



Tandem Diabetes Care Announces Health Canada Approval of the t:slim X2 Insulin Pump with Control-IQ Advanced Hybrid Closed-Loop Technology

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SAN DIEGO--(BUSINESS WIRE)--Nov. 23, 2020-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced Health Canada approval of the t:slim X2™ insulin pump with Control-IQ™ technology. Control-IQ technology is an advanced hybrid closed-loop feature designed to help increase time in range (3.9-10 mmol/L)¹ and deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. The system integrates with Dexcom G6 continuous glucose monitoring (CGM), which requires no fingersticks for calibration or diabetes treatment decisions.^{2,3,4}

All in-warranty t:slim X2 pump users in Canada will have the option to add Control-IQ technology to their existing pump beginning in March 2021 via remote software update. The update will be free of charge through December 31, 2021.⁵ Tandem expects to begin shipping t:slim X2 insulin pumps with Control-IQ technology in Canada in the first quarter of next year. The company will continue offering the t:slim X2 insulin pump with Basal-IQ™ predictive low glucose suspend technology for users seeking a system designed specifically to help prevent lows.

“The t:slim X2 insulin pump with Control-IQ technology is the most advanced automated insulin dosing system available in the world and is a testament to our commitment to improving the lives of people with diabetes,” said John Sheridan, president and CEO of Tandem Diabetes Care. “We are thrilled to be able to bring the benefits of this advanced hybrid closed-loop system to the Canadian diabetes community.”

Control-IQ technology uses Dexcom G6 CGM values to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly; including delivery of automatic correction boluses up to once per hour. If sensor glucose values are predicted to drop below 6.25 mmol/L, basal insulin delivery is reduced, and when predicted to be below 3.9 mmol/L, basal insulin delivery is stopped. If glucose values are predicted to be above 8.9 mmol/L, basal insulin delivery will be increased. If glucose values are predicted to be above 10 mmol/L, Control-IQ technology calculates an automatic correction bolus with a target of 6.1 mmol/L and delivers 60 percent of that value. It will do this up to once per hour as needed. Control-IQ technology also offers optional settings for sleep and exercise that will change the treatment values to better match the different physiologic needs during these activities.

Benefits of Control-IQ Advanced Hybrid Closed-Loop Technology

Predicts and helps prevent highs and lows – Control-IQ technology uses CGM readings to predict glucose values 30 minutes ahead and can increase, decrease, or stop basal insulin delivery to help keep glucose in range (3.9-10 mmol/L).¹

Automatic Correction Boluses – If glucose values are predicted to be above 10 mmol/L, Control-IQ technology calculates a correction bolus with a target of 6.1 mmol/L and delivers 60 percent of that value. It will do this up to once an hour as needed.

Accommodates for sleep and exercise – Control-IQ technology offers optional settings for sleep and exercise that change the treatment values to better match the different physiologic needs during these activities.

No fingersticks – With Dexcom G6 CGM integration, the Control-IQ feature works with no fingersticks required for mealtime dosing or calibration.² Other benefits of the Dexcom G6 CGM include an extended 10-day wear, acetaminophen blocking,⁶ and the ability to share real-time CGM data with up to 5 followers.⁷

Easy to use – The system has no complicated criteria to keep Control-IQ technology on. If the CGM signal is temporarily lost, the Control-IQ feature will resume automatically when the CGM is back in range. In the pivotal study, participants gave Control-IQ technology a 4.7 out of 5.0 for ease of use, and a 4.8 out of 5.0 for desire to continue use of the system.⁸

Standard Features of the t:slim X2 Insulin Pump

Colour touchscreen – The large colour touchscreen on the t:slim X2 pump is easy to read, simple to learn, and intuitive to use for anyone familiar with a smartphone or tablet.

Small and discreet – The t:slim X2 pump is up to 38 percent smaller than other pumps,⁹ yet can hold up to 300 units of insulin.

Can be used with or without the Control-IQ feature or CGM – When advanced features are turned off, the t:slim X2 pump removes the CGM chart from the screen and puts the Bolus and Option buttons front and center for easy access.

