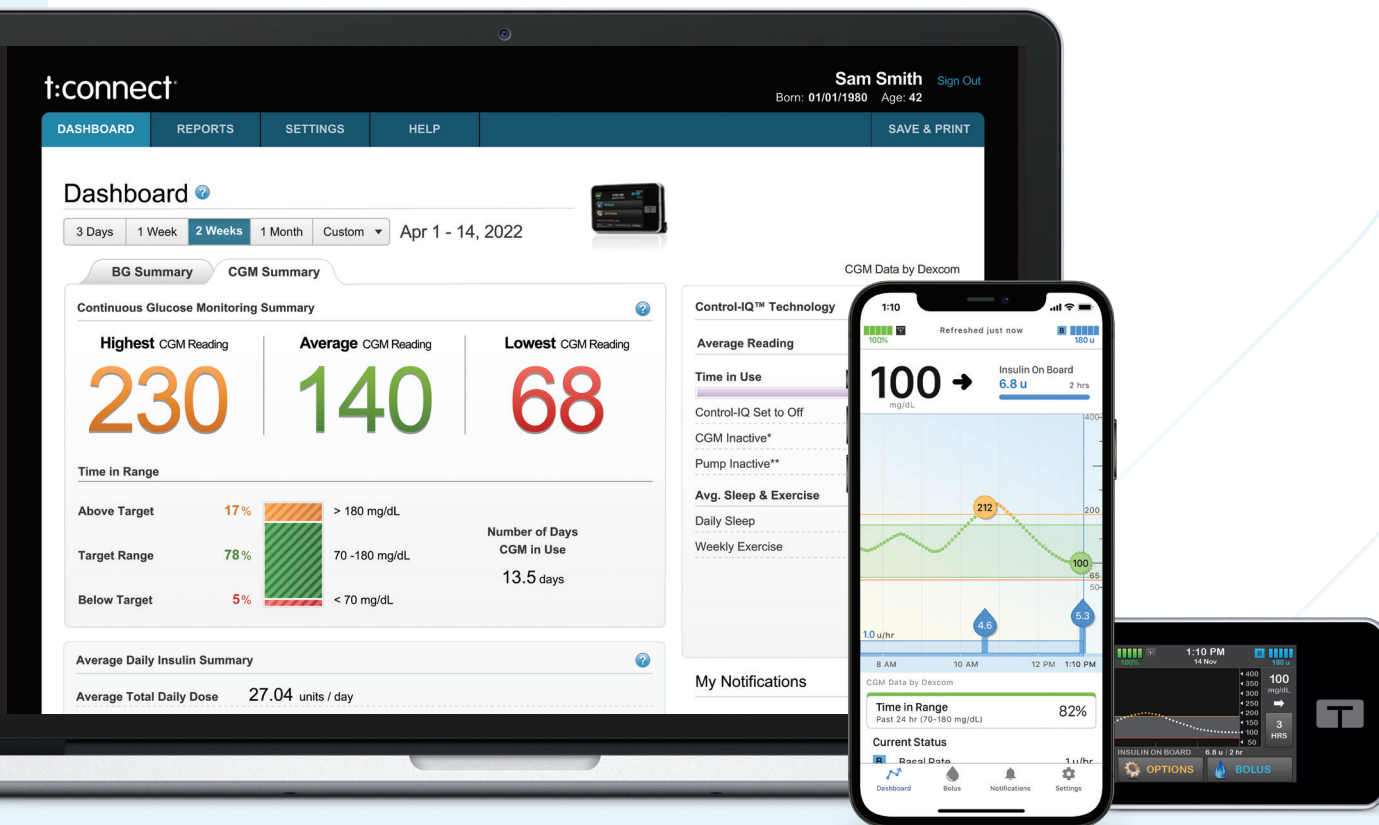


How to Make Control-IQ Technology Adjustments Using t:connect



Instructions for Use



View User's Pump Data

Visit tconnecthcp.tandemdiabetes.com and upload pump data or view reports. Set Target Range to 70-180 mg/dL as appropriate.



