Analyzing Control-IQ Technology Data

TANDEM Diabetes Care

PROFESSIONAL

The Tandem Source platform makes it easy to view and analyze Control-IQ technology data. Conveniently view three different reports so you can work with your patients to spot trends and make meaningful adjustments.

Overview Report

The Overview Report offers a summary of the patient's pump and therapy data, giving a high-level look at your patient's glycemic control.

- **A** Summary of CGM usage now includes:
  - 01 Standard Deviation – reflects how much CGM glucose readings rise and fall, also known as glycemic variability
  - 02 Coefficient of variation – assesses the magnitude of glucose variability. The larger the %CV, the larger the variability in CGM readings.
  - 03 GMI (Glucose Management Indicator) – approximates the laboratory A1c level expected based on average glucose measured using CGM
- **B** Time in range comparison of the current two weeks to the previous two weeks
- **C** The Glucose trends graph shows a summary of glucose values during the selected period, combined as one day
- **D** Insulin summary now includes average daily carbs
- **E** Bolus review is now part of the Overview Report and breaks down boluses by type

Daily Timeline Report

The Daily Timeline Report shows glucose readings, basal and bolus insulin delivered, insulin suspension events, and other pump and therapy-related events that occurred during the selected date range.

On your computer, hover your cursor over select events to display a tooltip with information about that event.

- A Programmed Basal Rate
- B Automatic Correction Bolus
- C Food Bolus with number of carbs entered
- D Cartridge Change or Infusion Site Change
- E Food + Correction Bolus with number of carbs entered
- F Sleep Activity
- G Automatic basal insulin suspension
- H Pump Alarm
- I Multiple Correction Boluses

General Approach to Analyzing Control-IQ Technology

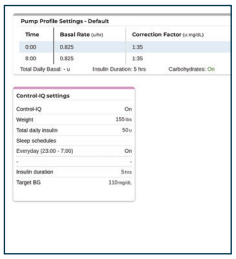
This section serves as a brief introduction to reviewing reports and highlights some items to look for within each reporting segment. For more information on how to analyze reports to make impactful settings adjustments, refer to "How to Make Control-IQ technology Adjustments Using Tandem Source."

1 Overview: Big Picture		
	**Control-IQ Technology**	If Time in Use is <90%, assess reason for pump or CGM inactivity • Assess use of Sleep Activity and Exercise Activity
	CGM Summary	Goal is <4% for Time Below Range (<70 mg/dL)[1]
		Goal is >70% for Time in Range (70-180 mg/dL)[1]
		Goal is <25% for Time Above Range (>180 mg/dL) with <5% Time above 250 mg/dL[1]
	Insulin Summary and Bolus Review	Assess ratio of basal to bolus delivery. Basal percentage typically between 40-60%
		Assess types of boluses • Use caution when overriding boluses. Extra insulin may already be on board from increased basal rates and automatic correction boluses.
	Glucose Trends	Combines all data in the reporting period into a 24-hour graph • Ideally, the lines would stay within the target range (70-180 mg/dL)
2 Daily Timeline: Glycemic Trends		
	**CGM Tracing**	Assess CGM tracing and identify if there are patterns (e.g., overnight, hypoglycemia, pre-prandial, and post-prandial)
	Bolus Delivery	Assess cause and effect relationships of bolus deliveries and Control-IQ technology events (i.e., Sleep Activity and Exercise Activity) • Consider discussing types of meals/timing of bolus, carb counting knowledge, and carb ratios
	Basal Rates	Assess differences between profile and Control-IQ technology basal rates
		Identify patterns associated with hypoglycemia or hyperglycemia

Continued on next page

continued...

3 Pump Settings



Personal Profile Settings

Review pump settings. If necessary, the following Personal Profile settings can be modified:

- Basal rate
- Correction factor
- Carb ratio

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

Up to six Personal Profiles can be created to personalize anticipated changes in insulin requirements

Consider programming a separate Personal Profile (e.g., weekday, weekend, exercise, hormones)

Responsible Use of Control-IQ Technology

Even with advanced systems such as the t:slim X2 insulin pump with Control-IQ technology, users are still responsible for actively managing their diabetes. Control-IQ technology does not prevent all high and low blood glucose events. The system is designed to help reduce glucose variability, but it requires that users accurately input information, such as meals and periods of sleep or exercise. Control-IQ technology will not function as intended unless all system components, including CGM, infusion sets and pump cartridges, are used as instructed. Importantly, the system cannot adjust insulin dosing if the pump is not receiving CGM readings. Because there are situations and emergencies that the system may not be capable of identifying or addressing, users should always pay attention to their symptoms and treat accordingly.

References: 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.

Important Safety Information: RX ONLY. 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 U-100 insulin only. 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 six 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 six 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, and the CGM transmitter and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.