

What's new this week in MedTech

23 to 30 October 2026

Remote stroke robotics

Neurocritical care

EU MDR reform

BCI funding

World Stroke Day on 29 October set the tone for a week in which remote robotics, AI imaging and new regulatory designations all pushed further into stroke and neurocritical care, while Brussels kept working on the MDR reform and investors put fresh money into brain implants, wearables and virtual testing.

1. XCath shows the first remote robotic stroke thrombectomy to the world on World Stroke Day

On 29 October XCath released a documentary on Operation Robo Angel, in which a neurointerventional surgeon at a control station in Santiago, Panama used the company's Iris robot to remove a clot from a stroke patient in Panama City on the first pass, a procedure first performed in March and followed by FDA Breakthrough Device designation and entry into the FDA TAP pilot. It matters because most thrombectomy capable hospitals are concentrated in a handful of countries, and remote intervention could bring that care to patients who today have no specialist nearby, although the Iris system is still in development and not cleared for sale.

Source: [Medical Device Developments](#) and [NeuroNews International](#)

2. FDA gives Breakthrough status to a system that filters blood from spinal fluid after brain bleeds

Pharaoh Neuro announced on 28 October that its Neurapheresis CSF Management System, a closed loop external platform that removes blood and its breakdown products from the cerebrospinal fluid of patients after aneurysmal subarachnoid hemorrhage, received FDA Breakthrough Device designation and is also taking part in the TAP pilot. It matters because there is currently no cleared or approved device that actively clears blood from the CSF in this young patient group, and the combination of designation and TAP gives the company a faster, more interactive route with the agency.

Source: [PR Newswire \(Pharaoh Neuro\)](#)

3. Brainomix AI on simple CT scans points to which severe stroke patients may benefit from a new drug

In a post hoc analysis of the Phase 3 CHARM trial announced on 28 October, Brainomix used automated non contrast CT analysis in 428 patients and found that the investigational drug CIRARA was significantly associated with better outcomes in the subgroup with an infarct core below 125 mL. It matters because selecting patients with the most widely available stroke scan, rather than advanced imaging, could open trials and future treatments to far more hospitals, although the findings are exploratory and the drug is not approved.

Source: [PR Newswire \(Brainomix\)](#)

4. Empatica launches an FDA cleared and CE marked Parkinson's wearable for home use

Reported on 29 October, WellPD pairs a wrist worn device with an app that turns movement and other signals into daily measures of activity, sleep, tremor, bradykinesia and dyskinesia, lets patients log medication against those changes, and is now available to order in the US and several European countries. It matters because it is a clear example of neurology monitoring moving out of the clinic and into the home, giving clinicians data on what happens between appointments.

Source: [Medical Device Network](#)

5. EU Council working party takes up a third compromise on the MDR and IVDR reform

On 26 and 27 October the Council's Working Party on Pharmaceuticals and Medical Devices met in Brussels to exchange views on the Presidency's third compromise text of the regulation simplifying the medical device rules, with expert panels and the link to the AI Act on the table. It matters because the proposal would replace the five year certificate cycle with risk based reviews, move much medical software from Class IIa to Class I and cut notified body fees for micro and small manufacturers, but it is still a proposal and today's MDR and IVDR rules apply until a final text is adopted.

Source: [Council of the EU meeting notice](#) and [The European Post](#)

6. adsilico raises £10M to test devices in AI generated virtual patients

The University of Leeds spinout announced on 27 October a Series A led by PXN Ventures to expand its technology, which builds virtual hearts and vessels from anonymised scans and simulates device performance across populations, and to extend it to brain devices such as flow diverters for aneurysms. It matters because in silico evidence could help manufacturers answer questions about diverse patient groups earlier and more cheaply, particularly in neurovascular areas where trials are small.

Source: [Intelligent Health.tech](#)

7. StimCardio closes a \$30M Series A for a wrist worn atrial fibrillation therapy

Announced on 29 October and led by Metis MedTech, the round funds the NeuroPulse 2 pivotal study of Rhyvive, an investigational wearable that delivers non invasive median nerve stimulation to reduce AF recurrence after catheter ablation, and preparation for an FDA De Novo submission. It matters because it shows investors backing non invasive neuromodulation as a therapy category in its own right, a trend that is equally relevant to neurology and rehabilitation devices.

Source: [PR Newswire \(StimCardio\)](#)

8. NeuroXess raises RMB 700M for a fully implanted wireless brain implant

The Chinese brain-computer interface company reported on 28 October a Series B co-led by SDIC Juli, Shenzhen Capital Group and Qinzhi Capital, saying it has completed 65 clinical cases and began a registration trial with nearly 20 hospitals in July. It matters because China's implant developers are moving quickly from clinical cases toward registration and large scale manufacturing, adding real competition to the US led brain-computer interface field.

Source: [TechNode](#) and [36Kr](#)

Gary's take

What stands out for me this week is how much of the progress in stroke and neurocritical care is now coming through regulatory tools like Breakthrough designation and the TAP pilot, which give small companies a real seat at the table with FDA long before they file, and I would encourage any neuro startup with a serious unmet need to look at that route early. At the same time the EU reform is getting closer but is not there yet, so my advice remains to plan your CE strategy on today's MDR and treat the proposed relief for software and small manufacturers as an upside rather than a planning date.

Which of these developments matters most for your company, and is there an area you would like me to cover in more depth next week? You are always welcome to write to me directly, and you can find more of my articles, and book a short introductory call, at synergenmedtech.com.

Sources note: all items were found through a public web scan of the week and each was checked against the linked original source.