

## Tandem announces expanded pediatric indication for t:slim X2 with Control-IQ for children ages 6-13 - June 17, 2020

*"More than 40,000" have updated to Control-IQ; quick ~three-month review following strong pivotal data presented at [ATTD 2020](#)*

This morning, Tandem [announced](#) FDA clearance for an expanded pediatric indication Control-IQ in children ages 6-13 years. We've [previously speculated](#) Control-IQ in pediatrics could launch before summer, but that was before the FDA (understandably) announced it would prioritize COVID-19 related devices. Of course, Control-IQ has been available for users over 14 years old since FDA clearance [in December](#) and official launch [in January](#). Today's press announcement also notes that "more than 40,000" t:slim X2 users had already updated to Control-IQ - at the [end of April](#), this figure was "more than 30,000." We got a look at real-world data from the first few thousand updaters this weekend [at ADA](#): through the first 30 days of Control-IQ use, Time in Range was increased by 2.4 hours/day and users spent a remarkable 96% of time in closed loop.

The submission for pediatric indication was filed ~March, following very positive data from the pivotal study read out at ATTD back [in February](#). Results with Control-IQ in children ages 6-13 were similar to those of the adult pivotal ([ADA 2019](#)). Control-IQ in children ages 6-13 was shown to drive significant improvement compared to sensor-augmented pump: Time in Range was 67% vs. 55% (+2.9 hour/day). Much of this improvement took place at night with closed loop users reaching 80% Time in Range compared to 54% in the control group. There was no announcement of launch timing, but we'd imagine it will be quite soon. Medtronic's MiniMed 670G (approved for children 7+ years old) has been the only hybrid closed loop system available in this population [since 2018](#).

- **Control-IQ still has a boxed warning against use in children under the age of 6 years old**, in patients who require less than 10 units of insulin/day, or who weigh less than 55 pounds. However, data [presented at ADA from a small study](#) (n=12) of children ages 2-5 demonstrated Tandem's Control-IQ increased Time in Range by 1.8 hours/day and also drove a reduction of 32 min/day in time <70 mg/dl. Presumably, this study will lay the groundwork for larger and longer clinical studies.

*--by Hanna Gutow, Albert Cai, and Kelly Close*