

The International Diabetes Closed-Loop Trial, Protocol 3¹

The t:slim X2 Insulin Pump With Control-IQ Technology



The objective of this randomized, controlled trial was to determine the safety and efficacy of an advanced hybrid closed-loop system integrated with the t:slim X2 insulin pump to increase time in range (70-180 mg/dL)*.

Control-IQ™ technology on the t:slim X2™ insulin pump adjusts basal insulin delivery using Dexcom G6 continuous glucose monitoring (CGM) values and has several unique features. These include automatic correction boluses (up to one per hour), a dedicated hypoglycemia safety system, and gradual lowering and narrowing

of basal insulin delivery overnight designed to achieve glucose levels of approximately 110-120 mg/dL by morning.

Study Methods

The National Institutes of Health-funded study consisted of a 6-month multi-center trial, with participants (N=168) random-

ized 2:1 to use Control-IQ vs. a sensor-augmented pump (SAP). The primary outcome was percent time spent between 70-180 mg/dL, as measured by CGM.

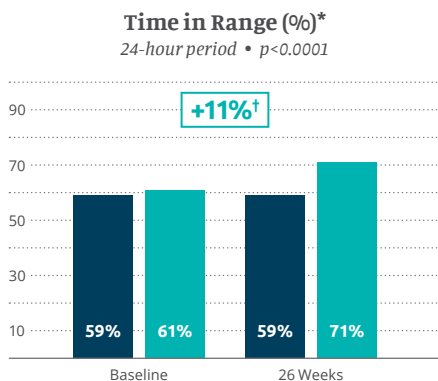
Inclusion Criteria

- Diagnosis of Type 1 for at least one year
- Age ≥14
- Insulin pump or multiple daily injections
- CGM user or naïve
- **No baseline HbA1c restrictions**

STUDY RESULTS

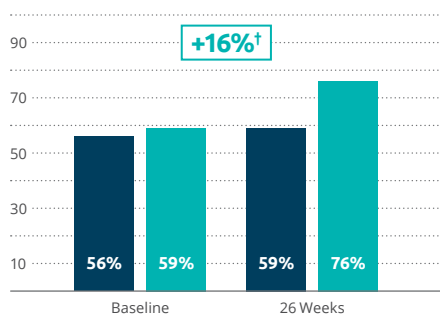
Increased Time in Range

Results showed 71% mean sensor time in range (70-180 mg/dL) for the Control-IQ (■) pump arm; an 11% increase† (an average of 2.6 hours per day) compared to SAP (■). The treatment effect was evident in the first month and was consistent over 6 months. There was improvement in time in range* during the overnight hours.

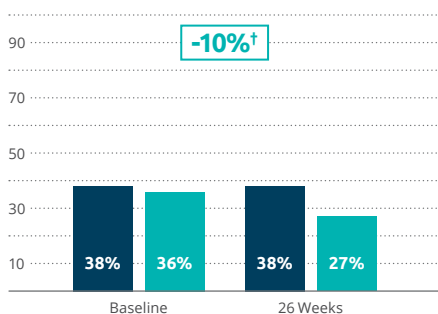


Average additional time per day that Control-IQ participants spent in range compared to SAP users.

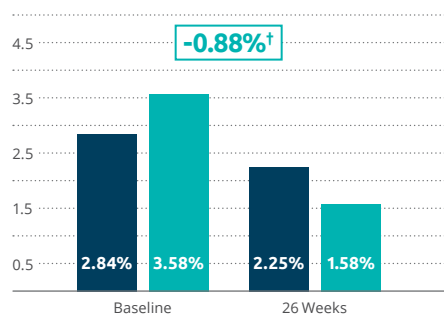
Overnight Time in Range (%)*
12 AM - 6 AM • p<0.0001



Hyperglycemia Time >180 mg/dL (%)*
p<0.001



Hypoglycemia Time <70 mg/dL (%)*
p<0.001



* As measured by CGM † Risk-Adjusted Difference (95% CI), Control-IQ (Closed-Loop) Minus SAP (Control) Arms. All results are represented in mean values.



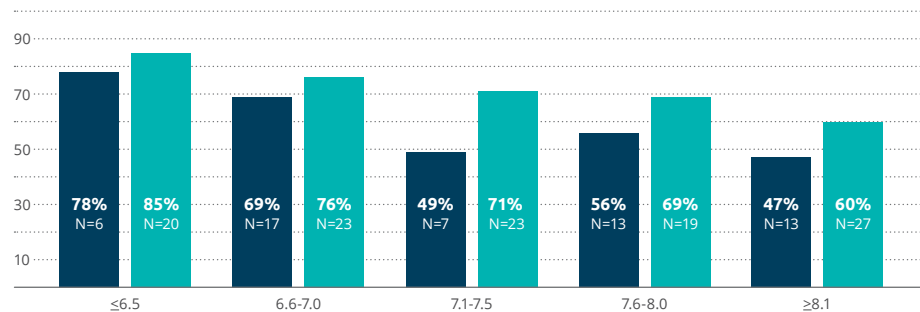
RESULTS (continued)

Time in Range Improvements

Time in range* improvements were observed at the end of the 6-month study for a wide variety of Hemoglobin A1C (HbA1C) groups when comparing Control-IQ (■) technology to SAP (■).

*As measured by CGM

CGM Mean Time in Range (%)* by Baseline HbA1C Level



USABILITY RESULTS

Easy to Learn and Use²

All 168 participants completed the 6-month study, and participants in the Control-IQ arm spent 92% of the time with Control-IQ technology active and available. At the conclusion of the study, participants completed a technology acceptance survey and the system was found to be easy to use.



said Control-IQ technology was **easy to use.**



said they **trusted the device** with the Control-IQ feature.



felt it was useful in **managing their diabetes.**

Go to tandemdiabetes.com/providers to learn more about Control-IQ technology on the t:slim X2 insulin pump.



Responsible Use of Control-IQ Technology

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 patient's CGM is not working properly or is unable to communicate with their pump. Patients 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.



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t:simulator App
A free virtual pump demo



Reference: 1. Brown SA, Kovatchev BP, Raghinaru D, et al. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. *N Eng J Med.* 2019;381(18):1701-1717. 2. 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: 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 insulin pump with integrated 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. 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. Control-IQ technology is intended for single patient use. Control-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin.

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. Users of the pump and Control-IQ technology must: use the insulin pump, iCGM, 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. For additional important safety information, visit tandemdiabetes.com/safetyinfo.

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