TANDEM DIABETES CARE

Air Liquide HEALTHCARE

CLINICAL STUDY RESULTS

The International Diabetes Closed-Loop Trial, Protocol 3[1]

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

The objective of this randomised, 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 or 3.9-10.0 mmol/L).*

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 hypoglycaemia safety system, and gradual lowering and narrowing of basal insulin delivery overnight designed to achieve glucose levels of approximately 110-120 mg/dL or 6.1-6.7 mmol/L by morning.

Study Methods

The US National Institute of Health (NIH)-funded study consisted of a 6-month multi-center trial, with participants (N=168) randomised 2:1 to use Control-IQ technology vs. a sensor-augmented pump (SAP). The primary outcome was percent time spent between 70-180 mg/dL or 3.9-10.0 mmol/L, as measured by CGM.

Inclusion Criteria

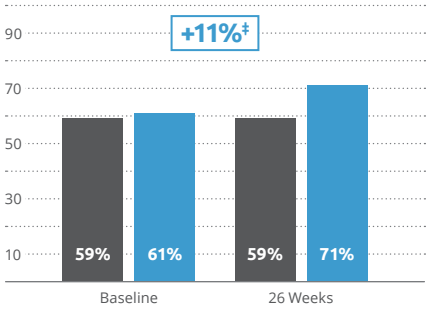
- Diagnosis of Type 1 for at least one year
- Age ≥14
- Insulin pump or multiple daily injections
- CGM user or naïve
- **No baseline HbA1c restrictions**

STUDY RESULTS

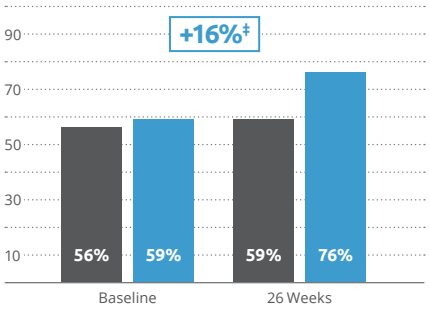
Increased Sensor Time in Range

Results showed 71% mean sensor time in range (70-180 mg/dL or 3.9-10.0 mmol/L) for the Control-IQ technology (■) 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.

Time in Range (%)*
24-hour period • p<0.0001



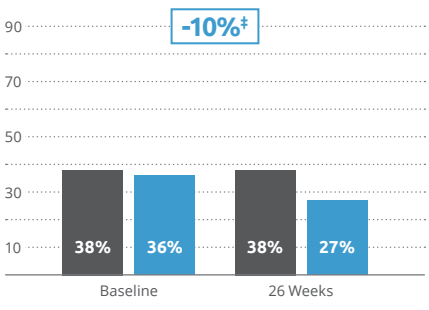
Overnight Time in Range (%)*
12 AM - 6 AM • p<0.0001



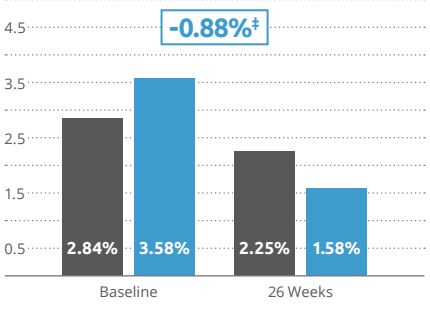
2.6 hours

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

Hyperglycaemia Time >180 mg/dL / >10.0 mmol/L (%)*
p<0.001



Hyperglycaemia Time < 70mg/dL / < 3.9mmol/L (%)*
p<0.001



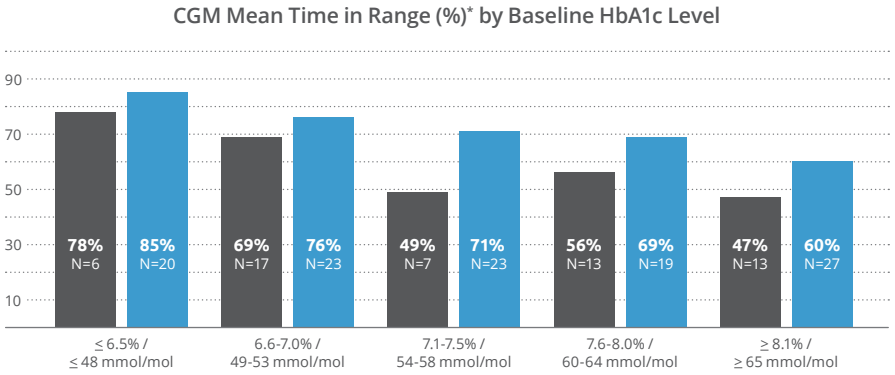
** As measured by CGM ‡ Risk-Adjusted Difference (95% CI), Control-IQ technology (Closed-Loop) minus SAP (Control) Arms. All results are represented in mean values.*

The International Diabetes Closed-Loop Trial, Protocol 3

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*



USABILITY RESULTS

Easy to Learn and Use²

All 168 participants completed the 6-month study, and participants in the Control-IQ technology 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.

97% said Control-IQ technology was **easy to use.**

91% said they **trusted the device** with the Control-IQ feature.

97% felt it was useful in **managing their diabetes.**

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.

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* As measured by CGM. † If glucose values are predicted to be above 180 mg/dL or 10.0 mmol/L, Control-IQ technology calculates a correction bolus using the Personal Profile settings and a target of 110 mg/dL or 6.1 mmol/L 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. ‡ Risk-Adjusted Difference (95% CI), Control-IQ technology (Closed-Loop) minus SAP (Control) Arms. **References: 1.** Brown SA, Kovatchev BP, Raghinaru D, et al. Six-month randomised, 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: The t:slim X2 insulin pump and the t:slim X2 insulin pump with Control-IQ technology are intended for single patient use. The t:slim X2 pump and the t:slim X2 pump with Control-IQ technology are indicated for use with NovoRapid or Humalog U-100 insulin. t:slim X2 insulin pump: The t:slim X2 pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices. The t:slim X2 pump is indicated for use in individuals six years of age and greater. t:slim X2 insulin pump with Control-IQ technology: The t:slim X2 pump with Control-IQ technology is intended for use with a compatible continuous glucose monitor (CGM, sold separately) and the t:slim X2 pump to automatically increase, decrease, and suspend delivery of basal insulin based on CGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. The t:slim X2 pump with Control-IQ technology is intended for persons six years of age and greater.

WARNING: The t:slim X2 pump with 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 25 kilograms.

The t:slim X2 pump with Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use the t:slim X2 pump with Control-IQ technology if using hydroxyurea. Users of the t:slim X2 pump and the t:slim X2 pump with 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 recognise all functions of the pump, including alerts, alarms, and reminders. All Tandem Diabetes Care pumps, transmitters, and sensors must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

For further information please contact us:
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Air Liquide Healthcare is a world leader in medical gases, home healthcare, hygiene products and healthcare specialty ingredients. It aims to provide customers in the continuum of care from hospital to home with medical products, specialty ingredients and services that contribute to protecting vulnerable lives.

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