TANDEM Diabetes Care + PANTHER® Diabetes Technology. Deciphered.

PROFESSIONAL

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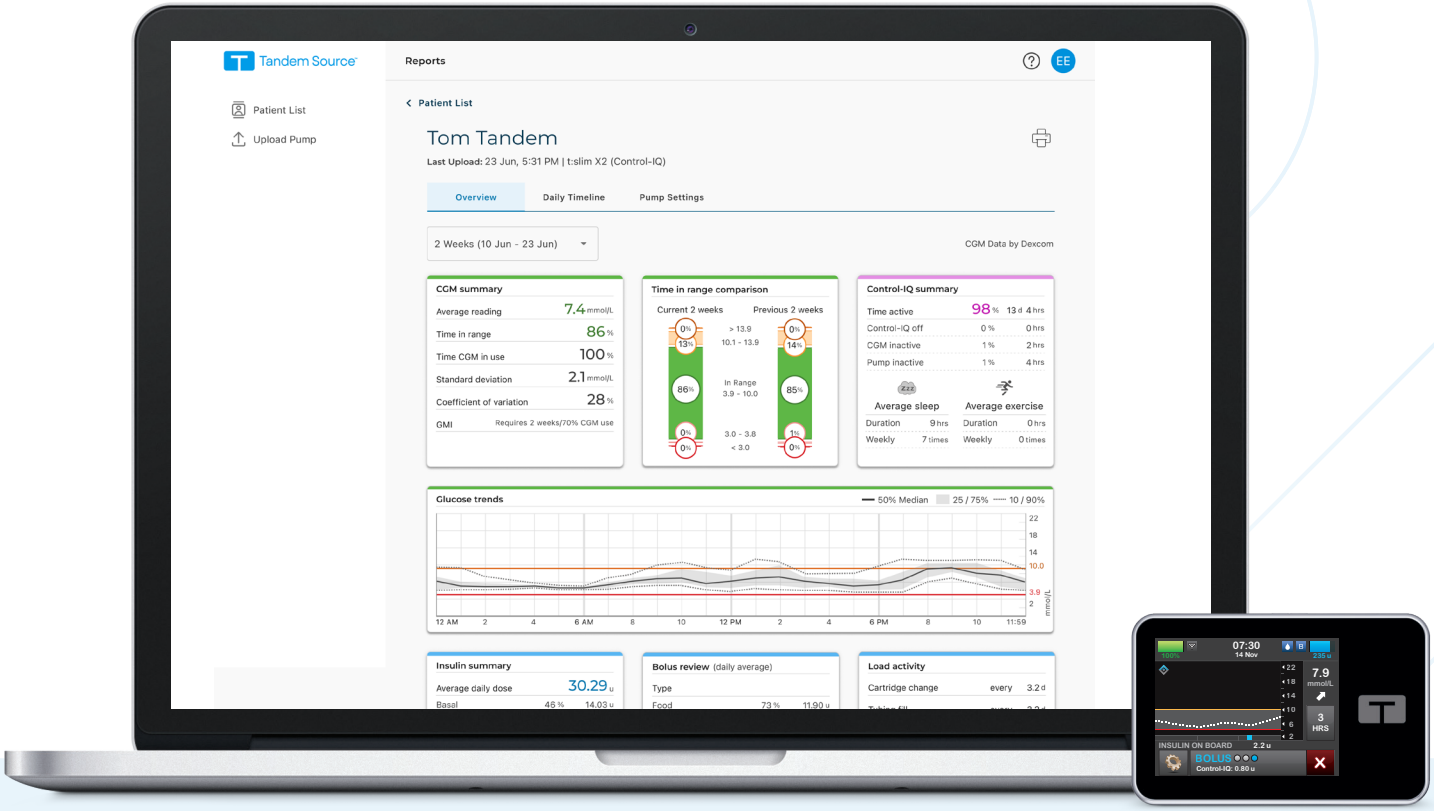
How to Make Control-IQ Technology Adjustments Using Tandem Source



Instructions for Use

View User's Pump Data

Visit **source.tandemdiabetes.com** and upload pump data or view reports.

