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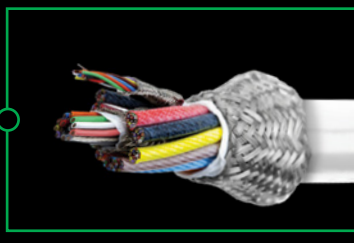

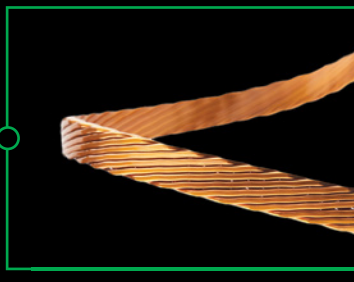

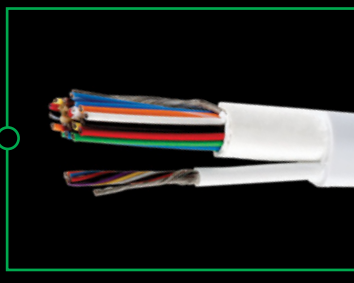

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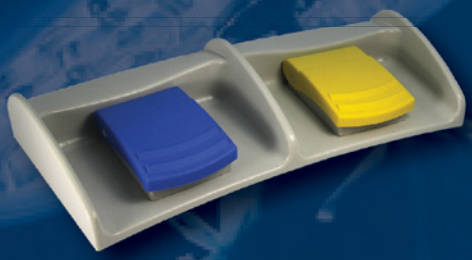

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ON THE COVER

Cardiovascular disease (CVD) remains a leading — and growing — cause of morbidity and mortality worldwide, with the economic burden of care projected to skyrocket over the coming decades. AI-enabled electrocardiogram (ECG) technology has the potential to offer a transformative approach to addressing these challenges. By leveraging AI to rapidly analyze and interpret near-real-time cardiac monitoring data, healthcare providers may be able to detect potential issues sooner, intervene earlier, and support improved outcomes — all while driving down the mounting cost burden of CVD. To learn how AI-powered solutions can meet the needs of a growing population at risk for CVD, read the article on page 14.

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U.S. Tariffs Cast Shadow Over Promising Growth of Pulsed Field Ablation Devices

The rapid ascent of pulsed field ablation (PFA) devices in the electrophysiology landscape has been a standout development in cardiovascular medicine over the past several years. But as these technologies gain clinical traction, they now face a different kind of obstacle. According to a report from GlobalData, just as the U.S. market for PFA systems begins to reach critical mass, tariffs on imported devices and components threaten to upend supply chains, inflate costs, and potentially slow adoption.

PFA, a nonthermal ablation technique that selectively targets cardiac tissue while sparing nearby structures, promises shorter procedure times, reduced complications, and improved patient outcomes. Systems like Boston Scientific's FARAPULSE, Medtronic's PulseSelect, and Johnson & Johnson's VARIPULSE have been hailed as breakthroughs, often replacing thermal ablation systems outright. The 2024 U.S. market for PFA is estimated at $535.9 million and had been projected to grow at a robust 31.65 percent CAGR over the next decade.

David Beauchamp, a medical analyst at GlobalData, notes that tariffs could significantly dampen that momentum. The very nature of globalized medical manufacturing means that punitive trade policies could reverberate throughout the value chain. With many PFA devices manufactured abroad for efficiency and access to advanced materials, new import costs could leave manufacturers with limited options: absorb the tariff hit or pass those costs along to hospitals and health systems already grappling with tightening budgets.

For medical device OEMs, strategic planning must now incorporate tariff risk alongside traditional product development and regulatory timelines. Companies may need to reevaluate supply chains, consider nearshoring or reshoring options, and increase investments in U.S.-based component manufacturing — moves that may yield long-term resilience but could stall short-term growth.

Tariff uncertainty adds another layer of complexity to an already fragmented global regulatory environment. With PFA currently approved in only a handful of markets, the U.S. remains critical to commercial viability. Any disruption in pricing or availability could incentivize providers to revert to older, more affordable ablation options, eroding the hard-won market share of newer systems.

For OEMs navigating the cardiovascular space, the current environment demands a balance of technical excellence and geopolitical awareness.

Sherrie Trigg
Editor and Director of Medical Content

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Inside the OEM:
Boston Scientific to Focus on Cardiology Innovation

Boston Scientific entered 2025 with significant momentum. Fresh off a standout first quarter, the company's leadership has outlined a compelling vision for sustainable long-term growth rooted in high-performing cardiology franchises, operational precision, and disruptive technologies in electrophysiology (EP). Leaders spoke at a recent Bank of America Healthcare Conference. The discussion marked outgoing CFO Dan Brennan's final investor presentation and underscored Boston Scientific's transformation into one of medtech's most durable growth stories.

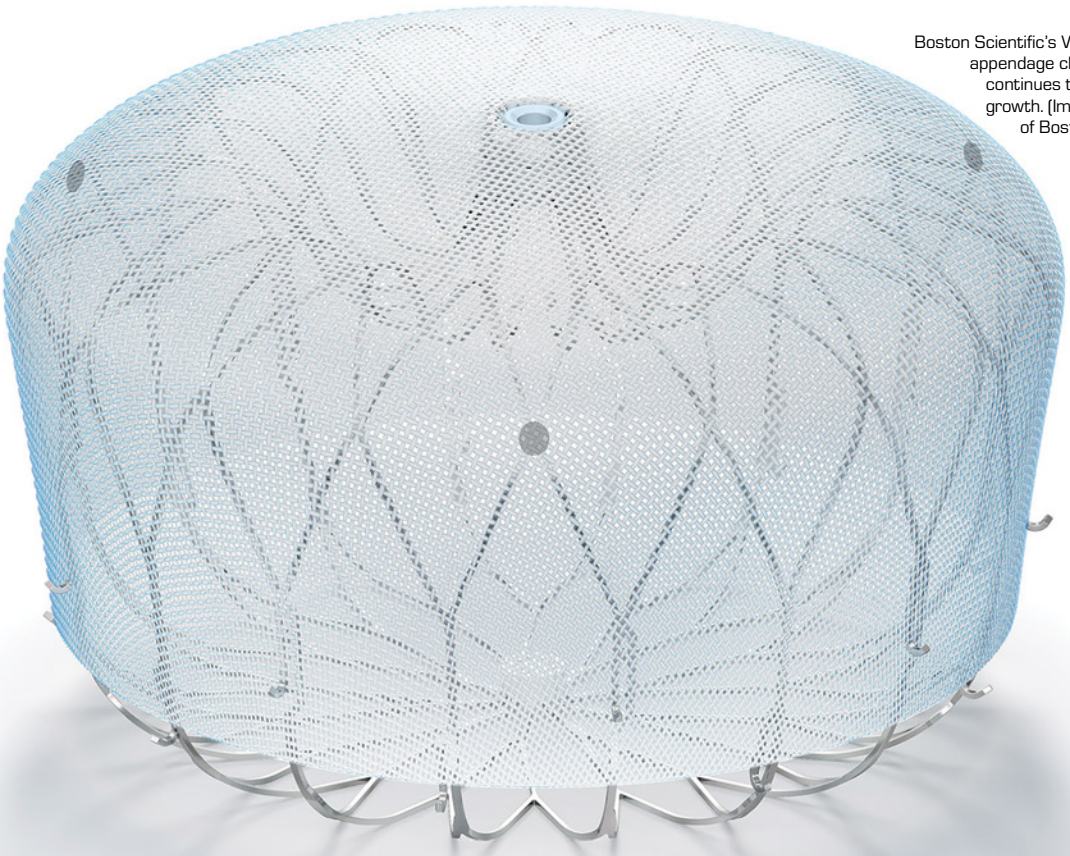
"Since 2014, Boston Scientific's stock has returned nearly 21 percent annually, vastly outperforming the healthcare sector and the S&P," noted the moderator. To that, Brennan noted "That takes the team. We have 55,000 global team members to make that happen."

Smooth Leadership Transition

Brennan's successor, John Monson, was chosen not only for his 25-year tenure at the company but for his recent experience in investor relations. Brennan emphasized the seamlessness of the CFO transition. "Everything [John] has ever done, he's done exceptionally well. He knows the business, he knows the team, and he knows the investors."

Q1 2025 validated that continuity. The company reported 18.2 percent organic revenue growth, a 28.9 percent adjusted operating margin, 34 percent adjusted EPS growth, and a gross margin of 71.5 percent. "That gross margin number is particularly exciting," said Brennan. "In 2019, we were at 72.4 percent. To be this close — just a fraction off — shows how focused we are on restoring margin leadership."

That performance enabled Boston Scientific to raise full-year revenue guidance from 11–13.5 percent in February to 12–14



Boston Scientific's WATCHMAN left atrial appendage closure (LAAC) system continues to be a major driver of growth. (Image provided courtesy of Boston Scientific. ©2025 Boston Scientific Corporation or its affiliates. All rights reserved.)

percent in April. "We couldn't have asked for a better start to the year," Brennan added.

The results are even more impressive considering the company faced a $200 million unanticipated tariff impact in April. "You don't want something like that to slow your momentum," Brennan said. "We offset half of it with revenue upside and favorable foreign exchange, and the other half through $100 million in smart discretionary spending reductions."

The company's long-standing focus on discipline and execution, even in the face of external shocks, reflects a broader cultural commitment. "When confronted with a $200 million hit, we didn't even consider lowering our margin guidance," said Brennan. "We said, 'We're going to offset it. We'll still deliver the 50–75 basis points of margin expansion.' That mindset is embedded in how we operate."

Margin Expansion Strategy

Boston Scientific's long-term target remains a 30 percent+ operating margin, and the leadership team sees ample runway ahead to achieve that. "Margin expansion has been a critical part of our success — not just in retrospect, but looking forward," Brennan said.

Unlike some in industry who use tariffs or macroeconomic volatility as reasons to temper financial performance, Boston Scientific continues to invest with precision. "We do a nice job as a team of looking at ways to reinvest to fuel the top line while maintaining financial discipline," Brennan noted.

This dual focus — strategic reinvestment and cost control — allows Boston Scientific to weather market shifts while still expanding its operational envelope. "If trade tensions ease and tariff burdens are reduced, we'll take a balanced approach," said Brennan. "We'll consider reinvestment in pipeline assets, but we're also committed to strengthening margins year over year."

M&A and Revenue Growth

With Boston Scientific now consistently posting low double-digit revenue growth, the conversation turned to sustainability. "A few years ago, our weighted average market growth rate was 5 percent. Now it's around 9 percent," said Brennan. "That shift reflects intentional portfolio moves."

That deliberate strategy spans several areas: expanding high-growth product lines, targeting adjacent therapy areas, and complementing organic R&D with disciplined M&A. "Go back five years, even 10 years, and you'll see a clear pattern: slow but steady expansion of our growth base," he explained.

"People ask, 'How long can Boston Scientific keep growing at this rate?' And our answer is: quite a while," he added. "We've delivered three consecutive strong years — 16.4 percent organic growth in 2024, and now we've raised 2025 expectations just a few months into the year."

While specifics for 2026 and beyond will be held until the medtech firm's September 30 Investor Day, Brennan hinted that the company has a clear line of sight into future catalysts. "Our leadership is focused not just on Q2 or full-year 2025," he said. "We're looking at 2026, 2027, 2028 — and even 2030. That's how you build a business that endures."

Boston Scientific's approach to mergers and acquisitions remains steadfast: prioritizing tuck-in deals that complement existing capabilities. "We've done nearly 30 acquisitions over the last decade, from $40 million to $4 billion," Brennan noted. "Every one of them was about fit — strategic, technological, and commercial."

Rather than targeting transformative acquisitions that could upend operations or culture, Boston Scientific focuses on technology platforms that plug into existing infrastructure. "It's not about size," said Joe Fitzgerald, executive vice president and group president, cardiology. "It's about strategic fit — whether it aligns with our commercial model and R&D expertise."

Notably, tuck-in acquisitions have played a pivotal role in Boston Scientific's entry and rise in the electrophysiology market, a segment that's undergoing a seismic shift thanks to pulsed field ablation (PFA).

Leading in Electrophysiology

The company's FARAPULSE platform has become the center of gravity in Boston Scientific's EP growth engine. "We did about a billion dollars in the first 12 months post-FDA approval," said Fitzgerald. "And this is just the beginning."

Previously, thermal ablation dominated the U.S. market. But now, with

The company's FARAPULSE platform has become the center of gravity in Boston Scientific's EP growth engine. (Image provided courtesy of Boston Scientific. ©2025 Boston Scientific Corporation or its affiliates. All rights reserved.)

Boston Scientific recently entered the mapping space with the addition of FARAVIEW NAV. (Image provided courtesy of Boston Scientific. ©2025 Boston Scientific Corporation or its affiliates. All rights reserved.)

FARAPULSE, PFA is quickly gaining share. "We estimate we'll move from 40 percent penetration in 2024 to 80 percent over the next several years," Fitzgerald explained.

Boston Scientific isn't just betting on one product, however. It's building an ecosystem. "We're developing multiple catheter types, building out mapping and imaging capabilities, and layering in software and diagnostic tools," he said. "This isn't just about being a strong player in ablation — it's about owning the EP lab."

Mapping and imaging are key focus areas. "Mapping can add up to $4,000 per procedure," Fitzgerald said. "In the U.S., 100 percent of EP procedures are mapped, and we only recently entered that space with FARAVIEW NAV. Now we're aiming to disrupt."

The company's acquisition of Cortex and its strategic work with intracardiac echocardiograph (ICE) guidance are also enabling access to additional untapped markets. "ICE catheters are a billion-dollar market where we currently have no presence," Fitzgerald said. "We're fixing that."

Early physician feedback on the mapping system has been positive. "If you use FARAVIEW NAV with Opal, you can eliminate $2,500 mapping systems in 85 percent of cases and reduce exchanges," he said. "That's cost savings, efficiency, and safety."

International Rollouts

Boston Scientific's approach to international expansion reflects the same strategic focus. In Japan, FARAPULSE received reimbursement in Q4 2024, leading to rapid adoption. "Penetration in Japan is tracking similarly to the U.S. — fast and deep," Fitzgerald said.

In contrast, China presents structural challenges. "You have to go province by province with tendering. We're still early in the game," he said. "But make no mistake. It's a billion-dollar opportunity, and we're building for the long term."

The Watchman Opportunity

Beyond EP, Boston Scientific's WATCHMAN left atrial appendage closure (LAAC) system continues to be a major driver of growth. With over 100,000 procedures expected in the United States this year and a growing trend toward concomitant ablation and LAAC procedures, the company sees strong near-term acceleration.

"Fifty percent of ablation cases now include Watchman. That's tremendous, and it's happening just months after [Centers for Medicare and Medicaid Services] introduced a [diagnosis-related group] that reimburses for same-setting procedures," said Fitzgerald. "We also presented Option trial data showing the safety and efficacy of the approach."

Looking ahead, the Champion trial could be transformative. The 3,000 patient study will provide head-to-head data versus anticoagulants, with endpoints in stroke and bleeding prevention. "We're 99 percent confident we'll present Champion in the first half of 2026," said Fitzgerald.

