

iLet Bionic Pancreas



How the iLet Algorithms Work: the iLet algorithms require initialization with body weight only and do not require (or allow) input on basal rates, insulin-to-carb ratios, or insulin sensitivity factors

- The only setting that can be changed is the CGM Target, which defaults to “usual” (120) and can be set to “lower” (110) or “higher” (130)
 - Basal and bolus algorithms aim to steer glucose level to the current CGM Target
 - A single CGM Target may be used at all times, or a Secondary CGM Target may be enabled for any start and any end time
- The control algorithms autonomously determine insulin doses every 5 minutes in response to glucose values from CGM, insulin dosing history, and user input (meal announcements, and when CGM values are not available, entered BG values)
- **Automated Insulin Delivery**
 - Once body weight has been entered, iLet begins regulating glucose levels automatically and does not require you to count carbs, program basal rate settings, carb ratios, correction factors or make corrections if BG is high
 - Adjust body weight settings for changes >15% only
 - When CGM is offline an alert indicating loss of CGM readings will display within 30 minutes
 - **BG-Run Mode:** This mode requires frequent entry of BG values to continue insulin dosing
 - Limited to a maximum of 48 hours (in first 7 days after starting iLet) and 72 hours thereafter
 - After BG-Run Mode expires and CGM values are not available, ALL insulin dosing will stop
 - An alert to enter BG value will display and continue until CGM is back online
 - If entered BG is high, iLet will deliver a correction
 - If entered BG is low, iLet will stop all insulin dosing for one hour
 - Basal insulin will continue to be delivered based on most recent adapted basal doses every 5 minutes
 - Continue to announce meals if eating – enter BG at the start of your meal and 2 hours after for optimal glucose control

Insulin doses are governed by three coexisting algorithms

- **Basal Algorithm:** Basal insulin doses are autonomously determined every 5 minutes based on the glucose profile of the previous 24 hours, the current glucose level, and the glucose trend. Basal insulin dosing may be entirely suspended for low or rapidly declining glucose levels
- **Bolus Correction Algorithm:** Bolus insulin doses provide insulin that is required above and beyond basal insulin. They are autonomously determined every 5 minutes based on the glucose profile of the previous 24 hours, the current glucose level, the glucose trend and insulin on board
- **Meal Announcement Algorithm:** Meal doses are automatically determined in response to user meal announcements, separately for breakfast, lunch and dinner. This algorithm will learn and adapt as you use the system more. Meal doses are capped at 24 units
 - Announce a meal up to 15 minutes before you start eating, right when you start eating or up to 30 minutes after you start eating
 - Choose meal type based on what you consider to be breakfast, lunch, or dinner
 - Meals are announced as having Usual, More, or Less carbs
 - Choose meal size based on the usual amount of carbs you eat of the chosen meal type
 - “Usual” for me should be chosen most of the time
 - Use “Less” if your meal has around 50% less the carbs of your “Usual” meal
 - Use “More” if your meal has around 50% more carbs than your “Usual” meal
 - If snack has as many carbs as your meal for that type, announce the snack
 - If snack has fewer carbs than your “Less” meal type, do not announce the snack
 - NEVER use the meal announcement to correct a high blood glucose
 - This will cause future meal announcements to be less effective and could lead to a severe hypoglycemic event

Exercise

- Disconnect from iLet up to 30 minutes before exercise
 - Pause insulin delivery when disconnected
 - Do not “preload” with carbs until you have disconnected – insulin delivery will increase as will risk for hypoglycemia
- Stay connected to iLet

Approved for people with T1D age 6+ using at least 13 units of insulin per day.

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