", "More" and "Less" for each meal type.
- "Usual for Me" meals are the foundation to the meal adaptation and should reflect the typical carb content for that person, and for most people, the majority of meal announcements.
- For best outcomes, all meals should be announced at the start of the meal. Do NOT announce a meal >30 minutes after starting to eat as this will increase the chance of hypoglycemia.
- Snacks should be announced only if they contain a similar carbohydrate amount to a meal size (Usual, More or Less) for that meal type (breakfast, lunch, dinner).

What if glucose levels are high or low at the start of the meal?

- Do NOT adjust the meal size based on pre-meal glucose values. This will impair the iLet's ability to adapt meal doses.
- If there is hypoglycemia prior to a meal, treat the hypoglycemia first and then announce the meal based on the meal size. Do not consider the carbs used to treat hypoglycemia in the meal size estimate.

Should you "Re-Set" Meal adaptation?

- If difficulty with post-prandial glycemic control persists, especially if the user has been inconsistent in how meal size is determined, consider re-adapting meal doses.

To re-set meal adaptation:

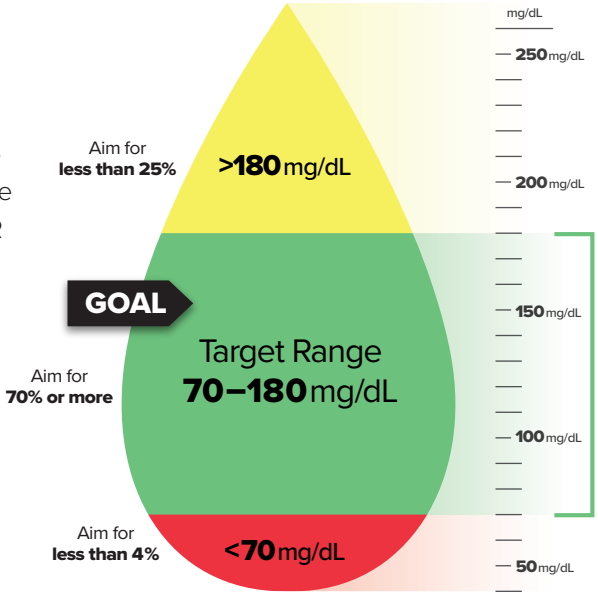
- ☑ Identify "Usual for Me", "More" and "Less" meal size for the user (see education tip)
- ☑ Eat primarily "Usual for me" meals for 1 week and space meals 4 hours apart
- ☑ Avoid unannounced snacks in between meals for 1 week
- ☑ Add in "More" and "Less" meals after this 1 week adaptation period, as applicable

AFTER VISIT SUMMARY

Great job using the **iLet!**

Using the iLet can help you achieve your diabetes goals.

The American Diabetes Association suggests aiming for **70%** of your glucose levels to be between **70-180 mg/dL**, called **Time in Range** or **TIR**. If you are not currently able to reach 70% TIR, don't be discouraged! Start from where you are and set smaller goals to increase your TIR. Any increase in your TIR is beneficial to your lifelong health!



REMEMBER...

Don't overthink what the iLet is doing in the background.
Focus on what *you* can do. See tips below...

TIPS for iLet Bionic Pancreas

- **Announce all meals at the start of the meal** so the iLet can deliver a meal bolus for you. Do not announce a meal more than 15 min. before or 30 min after you eat as this will increase the risk of a low glucose level later.
- **Be consistent in how you determine meal size.** In most cases, the majority of your meals should be "Usual for me". Announce "Less" if the meal has ~50% fewer carbs than a typical meal and "More" if the meal has ~50% more carbs than a "Usual" meal. Announce snacks if they have similar amount of carbs as a meal.
- **Do Not use Meal Announcements to try to correct hyperglycemia.** This increases the chance of a low glucose level and impairs the iLet's ability to learn the correct meal bolus doses for you.
- **Treat mild hypoglycemia with 5-10 g carbs** to avoid rebound hyperglycemia and WAIT 15 min. before treating again to give glucose time to rise. The iLet will have suspended insulin delivery if hypoglycemia occurs so smaller treatments will work better to avoid a large spike in glucose levels.
- **Avoid large carb snacks prior to aerobic exercise.** Large carb snacks may result in sharp rises to glucose and more insulin delivery from the iLet, increasing the chance of a low glucose level. Instead try smaller carb amounts before and during exercise. If you need a large snack, consider disconnecting from the iLet before you eat the snack. Do not stay disconnected for more than 1 hour.
- **Change your Infusion Set** every 2-3 days, or as needed if your glucose level is > 300 mg/dL for more than 90 minutes, and rotate infusion site locations.
- **Always carry a BG meter with you and an extra CGM sensor** so you can enter BG values into the iLet if your sensor falls off or fails unexpectedly and replace your CGM sensor.

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SCAN TO VISIT
PANTHERprogram.org

Have questions about your iLet?

betabionics.com

Customer Support
1-855-745-3800

Have questions about your CGM?

dexcom.com

Dexcom customer support
1-888-738-3646

Dexcom technical support
1-844-607-8398