Tandem Diabetes Care's Control-IQ+ Automated Insulin Delivery Technology Now FDA Cleared for Pregnancy in Type 1 Diabetes

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First and only commercially available AID technology for pregnancy use in the U.S.

SAN DIEGO--(BUSINESS WIRE)--Apr. 27, 2026-- Tandem Diabetes Care, Inc. (Nasdaq: TNDM), a leading insulin delivery and diabetes technology company, today announced that the United States Food and Drug Administration (FDA) has cleared Control-IQ+ automated insulin delivery (AID) technology for use in pregnancy complicated by type 1 diabetes mellitus. Control-IQ+ powers both insulin delivery systems from Tandem – the t:slim X2 and Tandem Mobi, the first and only commercially available AID systems cleared for use during pregnancy in the United States.

"Glycemic goals are tighter during pregnancy," said Dr. Jordan Pinsker, chief medical officer at Tandem Diabetes Care. "The higher time in the pregnancy-specific glucose range seen with Control-IQ can help improve pregnancy outcomes."

This expanded label indication for use in type 1 diabetes during pregnancy[1] is based on results from the CIRCUIT trial published in *Journal of the American Medical Association* (JAMA) in October 2025.[2] 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 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.[1] Maternal and neonatal outcomes were similar in both groups overall but favored those using Control-IQ.

"In the CIRCUIT trial, glycemic improvements were found across all sites and baseline HbA1c ranges, regardless of whether an insulin pump or multiple daily insulin injections were used at enrollment. Marked glycemic improvements occurred within the first week of initiation of Control-IQ that persisted for the duration of pregnancy," said Dr. Lois Donovan, principal investigator of the CIRCUIT study and Clinical Professor at the University of Calgary.

Tandem Diabetes Care will be performing a series of training events and webinars for healthcare providers related to pregnancy and type 1 diabetes management. The first event will be the Tandem product theater at the American Diabetes Association 2026 Scientific Sessions meeting in New Orleans, Louisiana, in June, discussing the study results.

Results from major studies of Control-IQ technology, including those published by the *New England Journal of Medicine* in October 2019, August 2020, March 2023, and March 2025, show immediate and sustained glycemic improvements, including more time in range and improved sleep.

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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Important Safety Information

RX ONLY. The Tandem Mobi system, the t:slim X2 pump with interoperable technology and Control-IQ+ technology are intended for single patient use. The pumps and Control-IQ+ are indicated for use with NovoLog or Humalog U-100 insulin. Tandem Mobi system: 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, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is intended for single patient, home use and requires a prescription. The pump is indicated for use in individuals 6 years of age and greater. t:slim X2 insulin pump: 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, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is indicated for use in persons 2 years of age and greater. Control-IQ+ technology: Control-IQ+ technology is intended for use with compatible integrated continuous glucose monitors (iCGM, sold separately) and alternate controller enabled (ACE) pumps 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 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater. Control-IQ+ technology 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 single patient use and requires a prescription.

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.

[1] Provided the linked continuous glucose monitoring system is suitable for pregnancy.

[2] 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

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