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Digital Health Roundup: VR, AI Trends In Rehabilitation; Cybersecurity Regulations; Medicare Updates

by [Marion Webb](#)

In this month's Digital Health Roundup, *Medtech Insight's* Marion Webb highlights VR, AI and other high tech trends in rehabilitation and gait training. Hannah Daniel discusses cybersecurity updates such as the new NIST published draft for an updated version of the Cybersecurity Framework, a recent report by Health-ISAC, and an interview with MedCrypt's Naomi Schwartz about the upcoming FDA cybersecurity regulations for premarket approvals.

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Rehabilitation Trends

Israeli-based medtech company GaitBetter has developed a digital therapeutic solution that adds VR-based experience to treadmills with the aim to reduce risk of falls in older adults and improve gait.

In the US alone, more than 3 million older adults are treated in emergency rooms for fall injuries each year, and more than 800,000 of those patients are hospitalized, according to the Centers for Disease Control and Prevention.

The company's technology uses semi-immersive VR and proprietary computer algorithms, which can be added to any treadmill. The software adds cognitive aspects to gait training to improve a person's ability to walk, and thus, reduce falls. According to GaitBetter its VR treadmill is two times more effective than regular treadmill use, reducing total number of falls by up to 80% in

studies.

GaitBetter, founded in 2018 with technology licensed from the Tel Aviv Sourasky Medical Center, was first introduced in physical therapy centers in Israel and made its debut in the US in 2021. The firm plans to expand its foothold in the US, but reimbursement remains the biggest barrier to wider adoption. (Also see "[GaitBetter On Mission To Bring VR, AI-Based Solution To Gait Training; Will Physical Therapists Pay For It?](#)" - Medtech Insight, 18 Aug, 2023.)

[ReWalk Robotics Ltd.](#) announced plans to acquire [AlterG, Inc.](#), a provider of anti-gravity systems for physical and neurological rehabilitation, is expected to put it on solid grounds to expand its portfolio and achieve profitability. The \$19m is expected to close 11 August.

AlterG uses NASA-derived differential air pressure technology to reduce gravitational load and weight body, which enables patients and athletes to move without restrictions or pain. AlterG products are in 4,000 facilities worldwide and in fiscal 2022 the company generated revenues of \$20m with positive operating profits.

By acquiring AlterG, ReWalk Robotics adds AlterG's current products and future products, which will expand customer-facing capabilities and advance future growth opportunities, the firms aid.

"This transaction will leverage our combined market presence from both businesses and by creating sales and support efficiencies across all product lines accelerate our path to profitability," said ReWalk CEO Larry Jasinski. (Also see "[ReWalk Robotics' Planned Acquisition Of Anti-Gravity Maker AlterG For \\$19M Paves Way To Profitability](#)" - Medtech Insight, 10 Aug, 2023.)

Detect Atrial Fib By Stepping On The Scale

[Withings SA](#), which develops and markets various "smart scales" to improve health and fitness received US Food and Drug Administration clearance for its Body Scan with Withings Scan Monitor 2.0, which can detect atrial fibrillation through the acquisition of a six-lead electrocardiogram.

The company announced the clearance on 28 August with availability of the scale starting this fall in the US for a cost of \$399.95. (Also see "[Withings' Smart Scale Passes US FDA Test; Clearance For Detecting Atrial Fibrillation](#)" - Medtech Insight, 28 Aug, 2023.)

Spotlight On Cybersecurity

The National Institute of Standards and Technology (NIST) published a draft for an updated version of its widely used Cybersecurity Framework. This guidance is a widely used framework across cybersecurity companies, including at digital health companies.

One of the largest changes is the guidance's scope, which now includes all organizations, not just

critical infrastructure. It underscores the necessity of cybersecurity in all business types. The document, which is now officially known by its former nickname “The Cybersecurity Framework,” also introduced a “Govern” function to its five pillars of cybersecurity, which are: Identify, Protect, Detect, Respond and Recover. (Also see "[NIST Cybersecurity Framework 2.0 Expands Guidance's Scope, Introduces 'Govern' Function](#)" - Medtech Insight, 17 Aug, 2023.)

For years, NIST has collaborated with federal offices to implement cybersecurity best practices across the government, including the US Food and Drug Administration.

Holistic cybersecurity for medical devices is important, because a report from Health-ISAC, Finite State and Securin Inc. found that there was a 59% increase in vulnerabilities in health care devices since last year. (Also see "[Vulnerabilities Up 59%: The State Of Healthcare Cybersecurity In 2023](#)" - Medtech Insight, 10 Aug, 2023.)

Vulnerabilities were found across product types, including software applications, operating systems and hardware. The report recommended regular penetration testing to detect vulnerabilities in devices, especially in large health care systems.

Additionally, keeping up to date with software updates is not only good practice but critical for keeping devices and IT safe.

Medtech Insight also spoke to a cybersecurity expert about new regulations from the FDA. Starting 1 October, the FDA will also begin to issue Refusal to Accept (RTA) decisions based on the requirements outlined in the Consolidated Appropriations Act of 2023. These include the submissions of software bills of materials (SBOMs) and other cybersecurity requirements. (Also see "['Refuse to Accept' Decisions For Cyber Devices To Begin In October](#)" - Medtech Insight, 29 Mar, 2023.)

Additionally, the FDA will require eSTAR forms for 510(k) submissions, which will help companies mitigate these RTA decisions. eSTAR forms walk companies through every piece of information they need for a submission, so fewer submissions will be rejected through an RTA decision. (Also see "[Cybersecurity Expert Says eSTAR Requirement Will Push FDA, Industry In Positive Direction](#)" - Medtech Insight, 16 Aug, 2023.)

Medicare Expands Coverage For SCS To Treat Diabetic Peripheral Neuropathy

Last month, US Medicare expanded its coverage of spinal cord stimulation (SCS) therapy to treat diabetic peripheral neuropathy, a move that could mean pain relief for an additional 11 million Americans with government insurance.

Some 37 million Americans have diabetes, according to the CDC, with many developing diabetic neuropathy, an often painful condition with symptoms usually starting in the feet and legs

before moving up to the hands and arms.

Common symptoms, which are usually worse at night, include numbness, reduced ability to feel pain or temperature changes, tingling and burning, sharp pain and cramps, muscle weakness, severe foot damage, and extreme sensitivity to touch.

But the problem for millions of Americans with painful diabetic neuropathy is that many do not respond well to medication or other traditional treatments, such as injections or surgery.

That's where spinal cord stimulation comes in.

SCS is a therapy in which an implantable pacemaker-like device delivers mild electrical impulses to the spinal cord to interrupt pain signals to the brain.

With its recent expansion into 12 states — Arkansas, Colorado, Delaware, Florida, Louisiana, Maryland, Mississippi, New Mexico, New Jersey, Oklahoma, Pennsylvania, and Texas as well as Washington, DC — Medicare now covers SCS across the entire US. (Also see "[Medicare Expands Coverage For Spinal Cord Stimulation To Treat Diabetic Peripheral Neuropathy](#)" - Medtech Insight, 15 Aug, 2023.)

Also in spinal surgery news, Suralign, which previously filed for bankruptcy, has shut down and offloaded its assets to [Xtant Medical Holdings, Inc.](#) and [Augmedics](#).

Xtant, which develops orthobiologics and spinal fixation systems, purchased Suralign's international biologics and spinal fixation assets for \$5m.

Augmedics will pay \$900,000 for Suralign's digital health assets, including HOLO, an intraoperative navigation and artificial intelligence to advise clinicians on planning, workflow and anatomical layouts of surgery.