

A Clinical Guide to Advanced Diabetes Devices and Closed-Loop Systems

Using the CARES Paradigm¹



For Healthcare Providers

In years past, insulin pumps functioned in essentially the same way.

Today, however, pumps with automated insulin dosing (AID) algorithms may differ fundamentally. The CARES model was designed by diabetes researchers to simplify the process of understanding different AID systems by asking the following questions:

Calculate	How does the system calculate insulin delivery?
Adjust	How does the system adjust insulin doses immediately and long term?
Revert	When should users revert to traditional insulin pump settings (open loop)?
Educate	What are the critical education points?
Sensor/Share	What are the key aspects of the system's sensor and sharing capabilities?

The table on the next page was developed by third-party researchers and is provided here with their permission. This is intended as a reference tool for use by healthcare providers who have general familiarity with insulin pumps and continuous glucose monitoring (CGM) to support their ability to provide comprehensive care to individuals with insulin-requiring diabetes.

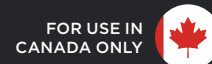


Control-IQ technology does not prevent all high and low blood glucose events, and is not a substitute for meal boluses and active self-management of diabetes. Control-IQ technology will not be able to predict sensor glucose values and adjust insulin dosing if a user's CGM is not working properly or is unable to communicate with their pump. Users should be instructed to always pay attention to their symptoms and blood glucose levels and treat accordingly. Please visit tandemdiabetes.com/tslimX2-use for more information.



(833) 509-3598
tandemdiabetes.ca

t:simulator App
A free virtual pump demo



Reference: 1. Brown, S. Clinical Acceptance of the Artificial Pancreas: Glycemia Outcomes from a 6-month Multicenter RCT. 2019 ADA 79th Scientific Sessions, San Francisco, CA.

Important Safety Information: The t:slim X2 insulin pump with Control-IQ technology (the System) consists of the t:slim X2 insulin pump, which contains Control-IQ technology, and a compatible continuous glucose monitor (CGM, sold separately). The t:slim X2 insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the System. When used with a compatible CGM, the System can be used to automatically increase, decrease, and suspend delivery of basal insulin based on CGM sensor readings and predicted glucose values. The System can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. The pump and the System are indicated for use in individuals six years of age and greater. The pump and the System are intended for single patient use. The pump and the System are indicated for use with NovoRapid or Humalog U-100 insulin. The System is intended for the management of Type 1 diabetes.

WARNING: Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in patients who require less than 10 units of insulin per day or who weigh less than 25 kilograms.

The System is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use the System if using hydroxyurea. Users of the pump and the System must: be willing and able to use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump and the CGM transmitter and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

© 2021 Tandem Diabetes Care, Inc. All rights reserved. Tandem Diabetes Care, Control-IQ, t:simulator, and t:slim X2 are either registered trademarks or trademarks of Tandem Diabetes Care, Inc. in the United States and/or other countries. Dexcom and Dexcom G6 are either trademarks or registered trademarks of Dexcom, Inc. in the United States and/or other countries. Apple and the Apple logo are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc. Google Play and the Google Play logo are trademarks of Google LLC. All other third-party marks are the property of their respective owners. ML-1007814_A

Comparison of Two Hybrid Closed-Loop Systems Using the CARES Paradigm*

	MiniMed 670G	t:slim X2™ insulin pump with Control-IQ™ technology
Calculate	<ul style="list-style-type: none"> Hybrid closed-loop (HCL) system (referred to as “Auto Mode”) Uses total daily insulin calculated from last 2-6 days to determine algorithm parameters Automated basal calculated by system every 5 minutes HCL set point = 6.7 mmol/L No automated correction doses. Manual correction doses based on HCL algorithm and target BG of 8.3 mmol/L. Does not use programmed sensitivity factors. 	<ul style="list-style-type: none"> HCL system (referred to as “Control-IQ”) Uses weight and total daily insulin input by user to determine algorithm parameters Automates basal by modulating programmed basal rates HCL target range = 6.25-8.9 mmol/L Automated correction dose (up to one per hour) uses programmed correction factor and target BG of 6.1 mmol/L and delivers 60% of calculated dose. User can also give manual correction doses using target of 6.1 mmol/L.
Adjust (for HCL)	<p>User can modify in HCL: Insulin-to-carb (I:C) ratios (for meal boluses), Active insulin time (for subsequent correction doses), Temp target of 8.3 mmol/L</p> <p>User cannot modify in HCL: Basal rates, insulin sensitivity factor, HCL set point of 6.7 mmol/L (except when using temp target)</p>	<p>User can modify in HCL:</p> <ul style="list-style-type: none"> I:C ratios (meal boluses), basal rates, sensitivity factor (for correction doses) HCL target range for Exercise Activity (target range 7.8-8.9 mmol/L) and Sleep Activity (target range 6.25-6.7 mmol/L) <p>User cannot modify in HCL: Active insulin time (5 hours), Correction target of 6.1 mmol/L</p>
Revert	Consider turning off for illness/ketones. Use temp basal rates in open loop during illness if persistent hyperglycemia	
	<ul style="list-style-type: none"> Will automatically revert to open loop (referred to as “Manual Mode”) if persistent hyperglycemia, max or min delivery thresholds, loss of CGM data, sensor integrity concerns Manually turn off hybrid closed loop for temp basal rates and/or combo boluses Consider turning off HCL for dramatic change in insulin sensitivity (e.g., steroid use) due to system taking days to readjust 	<ul style="list-style-type: none"> Will automatically revert to open loop if loss of CGM data for prolonged periods Manually turn off HCL to use temp basal rates
Educate	<ul style="list-style-type: none"> Consider treating hypoglycemia with less carbohydrates (e.g., 5-10) if system has not delivered insulin (been suspended) for period of time prior to low glucose Important to pre-bolus for optimal mealtime management (similar to traditional insulin pump) 	
	<ul style="list-style-type: none"> System may display “BG required” for HCL functioning: when user is required to enter a fingerstick blood glucose (BG) value into the pump. This is different from a sensor calibration, and users should understand difference Follow system prompts for “BG required” For insulin dosing adjustments, change I:C ratios (10-25%) and active insulin time Cannot use temp basal rates and/or combo boluses in HCL mode (“temp target” feature will allow for temporary reduction in basal insulin delivery in HCL mode) 	<ul style="list-style-type: none"> Can adjust insulin doses with many insulin pump parameters to improve system performance Do not override boluses: extra insulin already on board from auto-corrections and increased basal rates. Overriding may cause hypoglycemia Individuals with short active insulin times may need to adjust doses to accommodate for 5-hour active insulin time in HCL Cannot use temp basal rates in HCL (“Exercise Activity” will allow for temporary reduction in basal insulin delivery in HCL) Can program an extended bolus in HCL mode, but only for a maximum of 2 hours
	MiniMed Guardian 3	Dexcom G6 sensor
Sensor/Share	<ul style="list-style-type: none"> Requires 2-4 calibrations for optimal use; 6-7 day sensor life Perform BG check for diabetes management decisions Calibrate when glucose is stable (ie, before meals, bedtime, or when no sensor trend arrows) to prevent calibration errors 	<ul style="list-style-type: none"> Factory calibrated sensor (manual calibrations optional, not required) 10-day sensor life Can use sensor for diabetes management if sensor value and arrow present Can remotely follow glucose levels with Follow app

*Adapted from Messer, Laurel. Website of the Barbara Davis Center for Diabetes at the University of Colorado, Aurora, Colorado. https://bdcpantherdiabetesdotnet.files.wordpress.com/2019/06/cares_paradigm.pdf Updated May 15, 2019. Accessed August 12, 2019.