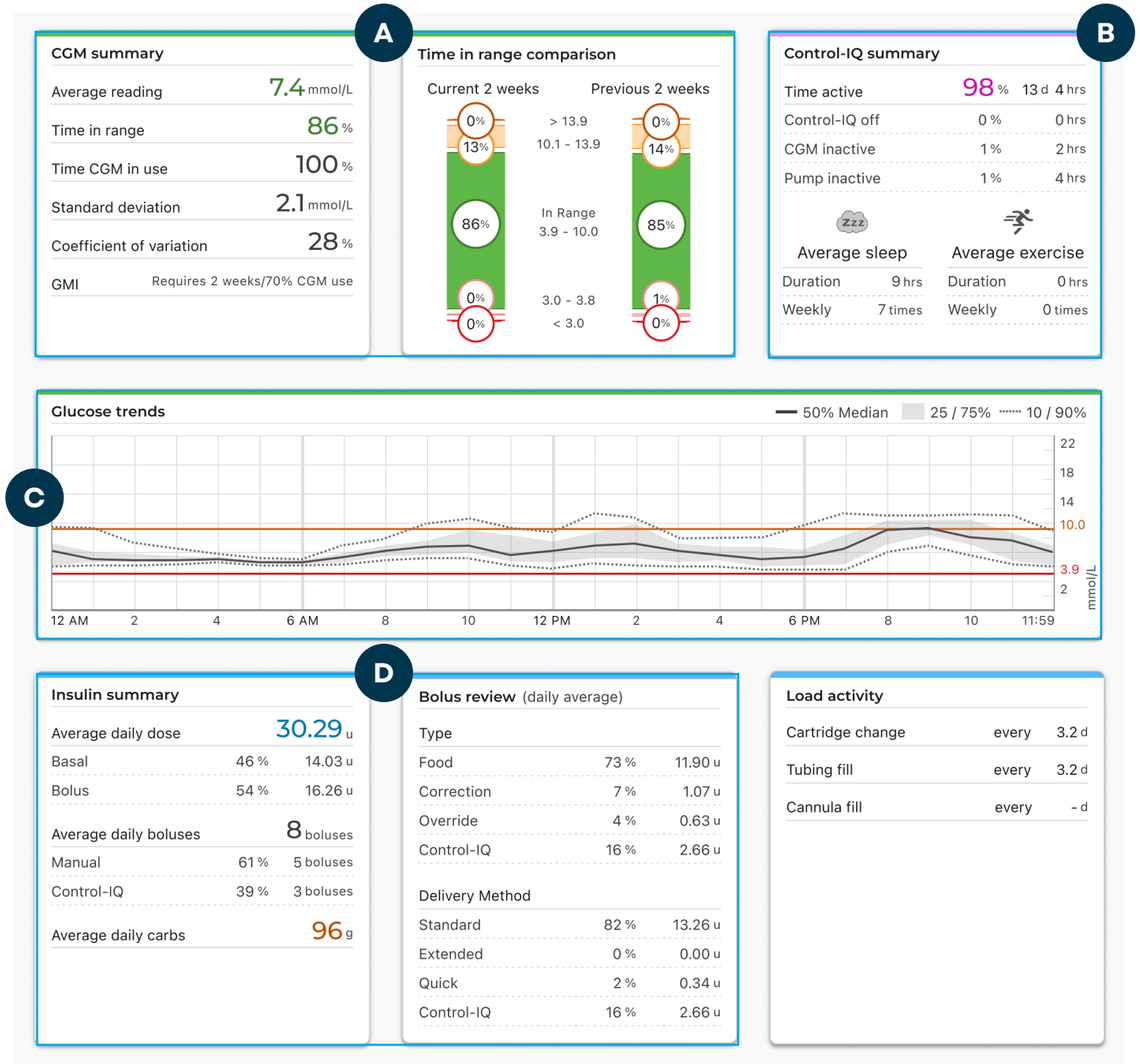
Save and Print Reports

Select Overview, Daily Timeline, and Pump Settings at last upload, and select a two week date range.

Follow the Worksheet

Get step-by-step guidance on clinical assessment, user education, and insulin dose adjustments.