With a total addressable market of 4 million patients under the current label, Boston Scientific sees Watchman as still early in its life cycle. "We're proud of how the safety profile has improved across generations," said Fitzgerald. "Watchman Flex Pro represents our most refined version yet."

Conclusion

At a time when many medtech firms are grappling with regulatory headwinds, pricing pressures, and geopolitical disruptions, Boston Scientific is focused, aligned, and thriving. The company's growth in electrophysiology, strength in LAAC, disciplined margin expansion, and pipeline visibility have all contributed to its standing as one of the industry's top-performing players.

"Our growth strategy is intentional, and our margin journey is very much alive," said Brennan. "We're not just executing in 2025. We're building for 2030."

Boston Scientific is all-in on platform innovation, procedural efficiency, and durable leadership in high-growth therapy areas. As the company prepares to unveil more of its long-range strategy in September, the medtech industry will be watching closely.

This article was written by Sherrie Trigg, Editor and Director of Medical Content. She can be reached at sherrie.trigg@saemediagroup.com.

The FARAVIEW™ Software Module, coupled with the FARAWAVE NAV Pulsed Field Ablation (PFA) Catheter, provides an integrated solution for cardiac mapping and ablation procedures, specifically for treatment of atrial fibrillation (AFib). (Image provided courtesy of Boston Scientific. ©2025 Boston Scientific Corporation or its affiliates. All rights reserved.)

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Micro Solutions, Major Advances: Micromolding Fuels the Next Generation of Medical Devices

As medical technologies continue to evolve, the demand for miniaturized components with tight tolerances and high performance is accelerating. Meeting these requirements calls for advanced manufacturing methods that can deliver both precision and scalability. One process rising to the challenge is micromolding — a technology that is quietly powering some of the most significant advances in modern medical devices.

Micromolding is particularly critical in medical applications where small size, complex geometries and accelerated development time frames are non-negotiable. It enables the creation of components that not only meet rigorous quality and regulatory requirements but also support next-generation devices such as wearable monitors, diagnostic sensors, and self-administrated drug-delivery tools. These innovations are reshaping healthcare by empowering patients with more accessible, user-friendly solutions, and supporting the shift toward personalized, at-home, and minimally invasive care.

However, successfully leveraging micromolding in medical device manufacturing requires more than just precision engineering. It demands a strategic, end-to-end approach — from initial design and prototyping through tooling and full-scale production.

Accelerating Medical Device Innovation with Micromolding

A growing trend in micromolding is its use in low-volume prototyping to save time and cost while identifying potential manufacturability issues before investing in expensive production tooling. Traditional prototyping leverages additive manufacturing practices like 3D printing to design models. While these methods can be useful for early-stage concept validation, they do not provide insights into material properties and precision required for full production.

Micromolding enables engineers to rapidly produce precise, functional prototypes for evaluation before transitioning to full-scale production. This process enables manufacturers to test the designs, assess material compatibility, and refine complex features earlier than traditional prototyping. Micro-

Collaborative engineering and micromolding innovation drive the development of next-generation medical devices — from concept to scalable production.

Micromolding enables complex, miniaturized medical components for next-generation devices like wearables, sensors, and drug-delivery tools — supporting faster development and personalized care.

Cutting-edge micromolding techniques enable the creation of ultra-precise medical components, fueling the innovation behind today's most sophisticated healthcare devices.

molded prototypes can allow engineers to simulate real-world performance, ensuring validation of functionality, achievability of tight tolerances and geometries, and that the final product meets both performance expectations and regulatory requirements.

This ability to rapidly iterate and test is particularly vital for medical devices like wearables and noninvasive components. For instance, in devices such as diagnostic tools and sensors, micromolding ensures that lightweight and compact components are durable and capable of withstanding prolonged use, crucial for patient safety and device reliability. By enabling faster refinement of these complex components during initial stages of development, micromolding helps accelerate development timelines, reduce time to market, and ultimately bring life-saving technologies to patients sooner.

While micromolding is becoming more accessible as a prototyping tool, developing a successful prototype is just the first step. This article presents three key areas of expertise that drive quality, efficiency, and production readiness in micromolded parts.

Design for Manufacturability. Prototyping is a critical component of design for manufacturability (DfM) — but it's only part of the process. DfM is an engineering practice that optimizes part design, tooling, material selection, and more. It starts with initial part or product design. From there, design engineers collaborate with OEMs to determine moldability, dimensional stability, material compatibility and performance, and beyond. In this process, engineers can carefully evaluate whether the methods used for prototyping can be effectively scaled to full production while maintaining precision and efficiency.

The DfM process helps bridge the gap between design intent and actual production, helping manufacturers avoid costly rework once your product moves into production. Involving suppliers from the very beginning helps optimize material selection, tooling design, and manufacturing processes. Suppliers bring invaluable insights that help reduce costs and lead times, while also identifying potential production hurdles. This collaborative approach leads to smoother, faster, and more efficient product development.

Tooling and Mold Design. High-quality precision tooling is critical in medical device manufacturing. In the medical device space, where even the slightest variation can compromise performance or compliance, tooling must deliver repeatable accuracy down to the sub-micron level. Early insights from DfM and prototyping phases play a pivotal role in helping refine part and mold geometry before investing in expensive tooling.

Following a successful prototyping process, companies can work with tooling partners to confidently scale tooling cavitation for micromolded components while ensuring that all parts remain identical and within required tolerances. Through precision tooling expertise, process control, and continuous quality monitoring, companies can make the successful transition from prototype tooling to full-scale production tooling.

Scalability: From Prototype to Production. With the right process, part design, and tooling, OEMs can accelerate their ability to successfully scale production from low-volume prototype parts to full-scale production. Recognizing the need for quality, safety, and reliability, leveraging the learnings from prototyping, DfM and tooling design process can help OEMs move smarter as they prepare to increase part volumes. Micromolding plays a crucial role in this process by enabling a

faster more efficient transition from design validation to full-scale production of highly precise, miniature components. This is due to a couple of key factors:

- **Process Validation:** With micromolded prototypes, manufacturers gain access to real performance data of the part design, the material, and the equipment. This allows OEMs to transition to production with the data needed to ensure a seamless transition.
- **Material Selection:** By prototyping with end-use materials like polyetheretherketone (PEEK), liquid crystal polymer (LCP), and medical-grade nylons, micromolding offers early visibility into critical material behaviors such as flow dynamics and shrinkage, streamlining the path to scalable production.

Together, these insights help manufacturers reduce development timelines, minimize technical uncertainty, and ensure production readiness. In doing so, micromolding not only meets the demands for complex, high-performance components, it enables faster, more reliable delivery of life-changing medical devices to patients.

Collaborative engineering and micromolding innovation drive the development of next-generation medical devices — from concept to scalable production.

Shaping the Future of Medical Devices Through Micromolding

With its unmatched precision and scalability, micromolding is reshaping what is possible in medical device manufacturing. From early prototyping to high-volume production, this technology empowers manufacturers to meet demanding requirements while accelerating innovation. The result? Advanced medical devices that are not only smaller and more sophisticated, but also more accessible — improving care delivery and enhancing outcomes for patients.

This article was written by Brian Beringer, Director of Engineering, Hoffer Plastics, South Elgin, IL. For more information, visit https://hofferplastics.com.

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Cracking the Code of Cardiac Care:

How AI-Enabled ECG Could Solve Key Challenges in CVD Diagnosis

Cardiovascular disease (CVD) remains a leading — and growing — cause of morbidity and mortality worldwide, with the economic burden of care projected to skyrocket over the coming decades.

Recent findings on heart failure published by the Heart Failure Society of America reveal a rise in the prevalence, mortality, and impact of this condition in the United States.[1] And a recent study estimates that by 2050, the total costs associated with cardiovascular disease in the U.S. will surpass $1 trillion annually, placing unprecedented strain on healthcare systems.[2] Early detection and intervention remain the most effective strategies for mitigating these costs for this growing problem, yet systemic barriers often delay diagnosis and treatment.

AI-enabled electrocardiogram (ECG) technology has the potential to offer a transformative approach to addressing these challenges. By leveraging artificial intelligence (AI) to rapidly analyze and interpret near real-time cardiac monitoring data, healthcare providers may be able to detect potential issues sooner, intervene earlier, and support improved outcomes — all while driving down the mounting cost burden of CVD.

The Cost of CVD: Earlier Is Always Better

Cardiovascular disease is not only the leading cause of death globally, but also one of the most cost-intensive conditions. According to the American Heart Association, total cardiovascular disease-related costs in the United States are projected to triple to $1.8 trillion by 2050.[3] This includes direct medical expenses, such as hospitalizations, procedures, and medications, as well as indirect costs like lost productivity and long-term disability care.

On an individual level, the average cost per patient with heart failure is estimated to be approximately $24,383 annually.[4] Much of this financial burden is driven by acute episodes requiring emergency intervention, frequent hospital readmissions, and intensive long-term management. Most of these costs stem from treating disease at advanced stages when options are fewer, interventions are more expensive, and outcomes are poorer.

The solution is prevention and early intervention. When cardiac issues are detected and managed early — before they progress to severe or chronic stages — patients may experience better health outcomes, and the healthcare system can avoid the costliest interventions. While the solution to reducing costs has long been clear, the path to achieving it has not been. Several complex barriers stand in the way of proactive, early-stage CVD diagnosis.

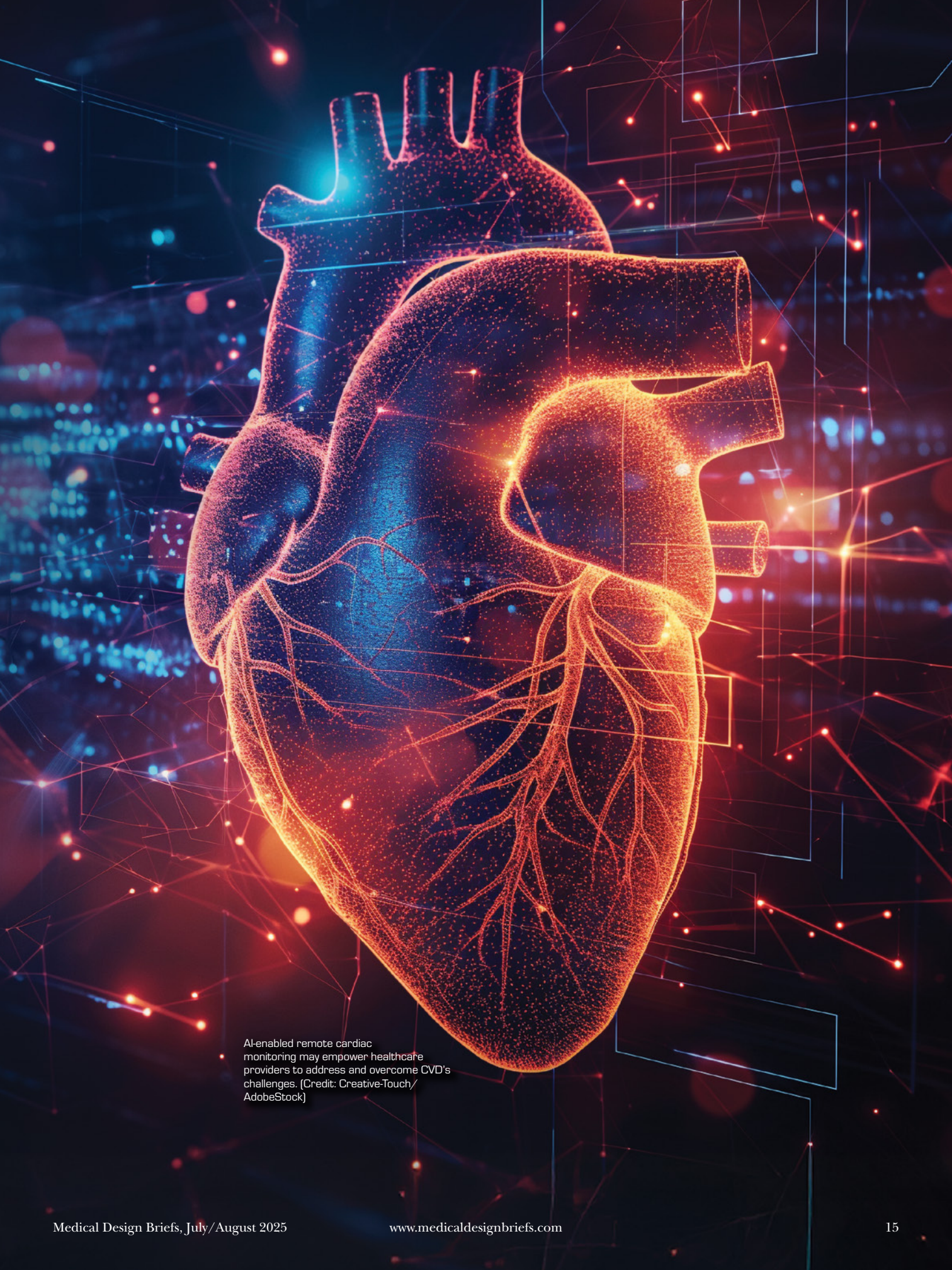
The Systemic Challenge: Barriers to Preventive Cardiac Care

Despite the increasing availability of advanced diagnostic tools, numerous systemic barriers continue to hinder the shift from reactive to preventive cardiac care. Patients are commonly diagnosed after symptoms become acute — by which time treatment is more complex, costly, and less likely to succeed.

One challenge is the limited access to continuous, high-quality cardiac monitoring, especially in underserved or rural populations. Furthermore, common issues like intermittent snapshots, false alarms, clinical overload, fragmented care coordination, and data interpretation difficulties also contribute to missed opportunities for early detection.

Heart failure, in particular, often remains undetected until patients experience severe exacerbations. A survey by the American College of Cardiology found that only 62 percent of patients had been diagnosed with heart failure prior to their hospitalization for acute decompensated heart failure.[5]

The median time from symptom onset to diagno-



AI-enabled remote cardiac monitoring may empower healthcare providers to address and overcome CVD's challenges. (Credit: Creative-Touch/AdobeStock)

sis can be several months, during which time the condition may worsen and become more difficult to treat. In fact, for an individual with newly developed heart failure, the timeline for diagnosis can take as long as 30 months from the initial onset of clinical symptoms.[6] These diagnostic delays not only reduce the chances of successful intervention but also drive up healthcare costs due to emergency care, extended hospital stays, and long-term medication use.

While initiatives like the American Heart Association's heart failure improvement campaign, for example, aim to close care gaps,[7] the reality is that without scalable, integrated solutions capable of supporting early diagnosis and continuous monitoring, patients will continue to fall through the cracks. The need for preventive-focused infrastructure has never been more urgent.

How AI-Powered Remote Cardiac Monitoring Solves the Problem

AI-enabled ECG technology, frequently referred to as remote cardiac monitoring, has the potential to address the persistent challenges in cardiac care by offering solutions that enhance detection, reduce costs, and improve patient outcomes. Following are five ways AI-powered remote cardiac monitoring could mitigate the issues contributing to delayed cardiac diagnosis.

