

Tandem's Hybrid Closed Loop Control-IQ Officially Launches - January 16, 2020

New pumps with Control-IQ now shipping, "batches" of emails being sent to in-warranty users; first new automated insulin delivery system since 2017

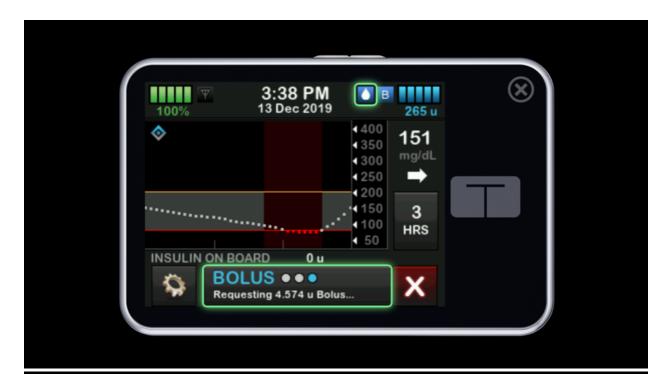
In exciting news for the diabetes community, Tandem has <u>officially announced</u> commercial launch of the hybrid closed loop system Control-IQ. New t:slim X2 pumps with Control-IQ are "now shipping" to new customers, while "emails are being sent out in batches" to all current in-warranty t:slim X2 users. For current t:slim X2 users, Control-IQ will be a free software upgrade that can be done at home, but will require a new prescription and completion of online training, similar to the update process <u>when Basal-IQ launched</u>. Tandem's emails to current users will provide access to an "online portal" where users can request a new prescription and complete their online training - for context, the training for Basal-IQ took ~45-minutes to complete.

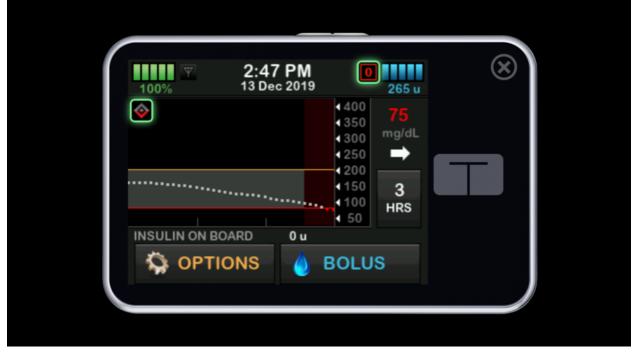
Tandem's official Control-IQ launch comes right in line with Tandem's expectations to launch by "end of January" when the FDA <u>cleared the algorithm</u> in December. Control-IQ is the first automated insulin delivery (AID) system to enter to the market since <u>MiniMed 67oG in 2017</u> and the first system with a no-fingersticks CGM (Dexcom G6), automatic correction boluses, free at-home updates, and built-in Bluetooth. Control-IQ was also cleared as the first-ever "interoperable automated glycemic controller" (iController), meaning the algorithm is a lower-risk class II device and interoperable. See <u>our report from FDA clearance</u> for a much more detailed look at Control-IQ and iController implications.

Control-IQ is the first of what we expect to be a number of AID systems coming to market in 2020 - by way of context, we've never seen people with type 1 diabetes as excited about any new technology or new movement in diabetes. Earlier this week, we learned that Medtronic is expecting to present pivotal data for MiniMed780G at ADA 2020, with preliminary data shown at ATTD next month. We also just learned that the pivotal for Insulet's Omnipod Horizon has also begun with primary completion expected in May 2020; Insulet has maintained 2H20 launch plans for Horizon. Depending on Tidepool Loop, we could see as many as four new AID systems launched by the end of the year. See our AID competitive landscape for the latest timing and product feature updates.

- We have not heard any updates on Tandem's t:slim X2 smartphone app, which was supposed to launch concurrently with Control-IQ. Importantly, the app will allow patients to upload their t:slim X2 pump data and Dexcom G6 CGM data to the t:connect web platform wirelessly. The app will also include secondary display for pump information, including CGM trace, insulin on board, recent boluses, and basal information.
- Tandem has also updated its t:simulator app (Apple, Android), allowing prospective users to experience the t:slim X2/Control-IQ Technology directly on a mobile device see screenshots below. The interface looks outstanding and does an outstanding job flagging for the user what has been happening. The diamond on the left side and the indicator on the top right indicates boluses, automated basal actions, and shut-offs. Insulin-on-board also includes both automated basal and bolus insulin, key for users making decisions. We've come a long way since patients just wanted to see *any* insulin-on-board data at all, as recently as 2018.

Control-IQ Screenshots







--by Albert Cai and Kelly Close