01 Patterns



01 Patterns

A	B	C	D
Are glycemic targets being met?[1]	**Is Control-IQ technology being used?**	**Are there patterns of hypoglycemia and/ or hyperglycemia?**	**Assess insulin delivery**
Level 2 hypoglycemia: Time Below Range (TBR) <3.0 mmol/L, goal is <1% **Level 1 hypoglycemia:** TBR 3.0-3.8 mmol/L, goal is <4% **Time in range (TIR):** 3.9-10.0 mmol/L, goal is >70% **Level 1 hyperglycemia:** Time Above Range (TAR) 10.1-13.9 mmol/L, goal is <25% **Level 2 hyperglycemia:** TAR >13.9 mmol/L, goal is <5%	**Time Control-IQ in use (Percent of time that Control-IQ technology is in use):** Aim for >90%. If less, assess why. **CGM inactive (Time sensor not active):** Aim for <10%. If more, assess why. **Daily sleep:** Recommended to program Sleep Schedule. **Weekly exercise events:** Assess use of Exercise Activity and outcomes.	**Use Glucose trends to understand average glucose data throughout the day.** Focus on the areas where the average glucose is out of target range. The median line should ideally be mostly flat and within the target range of 3.9-10.0 mmol/L. 25/75% shows 50% of the glucose values; ideally, shaded area is narrow. 10/90% shows where 10% of values are below and 10% are above; ideally the closer the dotted lines are to the darker shaded area, the better.	**Ratio of basal to bolus delivery:** Basal percentage typically between 40-60%[2] If not, assess why (activity level, bolus behaviors, types of meals, increased interaction with system). **Consider verifying user's settings:** See back of handout for instructions on how to calculate. **Types of boluses:** Assess types of meals/ timing of bolus, carb counting knowledge, and carb ratios.

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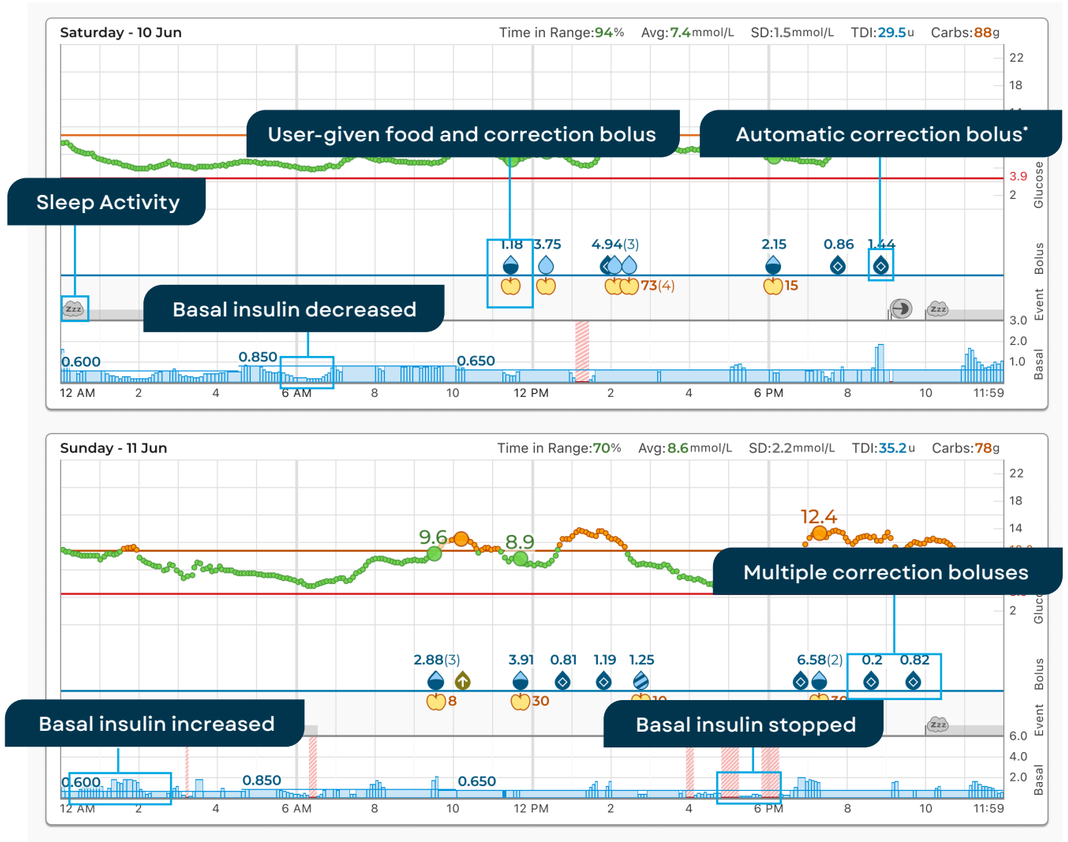
02 Reasons



Identify the predominant causes of a hypoglycemia or hyperglycemia pattern

Is a hypoglycemia pattern occurring?

- ✓ Fasting/overnight?
- ✓ After meal bolus? (1-3 hours after)
- ✓ Following hyperglycemia events?
- ✓ During or after exercise?

Is a hyperglycemia pattern occurring?

- ✓ Fasting/overnight?
- ✓ After meal bolus? (1-3 hours after)
- ✓ Following hypoglycemia events?