Save and Print Reports

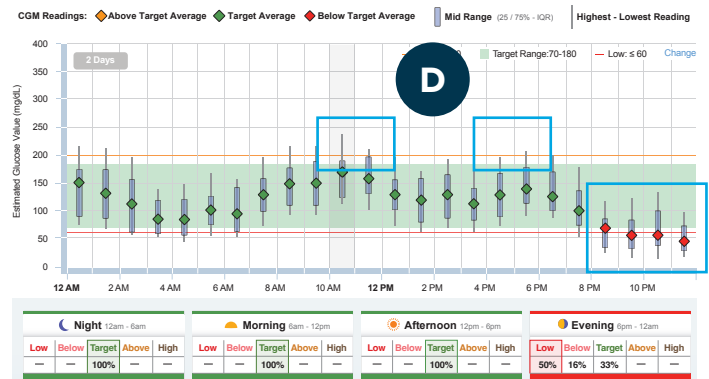
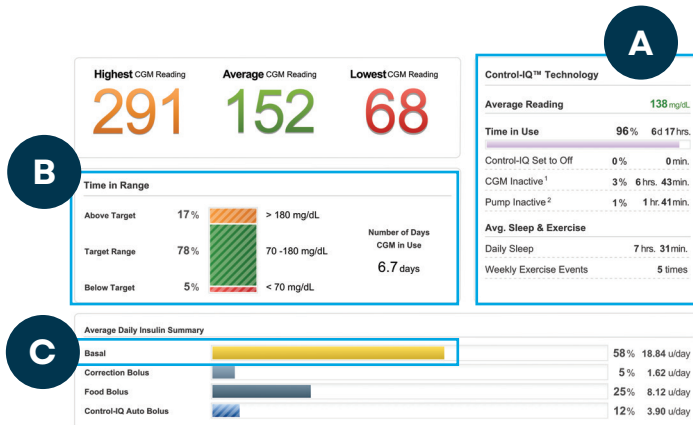
Select two weeks.
Select Dashboard,
Therapy Timeline, CGM
Hourly, Device Settings.



Follow the Worksheet

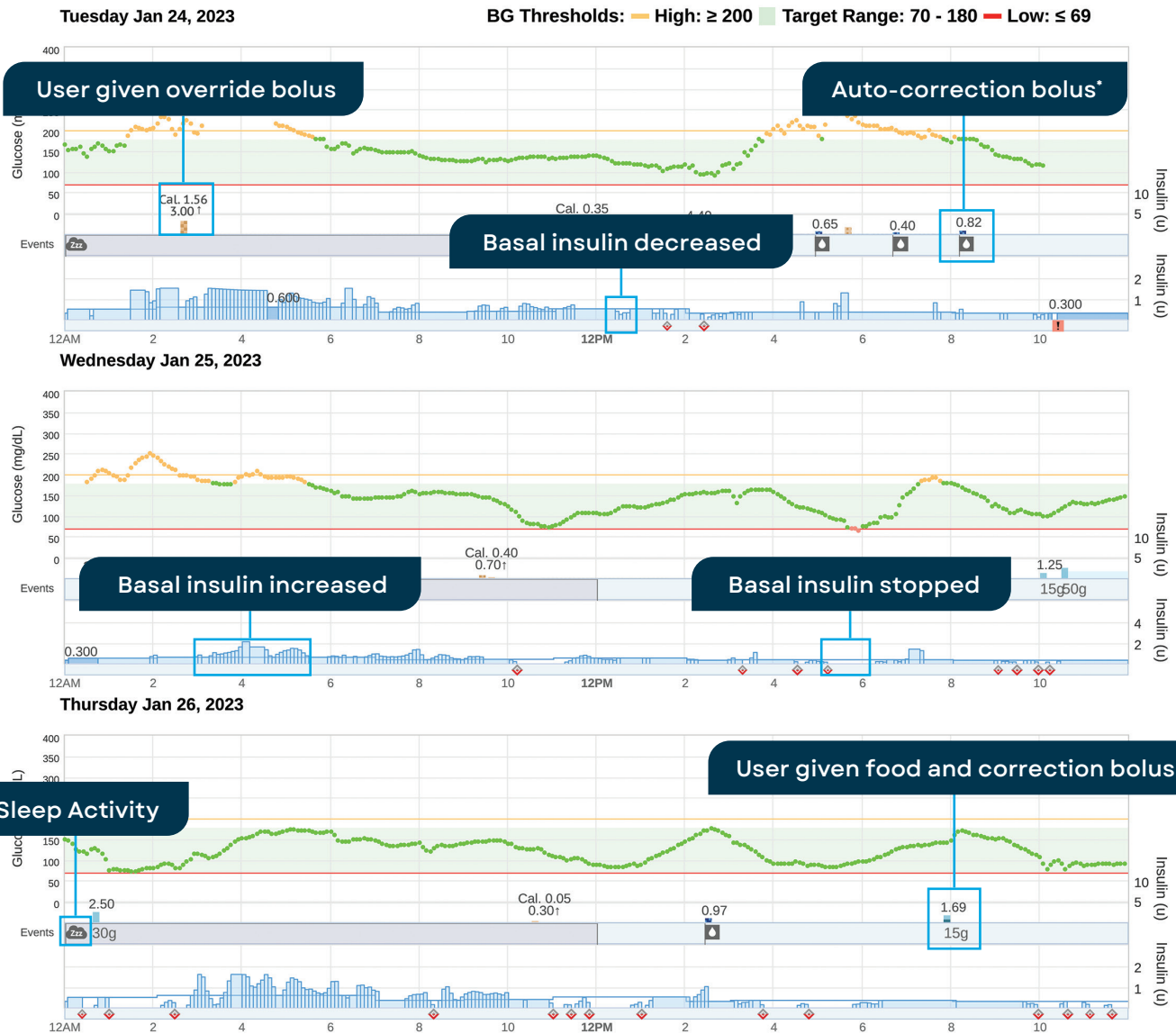
Step-by-step guidance
on clinical assessment,
user education, and insulin
dose adjustments.