From Intermittent Snapshots to Continuous Monitoring. Traditional monitoring methods rely on intermittent snapshots of heart activity, which often miss critical abnormalities and lead to delayed diagnoses and more costly interventions down the line. AI-enabled RPM platforms, however, could provide continuous, high-fidelity monitoring, capturing a rich dataset over extended periods.

By detecting transient yet clinically significant events — such as brief arrhythmias — earlier, clinicians may be able to take action before conditions worsen, helping reduce costly emergency visits, hospital admissions, and invasive surgical procedures. In fact, remote patient monitoring has been associated with significantly lowering 30-day readmission rates (10 percent) compared to traditional care (23 percent).[8]

From Manual Interpretation to AI-Powered Insight. Unlike manual data interpretation, which can be prone to human error, delays, or missed diagnoses, AI has the potential to offer immediate, actionable insights that may improve diagnostic accuracy. AI algorithms could excel at rapidly analyzing complex cardiac data to identify patterns indicative of cardiac events. One study showed that an AI-enabled ECG correctly identified subtle patterns of atrial fibrillation (AFib) with 90 percent accuracy.[9]

Faster, more accurate detection allows for more timely intervention, potentially reducing the need for expensive acute care and lowering the long-term costs associated with advanced disease progression.

InfoBionic.Ai's MoMe ARC® is an innovative remote cardiac monitoring platform that leverages leading-edge AI analysis and native business intelligence to deliver quality, convenience, and flexibility to providers and patients. (Credit: InfoBionic.Ai)

From False Alarms to High-Fidelity Diagnoses. False alarms are a common problem that plagues monitoring systems,[10] and a major cost driver in cardiac care are the follow-up tests and treatments prompted by these false alarms. AI models that are trained on vast datasets, however, could filter out benign irregularities and noise, ensuring that clinicians are alerted to the most meaningful anomalies.

This kind of precision may be able to minimize unnecessary tests, consultations, and interventions, mitigating the overutilization of resources and reducing patient burden. One study, for example, showed that an AI system was able to eliminate more than two-thirds (approximately 70 percent) of AFib false positives.[11]

From Post-Symptomatic Intervention to Predictive, Preventive Care. Intervention often happens after an event, when it may be too late. AI has the potential to go beyond near real-time detection and could anticipate adverse cardiac events such as AFib or heart failure exacerbations by analyzing long-term trends.

Predictive insights could enable providers to act before conditions escalate, e.g., by prescribing medication adjustments, lifestyle interventions, or closer monitoring. Proactive care not only may improve a patient's quality of life but might also prevent expensive hospitalizations, emergency care episodes, and chronic disease complications, offering substantial long-term savings. This care makes a difference: according to reports, approximately 80 percent of premature heart disease and strokes are actually preventable through early intervention and risk management.[12]

From Clinical Overload to Reduced Burden. According to a 2024 report, ~81 percent of providers say they're overworked.[13] But technology can help by eliminating tedious tasks and freeing up more time for patient care. The adoption of digital health tools among physicians is growing, and they report improved clinical outcomes and work efficiency as the top factors influencing their interest.[14]

Many AI-powered platforms are being designed to integrate smoothly with existing clinical workflows and electronic health record (EHR) systems. With user-friendly interfaces and seamless in-

teroperability, clinicians could use these tools without disruption or additional administrative burden. This streamlined approach may reduce time spent on manual data review and documentation, saving operational costs and improving staff efficiency.

Putting AI-Enabled Remote Cardiac Monitoring into Practice

Scalability and seamless integration are essential for AI-enabled remote cardiac monitoring to deliver its full benefits. Implementing these technologies across healthcare systems requires compatibility with existing infrastructure and workflows to ensure ease of use and foster broad adoption.

When properly integrated, AI-powered monitoring has the potential to extend advanced diagnostic capabilities beyond traditional hospital settings, making high-quality care accessible to underserved populations. By enabling continuous, remote monitoring, these systems are able to bridge critical gaps in care and enhance patient outcomes.[15]

Furthermore, AI-enabled remote cardiac monitoring may improve diagnostic accuracy, reduce unnecessary hospital readmissions, and lower the need for emergency interventions. Predictive capabilities could support preventive care, helping clinicians address potential issues before they escalate. This efficiency may ultimately lead to substantial cost savings and better patient outcomes.

To support the integration and scalability of AI-enabled remote cardiac monitoring, providers may want to consider performing the following tasks:

- Conduct readiness assessments to understand the current infrastructure and identify gaps.
- Prioritize solutions that are interoperable with existing EHRs and devices.
- Train clinical staff to build familiarity and trust in new AI tools.
- Establish standardized protocols to guide when and how AI insights are acted upon.
- Collaborate with technology partners to ensure compliance, cybersecurity, and ongoing support.

As healthcare systems continue to confront rising costs associated with CVD, AI-enabled remote cardiac monitoring could offer a practical, scalable solution to enhance care quality while reducing expenditures.

The Future of CHD Looks Brighter with AI-Enabled Technologies

The escalating costs and prevalence of cardiovascular disease demand innovative solutions that can enhance care quality while alleviating financial burden. AI-enabled ECG technology may offer a compelling and actionable response to these challenges.

By providing clinicians with near real-time insights and empowering them to detect potential issues sooner, AI-driven platforms may be able to simultaneously address the challenge of poor outcomes along with the issue of outsized costs. As the healthcare landscape continues to evolve, adopting these technologies may be critical for

achieving better, more efficient care. Now is the time for healthcare providers to think about integrating scalable, AI-powered solutions to potentially meet the needs of a growing population at risk for cardiovascular disease. Finally, solving the pervasive CVD problem might become much more achievable.

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This article was written by Stuart Long, CEO of InfoBionic.Ai, Chelmsford, MA. For more information, visit https://infobionic.ai.

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Ablation is a cornerstone of minimally invasive medicine, offering targeted tissue destruction with precision unattainable by traditional surgical methods. (Credit: Damian/AdobeStock)

Burn, Freeze, Shock, or Shear: The Expanding Frontiers of Ablation Therapies

Pulsed-field ablation (PFA) has dominated the medical device news in recent years, yet it is only one modality among many in the world of ablation therapies, and while groundbreaking, it is limited to a few diseases. It's time to broaden the conversation and highlight the myriad innovations in ablation technology transforming medical practice.

What Is Ablation?

Ablation refers to the selective destruction of tissue to treat a disease or disorder. Common applications include killing tumors, correcting heart arrhythmias, and deadening pain from over-active sensory nerves. Other applications include conditions spanning from literally head-to-toe on the human body and include everything from the most cutting-edge life-saving treatments (brain surgery) to the most superficial (killing sweat glands to reduce underarm perspiration).

Ablation is a cornerstone of minimally invasive medicine, offering targeted tissue destruction with precision unattainable by traditional surgical methods. Ablation technologies encompass a wide variety of modalities, including:

- Extreme cold (cryoablation).
- Heat (microwave and radiofrequency ablation).
- Mechanical forces (focused ultrasound).
- Electric fields (electroporation and PFA).

What all these modalities have in common is that they require interdisciplinary expertise spanning device engineering, tissue biology, and computational modeling to ensure they are safe, effective, and market ready.

Mechanisms of Action

Cryoablation is the simplest ablation modality, using extreme cold to induce frostbite in a controlled manner. This process kills cells by freezing their intracellular fluid, leading to ice crystal formation and cell rupture. While commonly used for superficial applications, advancements in needle and catheter design have enabled deep-tissue treatments, such as for prostate or liver tumors.

Despite its effectiveness, cryoablation has limitations. The process can be unwieldy, and controlling the spread of freezing can be challenging, making it less precise than some other ablation modalities.

Microwave and *radiofrequency (RF) ablation* both rely on heat to destroy tissue, but their mechanisms differ:

1. Microwave ablation excites water molecules in tissue, generating heat

RF Ablation	Microwave Ablation
Thin, low-cost electrodes	Larger, more expensive antennas
Ideal for small targets	Suitable for larger-volume targets
Requires electrical conduction	Operates without full tissue contact

Table 1. Strengths and applications for RF ablation and microwave ablation.

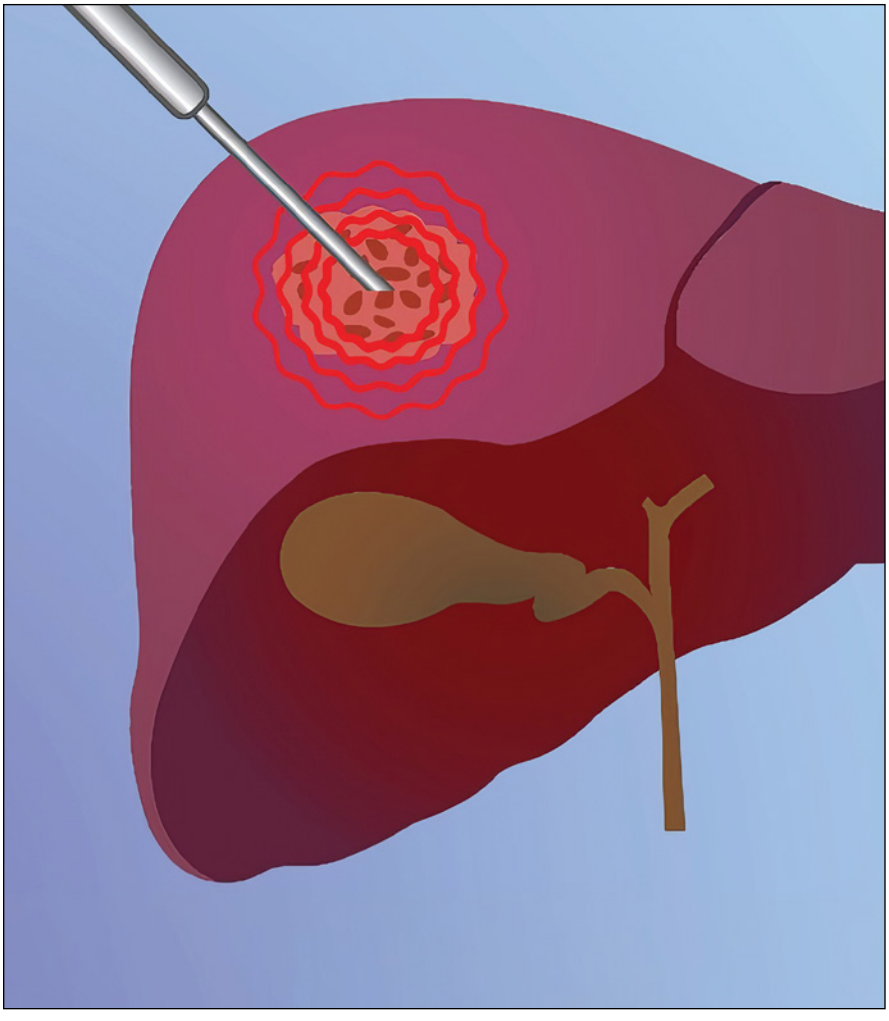

Fig. 1 – RF ablation applied to liver tumor.

through molecular vibrations (similar to a microwave oven heating food).
2. RF ablation conducts electrical current through tissue, producing heat via resistance.

Each technique has distinct strengths and applications as shown in Table 1. The choice between these technologies depends on the target tissue and clinical requirements. For example, RF ablation excels in smaller, electrically conductive tissues, while microwave ablation is preferred for larger, less conductive structures such as the lung (see Figure 1).

Ultrasound ablation uses high-intensity sound waves, and again, has a different mechanism of action depending on the specific implementation.

1. Thermal ultrasound devices generate sound waves with enough intensity that they produce significant heating when absorbed by tissue; this has applications in catheter-based intraluminal therapies and directional needle-based ablation therapies.
2. Cavitational ultrasound devices use high-frequency sound waves to induce cavitation (a mechanical shearing of tissue), which produces tiny, localized bubbles that disrupt tissue at the cellular level. Particularly exciting about this approach is the ability to generate ultrasound waves outside of the body then focus them at a target deep within the body — to say this therapy is minimally invasive is insufficient; this approach is completely noninvasive.

Electric field ablation encompasses PFA and irreversible electroporation (IRE), which use high-intensity electric fields to open pores in the walls of cells (and/or their nuclei), causing a loss of cellular homeostasis and eventual cell death (see Figure 2). Key benefits of this approach include:

1. Tissue selectivity: Different types of tissues are dramatically more (or less) susceptible to electroporation. In cardiac electrophysiology, this allows electric fields to ablate errant conduction pathways in myocardial tissue without damaging sensitive nearby nerves or muscles.
2. Nonthermal mechanism: Electroporation uses essentially the same type of thin needles and catheters that physicians are familiar with using in RF ablation yet ablates tissue in a non-thermal manner. This apoptotic mechanism of cellular death (versus the necrotic mechanism of thermal ablation) minimizes inflammation, resulting in faster healing and less pain.
3. Predictability: Thermal ablation therapies are less predictable and controllable in tissues with different heat capacities, different thermal conductivities, or heat sink effects (such as blood flow) present. Preprocedure planning and prediction of thermal ablation therapies is difficult, as the heat transfer equations and computational models are complex. Electric field ablation, however, is unaffected by any of these confounders, and the equations and models are simple, allowing meaningful and reliable preplanning of treatments, improving efficacy and outcomes.

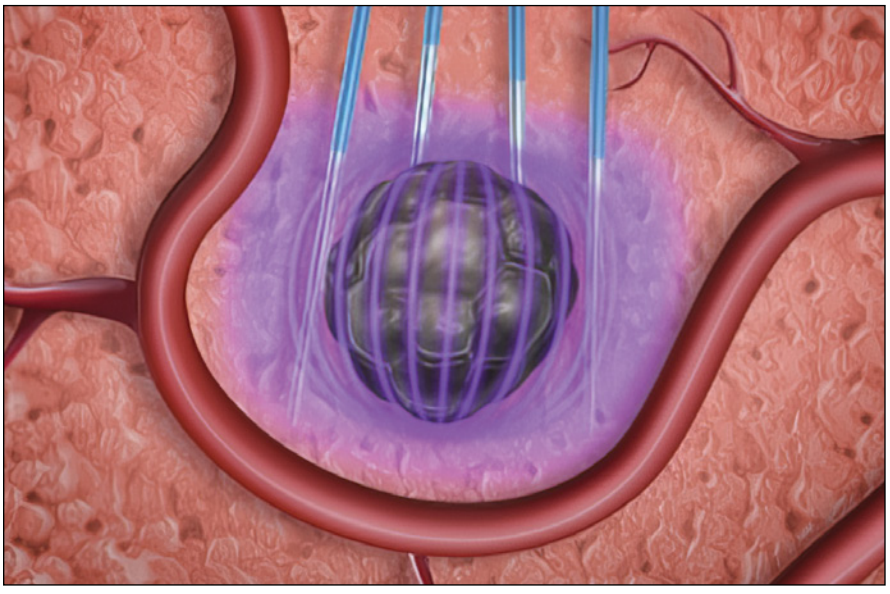

Fig. 2 – Electric field ablation targeting a tumor.

