

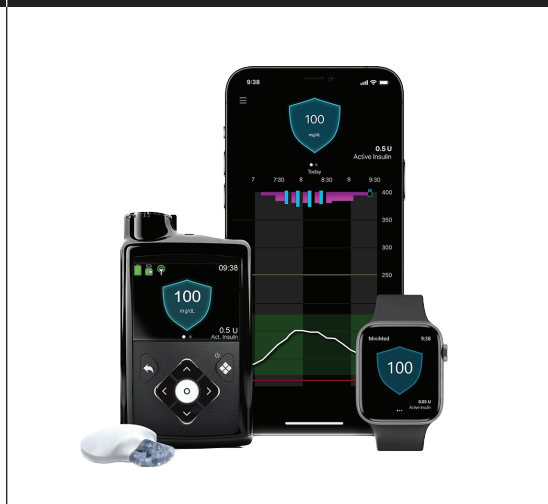
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## iLet Bionic Pancreas



## MiniMed™ 780G



## t:slim X2™ Control-IQ™



## Omnipod® 5



### CALCULATE

### iLet

### 780G

### Control-IQ

### Omnipod 5

**What is automation called?**

iLet Bionic Pancreas

SmartGuard™

Control-IQ™

Automated Mode

**Basal automation?**

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.

"Auto Basal" calculated from total daily insulin, which is updated each day at midnight. Auto Basal is adjusted every 5 min based on recent CGM glucose trends, aiming for the target glucose value.

Increases or decreases the programmed basal rates every 5 minutes based on a 30 min prediction of CGM glucose, aiming for the target glucose range.

"Adaptive Basal" calculated from total daily insulin, which is updated at each Pod change. Adaptive Basal is adjusted every 5 min based on a 60 min prediction of CGM glucose, aiming for the target glucose value.

**Bolus automation?**

All meal bolus doses and correction bolus doses are automated.

Auto correction boluses (max. every 5 min) if glucose is >120 mg/dL. Auto corrections can be turned on or off.

Auto correction boluses (max once/hr) if glucose is predicted to be >180 mg/dL in 30 min.

No automated boluses

**Algorithm target glucose / target range?**

3 target options: "Usual", "Lower", "Higher"

3 target options: 100, 110, 120 mg/dL

Target range: 112.5-160 mg/dL

5 target options: 110, 120, 130, 140, 150 mg/dL

**Which insulin does the user give?**

User completes a meal "announcement" to prompt the iLet to deliver a meal bolus, which involves indicating the carbohydrate amount for each meal ("Usual for Me"/"More" than usual/"Less" than usual).

User gives boluses for meals by entering total grams of carbs in the bolus menu / bolus calculator.

User can deliver correction boluses as needed in the bolus menu / bolus calculator.

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### ADJUST iLet 780G Control-IQ Omnipod 5

<b>Can users adjust basal rates?</b>	N/A	No (programmed basal rates are not used in SmartGuard)	Yes	No (programmed basal rates are not used in Automated Mode)
<b>Can users adjust I:C ratios?</b>	There are no pump settings programmed into the iLet. All insulin delivery is automated by the algorithm without the use of any programmed pump settings.	Yes	Yes	Yes
<b>Can users adjust correction factor (sensitivity)?</b>		No (the programmed sensitivity is not used for correction bolus calculations when in SmartGuard)	Yes	Yes
<b>Can users adjust active insulin time?</b>		Yes	No, fixed at 5 hrs when Control-IQ is on	Yes
<b>Can users adjust the correction bolus target?</b>	Yes, same as algorithm target ("CGM Target")	No, fixed at 120 mg/dL	No, fixed at 110 mg/dL	Yes, same as algorithm target ("Target Glucose")
<b>Can user give extended boluses?</b>	N/A	No	Yes (extend up to 2 hours)	No
<b>Can user change/override recommended bolus doses in bolus calculator?</b>	There is no bolus calculator in the iLet. All meal and correction bolus doses are automated.	No	Yes	Yes
<b>What are the special features in automated insulin delivery?</b>	None	Temp Target: Changes target glucose to 150 mg/dL to reduce auto-basal delivery for chosen duration (30 min – 24 hr) and disables auto correction boluses.	Exercise Activity: Changes target range to 140-160 mg/dL to reduce basal delivery (user has to manually start/stop).  Sleep Activity: Narrows target range to 112.5-120 mg/dL and prevents auto correction boluses. Can program a sleep schedule or manually start/stop.	Activity Feature: Changes target glucose to 150 mg/dL and decreases the doses by ~50% to reduce adaptive basal delivery for chosen duration (1–24 hrs).
<b>Which pump settings can be adjusted to change automated insulin delivery (insulin delivered by the algorithm)?</b>	User can set up to 2 target settings per 24 hr period: "CGM Target" and "CGM Sleep Target". Different targets ("Usual", "Lower", "Higher") can be chosen for each setting.	Auto Basal Target: 100, 110, 120 mg/dL; only 1 target can be set.  Active Insulin Time (2 hrs for most aggressive insulin delivery—will mainly impact auto correction bolus doses).	Basal rates  Correction factor (for auto correction bolus doses)	Target Glucose: Can set up to 8 target settings per 24 hour period.  5 target options: 110, 120, 130, 140, 150 mg/dL
<b>Which pump settings can be adjusted to change meal and/or correction bolus doses (insulin delivered by the user)?</b>	None. There are no traditional pump settings programmed into the iLet.	I:C Ratios  Active Insulin Time	I:C Ratio  Correction factor	I:C Ratio  Correction Factor + Correction Threshold  Active Insulin Time

