



Tandem Diabetes Care Automated Insulin Delivery Systems Receive CE Mark for Type 2 Diabetes and Type 1 Diabetes During Pregnancy

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SAN DIEGO--(BUSINESS WIRE)--Jun. 5, 2026-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM), a leading insulin delivery and diabetes technology company, today announced receipt of CE mark for expanded indications of its automated insulin delivery (AID) systems in Europe. The t:slim X2 and Tandem Mobi insulin delivery systems running Control-IQ+ AID technology are now approved for use by people with type 1 diabetes during pregnancy and adults with type 2 diabetes.

"These expanded indications 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 expanding access to our AID technology, we're broadening our impact and advancing our mission to improve lives across the diabetes community."

Pregnancy in Type 1 Diabetes

This expanded label indication for use in type 1 diabetes during pregnancy is based on results from the CIRCUIT trial published in 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.

Data from the CIRCUIT Trial will be presented this weekend during a product theater at the 2026 Scientific Sessions of the American Diabetes Association in New Orleans, Louisiana. The presentation takes place on Saturday, June 6 from 10:15 am to 11:00 am Central Time in Product Theater #1.

Adults with Type 2 Diabetes

"The benefits of Control-IQ+ technology were evident across an incredibly diverse population of people with type 2 diabetes, regardless of pre-study glycemic control or experience with diabetes technology," said Jordan Pinsker, MD, chief medical officer.

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 Automated Insulin Delivery Systems

Tandem Diabetes Care manufactures the t:slim X2, the all-in-one insulin delivery system for convenient diabetes management, and the Tandem Mobi, the world's smallest durable AID system. Both systems are powered by Control-IQ+ AID technology to provide proven, best-in-class outcomes. Results from major studies in type 1 and type 2 diabetes, including those published by the New England Journal of Medicine ([October 2019](#), [August 2020](#), [March 2023](#), and [March 2025](#)), show immediate and sustained glycemic improvements, including more time in range and improved sleep.

The t:slim X2 insulin pump is currently available in several European countries. The Tandem Mobi system is expected to begin launching in select countries in the second half of 2026. For more information, visit tandemdiabetes.com.

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, Tandem's expected timeline and ability to launch the Tandem Mobi system in select European countries. 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.

Important Safety Information

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.

The Tandem Mobi insulin pump with interoperable technology (the 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 intended for single patient use. The pump is intended 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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