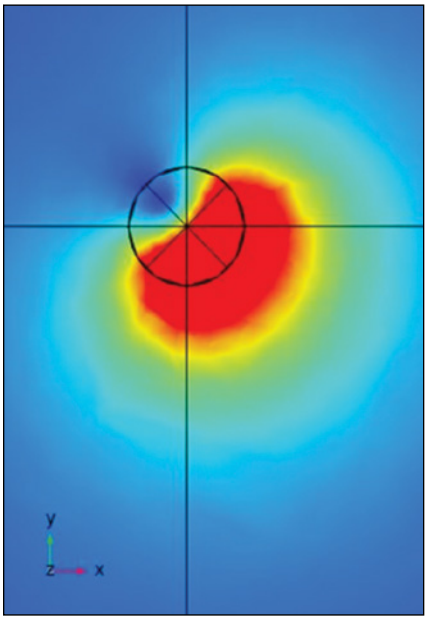

Fig. 3 – Simulated thermograph of steerable ablation probe.

Emerging Innovations in Ablation

Two major themes are emerging in ablation innovation today: 1) even less-invasive procedures, and 2) even more selective and effective approaches.

Less-invasive Procedures. Across all medical disciplines, there is a push toward less-invasive techniques, and ablation therapies are no exception. Innovations focus on enhancing existing technologies to reduce patient recovery time and improve outcomes. Examples include:

1. Intraluminal ablation catheters: These catheters circulate coolant to protect surrounding tissues while creating precise, uniquely shaped ablation zones.
2. Expandable RF needles: By mechanically expanding around the target tissue, these instruments shorten procedure times and improve durability of the therapy.
3. Integrated sensors: Advanced sensor systems can identify target tissues, assess therapy success in real-time, and reduce the risk of complications.

Enhanced Selectivity and Efficacy. While many ablation techniques rely on basic mechanisms like heating or freezing, new advancements aim to improve tissue selectivity, efficacy, and controllability. Notable examples include:

- Expanding PFA applications: Beyond its established use in cardiac therapies, PFA is being adapted for non-cardiac applications. Researchers are exploring tissue-specific electric susceptibilities to develop treatments with reduced collateral damage and fewer side effects.
- Steerable probes: These allow clinicians to precisely direct energy to diseased tissues while avoiding healthy structures. Additionally, their ability to adjust in real-time eliminates the need for repositioning electrodes during procedures (see Figure 3).

Challenges and Opportunities

Despite their transformative potential, ablation technologies face several challenges:

- Thermal modalities require complex modeling to predict heat transfer accurately, especially in tissues with varying thermal properties or blood flow.
- Cryoablation's limitations in controllability can restrict its use for certain applications.
- Electric field ablation, while highly promising, is still in the early stages of clinical adoption for noncardiac uses.

Opportunities lie in addressing these challenges through interdisciplinary innovation. Combining modalities, such as pairing thermal ablation with sensors for real-time feedback, could significantly enhance outcomes. Similarly, advancements in computational modeling and AI-driven planning systems promise to improve precision and predictability across all modalities.

Future Directions and Conclusions

Ablation therapies have become indispensable in modern medicine, and their influence will only grow as innovation drives less-invasive, more-effective solutions. The next wave of advancements is likely to emerge from the convergence of technologies, leveraging engineering, biology, and clinical insights to overcome current limitations. Those innovators with multi-disciplinary technology breadth, the ability to work with users to understand their needs and pains, and the ability to straddle the biological, electrical, and mechanical domains, will be the leaders in the ablation technologies of the future.

This article was written by Dan Friedrichs, PhD. He leads development engineering efforts at Minnetronix Medical, St. Paul, MN. For more information, visit www.minnetronix.com.

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Paper-Based Diagnostic Provides Rapid Disease Detection

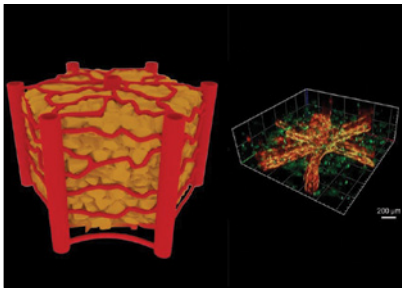
A paper-based diagnostic device can detect COVID-19 and other infectious diseases in under 10 minutes, without the need for sophisticated lab equipment or trained personnel.

The breakthrough device detects even minute traces of viral genetic material using a droplet of fluid and a visible color change. It operates without electricity or special equipment, needing just a source of mild heat at around 65 °C, similar to the temperature of warm water. Its compact design, engineered from a single sheet of paper, integrates miniature components such as sample ports and vents, fluidic resistors, and reaction chambers preloaded with primers, enzymes, and gold nanoparticles.

The device supports multiplex testing, meaning it can detect several gene targets in a single run. This improves efficiency while reducing sample volume and cost. Its flexible design can be adapted to detect various pathogens (bacteria, viruses, etc.), across sample types such as saliva, blood, and environmental sources. (Image credit: NYU Abu Dhabi)

For more information, visit www.medicaldesignbriefs.com/roundup/0725/rapid-diagnostic.

A Chip with Natural Blood Vessels



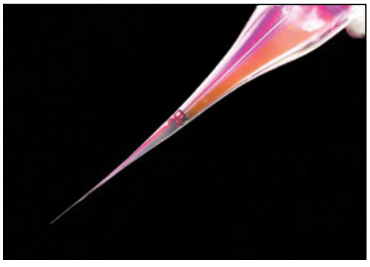
Mini organs are incomplete without blood vessels. To facilitate systematic studies and ensure meaningful comparisons with living organisms, a network of perfusable blood vessels and capillaries must be created — in a way that is precisely controllable and reproducible. A team has established a method using ultrashort laser pulses to create tiny blood vessels in a rapid and reproducible manner. Experiments show that these vessels behave just like those in living tissue. Liver lobules have been created on a chip with great success.

The team relied on advanced laser technology: with the help of ultrashort laser pulses in the femtosecond range, highly precise 3D structures can be written directly into the hydrogel — quickly and efficiently.

Using this approach, they were able to vascularize a liver model, developing a liver lobule-on-chip that incorporates a controlled 3D vascular network, closely mimicking the in vivo arrangement of the central vein and sinusoids. (Image credit: TU Wien)

For more information, visit www.medicaldesignbriefs.com/roundup/0725/lab-on-a-chip.

Pipette Activates Individual Neurons



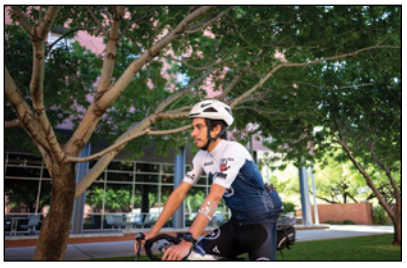
Researchers have developed a new type of pipette that can deliver ions to individual neurons without affecting the sensitive extracellular milieu. Controlling the concentration of different ions can provide important insights into how individual brain cells are affected and how cells work together.

The micropipette measures only 2 µm in diameter. For comparison, human hair measures 50 and a neuron about 10 µm in diameter. Using this so-called iontronic micropipette, the researchers can add only ions, such as potassium and sodium, to the extracellular milieu to see how this affects the neurons. Glial cells, specifically astrocyte, activity is also measured.

The pipette is manufactured by heating up a glass tube and pulling it to the breaking point. This produces a very thin and tapered tip. This type of micropipette is usually used in neuroscience to create and measure electrical activity in the brain. The researchers' iontronic micropipette has a tip filled with a specially adapted ion-exchange membrane, which makes it possible to create activity by chemical means. (Image credit: Thor Balkhed)

For more information, visit www.medicaldesignbriefs.com/roundup/0725/pipette.

Long-Lasting 3D Printed Wearable Transforms Health Monitoring



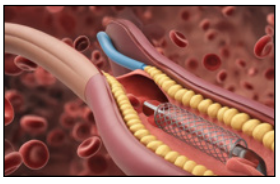
A long-lasting, 3D printed, adhesive-free wearable provides a more comprehensive picture of a user's physiological state. The device, which measures water vapor and skin emissions of gases, continuously tracks and logs physiological data associated with dehydration, metabolic shifts, and stress levels.

The device, worn on the forearm, resembles a small 3D printed cuff and can be worn continuously. The device sensors constantly measure gases emitted by the user, comparing their concentrations against normal outside air.

The wearable delivers continuous, real-time data viewable on a smartphone or computer via secure Bluetooth. With a device such as this, athletes can monitor hydration and exertion during training. The wearable could also record mental health and chronic disease symptoms to aid in prevention and treatment. In fact, tracking and monitoring physiological signs of stress in gas emissions can even help identify early metabolic disturbances. (Image credit: Gutruf Lab)

For more information, visit www.medicaldesignbriefs.com/roundup/0725/health-monitoring.

AI-Powered Analysis of Stent Healing



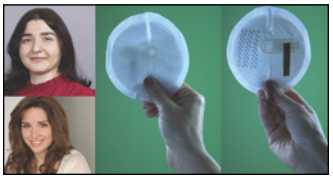
A research team has developed DeepNeo, an AI-powered algorithm that automates the process of analyzing coronary stents after implantation. The tool matches medical expert accuracy while significantly reducing assessment time. With strong validation in both human and animal models, DeepNeo has the potential to standardize monitoring after stent implantation and thus improve cardiovascular treatment outcomes.

The AI algorithm can automatically assess stent healing in OCT images. DeepNeo differentiates between different healing patterns with an accuracy comparable to clinical experts — but in a fraction of the time. The AI tool also provides precise measurements, e.g., regarding tissue thickness and stent coverage, offering valuable insights for patient management.

To train DeepNeo, researchers used 1,148 OCT images from 92 patient scans, manually annotated to classify different types of tissue growth. They then tested the AI algorithm in an animal model, where it correctly identified unhealthy tissue in 87 percent of cases when compared to detailed laboratory analysis, the current gold standard. When analyzing human scans, DeepNeo also demonstrated high precision, closely matching expert assessments. (Image credit: Helmholtz Munich)

For more information, visit www.medicaldesignbriefs.com/roundup/0725/AI-stent.

Wearable Lactation Pads Detect Chemicals in Milk



Engineers have developed a smart lactation pad that can quantify a wide range of chemicals in breast milk in real time. This work is pioneering the first wearable, rapid sensor for at-home measurement of chemicals in breast milk, addressing an important technology gap for improving the health of the mother and the baby.

The researchers transformed a simple lactation pad into a smart health device. They built in tiny microfluidic channels that guide the milk to a sensing area. Low-cost electrochemical sensors detect and measure important health markers in the milk. The sensor, built into the absorbent lactation pad, collects small amounts of breast milk naturally released during the let-down reflex throughout the day. It then sends real-time readings to the user's smartphone via a compact, portable detector, using electrical pulses to measure levels of acetaminophen. With this information, users can make informed decisions — such as choosing to pump and discard milk containing medication. Researchers verified that the sensor worked throughout the changing composition of breast milk, from colostrum to mature milk. (Image credit: USC Viterbi)

For more information, visit www.medicaldesignbriefs.com/roundup/0725/wearable-pads.

Advanced Laser Welding Techniques for Titanium Pacemaker Housing: Achieving Precision, Reliable and Hermetic Sealing

By Dr. Najah George, Photon Automation, Inc.

A pacemaker helps control your heartbeat so you can return to your normal life. It has three main parts: a pulse generator that creates electrical signals, a controller-monitor that manages these signals, and leads that deliver the signals to the heart. One key benefit of the pacemaker is its strong titanium casing. Titanium is very strong and lightweight, and it is biocompatible, meaning it works well with the body without causing harmful reactions. This metal is highly resistant to corrosion, which helps keep the casing intact and protective even when exposed to bodily fluids. Titanium is also used in everyday appliances because it shields internal parts from strong electrical and magnetic fields. This means that people with pacemakers can use items like hair dryers, electric razors, TVs, radios, and computers, ensuring safe operation, although caution is needed near strong electromagnetic fields.

Additionally, titanium's durability effectively shields internal components like sensitive electronics and long-lasting batteries from moisture and other elements. A medical-grade plastic header securely connects the leads to the internal circuit. Once assembled, the final step is to weld the titanium casing shut, forming a hermetic seal that further protects the pacemaker's parts and ensures long-term, reliable performance (see Figure 1).

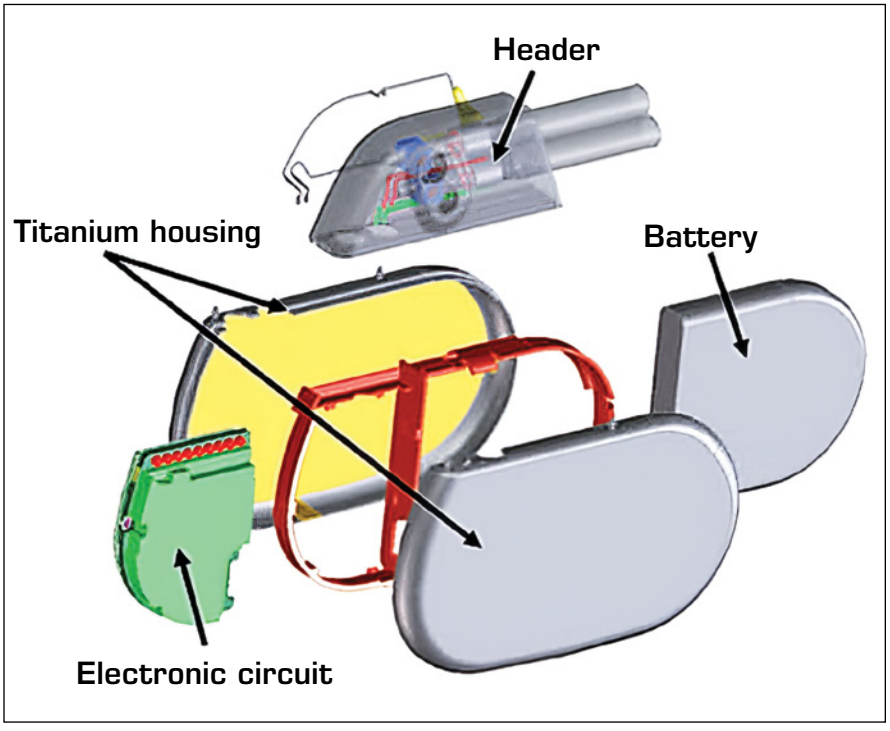


Fig. 1 – Pacemaker components assembly diagram. (Credit: BIOTRONIK-patient's manual)

Challenges in Welding Titanium

Despite claims that titanium exhibits good weldability using a Nd-YAG laser (1.06 µm wavelength) or a fiber laser (1.07 µm wavelength) with 77 percent coupling efficiency, welding titanium is challenging. It is sensitive to contamination and reactive at high temperatures. Welding titanium is also challenging due to its high sensitivity to contamination and its reactivity at high temperatures.