03 Solutions

Primary Safety Goal: Reduce Hypoglycemia (<3.9 mmol/L) to <4%
Primary Overall Goal: Increase TIR (3.9-10.0 mmol/L) to >70%

Pattern	Hypoglycemia Solution	Hyperglycemia Solution
Fasting/overnight	Recommend Sleep Schedule is set nightly. Reduce basal rates 10-20% 1-2 hours prior to hypoglycemia.	Recommend Sleep Schedule is set nightly. Increase basal rates 10-20% 1-2 hours prior to hyperglycemia.
After mealtime (1-3 hours after meal boluses)	Weaken the carb ratios by 10-20% (e.g., if 1:10, change to 1:12).	Strengthen carb ratios by 10-20% (e.g., if 1:10, change to 1:8). Consider timing of bolus.
Following high glucose	Weaken the correction factor by 10-20% (e.g., if 1:2.8, change to 1:3.0). This will impact both user-given and automatic correction boluses.	Strengthen the correction factor by 10-20% (e.g., if 1:2.8, change to 1:2.5). If unexplained hyperglycemia persists, refer to “Infusion Site Tips” on next page.
Following low glucose	Evaluate Insulin on Board. Treat extended hypoglycemia with 15g of carbs and recheck glucose in 15 minutes. Repeat as necessary.	Treat mild hypoglycemia with fewer grams of carbs (5-10g), especially after periods of reduced/suspended insulin delivery.
After a correction bolus was given (1-3 hours after)	Weaken the correction factor by 10-20% (e.g., if 1:2.8, change to 1:3.0). Avoid overriding recommended doses.	Strengthen correction factor by 10-20% (e.g., if 1:2.8, change to 1:2.5).
During or after exercise	Use Exercise Activity feature (timing varies based on intensity of physical activity). Consider alternate Personal Profile.	Educate on proper type, amount, and timing of additional carb intake prior to exercise.

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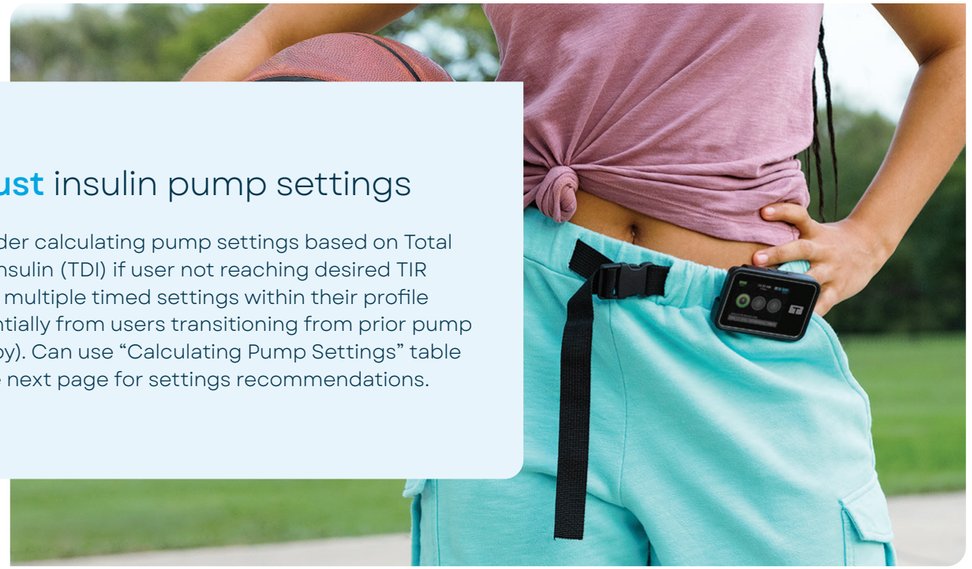


Adjust insulin pump settings

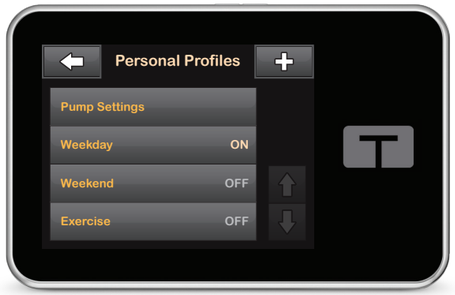
Consider calculating pump settings based on Total Daily Insulin (TDI) if user not reaching desired TIR or has multiple timed settings within their profile (potentially from users transitioning from prior pump therapy). Can use “Calculating Pump Settings” table on the next page for settings recommendations.

