# Automated Insulin Delivery iLet Bionic Pancreas

## How does the iLet work?

The iLet Bionic Pancreas automates all insulin delivery, including basal insulin doses and meal and correction bolus doses. Insulin automation is initiated by programming your weight. As you use the system, insulin doses adapt over time based on your daily glucose patterns. You can request a meal bolus from the iLet by entering a meal announcement, where you indicate which meal you are eating, (breakfast, lunch, or dinner) and the amount of carbohydrates in the meal relative to what you typically eat ("Usual for Me", "More" than usual or "Less" than usual). No carbohydrate counting is required to announce a meal. When a meal is announced, the iLet will calculate and deliver a meal bolus dose.

#### What happens if the CGM loses connection with the pump or I stop wearing the CGM for a period of time?

If the iLet loses connection with the CGM, it can still automate all insulin delivery. If there is no CGM data available to the iLet, you will need to enter fingerstick BG values into the iLet periodically to provide the iLet with glucose information. The iLet will continue to automate all insulin delivery based on the BG values entered, as well as saved information it has kept on your basal insulin needs. You can still announce meals and receive automated meal bolus doses as well.

The iLet does not have any programmed pump settings (e.g., no basal rates, carb ratios or correction factors), therefore there is no manual mode on the iLet. The iLet will display information on recent insulin doses, including total daily insulin, total daily basal dose and meal doses, that could be used if you need to switch to insulin injections for any reason.

#### Which CGM does it use?

Dexcom G6: Factory calibrated (does not require calibration with BG meter checks)

The iLet uses data from the Dexcom CGM to determine insulin doses and makes real-time adjustments to the doses based on current CGM glucose trends.

#### How can I use it best?

Announce your meals at the start of each meal so the iLet can deliver a meal bolus. Most of the meals you announce should be "Usual for Me" because the meal announcement is related to your routines and what is a typical amount of carbohydrate in a meal for you. Remember that the iLet adapts to each meal (breakfast, lunch, dinner) independently. So the "Usual" amount of carbohydrates for breakfast, for example, may be different than the "Usual" amount for lunch. You do not need to announce snacks, unless the snack has a similar amount of carbs as a meal.

In the first week using the iLet, it is helpful to space your meals at least 4 hours apart to help the iLet learn your meal doses.

The iLet is designed to automate all insulin delivery without you doing anything other than announcing meals. There are no pump settings programmed in the pump and there is no option for you to give a bolus yourself. A hands-off approach is necessary when using this system and some patience is needed as the iLet adapts to changing insulin needs and identifies effective meal bolus doses.

There are 3 target glucose options: ("Usual", "Lower", "Higher") and you can set up to 2 targets throughout the day as desired to personalize your diabetes mangement. The Lower target will result in more insulin delivery and lower glucose levels compared to the Usual target. The Higher target will result in less insulin delivery and higher glucose levels compared to the Usual target.



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Announce your meals right before eating, indicating the amount of carbohydrates in the meal relative to your typical carbohydrate intake at that meal ("Usual for Me", "More" than Usual, "Less" than Usual). Most meals should be announced as "Usual for Me".

Treat mild hypoglycemia with 5-10 grams of carbs to avoid rebound hyperglycemia and WAIT 15 minutes before treating with more carbs to give glucose time to rise. The iLet will have already suspended insulin delivery if low glucose occurs, resulting in little insulin on board.

Always carry a BG meter with you so you can enter BG values into the iLet if your sensor falls off or fails unexpectedly.

Do NOT use meal announcements to try to get more insulin from the iLet or correct a high glucose level. This will disrupt the systems adaptation and increase the chance of low glucose levels.

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