When titanium is heated during welding, it easily absorbs gases such as oxygen,

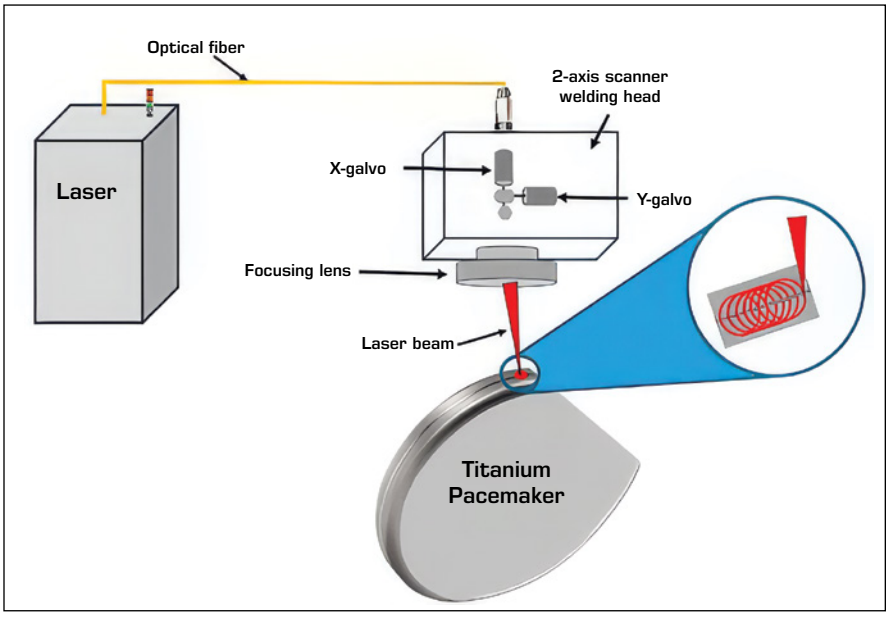


Fig. 2 – Illustration diagram of WonderBoard™ integration with a laser and scanner head.

hydrogen, and nitrogen from the air. Without proper shielding, these gases mix with the metal, forming brittle compounds like carbides, nitrides, and oxides that weaken the weld. The cooling rate and heat input are critical; slow cooling may cause grain growth, while excessive heat can produce brittle phases and high stresses that lead to cracks. Strict process control is essential for a reliable weld.

Many welding methods exist for titanium, including tungsten inert gas arc welding (TIG), electrical beam welding (EBW), resistance welding, and diffusion welding, yet these methods can risk heat damage to sensitive electronics. Laser welding stands out by minimizing the heat-affected zone (HAZ) and producing high-quality, low-porosity joints that are easily automated for fast production (see Figure 2).

Pacemaker Manufacture Joining Design

The joining design is important in pacemaker manufacturing, when designing the joint to connect the two titanium pieces for pacemaker housing, we should aim to simplify equipment production by incorporating a hermetic seal welding joint, such as a stepped butt joint.

In a stepped butt joint, the geometry creates a larger, more defined target area for the laser, allowing for more flexibility in laser positioning compared to a standard butt joint, where alignment must be much more precise. Essentially, the stepped design provides a buffer zone, permitting slight deviations in laser positioning while still ensuring an effective, high-quality weld. Additionally, there will be less chance for welding smoke or particles to get inside the pacemaker housing, thereby reducing the risk of harming the circuit control unit.

Welding Medical Tool Devices: Regulation

Medical welding tools must meet strict standards for compliance, safety, precision, biocompatibility, hermetic seal, and durability. Key requirements include:

- ISO 13485: Quality management system for medical device manufacturing.
- FDA regulations (21 CFR Part 820): Ensures compliance with Good Manufacturing Practices (GMP).
- ISO 10993: Biocompatibility testing for medical devices.
- ASTM F2063 and F136: Standards for materials like nitinol and titanium used in medical devices.

Selecting the Right Laser Welding Processing Equipment

Selecting the right laser welding process is crucial, especially when working with heat-sensitive materials like titanium. However, welding medical materials requires precise heat control. Quasi-continuous wave (QCW) fiber lasers operate in a high-frequency pulsed mode, delivering bursts of energy that mimic continuous wave (CW) output but with higher peak power and minimum pulse duration in millisecond level. Laser welding heads guide the beam through fixed optics but have limitations in medical welding.

Oscillating laser welding using galvanometer scanners (galvo-based beam oscillation), which moves the laser beam over the molten pool, is a promising technique for welding medical parts. It spreads the energy over a slightly larger area and allows more of the joint volume to be heated effectively. In addition, it contributes to improved hermetic sealing. In addition, beam oscillation can also help bridge gaps even when the fit-up is not perfect.

Advanced welding techniques such as microsecond-pulse laser welding with beam oscillation is the right approach for welding medical materials like titanium, which is highly susceptible to heat-induced degradation or distortion. This method delivers energy in very short, controlled bursts while oscillating the beam, which helps control and distribute heat evenly and further minimizes the heat-affected zone.

Photon Automation, Inc. has developed WonderBoard™, a pulse and power profile controller that manages lasers at the microsecond level, enabling custom pulse shapes. This increases peak power from kilowatts to megawatts while maintaining average power. By precisely shaping pulses, it reduces localized thermal stress, ensuring that the titanium retains its desirable mechanical properties, minimizes the HAZ, and improves durability. Additionally, WonderBoard controls galvanometer mirrors that can achieve a consistent and even distribution of laser energy across the target area, as the rapid movement of the beam can lead to hot spots and uneven heating.

Combining the right join design with advanced techniques provides a better hermetic seal, resulting in a tighter, more contamination-resistant joint that is essential for applications requiring high integrity, such as pacemaker housing, and for keeping internal components safe.

This article was written by Dr. Najah George, Senior Director of R&D at Photon Automation Inc., Greenfield, IN. Photon Automation develops advanced laser processes for medical devices. For more information, contact Najah George at ngeorge@photonautomation.com or visit https://www.photonautomation.com.

Medical Device Makers: Ask These 7 Questions for an Effective Wireless Test Program

By Khushboo Kalyani, LitePoint

When it comes to technology adoption, the healthcare industry is historically risk averse. Despite strict regulations protecting patient data and concerns over medical outcomes, a new report from Mordor Intelligence reports that the global market for wireless portable medical devices is expected to exceed $31.4 billion this year.[1] The same report projects 12.14 percent compound annual growth through 2030 to meet the demands of a burgeoning geriatric population for wearable and implantable devices and in-home vital signs monitoring.

The primary role of many portable wireless medical devices is to perform essential clinical functions, such as patient monitoring, infusion, or diagnosis (see Figure 1). While medical device manufacturers excel at designing solutions to meet these critical healthcare needs, their skills may not inherently include wireless technology. Adding wireless components — Wi-Fi or Bluetooth, for instance — to transmit patient data securely and reliably in real time to nursing stations or electronic health records systems is a complex task.

The wireless connectivity knowledge gap can create a blind spot in which medtech companies may inadvertently neglect to adequately test their devices as they graduate from a concept in the lab to the volume production line. This oversight can lead to device underperformance in which patients may experience poor connections and delays in clinical notifications. In the worst cases, devices may fail, which for manufacturers can trigger product recalls, compliance violations, and an erosion of customer trust.

With adoption rates rising, the wireless technology landscape is increasingly complicated to manage as it moves from discrete and comparatively simplistic electronic components to highly integrated modules housing multiple wireless protocols such as 5G cellular, Wi-Fi, and Bluetooth Low Energy (see Figure 2).

This article presents seven critical questions that medical device designers should be asking as they build the next generation of wireless products to improve quality of life for millions of patients.

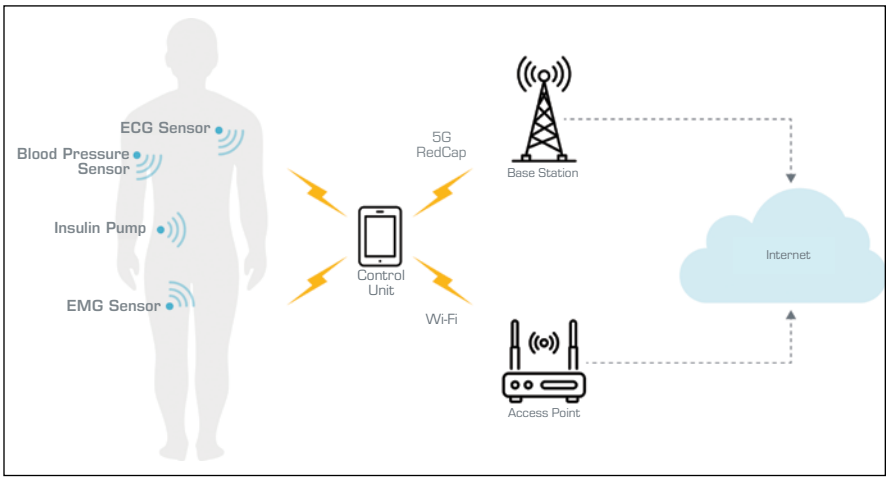


Fig. 1 – The primary role of many portable wireless medical devices is to perform essential clinical functions, such as patient monitoring, infusion, or diagnosis.

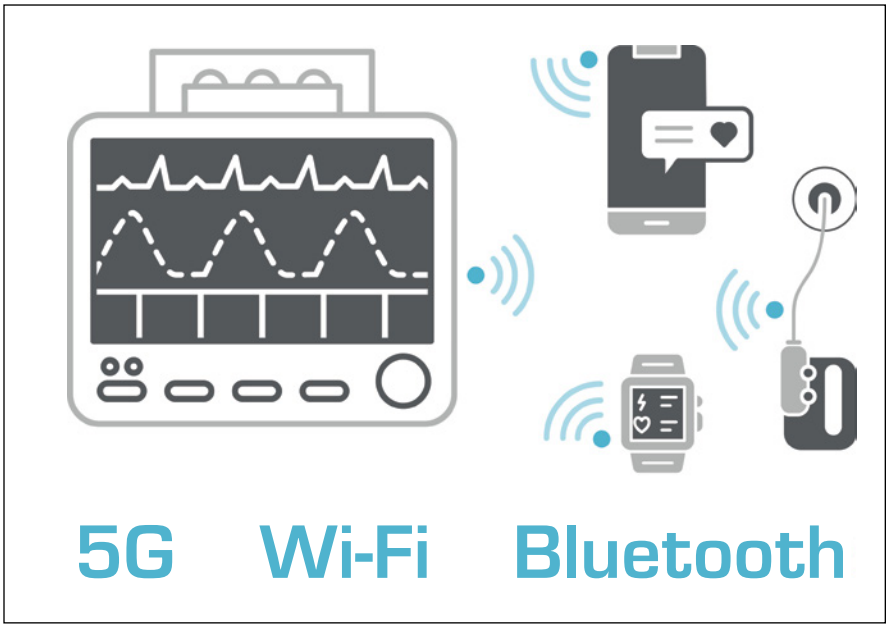


Fig. 2 – The wireless technology landscape is increasingly complicated to manage as it moves from discrete and comparatively simplistic electronic components to highly integrated modules housing multiple wireless protocols such as 5G cellular, Wi-Fi, and Bluetooth Low Energy.

Top Questions for Wireless Medical Device Testing

Which wireless technology is best suited to my product? Whether Wi-Fi, Bluetooth, or cellular, the choice depends on how much data needs to be transferred, how swiftly, and over what distance. Medical devices carrying large data volumes that require reliable, always-on connections may be better suited to Wi-Fi.

These include insulin pumps and devices for monitoring blood pressure and heart rate. Others, like blood glucose monitors and pulse oximeters, transmit small amounts of data just a few times a day and may be better candidates for Bluetooth.

Cost is another important consideration, with Bluetooth modules generally adding less to bill of materials budgets than Wi-Fi or cellular modules. Designers should also familiarize themselves with compliance and regulatory requirements that may influence their connectivity decisions.

What are the different stages of wireless test and how do they differ? Typically, during R&D and design verification testing, the focus is on validating fundamental RF parameters (e.g., power output, receive sensitivity, and error vector magnitude) across different frequency bands of operation.

During quality and assurance testing, the focus shifts to the user experience. This includes validating performance across real-world use cases and conducting coexistence and over-the-air (OTA) interference testing to determine whether the product will perform well in the field. It's important to test full parametric performance and not just rely on go/no-go tests that only indicate whether the device is functional.

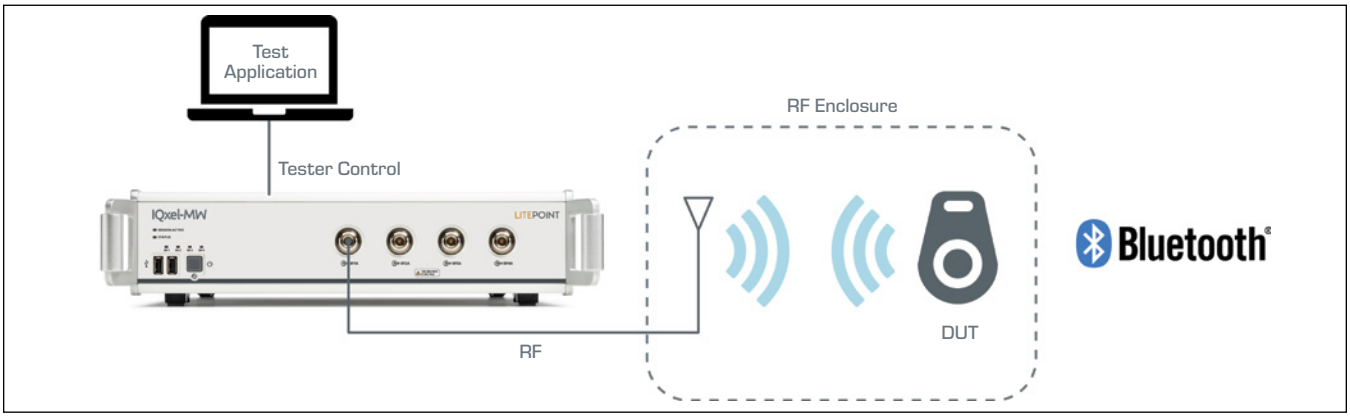


Fig. 3 – A cost-of-test analysis can help manufacturers reduce costs and expedite time to market.

Production testing requires an optimum balance of quality and cost economics. That means checking the device's bare minimum functional performance and then testing multiple devices simultaneously to reduce the cost of test and expedite time to market.

There are two common denominators that cut across these different test stages. The first is hardware test equipment that is capable of scaling from lab to manufacturing. The second is a user-friendly yet advanced automated software tool that reduces RF testing overhead to minimize test-suite development and design and execution times.

What is the best way to comprehensively test wireless performance? As you progress through the product development cycle, what you test and the way you test will vary. When designing a product from scratch, for example, it's important to measure the performance of the RF transceiver in isolation to ensure that it meets design specifications.

Once the device is validated, it must be tested in its entirety. Real-world scenario testing entails attaching the device antenna and casing to ensure that the final hardware and software are not impacting wireless performance.

