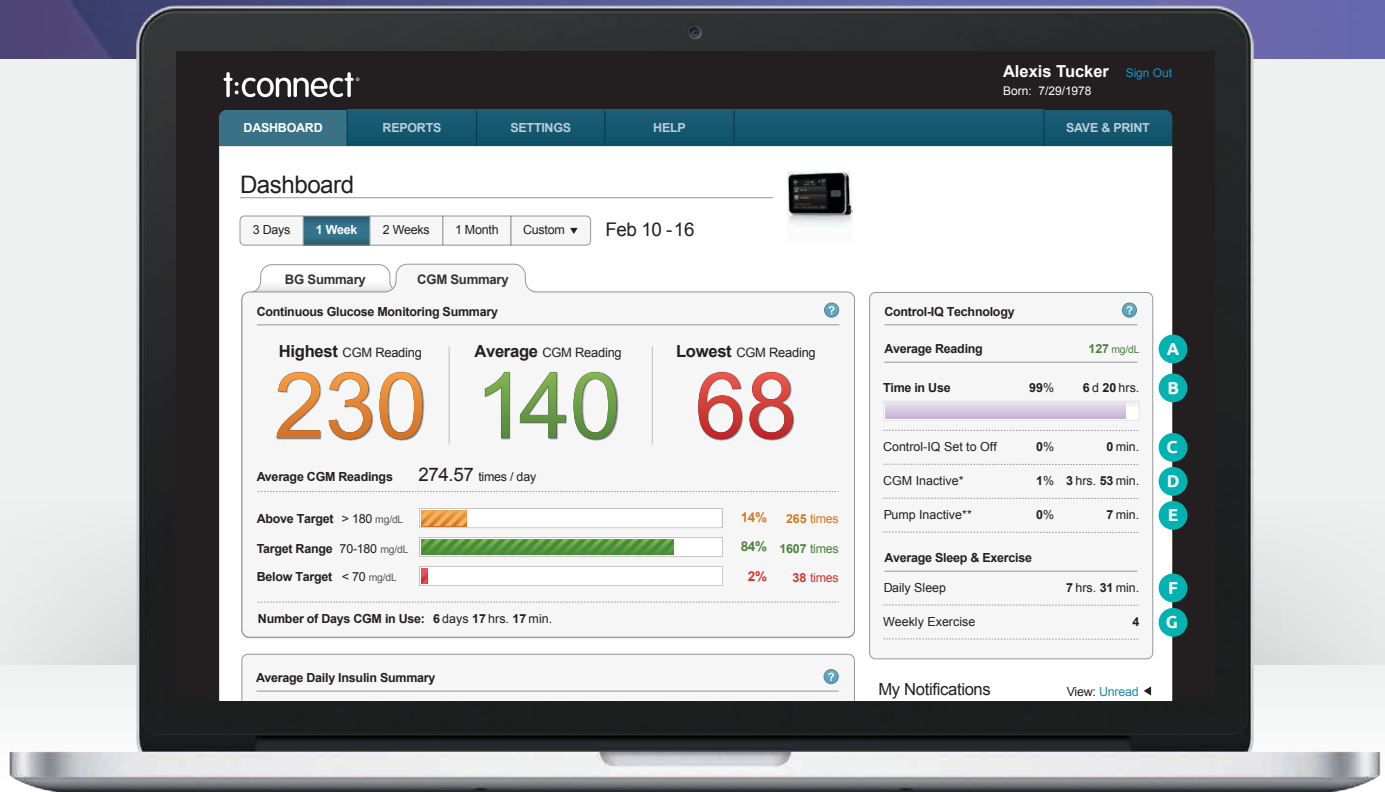


Analyzing Control-IQ Technology Data

With t:connect Web Application Reports



For Healthcare Providers



Our t:connect web application and reports have been updated with Control-IQ technology. Take a moment to see what's new.

Dashboard

The Dashboard on the t:connect® web application provides a general overview of overall glycemic control including percentage of time above, within, and below the target range. It also summarizes average daily insulin use and data from Control-IQ™ technology.

- A** The average continuous glucose monitoring (CGM) value when Control-IQ technology is in use. This may differ from the average CGM reading on the dashboard.
- B** The amount of time Control-IQ technology was in closed-loop.
- C** The amount of time the patient turned off Control-IQ technology.
- D** The amount of time CGM is inactive

due to loss of signal, sensor errors or the sensor session is inactive.

- E** The amount of time the t:slim X2™ insulin pump is inactive due to a cartridge change, manual suspension, or alarm suspension.
- F** The average duration the Sleep Activity setting was in use.
- G** The number of times that the Exercise Activity was started.

Logbook

The Logbook displays the total basal delivered within each hour (**H**) and the programmed Basal Profile Setting (**I**). With Control-IQ technology these basal rates may differ.