Adjustable parameters

Basal rates, carb ratios, and correction factors can be modified to patient needs. Target range values are preset to 6.25-8.9 mmol/L if Control-IQ technology is enabled, or modified to 6.25-6.7 mmol/L during Sleep Activity and 7.8-8.9 mmol/L during Exercise Activity. Correction factor directly impacts how Control-IQ technology automates insulin delivery, including bolus delivery. Studies show a more aggressive correction factor is associated with higher time in range with negligible impact to hypoglycemia.[3]

Personal Profiles

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



04 Education

Infusion Site Tips

When in doubt, change it out	Other times to change infusion set	Disconnecting
✓ If unexplained hyperglycemia persists (i.e., >13.9 mmol/L for >90 minutes) 01 Correct by injection 02 Change infusion set, site, and cartridge 03 Check for ketones	✓ If wetness (possible leaking) or redness/swelling (possible infection) at site ✓ If not changed within 2-3 days ✓ If insulin or infusion set is expired ✓ Rotate site often to avoid scar tissue/lipohypertrophy ✓ If experiencing repeated infusion site problems, try different cannula length or infusion set	✓ If disconnecting from the pump, suspend insulin so Control-IQ technology calculates insulin on board accurately and continue to monitor glucose ✓ If disconnecting for 1-4 hours, reconnect and deliver bolus if hyperglycemia occurs. Reduce amount for activity if neccessary. ✓ Always disconnect from site on body, not the tubing connector

Calculating Pump Settings

Basal Rate	Total Daily Basal Units	Pump TDI x %Basal (40-60%) = Total Daily Basal[2,4,5]	$\frac{\text{Pump TDI}}{\text{UNITS/DAY}} \times \frac{0.4\text{-}0.6}{\%\text{Basal}} = \frac{\text{UNITS/DAY}}{\text{(Total Daily Basal)}}$	
	Initial Basal Rate	Total Daily Basal ÷ 24 hours = Initial Basal Rate[2,4,5]	$\frac{\text{Total Daily Basal}}{\text{UNITS/DAY}} \div \frac{24}{\text{HOURS}} = \frac{\text{UNITS/HOUR}}{\text{(Initial Basal Rate)}}$	
Correction Factor	–	90† ÷ Pump TDI = Correction Factor[2,4]	$90 \div \frac{\text{Pump TDI}}{\text{UNITS/DAY}} = \frac{\text{MMOL/L: 1 UNIT}}{\text{(Correction Factor)}}$	
Carb Ratio	–	450 ÷ Pump TDI = Carb Ratio[5]	$450 \div \frac{\text{Pump TDI}}{\text{UNITS/DAY}} = \frac{\text{GRAMS: 1 UNIT}}{\text{(Carb Ratio)}}$	

†Can recalculate using 80-100

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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.

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***** If glucose values are predicted to be above 10.0 mmol/L, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 6.1 mmol/L and delivers 60% of that value.

References: 1. Diabetes Technology: Standards of Care in Diabetes - 2024. *Diabetes Care.* 2024;47(Suppl. 1):S126-S144. doi: 10.2337/dc24-S007. **2.** Walsh J, Roberts R. *Pumping Insulin: Everything for Success on an Insulin Pump and CGM.* 6th ed. San Diego, CA: Torrey Pines Press; 2016. **3**. Messer LH, Breton M. Therapy Settings Associated with Optimal Outcomes for t:slim X2 with Control-IQ Technology in Real World Clinical Care. *Diabetes Technol Ther.* 2023;25(12):877-882. doi: 10.1089/dia.2023.0308 **4.** Grunberger G, Abelseth JM, Bailey TS, et al. Consensus Statement by the American Association of Clinical Endocrinologist/American College of Endocrinology Insulin Pump Management Task Force. *Endocr Pract.* 2014;20(5):463-489. doi: 10.4158/EP14145.PS **5.** Hinnen D, DeGroot J. Therapy Intensification: Technology and Pain Management. In: *The Art and Science of Diabetes Care and Education.*5th ed. Chicago: Association of Diabetes Care and Education Specialists; 2021:592-593.

This product may not be right for you. Always read and follow the label.

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 indicated for use with NovoRapid, Admelog, 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 users 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 users. 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.

The **Tandem Source platform** is intended for use by individuals with diabetes mellitus who use Tandem Diabetes Care insulin pumps, their caregivers, and their healthcare providers in home and clinical settings. The Tandem Source platform supports diabetes management through the display and analysis of information uploaded from Tandem insulin pumps.