

Cellnovo receives CE mark for next-gen Bluetooth- and Android-enabled pump, announces first PEPPER clinical study - December 18, 2017

Cellnovo [announced](#) that it has received a CE mark for its next-generation pump, the Cellnovo System with Android. The pump will communicate via Bluetooth with Cellnovo's proprietary touchscreen handset, which uses the Android mobile operating system. The [press release](#) notes that incorporation of Android technology will improve the performance of Cellnovo's handset, facilitating interoperability for its automated insulin delivery pipeline and the world of connected diabetes and consumer devices. No launch timing is shared in the announcement, but it is already being used by participants in the PEPPER clinical study.

Cellnovo's addition of Bluetooth continues a positive trend for diabetes devices. In the pump world, Roche's Accu-Chek Spirit Combo was quite early to add Bluetooth, and it's also now in Tandem's t:slim X2, SOOIL's DANA pump (OUS), Ypsomed's YpsoPump (OUS), and Insulet's soon-to-launch Omnipod Dash (FDA submission "around the end of this year"). Cellnovo's shipments in the [10 countries](#) in which the original patch pump system is available have been [sluggish](#) (partially due to manufacturing scale), and FDA clearance is now expected in 2018 - we're not sure how the company will handle submitting the Bluetooth-enabled pump to FDA, if at all.

Cellnovo also [announced](#) that the EU-funded [PEPPER Project](#) led by Oxford Brookes University will launch its first clinical study, leveraging Cellnovo's system to test a personalized decision-support solution for pumpers with type 1 diabetes. The trial will investigate two algorithms, which process data from wearables like activity bands and CGM devices to: (i) provide insulin dose recommendations; and (ii) alert the user to the risk of hyperglycemia and hypoglycemia, automatically suspending the insulin pump as necessary. In essence, it sounds similar to a patient-facing version of Dreamed's pump advisor (with guidance for basal rate, ICR, etc. adjustments), combined with some kind of predictive low glucose suspend system. The four-month, multi-center clinical study (n=15) will take place in London, UK and Girona, Spain. The [press release](#) curiously notes that Cellnovo is the only medical device company participating in the project; it is also the only company mentioned on the [Project website](#) - activity monitors, pens, and BGM/CGM devices are included in the study, but unnamed. As a reminder, Cellnovo's pump is already being used with Dexcom CGM in [Diabeloop's system](#). Cellnovo has also licensed TypeZero's software for AID; per 3Q17, the integration was being finalized, with a small pilot study to follow.

-- by Maeve Serino, Brian Levine, Adam Brown, and Kelly Close