

*Information is specific to use of each pump's AID features*

## iLet Bionic Pancreas



### CALCULATE

<b>Basal automation?</b>	Insulin Automation is initialized by entering user's weight. Basal insulin delivery adjusts every 5 minutes based on CGM glucose trends and adapts over time based on the iLet's analysis of the user's daily glucose patterns.
<b>Bolus automation?</b>	All meal bolus doses and correction bolus doses are automated. Auto correction boluses max. every 5 minutes as needed if glucose > CGM target setting.
<b>Algorithm target glucose / target range?</b>	3 target options: Usual (120 mg/dL), Lower (110 mg/dL), Higher (130 mg/dL) User can set up to 2 target settings per 24 hr period
<b>Which insulin does the user give?</b>	User completes a meal "announcement" to prompt the iLet to deliver a meal bolus, which involves estimating the carbohydrate amount for each meal ("Usual for Me" / "More" than usual / "Less" than usual).

### ADJUST

When using AID, what settings can you adjust?	Basal Rates	I:C Ratios	Correction/Sensitivity Factor	Active Insulin Time
	N/A There are no pump settings programmed into the iLet. All insulin delivery is automated by the algorithm and continuously adapted without the use of any programmed pump settings.			
<b>Can user give extended boluses?</b>	N/A There is no bolus calculator in the iLet. All meal and correction bolus doses are automated.			
<b>Can user change/override recommended bolus doses in bolus calculator?</b>				
<b>What are the special features in automated insulin delivery?</b>	Pause Insulin Feature: Users can pause (suspend) insulin delivery for a specified timeframe.			
<b>Which pump settings impact automated insulin delivery (insulin delivered by the algorithm)?</b>	User can set up to 2 target settings per 24 hr period: "CGM Target" and "Secondary CGM Target". Different targets ("Usual", "Lower", "Higher") can be chosen for each setting.			

### REVERT

<b>Is there a limited automation mode the system may revert to if there is a loss of CGM communication or other reasons?</b>	Yes, BG-run mode: If the iLet loses communication with the CGM, it will prompt the user to enter BG values periodically. As long as the user enters BG values into the iLet, it will continue to automate all insulin delivery based on the entered BG values and previously stored information on the user's basal insulin needs.  The user can continue to announce meals in BG-run mode to receive meal boluses from the iLet.  iLet can operate in BG-run mode for up to 72 hrs.
<b>When will the system automatically revert to manual mode (conventional pump therapy using programmed basal rates — no insulin dose automation)?</b>	There is no option for manual mode in the iLet.  After 72 hours in BG-run mode, the iLet can no longer deliver insulin. It will resume insulin delivery once the CGM is re-connected.  The iLet will display total daily insulin dose, basal insulin and meal insulin doses, which could be used to inform multiple daily injection doses, if needed.

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### EDUCATE

<p><b>Mealtime and Bolus Considerations</b></p>	<p>User should “announce” meals at the start of the meal by indicating meal type (“Breakfast” “Lunch” or “Dinner”) and meal size (“Usual for me”, “More” than usual, or “Less” than usual) relative to the user’s typical carbohydrate intake for each meal type. Do not announce the meal if &gt; 30 min. after eating.</p> <p>In the first week of using iLet, space meals at least 4 hours apart and eat primarily “Usual for me” meals to help the iLet learn meal bolus doses.</p>
<p><b>Sleep Considerations</b></p>	<p>Can use the Secondary CGM Sleep Target and choose the start and end times to correspond with user’s sleep schedule.</p> <p>Review evening/bedtime behaviors to identify causes of high or low glucose patterns, if they are occurring in the several hours after bedtime (e.g., are dinner meals or subsequent snacks being announced appropriately?).</p>
<p><b>Exercise Considerations</b></p>	<p>Managing glucose levels with exercise must be personalized for each individual based on previous experience and type of exercise.</p> <p>Considerations with AID include: Avoid large carb snacks prior to exercise as large spikes in glucose will result in increases in insulin delivery and greater risk of hypoglycemia. Instead, consider consuming small quantities of carbohydrates during exercise as needed and/or disconnecting from the device as needed.</p> <p>If you require a large snack prior to exercise, disconnect the iLet or pause insulin before you eat that snack (do not disconnect or pause insulin for more than 1 hour at a time).</p>
<p><b>Other Considerations</b></p>	<p>The iLet is designed to automate all insulin delivery, and continuously adapts with no user interaction except for meal announcements. Users cannot give a manual bolus. A hands-off approach is necessary.</p> <p>Don’t use meal announcements to try to correct high glucose levels; this will disrupt the system’s adaptation and increase the chance of hypoglycemia.</p> <p>It’s important to carry a BG meter at all times so the user can use the BG-run mode if there are unexpected problems with the CGM at any time. BG-run mode lasts max. 72 hours, so if CGM wear is interrupted for longer, a back up insulin delivery plan is vital.</p> <p>Consider treating mild hypoglycemia with less carbohydrates (5-10 g) than the traditional rule of 15g. If hypoglycemia occurs, the algorithm will have already decreased or suspended insulin delivery and treating with too many carbs may result in large rebound hyperglycemia.</p>

### SENSOR/SHARE

<p><b>Which CGM is compatible?</b> <i>*CGM options may vary by region</i></p>	<p>Dexcom G6 and G7: Use of Dexcom G6 or G7 mobile app is optional; cannot use the Dexcom receiver when the Dexcom is paired to the iLet. Freestyle Libre 3 Plus: Must pair on iLet app only; cannot use Freestyle Libre apps or reader.</p>
<p><b>How long does the sensor last?</b></p>	<p>Dexcom G6 &amp; G7: 10 days maximum Freestyle Libre 3 Plus: 15 days maximum</p>
<p><b>Can user see real-time data on personal cell phone?</b></p>	<p>Dexcom G6/G7 mobile app (CGM data) iLet Mobile app (pump + CGM data)</p>
<p><b>Can others see data remotely?</b></p>	<p>Dexcom Follow app (CGM data) Bionic Circle app (pump + CGM data)</p>
<p><b>Is data automatically stored in the cloud?</b></p>	<p>Automatic uploads to the Beta Bionics portal via iLet app</p>