MEDTECH INSIGHT
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News We're Watching: FDA Approves Medtronic's Affera, Roche's CGM Moves Closer To Approval, And More

by Reed Miller

Medtech Insight's News We're Watching covers medtech industry and research news you may have missed. This week, the Advanced Technologies and Treatments for Diabetes (ATTD) conference in Florence, Italy, included new results from studies of Roche's continuous glucose monitor and Medtronic's 780G insulin pump, Medtronic moved closer to earning FDA approval for its Affera ablation mapping and ablation system, and Linus Health expanded its technology for finding signs of cognitive problems in speech data.

FDA Clears Medtronic's Affera EP Mapping System

The US Food and Drug Administration *cleared* *Medtronic*'s Affera electrophysiology mapping system, moving the company closer to a US launch for the Affera mapping and cardiac ablation system, which also includes the Sphere-9 ablation catheter.

Sphere-9 can deliver either radiofrequency or pulsed field ablation (PFA) ablation, so Medtronic will eventually integrate its PulseSelect PFA system with Affera. (Also see "*'There Is Work To Do:' Sean Salmon Discusses Medtronic's Recent Hard-Won Cardio Breakthroughs*" - Medtech Insight, 1 Mar, 2024.)

However, the 510(k) clearance for the mapping system, announced on 11 March, does not cover Sphere-9 catheter. That will require a separate FDA decision. In a 11 March note, Wells Fargo analyst Larry Biegelsen predicted the FDA will approve Sphere-9 through its premarket approval application (PMA) process by the end of 2024.

FDA cleared the Affera mapping system based on yet-to-be published results from *Sphere PerAF*, a 477-patient randomized trial comparing the Affera system to Biosense Webster's Thermocool

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SmartTouch in patients with persistent atrial fibrillation.

Biegelsen expects results from Sphere Per-AF will be announced at the Heart Rhythm Society conference in May in Boston.

The system was originally developed by Affera, a Boston-based cardiac mapping company that Medtronic acquired for $925m in late 2022. (Also see "*JPM 2022: Dexcom, Edwards, J&J, Medtronic, ResMed*" - Medtech Insight, 10 Jan, 2022.)

Roche Touts Accuracy Of Accu-Chek SmartGuide Real-Time CGM

Early experience with *Roche*'s Accu-Chek SmartGuide real-time continuous glucose monitoring (rtCGM) system showed a high system accuracy with an overall *mean absolute relative deviation (MARD)* of 9.2%.

Accu-Check SmartGuide includes two apps that display current glucose values and predictions along with a risk predictor for nocturnal hypoglycemia.

At the company's symposium at the Advanced Technologies and Treatments for Diabetes (ATTD) conference in Florence, Italy, on 7 March, Julia Mader from the University of Graz in Austria, presented results from 48 people with type 1 or type 2 diabetes who wore three Accu-Check sensors for two weeks.

The overall mean MARD was 9.2% and 99.8% of the measured glucose values fell within in *zones A and B on the Parkes Error Grid*, showing that "the Accu-Chek SmartGuide solution is not only highly accurate and robust in its performance in a clinical setting, but also during routine day evaluation", Mader said.

Also, 83% of the study participants said they liked their experience with Accu-Chek SmartGuide and about 80% liked the app design.

"Providing users with predictive capabilities will empower them to proactively adapt their therapy so they can maintain optimal glycemic control and prevent dangerous short- and long-term complications," said Marcel Gmuender, the global head of Roche Diabetes Care.

Roche expects to obtain a CE mark for Accu-Check SmartGuide and launch it in Europe in 2024. (Also see "*News We're Watching: LivaNova Names CEO; Surgical Robot Goes To Space, And More*" - Medtech Insight, 5 Feb, 2024.)

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Registry Data Shows Medtronic's 780G Helps People With Type 1 Diabetes

Registry data from 7,499 people in the US showed Medtronic's MiniMed 780G insulin pump system can help users with type 1 diabetes achieved over 80% "*time in range*" when employing the recommended optimal settings.

By comparison, American Diabetes Association guidelines recommend 70% time in range.

James Thrasher of the Arkansas Diabetes and Endocrinology Center in Little Rock presented the results at the Advanced Technologies and Treatments for Diabetes (ATTD) conference in Florence, Italy, on 9 March.

"The advent of automated insulin delivery systems has been nothing short of transformative in the practice of endocrinology and is really pushing all of us to introduce its protective benefits on overall health as early and often as possible," Thrasher said. "This data reinforces that the determinant of choice for AID systems should be first and foremost the power of the algorithm."

Robert Vigersky, the chief medical officer for Medtronic's diabetes business said, "The preponderance of data across randomized controlled trials and real-world studies show that the MiniMed 780G system is maximizing time in range, far surpassing international targets and is taking it a step beyond by getting people closer to euglycemia."

"In the absence of a cure, our goal is to relentlessly innovate therapies to help people maximize their health without adding burden, which our newest AID system has proven to do."

Linus Health Buys Aural Analytics, Expands Cognitive-Assessment Platform

Linus Health acquired Arizona-based Aural Analytics, a developer of clinical speech analytics, the companies announced on 11 March. Terms of the deal were not announced.

Aural Analytics' Speech Vitals technology is designed to detect multiple neurological conditions, such as dementia, autism and amyotrophic lateral sclerosis (ALS), by analyzing precise data derived from the sound of the user's voice. (Also see "*Canary Speech's Voice AI Can Help Detect Alzheimer's With 40-Second Conversation*" - Medtech Insight, 23 Feb, 2024.)

Linus Health will integrate Aural Analytics' Speech Vitals voice metrics technology into its own growing platform to expand its digital cognitive assessment tools, which include its digital clock and recall (DCR).

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Linus Health previously tested some aspects of Aural Analytics' voice analysis with its own multimodal algorithms and found the combination outperformed the "paper-and-pencil" assessments physicians have traditionally relied upon for cognitive assessment.

The Speech Vitals ALS assessment earned the US Food and Drug Administration's breakthrough status in 2023.

In 2020, Linus Health acquired Kinesis Health Technologies, developer of a physical function assessment tool for older adults and Digital Cognition Technologies, another digital cognitive assessment developer.

Boston-based Linus Health also announced expansions of its of line of cognitive health assessment; the new Hearing Screener and the Digital Trail Making Test Part B are designed to accelerate and simplify early detection and management of mild cognitive impairment indicating the possible onset of Alzheimer's disease.

Linus Health will demonstrate its new Hearing Screener and Digital Trail Making Test Part B at the 2024 Healthcare Information and Management Systems Society conference in Orlando, 11 to 15 March.

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