



Tandem Diabetes Care Announces Commercial Launch of the t:slim X2 Insulin Pump with Control-IQ Technology in the United States

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SAN DIEGO--(BUSINESS WIRE)--Jan. 15, 2020-- Tandem Diabetes Care, Inc. (NASDAQ: TNDM), a leading insulin delivery and diabetes technology company, today announced its commercial launch of the t:slim X2™ insulin pump with Control-IQ™ technology, an advanced hybrid-closed loop feature designed to help increase time in range (70-180 mg/dL)¹. It is the first and only system cleared to 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} The Company will soon begin sending emails with update instructions to all in-warranty t:slim X2 users in the United States, who have the option to add the new feature free of charge via remote software update. t:slim X2 pumps pre-loaded with Control-IQ technology are now shipping to new customers.

The t:slim X2 insulin pump with Control-IQ technology uses CGM values, in conjunction with other variables such as insulin on board, to predict sensor glucose levels 30 minutes ahead and adjust insulin delivery accordingly. If glucose values are predicted to drop below 112.5 mg/dL, basal insulin delivery is reduced, and when predicted to be below 70 mg/dL, basal insulin delivery is stopped. If glucose values are predicted to be above 160 mg/dL in the next 30 minutes, basal insulin will be increased. If glucose values are predicted to be above 180 mg/dL, Control-IQ technology calculates a correction bolus with a target of 110 mg/dL, and delivers 60 percent of that value up to once an hour as needed. Control-IQ technology also offers optional settings for sleep and exercise that will change treatment values to better match the different physiologic needs during these activities.

"Control-IQ technology has been described by study participants and investigators as 'life-changing,' 'easy to use,' and 'a new standard of care in insulin therapy management,' which is incredible feedback as we commence this commercial launch and begin bringing its benefits to more people with diabetes," said John Sheridan, President and Chief Executive Officer. "We began processing orders earlier this month and are excited about the opportunity this launch presents for 2020. As these new customers move through the insurance verification process it will provide us with valuable trend information that will be used in setting our financial guidance for the year."

Update Instructions for Current t:slim X2 Pump Users

No action is required at this time. Individual emails are being sent to all in-warranty t:slim X2 pump users in the United States with information on how to start the update process. Emails are being sent out in batches, with all users anticipated to have received the information by the end of January. The Control-IQ technology update will require a new prescription and completion of online training, all of which will be coordinated through a simple-to-use online portal. Internet and computer access are required for pump updates. Control-IQ technology is only compatible with the Dexcom G6 CGM System. t:slim X2 insulin pumps updated to Control-IQ technology cannot revert to previous software versions following this software update. More information about the update process and system requirements is available at www.tandemdiabetes.com/X2update.

Free Demo App – Control-IQ Technology

Tandem's free t:simulator™ app lets people experience the touchscreen interface of the t:slim X2 pump with Control-IQ technology directly on a mobile device. For more information and to download the app, visit <http://www.tandemdiabetes.com/tsimulator>.

For additional product and safety information, or to begin the order process, visit www.tandemdiabetes.com/controliq

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. Tandem is based in San Diego, California.

Important Safety Information for the t:slim X2 Insulin Pump with Control-IQ Technology

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.

Indications for Use:

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 persons 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 pump is indicated for use in individuals 6 years of age and greater. The pump is intended for single patient, home use and requires a prescription. The pump is indicated for use with NovoLog or Humalog U-100 insulin.

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 CGM 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.

Contraindications and Warnings:

BOXED 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, persons on dialysis, or critically ill patients.

Users of the t:slim X2 pump and Control-IQ technology must:

- be able and willing to 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, transmitter, and sensor must be removed before MRI, CT, or diathermy treatment. For additional important safety information, visit tandemdiabetes.com/safetyinfo.

Tandem Diabetes Care and Basal-IQ are registered trademarks, and t:slim X2, Control-IQ and t:simulator are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are registered trademarks of Dexcom, Inc. 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 and our ability to offer the Control-IQ software update for current t:slim X2 pump users. These statements are subject to numerous risks and uncertainties, including our ability to commence commercial scale manufacturing of the t:slim X2 pump with Control-IQ technology, our ability to operate and maintain a system to facilitate online training and prescription handling for existing t:slim X2 pump customers upgrading their existing devices, and the risk that we may encounter other challenges that may delay the commercial launch of t:slim X2 pump with Control-IQ technology, 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.

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