Can testing help ensure patient data accuracy? Hospitals and home environments can be crowded RF spaces, with multiple devices operating at similar frequencies. Interference can lead to dropped signals, corrupt data, or incomplete transmissions. Even a small percentage of lost or distorted data can undermine the reliability of clinical decisions.

Interference testing that measures device sensitivity, packet error rate (PER), and bit error rate (BER) can indicate how often transmissions are corrupted under different conditions. Some throughput tests can also identify design flaws by measuring data transfer rates between devices on a wireless network.

Should I use an off-the-shelf RF module or design in a chipset technology? When you buy off the shelf, you typically don't have access to the wireless chipset and controls for testing. That means you need to use the command provided by the module vendor, write your own software, or rely on a test vendor like LitePoint, which has a test methodology setup to quickly validate performance.

The choice is contingent on two factors: Time to market and form factor.

Time to market: Off-the-shelf modules can be expensive but often reduce development time, as they come precertified and precalibrated. Generally, that eliminates time spent working with regulatory labs for compliance testing. On the other hand, commissioning a chipset design means working extensively with the chipset supplier to ensure seamless integration into your product. This can be a complicated, time-consuming process and can add overhead to the design process.

Form factor: Chipset-based designs offer better control over the end-device form factor by accommodating smaller, compact designs compared to off-the-shelf modules.

Whether you design your chipset or buy an off-the-shelf module, LitePoint, for example, provides automation software through the IQfact+ tool that supports the gamut of chipset-specific test packages and can be used out of the box.

Are there additional test considerations when I move into high-volume device production? Many medical devices sell in the hundreds of thousands or even millions of units, so the ability to scale testing is an important step for accurately determining device yield. Just as importantly, designers want to make sure they aren't incorrectly failing good units and/or passing bad units. An inaccurate test is as harmful as no test at all.

How can I better manage test costs? If manufacturing volumes are high and test costs are rising, you should consider a cost-of-test analysis, which includes single-test and multi-test options. This can help manufacturers reduce costs and expedite time to market by determining how much time it takes to test one device as a percentage of overall capital equipment costs compared to how long it takes to test multiple devices in parallel (see Figure 3).

As many in the medical community are discovering, portable wireless medical device technology is a game — and life — changer. Accurate, repeatable, scalable testing is a key step in delivering the highest levels of care.

Reference

1. Wireless Medical Devices Market Size & Share Analysis — Growth Trends & Forecasts (2025–2030), https://www.mordorintelligence.com/industry-reports/wireless-medical-devices-smarket, Mordor Intelligence.

This article was written by Khushboo Kalyani, Product Manager, LitePoint, San Jose, CA. For more information, visit www.litepoint.com.

Common Pitfalls When Specifying Bearings for Medical Devices

By Jason Flanzbaum, Boca Bearings

Engineering precision is an art of nuance — especially when it comes to selecting the right bearing for medical devices. What begins as a straightforward specification process quickly becomes a complex yet familiar puzzle of competing requirements. Oftentimes, engineers discover that a bearing's performance extends beyond its basic dimensional specs, involving considerations of material properties, system integration and supply chain dynamics.

The consequences of bearing choice can ripple through design, manufacturing and ultimately, device performance. A seemingly minor technical oversight can compromise device reliability, increase production costs or introduce unexpected failure modes. In medical device engineering, these aren't just technical challenges — they're critical decisions that can directly impact clinical outcomes.

Most engineers initially approach bearing selection through a lens of technical specifications like internal and external diameters, load-bearing capacities and force calculations: either a bearing fits or it doesn't. Either a bearing can handle the required forces, or it can't. Yet these metrics tell only part of the story.

This article delves into some of the design engineering and supply chain issues for medical device bearings, providing insights into their implications. It also offers guidance on how to optimize the bearing selection process with your supplier, ensuring your components perform reliably.

The consequences of bearing choice can ripple through design, manufacturing, and ultimately, device performance.

Navigating Bearing Selection

Selecting the optimal bearing for a medical device is a critical decision with far-reaching implications. Partnering with an experienced bearing supplier is crucial for successful medical device design. A supplier can help an OEM understand the specific needs of the bearing in a way that avoids costly over- specification. Part of this process involves the material selection. Bearings made from ceramic or stainless steel, for example, provide the necessary corrosion resistance and compatibility with sterilization processes, ensuring the bearings perform optimally without unnecessary, costly enhancements (see the Sidebar, "Bearing Materials").

It's also important to work with a supplier that emphasizes the integration of bearings into the overall medical device design. These suppliers collaborate closely with device manufacturers to ensure that components aren't considered in isolation, leading to better device performance.

Instead of reaching for the most complex or costly solution, the best bearing suppliers focus on precise optimization, treating each medical device as a unique engineering challenge. In some cases, the ideal bearing solution requires a custom component that transcends what standard off-the-shelf bearings can offer. In practice, this means going beyond simple dimensional matching and understanding how features like bearing stiffness, radial loads, and axial play affect the device's mechanical ecosystem.

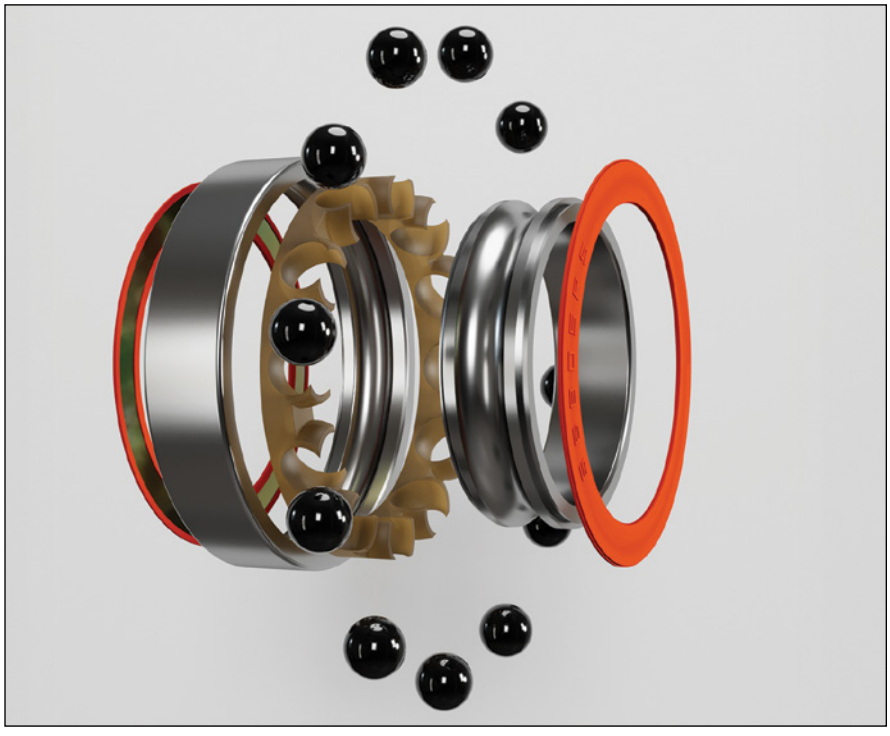
For example, an application involving a molecular diagnostic testing system required modified versions of standard bearings from Boca Bearings. Engineers implemented specific design modifications, including specialized corner breaks and lubrication systems, ensuring

Bearing Materials

Corrosion-resistant bearings are made from materials such as stainless steel, silicon nitride, alumina oxide, zirconia oxide, polyetheretherketone (PEEK), and titanium. These noncorrosive materials are suitable for demanding applications like medical devices, ensuring that the bearings can withstand harsh environments, maintain machine uptime, and ensure patient safety.

Meeting ISO 9001 Quality Standards

A robust quality management system (QMS) that aligns with ISO 9001 standards ensures that a company such as Boca Bearings meets the highest standards of quality and safety. A QMS encompasses several core processes, including inquiry, quote, order, pick, pack and ship, delivery and follow-up — all designed to ensure products meet customer expectations and regulatory requirements. Implementing quality control measures reduces downtime and maintenance costs associated with bearing failures.



Bearings are important elements of complex mechanical systems. (Credit: Boca Bearings)

that these components were optimized for the diagnostic equipment. The bearings play an important role in this point-of-care platform, which delivers fast, accurate PCR results — the gold standard for diagnostics in hospitals, laboratories, and near-patient settings.

In another application, engineers selected units with specific clearance levels and specialized lubrication that met performance requirements for a breast biopsy tool. The end-user had been using bearings with MC3 clearance yet required components with MC5 clearance. The MC3 bearings were replaced with stainless-steel bearings with MC5 clearance, along with ABEC#5/ISOP5 ratings and AF2 lubricant.

Driving Cost and Complexity with Overengineering

Engineers face two primary challenges when selecting bearings for medical equipment: overengineering and failure to consider bearings as part of an integrated system. Overengineering occurs when designers select bearings with specifications that exceed the actual requirements of the medical device. For example, a designer may choose a bearing with unnecessarily high precision levels, excessive load capacities, or advanced materials. While this approach may seem harmless at first, it can significantly increase cost without contributing to the device's performance in any meaningful way.

The role of a bearing partner is to help identify the appropriate level of precision and specifications needed for your device to function optimally and reliably, avoiding unnecessary expense. Here are a few common scenarios.

Precision Levels. Many engineers select bearings with very high Annular Bearing Engineers' Committee (ABEC) ratings, selecting units with precision levels that far exceed the medical device's actual operational needs. While highly precise bearings reduce wear and improve performance in extreme conditions, they are not always required. An imaging device or laboratory centrifuge, for example, rarely requires the same precision as a high-speed aerospace system.

Load Capacities. While it may seem prudent to select bearings with load capacities that exceed an application's requirements, this approach can lead to increased costs without any tangible benefits in terms of device performance or lifespan.

Material Selection. Specialized polymers and other advanced materials may be beneficial in certain applications, but they may be overkill in others. Again, this approach not only increases the material costs but can also complicate the manufacturing process.

In addition to driving costs, the consequences of bearing overengineering extend to the supply chain. Bearings with high precision and load specifications, for example, may not be readily available in large quantities, leading to manufacturing delays and longer lead times. This is especially the case for medical devices that don't have high production volumes.

Bearings as Part of an Integrated System

A second pitfall many engineers and designers face involves treating bearings like standalone components, which can lead to design and performance challenges that compromise device functionality. Rather, it's important to remember that bearings are important elements of complex mechanical systems. Failure to consider this integration can cause the following issues.

Tolerance Stack-up. One possible effect of considering bearings in isolation is tolerance stack-up, where the cumulative effect of individual component tolerances can lead to misalignment, poor mechanical fit, and reduced device reliability. In medical imaging devices, for example, even minor misalignments can compromise image quality.

Assembly Issues. Bearings designed without considering the entire manufacturing process can cause downstream

complications, increasing assembly time, raising the defect rates and even compromising device integrity.

Performance Degradation. Bearings that don't integrate well with other components in the assembly can erode device performance, causing increased friction, noise, and wear, for example. These issues can reduce the lifespan of the device and drive maintenance, which can cost the company significantly in engineering maintenance and machine downtime. A medical imaging machine down for a few hours can impact revenue by $100,000.

In medical equipment, these implications carry particularly high stakes, as device performance and reliability directly impact patient safety and treatment efficacy. By working closely with an OEM's design team, bearing suppliers help ensure that the selected bearings integrate seamlessly into the overall system, minimizing tolerance issues, facilitating efficient and reliable production, preventing performance degradation and ensuring long-term device reliability.

The Importance of Quality Control

Throughout the bearing selection process, quality control is paramount. This process involves rigorous component testing, verification of medical-grade standards and detailed specification reviews. In addition to technical know-how, bearing suppliers should be certified to ISO 9001 — a global benchmark for quality management. This certification demonstrates a commitment to quality control standards and ensures the bearings consistently meet regulatory requirements (see the Sidebar, "Meeting ISO 9001 Quality Standards").

The Device Development Cycle

It's worth noting that bearing selection extends beyond just engineering challenges and involves the complexities of medical device development cycles. Unlike other industries, medical devices often progress through extended development phases — from the prototype phase, which requires small quantities, to test production, which involves medium quantities, to full-scale production.

This cycle creates unique challenges in component sourcing and consistency. Suppliers like Boca Bearings can support customers throughout this entire journey, offering design engineering during initial phases, small-quantity prototyping capabilities during development, and the logistics and quality control systems necessary for full overseas production.

This end-to-end support ensures component reliability and performance throughout the medical device's life cycle. Selecting the right bearings for medical devices requires a holistic approach that transcends basic dimensional specifications and load calculations.

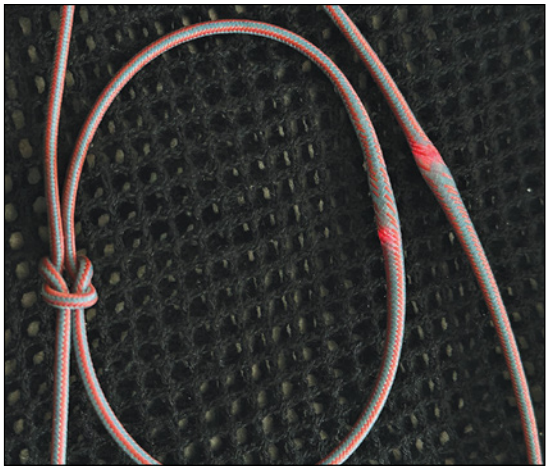
Successful engineers recognize that overengineering and failure to consider bearings as part of an integrated system can drive unnecessary costs and time without performance benefits.

This article was written by Jason Flanzbaum, President, Boca Bearings, Boynton Beach, FL. For more information, visit www.bocabearings.com.

Fiber Computer Allows Apparel to Run Apps and "Understand" the Wearer

The garment learns to identify physical activities.

Massachusetts Institute of Technology, Cambridge, MA



This single, elastic fiber contains a series of microdevices, including sensors, a microcontroller, digital memory, bluetooth modules, optical communications, and a battery, making up all the necessary components of a computer. (Credit: Yoel Fink, edited by MIT News)

What if the clothes you wear could care for your health? MIT researchers have developed an autonomous programmable computer in the form of an elastic fiber, which could monitor health conditions and physical activity, alerting the wearer to potential health risks in real time. Clothing containing the fiber computer was comfortable and machine washable, and the fibers were nearly imperceptible to the wearer, the researchers report.

Unlike on-body monitoring systems known as *wearables*, which are located at a single point like the chest, wrist, or finger, fabrics and apparel have an advantage of being in contact with large areas of the body close to vital organs. As such, they present a unique opportunity to measure and understand human physiology and health.

The fiber computer contains a series of microdevices, including sensors, a microcontroller, digital memory, Bluetooth modules, optical communications, and a battery, making up all the necessary components of a computer in a single elastic fiber.

The researchers added four fiber computers to a top and a pair of leggings, with the fibers running along each limb. In their experiments, each independently programmable fiber computer operated a machine-learning model that was trained to autonomously recognize exercises performed by the wearer, resulting in an average accuracy of about 70 percent.