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### REVERT

### iLet

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**Is there a limited automation mode the system may revert to if there is a loss of CGM communication or other reasons?**

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.

Yes, Safe Basal: the pump will deliver a basal rate determined by the algorithm, but without glucose-dependent basal adjustments and no auto correction boluses.

May activate due to max/min insulin delivery constraints, loss of CGM data or system concerns about sensor accuracy.

User needs to enter a BG value into the pump before the "time to exit" expires to prevent SmartGuard exit.

If the "time to exit" expires without a BG entry, the pump will revert to manual mode.

User must enter a BG value into the pump to return to SmartGuard following an exit to manual mode.

No, there is no limited automation mode.

If there is loss of CGM data, the pump will deliver the programmed basal rates without glucose-dependent basal adjustments and no auto correction boluses (manual mode).

If there is no CGM data ≥ 20 min, the pump will revert to manual mode.

When CGM data returns, Control-IQ will automatically turn back on.

Yes, Automated Limited: the Pod will deliver a basal rate determined by algorithm, but without glucose-dependent basal adjustments. May activate for two reasons:

1. If no CGM data for ≥ 20 min. Pod will resume full insulin automation once CGM data returns.

2. If there is an "Automated Delivery Restriction" alarm (if insulin has been suspended too long or if max delivery too long). Will remain in Automated Limited until the user clears the alarm.

If there is an "Automated Delivery Restriction" alarm, the user will be prompted to confirm CGM accuracy, and then will have to switch to manual mode. The user must switch back to automated mode after 5 min in manual mode (the Pod will not return to automated mode on its own).

**When will the system automatically revert to manual mode (conventional pump therapy using programmed basal rates — no insulin dose automation)?**