Logbook																								
	12AM	1	2	3	4	5	6	7	8	9	10	11	12PM	1	2	3	4	5	6	7	8	9	10	11
Feb 14																								
Glucose (mg/dL)							121	126			136			110		161	164		160 165		196			
Carbs (g)															20				25 45					
Bolus (u)							0.28	0.40			0.25			1.00	1.00	1.00	1.00		3.36 5.00		0.14			
H Basal Total Delivered (u)	0.033	0.473	1.365	1.062	0.828	0.715	0.847	0.722	1.020	1.249	1.098	1.028	0.955	0.694	0.850	1.191	0.850	1.223	1.001	0.900	1.675	1.620	1.480	0.695
I Basal Profile Setting (u/hr)	→ 1.100	→	→	→	→ 1.000	→	→ 0.950	→	→	→	→	→	→ 0.850	→	→	→	→	→	→	→ 0.900	→	→	→ 1.050	→
Avg. CGM (mg/dL)	71	90	117	119	111	107	114	114	113	126	135	136	128	117	137	157	161	157	169	186	190	188	168	120



Printed Therapy Timeline




The printed Therapy Timeline displays seven days of data across two pages including glucose readings, basal rates, and Control-IQ events (eg, Activity settings and correction boluses). A therapy summary box will also show pertinent CGM, insulin, and carbohydrate data.

- A** Automatic Correction Bolus
- B** Exercise Activity
- C** Sleep Activity
- D** Override Bolus
- E** Programmed Basal Rate
- F** Control-IQ Basal Rate
- G** Control-IQ Suspensions



Stepwise Approach to Analyzing Control-IQ Technology

The following section addresses two topics: the suggested order for reviewing reports and some items to look for within each reporting segment. Before printing reports, verify glycemic thresholds are set appropriately in the t:connect web application.

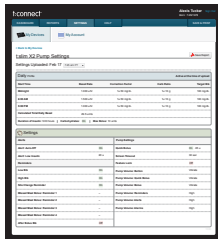
1 Dashboard: Overview		
	CGM Summary	Goal is <25% for Above Target Range (>180 mg/dL) ¹
		Goal is >70% for Target Range (70-180 mg/dL) ¹
		Goal is <4% for Below Target Range (<70 mg/dL) ¹
	Control-IQ Technology	If Time in Use is <90%, assess reason for pump or CGM inactivity
		Check if Sleep Activity is programmed and being used
		Check if Exercise Activity is being used for physical activity
	Average Daily Insulin Summary	Assess ratio of basal to bolus delivery
Update total daily insulin as needed		
Change Frequency	Check if infusion set is changed every two to three days	
2 CGM Hourly Report: Glycemic Patterns		
	Box-and-Whisker CGM Graph	Shorter boxes = Less glycemic variability
		Taller boxes = Greater glycemic variability
	Time of Day Boxes	Assess and identify glycemic trends throughout the morning, afternoon, evening, and overnight
3 Therapy Timeline: Glycemic Trends		
	CGM Tracing	Assess CGM tracing and identify if there are patterns (eg, overnight, hypoglycemia, pre-prandial, and post-prandial)
	Bolus Delivery	Assess cause and effect relationships of bolus deliveries and Control-IQ events (ie, Sleep and Exercise Activities)
	Basal Rates	Assess differences between profile and Control-IQ basal rates
		Identify patterns associated with hypoglycemia or hyperglycemia
Diabetes Self-Management Education	Determine if the patient needs additional self-management education (see Control-IQ technology therapy tips on back page) and/or their pump settings need adjustment (see step 4)	

continued on next page



Stepwise Approach to Analyzing Control-IQ Technology (continued)

4 Device Settings



Personal Profile Settings

Review pump settings. If necessary, the following personal profile settings can be modified:

- Basal rate
- Correction factor
- Insulin to carbohydrate ratio

Note: target blood glucose (110 mg/dL) and active insulin duration (5 hours) cannot be modified when using Control-IQ technology



Control-IQ Technology Therapy Tips²

- ✓ Use caution when overriding boluses. Extra insulin may already be on board from increased basal rates and automatic correction boluses.
- ✓ Consider programming a separate Personal Profile (eg, weekday, weekend, exercise, hormones)
- ✓ Continue to give manual correction boluses as needed.
- ✓ Pre-meal boluses are still required.
- ✓ Consider treating hypoglycemia with 5-10 grams of carbohydrate, especially if basal delivery has been stopped.
- ✓ Utilize the Exercise Activity to set a higher range of treatment values.
- ✓ Utilize the Sleep Activity and program Sleep Schedules for at least five hours.



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t:slim X2 Insulin Pump

Reference: 1. Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the international consensus on time in range. *Diabetes Care*. 2019;42(8):1593-1603. 2. Messer LH, Berget C, Forlenza GP. A clinical guide to advanced diabetes devices and closed-loop systems using the CARES paradigm. *Diabetes Technol Ther*. 2019;21(8):462-469.

Important Safety Information: Caution: Federal (USA) law restricts the t:slim X2 insulin pump and Control-IQ technology to sale by or on the order of a physician. The t:slim X2 pump and Control-IQ technology are intended for single patient use. The t:slim X2 pump and Control-IQ technology are indicated for use with NovoLog or Humalog U-100 insulin. **t:slim X2 insulin pump:** The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The t:slim X2 pump is indicated for use in individuals 6 years of age and greater. **Control-IQ technology:** Control-IQ technology is intended for use with a compatible integrated continuous glucose monitor (iCGM, sold separately) and ACE pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. **Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 14 years of age and greater.**

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 55 pounds.

Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use Control-IQ technology if using hydroxyurea. Users of the t:slim X2 pump and Control-IQ technology must: 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, transmitter, and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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