Surprisingly, once the researchers allowed the individual fiber computers to communicate among themselves, their collective accuracy increased to nearly 95 percent.

"Our bodies broadcast gigabytes of data through the skin every second in the form of heat, sound, biochemicals, electrical potentials, and light, all of which carry information about our activities, emotions, and health. Unfortunately, most — if not all — of it gets absorbed and then lost in the clothes we wear. Wouldn't it be great if we could teach clothes to capture, analyze, store, and communicate this important information in the form of valuable health and activity insights?" says Yoel Fink, a professor of materials science and engineering at MIT, a principal investigator in the Research Laboratory of Electronics (RLE) and the Institute for Soldier Nanotechnologies (ISN), and senior author of a paper on the research, which appears in *Nature*.

The use of the fiber computer to understand health conditions and help prevent injury will soon undergo a significant real-world test as well. U.S. Army and Navy service members will be conducting a month-long winter research mission to the Arctic, covering 1,000 kilometers in average temperatures of –40° F. Dozens of base layer merino mesh shirts with fiber computers will be providing real-time information on the health and activity of the individuals participating on this mission, called Musk Ox II.

"In the not-too-distant future, fiber computers will allow us to run apps and get valuable health care and safety services from simple everyday apparel. We are excited to see glimpses of this future in the upcoming Arctic mission through our partners in the U.S. Army, Navy, and DARPA. Helping to keep our service members safe in the harshest environments is a honor and privilege," Fink says.

He is joined on the paper by co-lead authors Nikhil Gupta, an MIT materials science and engineering graduate student; Henry Cheung MEng '23; and Syamantak Payra '22, currently a graduate student at Stanford University; John Joannopoulos, the Francis Wright Professor of Physics at MIT and director of the Institute for Soldier Nanotechnologies; as well as others at MIT, Rhode Island School of Design, and Brown University.

Fiber Focus

The fiber computer builds on more than a decade of work in the Fibers@MIT lab at the RLE and was supported primarily by ISN. In previous papers, the researchers demonstrated methods for incorporating semiconductor devices, optical diodes, memory units, elastic electrical contacts, and sensors into fibers that could be formed into fabrics and garments.

"But we hit a wall in terms of the complexity of the devices we could incorporate into the fiber because of how we were making it. We had to rethink the whole process. At the same time, we wanted to make it elastic and flexible so it would match the properties of traditional fabrics," says Gupta.

One of the challenges that researchers surmounted is the geometric mismatch between a cylindrical fiber and a planar chip. Connecting wires to small, conductive areas, known as *pads*, on the outside of each planar microdevice proved to be difficult and prone to failure because complex microdevices have many pads, making it increasingly difficult to find room to attach each wire reliably.

In this new design, the researchers map the 2D pad alignment of each microdevice to a 3D layout using a flexible circuit board called an interposer, which they wrapped into a cylinder. They call this the *maki* design. Then, they attach four separate wires to the sides of the maki roll and connected all the components together.

"This advance was crucial for us in terms of being able to incorporate higher functionality computing elements, like the microcontroller and Bluetooth sensor, into the fiber," says Gupta.

This versatile folding technique could be used with a variety of microelectronic devices, enabling them to incorporate additional functionality.

In addition, the researchers fabricated the new fiber computer using a type of thermoplastic elastomer that is several times more flexible than the thermoplastics they used previously. This material enabled them to form a machine-washable, elastic fiber that can stretch more than 60 percent without failure.

They fabricate the fiber computer using a thermal draw process that the Fibers@MIT group pioneered in the early 2000s. The process involves creating a macroscopic version of the fiber computer, called a *preform*, that contains each connected microdevice.

This preform is hung in a furnace, melted, and pulled down to form a fiber, which also contains embedded lithium-ion batteries so it can power itself.

"A former group member, Juliette Marion, figured out how to create elastic conductors, so even when you stretch the fiber, the conductors don't break. We can maintain functionality while stretching it, which is crucial for processes like knitting, but also for clothes in general," Gupta says.

Bring Out the Vote

Once the fiber computer is fabricated, the researchers use a braiding technique to cover the fiber with traditional yarns, such as polyester, merino wool, nylon, and even silk.

In addition to gathering data on the human body using sensors, each fiber computer incorporates LEDs and light sensors that enable multiple fibers in one garment to communicate, creating a textile network that can perform computation.

Each fiber computer also includes a Bluetooth communication system to send data wirelessly to a device like a smartphone, which can be read by a user.

The researchers leveraged these communication systems to create a textile network by sewing four fiber computers into a garment, one in each sleeve. Each fiber ran an independent neural network that was trained to identify exercises like squats, planks, arm circles, and lunges.

"What we found is that the ability of a fiber computer to identify human activity was only about 70 percent accurate when located on a single limb, the arms or legs. However, when we allowed the fibers sitting on all four limbs to *vote*, they collectively reached nearly 95 percent accuracy, demonstrating the importance of residing on multiple body areas and forming a network between autonomous fiber computers that does not need wires and interconnects," Fink says.

Moving forward, the researchers want to use the interposer technique to incorporate additional microdevices.

Karl Friedl, U.S. Army Research Institute of Environmental Medicine senior research scientist of performance physiology, noted that the MIT programmable computing fabric technology may become a "gamechanger for everyday lives."

"Imagine near-term fiber computers in fabrics and apparel that sense and respond to the environment and to the physiological status of the individual, increasing comfort and performance, providing real-time health monitoring and providing protection against external threats. Soldiers will be the early adopters and beneficiaries of this new technology, integrated with AI systems using predictive physiological models and mission-relevant tools to enhance survivability in austere environments," Friedl says.

This research was supported, in part, by the U.S. Army Research Office Institute for Soldier Nanotechnology (ISN), the U.S. Defense Threat Reduction Agency, the U.S. National Science Foundation, the Fannie and John Hertz Foundation Fellowship, the Paul and Daisy Soros Foundation Fellowship for New Americans, the Stanford-Knight Hennessy Scholars Program, and the Astronaut Scholarship Foundation.

This article was written by Adam Zewe, MIT. For more information, contact Yoel Fink at yoel@mit.edu or visit https://news.mit.edu.

Dental Floss Measures Stress, Other Cognitive States

Built-in sensors could also be adapted to track conditions like diabetes, heart disease, and cancer.

Tufts University, Medford, MA

Chronic stress can lead to increased blood pressure and cardiovascular disease, decreased immune function, depression, and anxiety. Unfortunately, the tools we use to monitor stress are often imprecise or expensive, relying on self-reporting questionnaires and psychiatric evaluations.

Now a Tufts interdisciplinary engineer and his team have devised a simple device using specially designed floss that can easily and accurately measure cortisol, a stress hormone, in real time.

"It started in a collaboration with several departments across Tufts, examining how stress and other cognitive states affect problem solving and learning," says Sameer Sonkusale, professor of electrical and computer engineering. "We didn't want measurement to create an additional source of stress, so we thought, can we make a sensing device that becomes part of your day-to-day routine? Cortisol is a stress marker found in saliva, so flossing seemed like a natural fit to take a daily sample."

Their design of a saliva-sensing dental floss looks just like a common floss pick, with the string stretched across two prongs extending from a flat plastic handle, all about the size of your index finger. The saliva is picked up by capillary action through a very narrow channel in the floss. The fluid is drawn into the pick handle and an attached tab, where it spreads across electrodes that detect the cortisol.

Cortisol recognition on the electrodes is accomplished with a remarkable technology developed almost 30 years ago called *electropolymerized molecularly imprinted polymers* (eMIPs). They work similarly to the way you might make a plaster cast of your hand. A polymer is formed around a template molecule, in this case cortisol, which is later removed to leave behind binding sites. These sites have a

physical and chemical shape memory of the target molecule so that they can bind free-floating molecules that are coming in.

The eMIP molds are versatile, so one can create dental floss sensors that detect other molecules that can be found in saliva, such as estrogen for fertility tracking, glucose for diabetes monitoring, or markers for cancer. There is also potential for detecting multiple biomarkers in saliva at the same time, for more accurate monitoring of stress, cardiovascular disease, cancer, and other conditions.

"The eMIP approach is a game changer," says Sonkusale. "Biosensors have typically been developed using antibodies or other receptors that pick up the molecule of interest. Once a marker is found, a lot of work has to go into bioengineering the receiving molecule attached to the sensor. eMIP does not rely on a lot of investment in making antibodies or receptors. If you discover a new marker for stress or any other disease or condition, you can just create a polymer cast in a very short period of time."

This dental floss pick has a sensor that can assess a person's stress level. (Credit: Atul Sharma and Nafize Ishtiaque Hossain)

Accuracy of the cortisol sensors is comparable to the best-performing sensors on the market or in development. Bringing this device into the home and in the hands of individuals without need for training will make it possible to fold stress monitoring into many aspects of health care. Currently Sonkusale and his colleagues are creating a startup to try and bring the product to market.

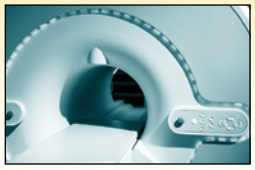
He points out that while the dental floss sensor is quantitatively highly accurate, the practice of tracking markers in saliva is best for monitoring, not for the initial diagnosis of a condition. That's in part because saliva markers can still have variations between individuals.

"For diagnostics, blood is still the gold standard, but once you are diagnosed and put on medication, if you need to track, say, a cardiovascular condition over time to see if your heart health is improving, then monitoring with the sensor can be easy and allows for timely interventions when needed," he says.

The new research, published in the journal *ACS Applied Materials and Interfaces*, adds to a number of thread-based sensor innovations by Sonkusale and his research team, including sensors that can detect gases, metabolites in sweat, or movement when embedded in clothing and transistors that can be woven into flexible electronic devices.

This article was written by Mike Silver, Tufts University. For more information, contact Sameer Sonkusale at sameer@ece.tufts.edu or visit https://now.tufts.edu.

PRODUCT OF THE MONTH



ENERGY STAR Certification

SGS, Geneva, Switzerland, has received EPA approval as a recognized third-party certification body for testing and certification of magnetic resonance imaging (MRI) machines under the ENERGY STAR® label. The certification allows brands and manufacturers to demonstrate that a device uses less energy in ready to scan mode as well as via an automated power down to an energy saving low power state. Once certified, the blue ENERGY STAR® label makes it easy for consumers and businesses to identify and purchase energy-efficient products that offer savings on energy bills without sacrificing performance.

www.sgs.com

Product Focus: Connectors/Wires/Cables

Panel-Mount Connectors

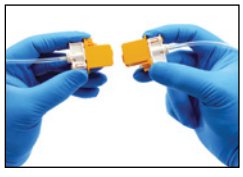
A range of panel-mount connectors is available from binder, Camarillo, CA. The M12 portfolio includes multiple coding options (e.g., A-, B-, D-, X-, S-, T- and L-coding), various termination styles (such as solder, dip solder, and stranded wire), housing materials, and mounting configurations. The connectors are designed for secure and reliable integration of signals, data, or power into enclosures and devices across a wide range of industrial applications. In addition to straight and angled versions, product variants also include different connection types — from stranded wires to soldering and THT technology through to THR and SMT.

www.binder.com

Sheet E Plug Connector

Adding to its line of molded IEC 60320 appliance and interconnection couplers, Interpower, Oskaloosa, IA, has launched its newly manufactured IEC 60320 rewirable Sheet E plug connector in a straight cable mount configuration. It is initially offered in black. The Sheet E plug connector recently obtained Japanese PSE approval. The connector carries a UL 94 V-0 flammability rating. The connector plug material is polybutylene terephthalate (PBT) with nickel-plated brass terminals, and is rated 10 A (international) and 15 A (North American) 250 VAC.

www.interpower.com



Aseptic Connector

Colder Products Company, Roseville, MN, has introduced the smallest aseptic connector available. The MicroCNX® Nano Series connectors help maintain sterility in CGT processes using ⅛- or 1/16-in. tubing. The connector's small size also allows it to fit directly into the freeze cassettes used in CGT product cryopreservation. The connectors can be frozen to –190 °C, which supports cell health during storage and transport. The new product's termination and flow path are made from polyphenylsulfone (PPSU). The series is compatible with tubing types that are commonly used in developing advanced therapies including silicone, thermoplastic elastomer (TPE), and polyvinyl chloride (PVC).

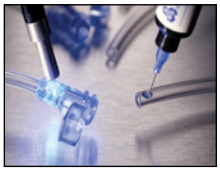
www.cpcworldwide.com

Push-Pull Connector

LEMO, Rohnert Park, CA, has released a new push-pull connector series. The REDEL MP Series features a wide choice of standard modules for power, signal, data, fiber optic, and fluidic connectivity that can be combined into one single connector to address an extensive range of applications. The series also introduces high contact density modules, an innovation that allows up to 144 contacts in a compact connector by using the Card Edge concept. These PCB modules can be further customized with the integration of intelligence, such as an EEPROM. The flexible and interchangeable design allows for easy transition to different configurations for future generations of a product without an interface design change.

www.lemo.com

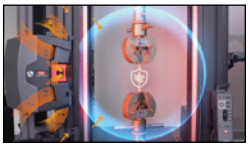
TPO-Free Light-Curable Adhesives



Dymax, Torrington, CT, has expanded its portfolio of TPO-free light-curable materials. The available TPO-free products have been rigorously tested. For medical device applications, the adhesives meet biocompatibility standards, including ISO 10993-5 cytotoxicity and others as appropriate, helping support internal validation or documentation requirements. Additionally, manufacturers that want to integrate the formulations into existing production environments can seek assistance from Dymax technical service specialists who can help customers move through validation processes with current applications or new product development efforts. Product data sheets are available for material property review prior to in-house validation.

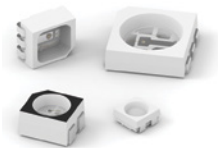
www.dymax.com

Video Extensometer



Instron, Norwood, MA, has released an advanced noncontacting video extensometer that delivers precise strain measurement with unparalleled, micron-level accuracy for tensile, compression, and bend testing. The AVE3 can measure both modulus and strain to failure on a diverse range of materials such as plastics, metals, composites, biomaterials, textiles, and elastomers — along with sensitive materials like films and foils. Compliant with ISO 9513 and ASTM E83, the AVE3 allows labs to reliably test to any standard with one device, without needing to purchase and maintain multiple clip-on extensometers. The unit can be configured to accommodate a range of gauge lengths and elongations. New kinematic mounting enables each lens to automatically snap into the factory-calibrated location, making it easy to capture accurate data every time.

www.instron.com



Heat-Resistant LEDs

Würth Elektronik, Waldenburg, Germany, has extended its RGB LED product series. The WL-SFTW SMT full-color TOP LED Waterclear RGB LEDs are characterized by excellent heat resistance. Their insensitivity to temperatures from –40 to +100 °C makes them ideal solutions for reliable, color-variable lighting in applications at high operating temperatures. The lens ensures clear, brilliant colors and precise color rendering. High-quality features such as silver-plated solder pads and heat-resistant PLCC housings ensure excellent solderability, high resistance to thermal shock, and high reliability in production.

www.we-online.com

High-Energy Magnets

Arnold Magnetic Technologies, Rochester, NY, offers a line of high-energy flexible magnets. PLASTIFORM® magnets are engineered specifically for applications that require increased magnetic field strength while maintaining the flexibility of a bonded magnet, even in environments with high temperatures, wide temperature ranges, or exposure to corrosive materials. With energy products ranging from 1.0 to 1.6 MGOe, the magnets are available in a wide selection of thicknesses, roll sizes, and finishes, allowing them to be precisely tailored for a broad range of applications.

www.flexmag.com

Medical-Grade Monitors

Medical-grade monitors and touchscreens from TRU-Vu, Fort Wayne, IN, are certified to the latest IEC and UL 60601-1 4th edition standards. They are designed for use in a wide range of medical OEM equipment and systems and hospital operating rooms. Each medical display has an IP65 edge-to-edge all-glass front design and comes with a medical-grade power supply and hospital-grade Green Dot power cord.