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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<b>Mealtime and Bolus Considerations</b>	<p>The iLet automates all meal and correction bolus doses. User cannot give a manual bolus.</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. If the user forgets to announce a meal, they can announce the meal late if within 30 min of starting to eat. If later than 30 min, do not announce the meal.</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>Pre-bolus for all meals and snacks, ideally 10-15 min before eating.</p> <p>It is common to need stronger I:C Ratios compared to manual insulin therapies due to reduced or suspended insulin delivery from the algorithm, which is common leading up to mealtime and/or after a bolus is given.</p>		
<b>Sleep Considerations</b>	<p>Can adjust the CGM Sleep Target setting and choose the start and end times.</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>Can adjust Target as needed (only 1 target setting for 24-hr period).</p> <p>Could also consider use of Temp Target if hypoglycemia is occurring during sleep (will disable auto correction boluses and raise auto basal target to 150 mg/dL).</p>	<p>Program the sleep schedule to ensure Sleep Activity activates each day automatically.</p> <p>If hypoglycemia is occurring with use of Sleep Activity, could consider not using Sleep Activity or could try using Exercise Activity during sleep (but know that auto correction boluses may be delivered).</p>	<p>Can adjust Target Glucose for sleep period, as needed.</p> <p>Could also consider use of Activity Feature during sleep if hypoglycemia is occurring.</p>
<b>Exercise Considerations</b>	<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, it is best to disconnect the iLet before you eat that snack (do not disconnect for more than 1 hour at a time).</p>	<p>Use Temp Target; turn on 1-2 hours prior to starting exercise and consider leaving on for several hours after exercise ends if delayed hypoglycemia is a concern.</p>	<p>Use Exercise Activity, but note that auto corrections still may occur; turn on 1-2 hours prior to starting exercise and consider leaving on for several hours after exercise ends if delayed hypoglycemia is a concern.</p>	<p>Use Activity Feature; turn on 1-2 hours prior to starting exercise and consider leaving on for several hours after exercise ends if delayed hypoglycemia is a concern.</p>
<b>Other Considerations</b>	<p>The iLet is designed to automate all insulin delivery, with no user interaction except for meal announcements. Users cannot give a manual bolus. A hands-off approach is necessary.</p> <p>The system adapts over time to optimize insulin delivery. It is important to allow the system time to adapt to insulin needs.</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.</p>	<p>Follow system prompts for “BG Required” to stay in SmartGuard.</p> <p>Consider using the 100 mg/dL Target and Active Insulin Time of 2 hours for optimal system performance as long as hypoglycemia is not &gt;4%.</p> <p>Do not enter “fake carbs” to try to get more insulin from the system. This will result in an increased risk of hypoglycemia, and greater glucose variability.</p>	<p>It is best to use the bolus calculator for meal and correction boluses and best NOT to override the bolus calculator’s suggested dose. The bolus calculator will subtract IOB from increased automated insulin delivery, helping to reduce the chance of hypoglycemia.</p> <p>User can give bolus doses remotely from a cell phone when using the t:connect mobile app.</p> <p>Control-IQ allows programming of more than 1 personal profile, where different basal rates, carb ratios and correction factors can be used. Consider programming more than 1 profile to help with changing insulin needs (e.g., menstrual cycle, illness, long sporting events, etc.).</p>	<p>It is best to use the bolus calculator for meal and correction boluses and best NOT to override the bolus calculator’s suggested dose. The bolus calculator will subtract IOB from increased automated insulin delivery, helping to reduce the chance of hypoglycemia.</p> <p>Insulin suspension may occur if glucose is trending down, even if the glucose level is above the programmed Target Glucose. This is expected and will be short in duration (e.g. 5-15 min) if the glucose level does not continue to drop.</p> <p>Avoid Pod area when using aerosolized sunscreens/bug sprays as they may cause Pod failures.</p> <p>Wear Pod and Dexcom in “line of sight” to optimize Bluetooth communication.</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>				

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### SENSOR/SHARE

### iLet

### 780G

### Control-IQ

### Omnipod 5

#### Which CGM is compatible with system?

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.

Guardian 3 or 4—varies by geographic location

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 pump.

Dexcom G6: Must use Dexcom G6 mobile app (on personal cell phone) to use Automated Mode.

Cannot use the Dexcom receiver when the Dexcom is paired to the Pod.

#### Calibration required?

No, factory calibrated

Guardian 3: Yes, every 12 hours minimum (3-4 calibrations per day recommended for best accuracy).  
Guardian 4: No routine calibration required, but the pump may request BG checks (which will calibrate sensor).

No, factory calibrated

No, factory calibrated

#### How long does the sensor last?

10 days maximum

Guardian 3 & 4: 7 days maximum

Dexcom G6 and G7: 10 days maximum  
Libre 2 Plus: 15 days maximum

10 days maximum

#### Can user see real-time data on personal cell phone?

Yes, Dexcom G6 mobile app (CGM data)

Yes, MiniMed mobile app (pump + CGM data)

Yes, Dexcom G6 mobile app (CGM data)  
t:Connect mobile app (pump + CGM data)

Yes, Omnipod 5 app (pump + CGM data, also used to operate pump; availability of app varies by region)  
Dexcom G6 mobile app (CGM data)

#### Can others see data remotely?

Yes, Dexcom Follow app (CGM data)

Yes, CareLink Connect app (pump + CGM data)

Yes, Dexcom Follow app (CGM data)  
\* If using Libre 2 Plus, there is no option for remote data sharing

Yes, Dexcom Follow app (CGM data)

#### Is data automatically stored in the cloud?

Yes, automatic uploads to the cloud via iLet app

Yes, automatic uploads to CareLink via MiniMed mobile app

Yes, automatic uploads to t:connect via t:connect mobile app

Yes, automatic uploads to Glooko after linking Omnipod 5 to the Glooko account