

NOTES from Sequel/twiist Presentation

12 May 2025

Speakers: Kate Farnsworth, Adam Cordova, Amy Malliett

- Discussed Dean Kamen, President of DEKA Research and Dev, Founder of Sequel “as *his* sequel”
- Algorithm built into pump
- Libre 3+
- Eversense 365 expected in Q3; looking at logistics
- Goal is compatibility with all commercial iCGMs
- Technology in pump detects occlusions up to 9x faster than other systems- with examples of folks who have had it happen before glucose rose
- iSure chamber with 4 checkpoints to validate dosing volume
- >30 Sequel employees started on twiist last week
- Comes with 4 batteries and 2 docks; charging is rapid
- Available through Rx benefits
- Waterproof (same as Omnipod)
- Insulin volume: 100-300 U
- One side is disposable & contains insulin cassette; other side is reusable & hosts battery
- Uses Luer Lock connection (so can use different and shorter tubing if desired) and Cleo 90 infusion set, which is exciting because it allows for 360-degree rotation at the connection point
- Every territory has a CDCES that Sequel will be training (don’t know the size of the territories)
 - Sequel clinician can teach user how to adjust settings if OK’d by user’s HCP
 - Will have follow-up training available
 - Initial training will be in person; will move to online
- Committed to getting people on the product within 10 business days (from date of order) & will be in communication with user
- If user tries and decides they don’t like twiist, OK- keep kit and not a financial loss
- Currently 2 manufacturing facilities in US; working on a 3rd (locations?)
- Acknowledged that there are supply chain concerns in the US
- Close to 80% commercial insurance co-coverage currently
- Not yet covered by Medicare- working diligently to get a national program
- IAGC: Interoperable Auto Glucose Control

- Retrospective study including data from DIY community (from 2019-2020) with guardrails imposed to keep FDA happy- this turned into the FDA clearance, which occurred in 2023, and this is the version twiist is using
 - This user population was extracted from a larger data set:
 - Correction range could only be within the range of 87-180 (range or single point)
 - The glucose safety limit is no lower than 67
 - Time in range (70 to 180) of 90% or better
 - 6 years+ of age
 - Using either Humalog or Novolog
- No autobolus; basal modulation only
- Libre reads every 1 minute and glucose value on screen updates every minute; forecasted glucose and graphs on the app screen update every 5 minutes and twiist loops every 5 minutes
- Depending on user, can set Max Basal up to 6x (higher than the recommended 4x)
- Actively looking at getting the next level of algorithm with GOAL of Fully Closed Loop.
- Discussed some scenarios/ ways to increase aggressiveness of twiist, such as increasing Max Basal to 6x, using Premeal button to lower target temporarily...
- Doesn't integrate with Nightscout, but does come with its own remote follow app with real-time glucose, insulin, carb data, and more; reports are available through Tidepool
- Can't remote bolus- FDA does not want to support that; will keep fighting for it
- Overrides are not currently included
- Sequel is marketing and supporting twiist, but it was made by DEKA
- DEKA is being very responsive to questions/ concerns about the app
- Sequel does not have a problem with people using other insulins and will have to see the outcomes anecdotally
- Afrezza? GLP-1s?
 - No way to announce non-pump insulin
 - People on meds (he mentioned RA meds) are "doing really well" on twiist
- 36 Sequel employees on twiist as of April 30; total of about 55, including investigator-initiated trials before they got on it
- App looks like Loop
- Don't need CGM app - can do everything through twiist app
- 24/7 support: clinical and product/technical; "won't have to be built within the community"
- **For suggestions and questions, email hello@twiist.com**