01 Patterns



A	B	C	D
Is Control-IQ technology being used?	Are glycemic targets being met?	Assess insulin delivery	Are there patterns of hypoglycemia and/or hyperglycemia?
<p>Time in Use (Percent of time that Control-IQ technology is in use): Aim for > 90%. If less, assess why.</p> <p>CGM Inactive (Time sensor not active): Aim for < 10%. If more, assess why.</p> <p>Daily Sleep: Recommended to program Sleep Schedule and set for at least five hours.</p> <p>Weekly Exercise Events: Assess use of Exercise Activity and outcomes.</p>	<p>Time Below Range (TBR) Goal is < 4%</p> <p>Time In Range (TIR) Goal is > 70%</p> <p>Time Above Range (TAR) Goal is < 25%</p>	<p>Ratio of basal to bolus delivery: Basal percentage typically between 40-60%¹</p> <p>If not, assess why (activity level, bolus behaviors, types of meals, increased interaction with system).</p> <p>Consider verifying user's settings: See back of handout for instructions on how to calculate.</p> <p>Types of boluses: Assess types of meals/ timing of bolus, carb counting knowledge, and carb ratios.</p>	<p>Use CGM Hourly to understand average glucose data throughout the day. Assess and identify glycemic trends throughout the morning, afternoon, evening, and overnight. Focus on the areas where the average glucose is out of target range.</p> <p>Short Boxes: Possible adjustments to pump settings if out of target range.</p> <p>Tall Boxes: Can indicate a wide fluctuation in glucose values if out of target range. Would need more data to assess in the therapy timeline and conversations with the patient.</p> <p>Whiskers: Show outliers.</p>

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 (<70 mg/dL) to <4%
Primary Overall Goal: Increase TIR (70-180 mg/dL) to >70%

	Hypoglycemia	Hyperglycemia
Pattern	Solution	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)	Reduce 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	Reduce correction factor by 10-20% (e.g., if 1:50, change to 1:55). This will impact both user-given and auto-correction boluses.*	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)	Reduce correction factor by 10-20% (e.g., if 1:50 change to 1:55). Avoid overriding recommended doses.	Strengthen correction factor by 10% (e.g., if 1:50 change to 1:45).
 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.

04 Education



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 back for settings recommendations.

Adjustable parameters: Include basal rates, carb ratios, and correction factors. Treatment values are modified to the following when Control-IQ technology is turned on (112.5-160 mg/dL), and when Sleep Activity (112.5-120 mg/dL) or Exercise Activity (140-160 mg/dL) are enabled.

Up to Six Personal Profiles: Can be created to personalize anticipated changes in insulin requirements.

Infusion Site Tips



When in doubt, change it out:

- ✓ If unexplained hyperglycemia persists (i.e., >250 mg/dL for >90 minutes)
 - 01 Correct by injection
 - 02 Change infusion set and site
 - 03 Check for ketones



Other times to change infusion set:

- ✓ 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



Disconnecting:

- ✓ 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, deliver bolus if hyperglycemia occurs. Reduce amount for activity if necessary.
- ✓ If disconnecting for more than four hours, have injections available as a backup plan
- ✓ 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 ^{1,2,3}	$\frac{\text{Pump TDI}}{\text{Pump TDI}}$	$\times \frac{0.4-0.6}{\% \text{Basal}}$	$= \frac{\text{UNITS/DAY}}{\text{(Total Daily Basal)}}$
	Initial Basal Rate	Total Daily Basal ÷ 24 hours = Initial Basal Rate ^{1,2,3}	$\frac{\text{Total Daily Basal}}{\text{Total Daily Basal}}$	$\div 24 \text{ HOURS}$	$= \frac{\text{UNITS/HOUR}}{\text{(Initial Basal Rate)}}$
Correction Factor	–	1700 [†] ÷ Pump TDI = Correction Factor ^{1,2}	$1700 \div \frac{\text{Pump TDI}}{\text{Pump TDI}}$	UNITS	$= \frac{\text{MG/DL: 1 UNIT}}{\text{(Correction Factor)}}$
Carb Ratio	–	450 ÷ Pump TDI = Carb Ratio ³	$450 \div \frac{\text{Pump TDI}}{\text{Pump TDI}}$	$\frac{\text{UNITS/DAY}}{\text{DAY}}$	$= \frac{\text{GRAMS: 1 UNIT}}{\text{(Carb Ratio)}}$

[†]Can recalculate using 1450-2200

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 180 mg/dL, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 110 mg/dL and delivers 60% of that value. An Automatic Correction Bolus will not occur within 60 minutes of a bolus that has been delivered or cancelled.

References: 1. Walsh J, Roberts R. *Pumping Insulin: Everything for Success on an Insulin Pump and CGM*. 6th ed. San Diego, CA: Torrey Pines Press; 2016. 2. Grunberger G, Abelson 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 3. 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.

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.

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