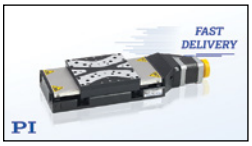
https://tru-vumonitors.com

Inventory Management

Cetec ERP, Austin, TX, offers advanced tools for flexible inventory management through a fully integrated platform that centralizes inventory control, eliminates redundant processes, and enables real-time coordination across teams. By consolidating quoting, purchasing, warehouse management, and accounting into one platform, the ERP eliminates the gaps between systems that disrupt execution resulting in increased profitability. The software is designed for small and mid-sized manufacturers and combines depth of functionality with accessibility.

www.cetecerp.com

Micropositioning Stage



A linear micropositioning stage from PI, Auburn, MA, is designed for applications requiring minimum incremental motion down to 20 nm, drive forces up to 22 lbs, and multi-axis configuration options. With linear travel up to 155 mm (6 in.), the L-511 can be combined to form XY or XYZ motion systems and can be integrated with rotary stages for enhanced flexibility. A variety of drive and encoder options (stepper and servo motors, rotary and linear encoders) enable ultra-fine sensitivity from 0.6 down to 0.005 µm. It features high-load recirculating ball bearings for exceptional durability, even under demanding, repetitive cycles.

www.pi-usa.us

Thread Seal Tapes

Fluoramics, Inc., Lewiston, MN, has launched two new full-density thread seal tapes engineered for demanding applications. Full Density Thread Seal Tape for Gas and LOX-8 Full Density Thread Seal Tape FDA-Approved are built to deliver superior sealing performance, extreme chemical resistance, and high-pressure durability. The tape is silicone-free, rated for extreme temperatures, and built from the same material as the company's green oxygen-approved tape.

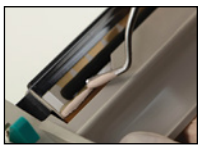
www.fluoramics.com.com

DC Brushless Drives

Dart Controls, Zionsville, IN, has introduced a compact, economical, energy efficient alternative in brushless DC motor control. The brushless drives are ideal for applications that require high speed or quiet operation, combined with a BLDC motor to eliminate brush wear. The 700 series models include 12–48 VDC voltage supply and 5–20 ADC current, in open or closed loop designs. A space-saving design allows the drives to fit in a tight footprint. Open chassis or NEMS 4/4X enclosed styles are available, along with panel mount design (BLM series). All Commutrol™ series models are designed for motors with Hall sensors included.

www.dartcontrols.com

PRODUCT SPOTLIGHT



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Master Bond Supreme 11AOHTMed is a two-component epoxy featuring thermal conductivity and electrical insulation. This system fully passes ISO 10993-5 testing for non-cytotoxicity and is recommended for bonding and sealing in medical device applications. https://www.masterbond.com/tds/supreme-11aohtmed

Master Bond

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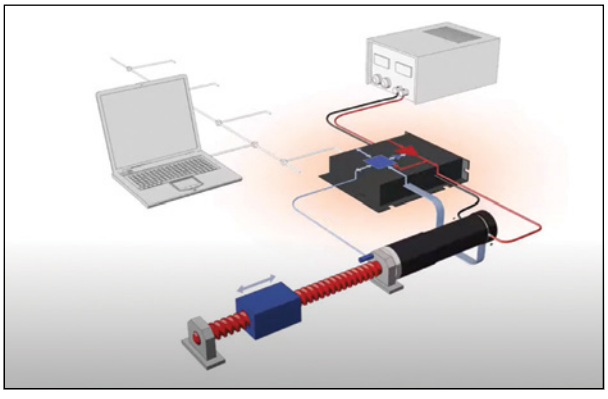
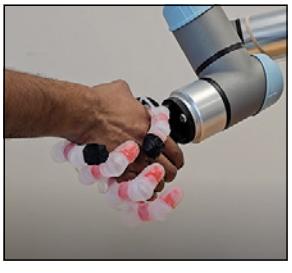


FEATURED SPONSOR VIDEO:

How to Select the Right Controller

What controller is best for your application? Learn about the different controllers and how to choose the right one in this short video.

www.techbriefs.com/tv/controller-selection



Prosthetic Hand Can Grip Like a Human

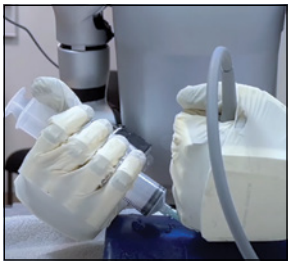
A new prosthetic hand created at Johns Hopkins University can grip plush toys, water bottles, and other everyday objects like a human can. The breakthrough brings prosthetic tech closer than ever before to truly mimicking the human touch.

www.techbriefs.com/tv/grip-like-a-human

Device Advances Field-Testing for Biologicals

A microfluidic immunoassay device makes it easier to detect proteins in biological samples. The device has the potential to help diagnose many infectious diseases by detecting key protein markers.

www.techbriefs.com/tv/microfluidic-device



Surgie: A Humanoid Robot Surgeon

Humanoid robots hcan help healthcare workers by leveraging their human-like dexterity and adaptability to assist with medical procedures. Watch this video to learn more about Surgie the Robot Surgeon.

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July/August 2025, Volume 15, Number 7.

Soft Brainstem Implant Delivers High-Resolution Hearing

EPFL
Lausanne, Switzerland

Over the last couple of decades, many people have regained hearing functionality with the most successful neurotech device to date: the cochlear implant. But for those whose cochlear nerve is too damaged for a standard cochlear implant, a promising alternative is an auditory brainstem implant (ABI). Unfortunately, current ABIs are rigid implants that do not allow for good tissue contact. As a result, doctors commonly switch off a majority of the electrodes due to unwanted side effects such as dizziness or facial twitching — leading most ABI users to perceive only vague sounds, with little speech intelligibility.

Now, a team at EPFL's Laboratory for Soft Bioelectronic Interfaces has developed a soft, thin-film ABI. The device uses micron-scale platinum electrodes embedded in silicone, forming a pliable array just a fraction of a millimeter thick. This novel approach, published in *Nature Biomedical Engineering*, enables better tissue contact, potentially preventing off-target nerve activation and reducing side effects.

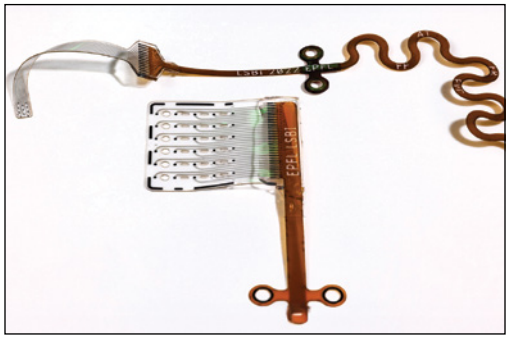
"Designing a soft implant that truly conforms to the brainstem environment is a critical milestone in restoring hearing for patients who can't use cochlear implants. Our success in macaques shows real promise for translating this technology to the clinic and delivering richer, more precise hearing," says Stéphanie P. Lacour, head of the Laboratory for Soft Bioelectronic Interfaces (LSBI) at EPFL.

Probing "Prosthetic Hearing" with a Complex Behavioral Task

Rather than simply relying on surgical tests, the researchers ran extensive behavioral experiments in macaques with normal hearing. This allowed them to measure how well the animals could distinguish electrical stimulation patterns as they would with natural acoustic hearing.

"Half the challenge is coming up with a viable implant, the other half is teaching an animal to show us, behaviorally, what it actually hears," says Emilie Revol, co-first author on the project and a former PhD student at EPFL. She meticulously trained the animals to perform an auditory discrimination task: the monkeys learned to press and release a lever to indicate whether consecutive tones were the "same" or "different."

"We then introduced stimulation from the soft ABI step by step, blending it with normal tones at first so the monkey could bridge the gap between acoustic and prosthetic hearing," says Revol. "Ultimately, the goal was then to see if the animal could detect small shifts from one electrode pair to another when only stimulating the soft ABI. Our results suggest that the animal treated these pulses almost the same way it treated real sounds."



The flexible auditory brainstem implant (ABI) closely conforms to the curved surface of the brainstem. (Credit: EPFL)

Why a Soft Array?

"Our main idea was to leverage soft, bioelectronic interfaces to improve electrode-tissue match," explains Alix Trouillet, a former postdoctoral researcher at EPFL and co-first author of the study. "If the array naturally follows the brainstem's curved anatomy, we can lower stimulation thresholds and maintain more active electrodes for high-resolution hearing."

Conventional ABIs rest on the dorsal surface of the cochlear nucleus, which has a 3 mm radius and a complex shape. Rigid electrodes leave air gaps, leading to excessive current spread and undesired nerve stimulation. By contrast, the EPFL team's ultra-thin silicone design easily bends around the tissue.

Beyond conformability, the soft array's flexible microfabrication means it can be reconfigured for different anatomies. "The design freedom of microlithography is enormous," says Trouillet. "We can envision higher electrode counts or new layouts that further refine frequency-specific tuning. Our current version houses 11 electrodes — future iterations may substantially increase this number."

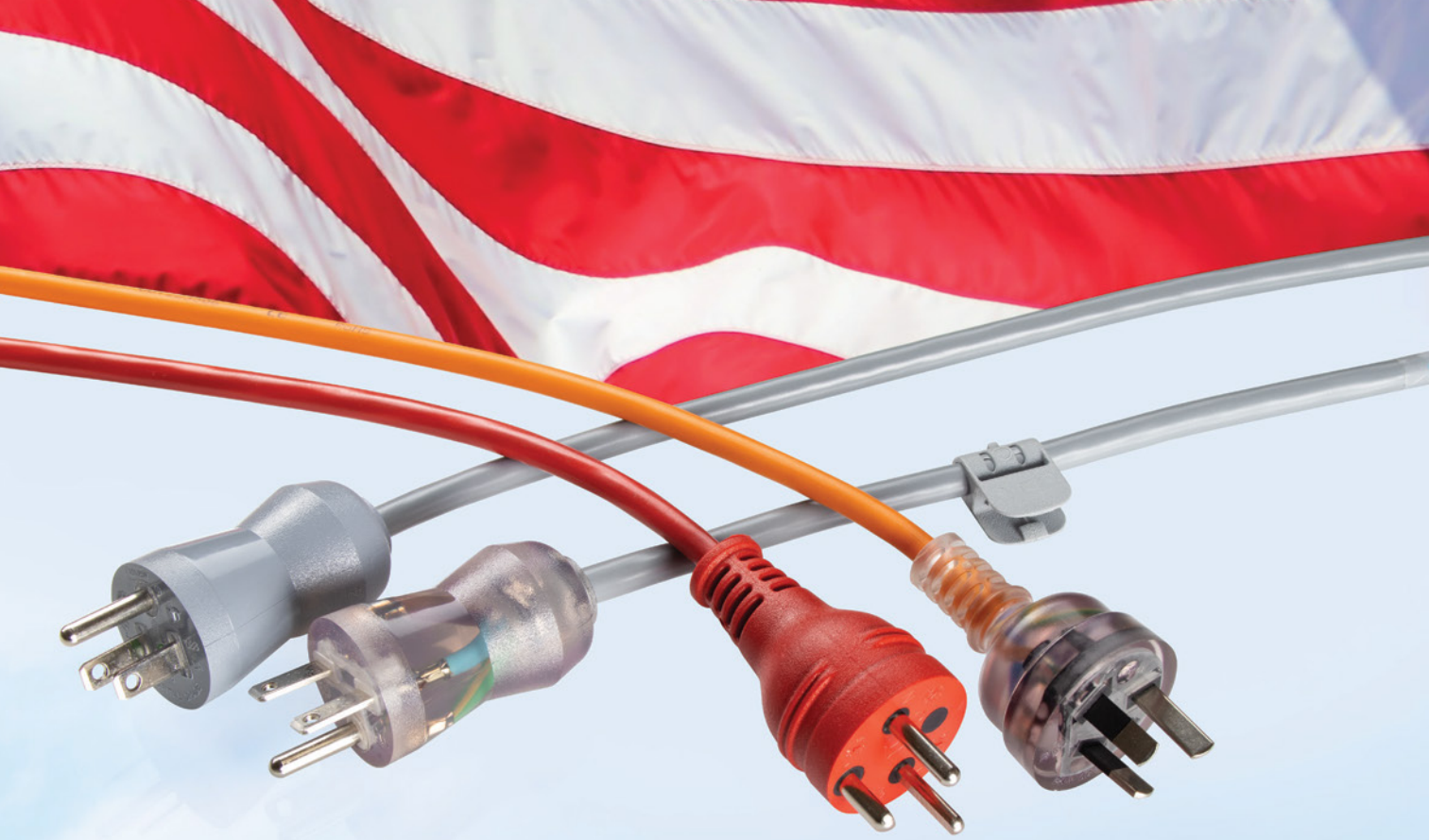
Improved Comfort and Fewer Side Effects

A crucial outcome of the macaque study was the absence of noticeable off-target effects. The researchers report that, within the tested range of electrical currents, the animal showed no signs of discomfort or muscle twitches around the face — common complaints from human ABI users. "The monkey pressed the lever to trigger stimulation itself, time and again," explains Revol. "If the prosthetic input had been unpleasant, it probably would have stopped."

Although these findings are promising, the path to a commercially available soft ABI will require additional research and regulatory steps. "One immediate possibility is to test the device intraoperatively in human ABI surgeries," says Lacour, noting that the team's clinical partners in Boston regularly perform ABI procedures for patients with severe cochlear nerve damage. "They could briefly insert our soft array before the standard implant to measure if we truly reduce stray nerve activation."

In addition, every material in an implant destined for human use must be fully medical grade and show robust, long-term reliability. Yet the researchers are confident, thanks to the demanding tests the device has already withstood: "Our implant remained in place in the animal for several months, with no measurable electrode migration," notes Trouillet. "That's a critical step forward given how standard ABIs often migrate over time."

This article was written by Michael David Mitchell, EPFL. For more information, contact Stéphanie P. Lacour at stephanie.lacour@epfl.ch or visit www.epfl.ch.



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