Tandem Diabetes Care Receives Multiple Health Canada Approvals for t:slim X2 Insulin Pump

November 12, 2026

Approvals include compatibility with Abbott's FreeStyle Libre 3 Plus sensor and indications for type 2 diabetes and for pregnancy in type 1 diabetes.

SAN DIEGO--(BUSINESS WIRE)--Nov. 12, 2026-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM), a leading insulin delivery and diabetes technology company, today announced receipt of Health Canada approval of a license amendment for the t:slim X2™ insulin pump with Control-IQ+™ automated insulin delivery (AID) technology. This approval adds compatibility with Abbott's FreeStyle Libre ® 3 Plus Sensor and expands the t:slim X2 system's indications for use to people with type 1 diabetes during pregnancy and to adults with type 2 diabetes in Canada. Compatibility with the Freestyle Libre 3 Plus Sensor and availability of these expanded indications are expected in the second quarter of 2027.

"These expanded indications for our Canadian customers underscore the strength of our portfolio and our commitment to bringing innovative diabetes technology to more people worldwide," said John Sheridan, president and chief executive officer. "By increasing access to our AID technology, we're broadening our impact and advancing our mission to improve lives across the diabetes community."

Abbott's FreeStyle Libre 3 Plus Sensor Compatibility

The FreeStyle Libre 3 Plus Sensor can be worn for up to 15 days and sends glucose readings to the pump every minute. This data is also available on the Tandem t:slim mobile app, giving users multiple convenient ways to view their current glucose trend.

The t:slim X2 insulin pump is powered by Control-IQ+ technology, the latest generation of the Tandem advanced hybrid closed-loop algorithm, which adjusts insulin every 5 minutes based on predicted glucose values. It's the only system with the unique AutoBolus™ feature that calculates and delivers a correction bolus to help with missed meal boluses. Control-IQ+ is easy to start, use, and personalize.

Pregnancy in Type 1 Diabetes

This expanded indication for use in type 1 diabetes during pregnancy is based on results from the CIRCUIT trial published in the Journal of the American Medical Association (JAMA) in October 2025.[1] Participants in this multi-center, randomized controlled trial were assigned to use a t:slim X2 insulin pump with Control-IQ technology or to continue their multiple daily insulin injections or insulin pump with continuous glucose monitoring. The Control-IQ group experienced 12.6% more time in the pregnancy glucose target range 3.5-7.8 mmol/L (63-140 mg/dL), approximately 3 hours more per day, compared to those using their standard therapy, from 16 weeks gestation to the end of pregnancy.

Adults with Type 2 Diabetes

This expanded label indication for adults with type 2 diabetes is based on strong clinical evidence from the first large-scale, randomized, controlled study of an automated insulin delivery system in type 2 diabetes (the 2IQP trial), completed in more than 300 people with type 2 diabetes, and published in the New England Journal of Medicine in March 2025.[2] The trial compared use of a t:slim X2 pump with Control-IQ+ technology to a control group who continued their existing insulin regimen. Both groups used a Dexcom G6 Continuous Glucose Monitoring (CGM) System for the duration of the study. In the pivotal study, people using Control-IQ+ achieved a 0.9% reduction in A1C, compared with 0.3% in the control group, with those entering the study at A1C levels of 9% or higher seeing a 2.3% reduction. The technology was shown to be safe, with low rates of hypoglycemia, no new safety signals identified, and no diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome events reported.

About Tandem Diabetes Care, Inc.

Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. The Company's pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ+ advanced hybrid closed-loop technology. Tandem Diabetes Care is based in San Diego, California. For more information, visit tandemdiabetes.com.

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Forward-looking Statements

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. These forward-looking statements relate to, among other things, the anticipated timing and scope of commercial availability in Canada of the FreeStyle Libre 3 Plus Sensor integration and expanded indications for the t:slim X2 insulin pump; the completion of post-approval activities, including translations, user guides, operational readiness, training and an Early Access phase; and anticipated software, mobile app and eligibility requirements. These and other risks are identified and described in greater detail under the "Risk Factors" heading of our most recent Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Actual results could differ materially from those anticipated or projected in the forward-looking statements. 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.

The FreeStyle Libre 3 Flash Glucose Monitoring System (FreeStyle Libre 3 Reader or Freestyle Libre 3 app used with FreeStyle Libre 3 Plus Sensor) is indicated for measuring interstitial fluid glucose levels continuously in people aged 2 years and older with diabetes mellitus. Always read and follow the label/insert.

Important Safety Information – Tandem Diabetes Care

RX ONLY. The t:slim X2 insulin 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 pump is indicated for the management of Type 1 diabetes mellitus in persons 2 years of age and greater who require a total daily insulin dose of at least 5 units and who weigh at least 9 kilograms, and of Type 2 diabetes mellitus in persons 18 years of age and greater. The pump is intended for use in pregnancy complicated by Type 1 diabetes mellitus, provided the linked CGM system is suitable for use in pregnancy.

Control-IQ+ technology is intended for use with a compatible continuous glucose monitor (CGM) and a Tandem insulin 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.

WARNING: Control-IQ+ should not be used in anyone under the age of 2 years old with Type 1 diabetes or under the age of 18 years old with Type 2 diabetes. It should also not be used in patients who require less than a total daily insulin dose of 5 units of insulin per day or who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed for Control-IQ+ to operate safely.

Users of the pump and Control-IQ+ must: use the insulin pump, iCGM, and all other system components in accordance with their respective instructions for use. Failure to follow these instructions for use could result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

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[1]Donovan LE, Lemieux P, Dunlop AD, et al. Closed-Loop Insulin Delivery in Type 1 Diabetes in Pregnancy: The CIRCUIT Randomized Clinical Trial. *JAMA*. 2025;334(24):2176-2185. doi:10.1001/jama.2025.19578

[2]Kudva YC, Raghinaru D, Lum JW, et al. A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes. N Engl J Med. 2025; 393(6):617-618. doi: 10.1056/NEJMc2507995.

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