t:slim X2 Insulin Pump™ with Control-IQ™ Technology Real-World Outcome

TANDEM DIABETES CARE

For Healthcare Professionals

STUDY OUTLINE

The t:slim X2™ insulin pump with Control-IQ™ technology† is designed to help increase time in range (TIR) of 3.9-10.0 mmol/L using Dexcom G6 CGM values to predict glucose levels 30 minutes ahead and adjust insulin dosing accordingly.

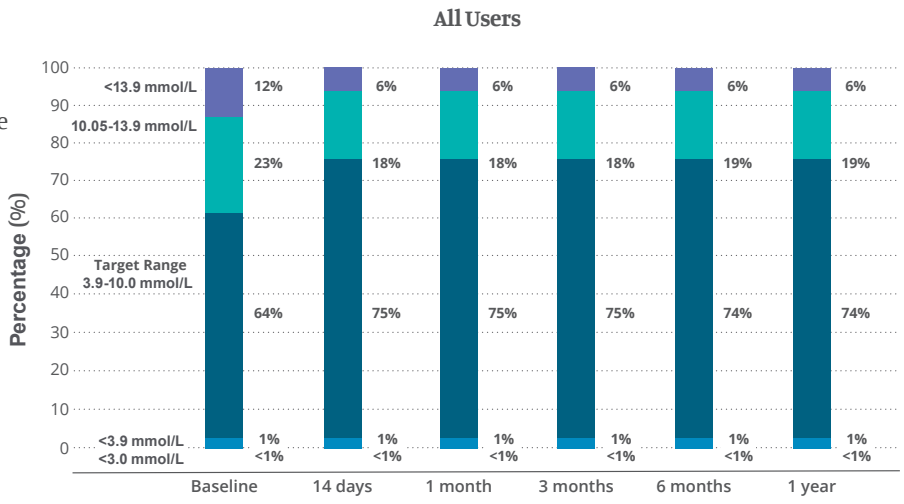
Data is based on a retrospective, longitudinal analysis of a Tandem web application†, using glycaemic data from 9,451 participants who had at least 12 consecutive months of data using t:slim X2 insulin pump with Control-IQ technology as of February 11, 2021. Participants were six years and older, 83% had type 1 diabetes, and had at least two weeks of CGM data with ≥75% CGM availability before Control-IQ technology initiation. This study was funded and published by academic researchers, Marc Breton and Boris Kovachev from UVA, Charlottesville, VA.[1]

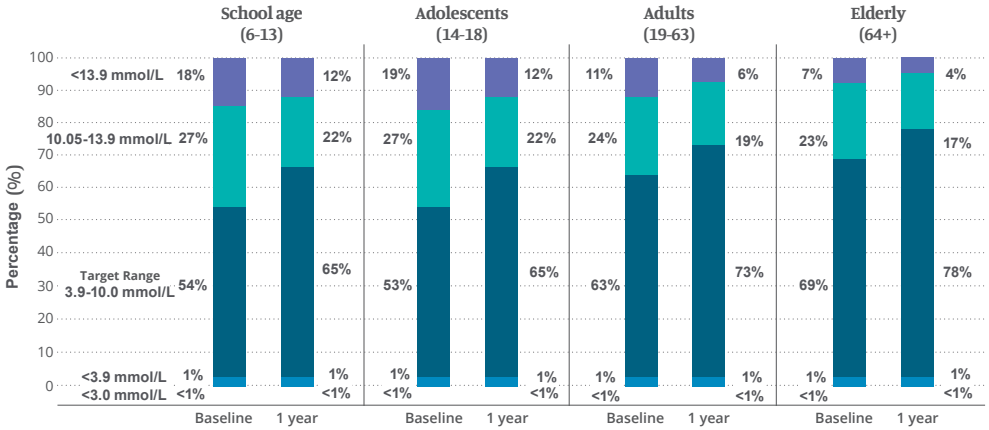
STUDY RESULTS

Immediate and sustained improvements in time in range*

Overall, sensor TIR increased from 63.6% at baseline to 73.6% (+10%) over the 12 months of Control-IQ technology use. Time spent below 3.9 mmol/L remained consistent at approximately 1%. These glycaemic results were immediate after two weeks and sustained across all participants for the 12-month period.

2.4 hours per day time spent in range[1] (3.9-10.0 mmol/L)*





Glycaemic improvement across all age groups

Improvement in TIR* was observed in all age groups which demonstrates the benefits of Control-IQ technology for both children and adults. Notably, there was an increased TIR* of 11% in the school age group and 12% in the adolescent age group.

94% of time in closed-loop automation

STUDY RESULTS

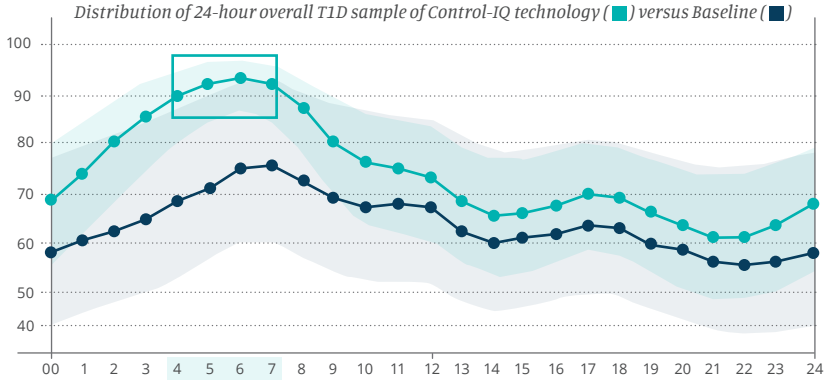
Improved time in range* overnight

With a dedicated Sleep Activity, Control-IQ technology is designed to gradually narrow and lower treatment values overnight to help achieve glucose levels of 6.1-6.7 mmol/L by morning.

Patients with T1D showed a profound increase in time in range* overnight, reaching a median above 90% between 04:00-07:00 highlighting the benefits of the Sleep Activity in Control-IQ technology.

Percentage of Time Spent 3.9-10.0 mmol/L*

Distribution of 24-hour overall T1D sample of Control-IQ technology ( ) versus Baseline ( )



Long term real-world outcomes of users of the t:slim X2 pump with Control-IQ technology retained, and to some extent exceeded, the results obtained in the randomised controlled trials, demonstrating glycaemic improvements.

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 your diabetes. Control-IQ technology will not be able to predict sensor glucose values and adjust insulin dosing if the CGM is not working properly or is unable to communicate with the pump. Always ensure patients pay attention to symptoms and blood glucose levels and treat accordingly.

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For more information on the t:slim X2 insulin pump, please contact us on **1300 851 056** or at **diabetes@amsl.com.au**

amsldiabetes.com.au

amsl diabetes
a Dexcom company

*As measured by CGM. †Tandem Web application are not currently available in Australia. References: 1. Breton MD, Kovatchev BP. One Year Real-World Use of the Control-IQ Advanced Hybrid Closed-Loop Technology. Diabetes Technol Ther. 2021. DOI: 10.1089/dia.2021.0097. Important Safety Information: Caution: The t:slim X2 pump with Basal-IQ and Control-IQ technology is intended for single patient use. The t:slim X2 pump is indicated for use with NovoRapid or Humalog U-100 insulin. 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 6 years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with the Dexcom G6 continuous glucose monitoring system (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 6 years of age and greater. Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. 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 professional; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare professional(s) regularly; and have adequate vision and/or hearing to recognise 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, consult the User Guide: amsldiabetes.com.au/resources.