CLOSER LOOK

MEMORANDUM

Tandem's Control-IQ+ receives CE-Mark for T2D as well as T1D during pregnancy – June 5, 2026

AID system becomes second with T2D indication and third with pregnancy indication in Europe

Tandem today announced two significant regulatory milestones for its next-generation Control-IQ+ algorithm: CE-Mark approval for use in adults with T2D and people with T1D during pregnancy. The expanded indications apply to existing European users of the t:slim X2 pump and will extend to Mobi once the pump launches internationally, which Tandem expects in 2Q26.

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Approval for use in T2D marks second AID system for the population

The CE-Mark approval of Control-IQ+ for use in adults with T2D makes Tandem the second AID system available for the population in Europe, following the CE-Mark approval of MiniMed 780G for people with T2D in July 2025.

While AID systems have been cleared for insulin-treated T2D for slightly longer in the US, adoption remains in early stages, with most estimates suggesting that fewer than 5% of insulin-treated adults with T2D are using an AID system. Still, the category has already begun reshaping the diabetes technology market. Following its landmark FDA clearance in August 2024, Insulet reported that nearly one-third of new Omnipod 5 starts came from people with T2D and has since identified international T2D expansion as a key part of its long-term roadmap. We expect even greater growth in AID use by people with T2D in Europe could also drive up the "Aaron Ratio" – the ratio of global AID to CGM users – which has held steady at 13%-14% for the last few years.

The approval was based on Tandem's 2IQP trial (n=319), which evaluated t:slim X2 with Control-IQ+ and Dexcom G6 against a control group using MDI or pump therapy without automated insulin delivery alongside Dexcom G6. After 13 weeks, participants using Control-IQ+ improved Time in Range by 16 percentage points (compared to MDI/pump) and reduced mean A1c from 8.2% to 7.3%. Notably, glycemic benefits were observed regardless of mealtime bolusing strategy, suggesting that users could achieve meaningful improvements whether they counted carbohydrates, announced meals, or interacted minimally with the system. Safety outcomes were similarly encouraging, with just one severe hypoglycemia event and no DKA across either study arm.

System	Regulatory Status	Key Evidence
Tandem Control-IQ+ (t:slim X2/ Mobi)	FDA cleared (February 2025) CE-Mark (June 2026)	2IQP
MiniMed 780G	CE-Mark (July 2025) FDA cleared (September 2025)	"Safety and Effectiveness of MiniMed 780G Advanced Hybrid Closed-Loop (HCL) Insulin Intensification in Adults with Insulin-Requiring Type 2 Diabetes"
Insulet Omnipod 5	FDA cleared (August 2024)	SECURE-T2D

Patients in Europe now have the choice between three covered systems during pregnancy

The expanded indication for use in T1D during pregnancy joins CamAPS FX (March 2020) and MiniMed 780G (July 2025), giving people in Europe three approved AID options during pregnancy. The approval comes shortly after Control-IQ+ became the first FDA-cleared AID system for pregnancy in the US in April 2026 and is in line with the timeline management outlined earlier this year.

Pregnancy presents one of the most demanding glycemic management settings in diabetes care, as it requires: (i) tighter targets represented by Time in Pregnancy Range (63-140 mg/dL); (ii) rapid adaptation to changing insulin resistance; and (iii) greater safety considerations. Historically, these challenges have left individuals to use many AID systems off-label. We look forward to Tandem's product theater highlighting pregnancy management at ADA tomorrow, as well as seeing where the company plans to launch this indication first and how reimbursement shapes up for this population.

CE-Mark approval is based on results from the CIRCUIT trial, a 14-site randomized controlled trial across Canada and Australia comparing the t:slim X2 pump with Control-IQ to standard care in pregnant women with T1D (n=88). From 16 weeks of gestation through delivery, participants using Control-IQ achieved a mean Time in Pregnancy Range of 65% versus 50% with standard care, a 12.6% (roughly three hours per day) improvement in the pregnancy target range. Glycemic improvements emerged within the first week after Control-IQ initiation with median Time in Pregnancy Range rising from about 55% to nearly 70% and remaining durable through gestation.

System	Regulatory Status	Key Evidence	CGM Integrations in Europe	Algorithm Targets
Tandem Control-IQ+ (t:slim X2/ Mobi)	FDA cleared (April 2026) CE-Mark (June 2026)	CIRCUIT (n=88)	Dexcom G6 and G7, FreeStyle Libre 3 Plus	Glucose target range of 112.5-160 mg/dL
MiniMed 780G	CE-Mark (July 2025)	CRISTAL (n=95)	Guardian 3 and 4, Simplera Sync, Instinct	100, 110, and 120 mg/dL
CamAPS FX	CE-Mark (March 2020) FDA cleared (May 2024) – though the algorithm still lacks an FDA-cleared pump partner	AiDAPT (n=124)	FreeStyle Libre 3, Dexcom G7	80-200 mg/dL

Control-IQ+ algorithm features key differences from Control-IQ

Control-IQ+ is compatible with both the t:slim X2 and Tandem Mobi pumps and features several enhancements compared to its predecessor Control-IQ. The updated algorithm was first rolled out to US users in March 2025. Enhancements include:

- **Expanded weight and total daily insulin inputs:** Control-IQ+ permits broader weight (20-440 lbs. compared to 55-308 lbs. with Control-IQ) and total daily insulin ranges (5-200 units compared to 10-100 units with Control-IQ), supporting wider insulin requirements.
- **Enhanced extended bolus:** The extended bolus feature can be enabled for up to eight hours with Control-IQ+ to improve postprandial glycemic management. Previously, extended boluses with Control-IQ enabled were restricted to two hours maximum, although extended boluses could be administered for up to eight hours if Control-IQ was disabled.
- **Increased flexibility for temporary basal rates:** Users can now enable temporary basal rates with Control-IQ+ active to address short-term needs, such as exercise, stress, and illness. With Control-IQ, temporary basal

rates were only available when Control-IQ was disabled.

Close Concerns' Questions

1. How many of Tandem's users in Europe are still using the Control-IQ algorithm, and what percentage are expected to transition to Control-IQ+?
2. In which European countries does Tandem expect to launch the pregnancy indication first, and what reimbursement discussions are underway?
3. What proportion of future European pump starts does Tandem expect will come from people with T2D?
4. How does Tandem plan to educate European primary care providers, who manage the majority of insulin-treated people with T2D, about AID therapy?
5. What have Tandem's learnings been from the early US rollout of Control-IQ+ in T2D, and how are those insights shaping its European strategy?

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