Free Software Update for Current t:slim X2 Pump Users

All in-warranty t:slim X2 pump users in Canada will have the option to add the Control-IQ feature free of charge through December 31, 2021 via a software update using a personal computer. Current in-warranty t:slim X2 pump users in Canada will receive emails with more information about the process, including a link to a 30 to 45-minute online training module which must be completed prior to updating their pump. Internet and computer

access are required for pump updates. Tandem Diabetes Care expects the Control-IQ technology software update to be available for current t:slim X2 pump users in March 2021. Information about the requirements and update process is available at <https://www.tandemdiabetes.com/controliq-update>

Control-IQ Technology – Clinical Outcomes

Data from the NIH-funded DCLP3 study, published by the *New England Journal of Medicine* in October 2019, compared use of a t:slim X2 insulin pump with Control-IQ technology and Dexcom G6 CGM integration (n=112) to a control group using a t:slim X2 pump with just Dexcom G6 CGM integration (n=56).⁶ This study was the first large-scale 6-month closed-loop study to include a dedicated control group. There were no exclusion criteria based on hemoglobin A1c, history of acute complications, or previous experience using an insulin pump, and all participants completed the study. Those using Control-IQ technology experienced 71 percent time in range (3.9-10 mmol/L) on average compared to 59 percent in the control group.¹ Sensor time spent above 10 mmol/L was 27 percent per day on average with Control-IQ technology and 39 percent in the control group. Sensor time spent below 3.9 mmol/L was 1.4 percent per day on average with Control-IQ technology and 1.9 percent in the control group. The system remained connected to CGM with Control-IQ technology on and active an average of 92 percent of the 26-week study period. In a five-point survey at the end of the study, users overwhelmingly rated the Control-IQ system as simple to use, giving it a 4.5 for trust, a 4.7 for ease of use, and a 4.8 for desire to continue using the system.⁸

Responsible Use of Predictive Technologies

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 accurate input of information, such as meals and periods of sleep or exercise. Control-IQ technology will not function as intended unless all system components are used as instructed, including CGM, infusion sets, and pump cartridges. Importantly, the system cannot adjust insulin dosing if the pump is not receiving CGM readings. Since there are situations and emergencies that the system may not be capable of identifying or addressing, users must always pay attention to symptoms and treat according to their healthcare provider's recommendations.

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 six years of age and greater. The pump is able to reliably and securely communicate with compatible, digitally connected devices.

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) 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 the management of Type 1 diabetes mellitus in 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 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](https://www.tandemdiabetes.com/safetyinfo) for additional important safety information.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, Inc. (www.tandemdiabetes.com) is a medical device company dedicated to improving the lives of people with diabetes through relentless innovation and revolutionary customer experience. The Company takes an innovative, user-centric approach to the design, development, and commercialization of products for people with diabetes who use insulin. Tandem manufactures and sells the t:slim X2 insulin pump with Control-IQ technology. The t:slim X2 pump is capable of remote feature updates using a personal computer, and is the only automated insulin dosing device approved for children as young as six years old. Tandem is based in San Diego, California.

Tandem Diabetes Care, Basal-IQ, Control-IQ, and t:slim X2 are either registered trademarks or trademarks of Tandem Diabetes Care, Inc. in the United States and/or other countries. Dexcom and Dexcom G6 are either registered trademarks or trademarks of Dexcom, Inc. in the United States and/or other countries. All other third-party marks are the property of their respective owners.

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. These forward-looking statements relate to, among other things,

the anticipated timing for the commercial launch of the t:slim X2 pump with Control-IQ technology in Canada and our ability to offer the Control-IQ technology software update for current t:slim X2 pump users in Canada. These statements are subject to numerous risks and uncertainties, including our ability to obtain and retain registration as an approved vendor for provincial device reimbursement programs, our ability to fulfill commercial demand for the t:slim X2 with Control-IQ technology, our ability to facilitate online training for existing t:slim X2 customers upgrading their devices, and the risk that we may encounter other challenges that may delay the commercial launch of the t:slim X2 pump with Control-IQ technology in Canada, as well as other risks identified in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and other documents that we file with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Tandem undertakes no obligation to update or review any forward-looking statement in this press release because of new information, future events or other factors.

¹ As measured by CGM

² If glucose alerts and CGM readings do not match symptoms or expectations or if taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions.

³ Dexcom G6 CGM sold separately

⁴ The Dexcom G6 CGM transmitter can only be paired with one medical device (either a Dexcom receiver or t:slim X2 pump) and one consumer device (phone or tablet) at the same time.

⁵ Additional training is required for this software update.

⁶ Dexcom G6 CGM readings can be used to make diabetes treatment decisions when taking up to a maximum acetaminophen dose of 1,000 mg every six hours. Taking a higher dose may affect the Dexcom G6 CGM readings.

⁷ Separate Follow App required.

⁸ Brown SA, Kovatchev D, Raghinaru JW, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *N Engl J Med.* 2019;381(18):1707-17.

⁹ 38 percent smaller than MiniMed 630G and 670G and at least 28 percent smaller than MiniMed 530G, Animas Vibe and Omnipod System. Data on file, Tandem Diabetes Care.

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