MEDICAL DESIGN BRIEFS
EBOOK

Technology Trends for Future Medical Devices

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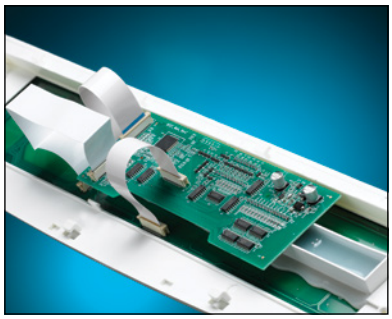

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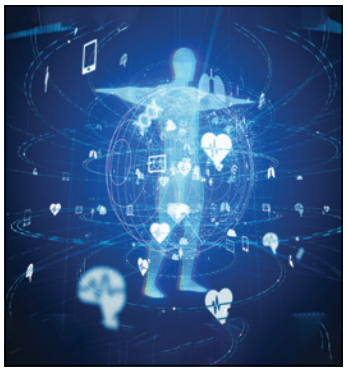
ABOUT

COVID-19 has shaped the future of healthcare delivery. Its immediate effect has been on medical technology — with a focus on digital devices and a shift toward a more collaborative product development process. The health system of the future will be digitally connected, with increased telehealth and remote monitoring. COVID-19 has propelled rapid technology advancement and rapid regulatory approval of technologies such as wearables, point-of-care diagnostics, and digital health. In this guide, learn about the key technology trends for future medical devices.

ON THE COVER

The COVID-19 pandemic has ushered in a new period of growth for wearables focused on monitoring. In particular, the pandemic has opened the door to enhanced patient monitoring, symptom monitoring, and location monitoring. Governments and regulators around the world are embracing this technology and loosening traditional oversight. Learn more in the article, "Can a Wearable Stop a Pandemic?", on page 17.



Technology Trends and the Future of Medical Devices

While the far-reaching effects of COVID-19 have introduced the world to a "new normal," the greatest impact has been in healthcare. In the long term, it has forever shaped the future of healthcare delivery, while its immediate effect has been on medical technology — with a focus on digital devices and a shift toward a more collaborative product development process.

"The health system of the future will be consumer-centric, wellness-oriented, care everywhere, and digitally connected," says Reenita Das, senior vice president and partner at Frost & Sullivan. "Healthcare stakeholders will need to adopt more virtual, innovative health management tools and techniques to support patients at home. While we acknowledge the adversities that the pandemic has caused the world, we also recognize that it has raised growth opportunities to enhance companies' performance in this new normal.

The Digital Revolution

COVID-19 ushered in a new era for telehealth and remote monitoring. The federal government made telehealth services easier to implement and access during the pandemic, spurring greater use of the technology. The growing trend toward digital technologies was already well on its way before COVID-19, but there have been dramatic changes in the areas of telehealth, teleradiology, telepathology, and other remote workflows, notes Ryan Warren, global lead for healthcare & life sciences, Lenovo Workstations. From a clinical perspective, he says Lenovo has seen customers embracing technology to deal with their changing environment while maintaining the high quality of standard of care expected of them.

"One example was when many in the industry were experiencing a shortage of PPE and other essential equipment," says Warren. "Lenovo partnered with Microsoft to develop a virtual rounding solution, whereby care providers would call into each patient's room via a smart display from their laptop and conference in their family as they performed their rounds."

Lenovo has worked to develop solutions to address the pain points of its customers. For instance, it provides a teleradiology solution with a diagnostic display that shifts the traditional work environment from a desktop to a completely mobile workstation. This allows radiologists to move from multiple locations while still having the right devices for a complete diagnostic workspace. This type of solution was essential as its customers needed to address moving non-frontline workers out of the hospital at the start of COVID while maintaining an efficient work environment.

OEMs will focus on making devices that perform with simplicity and that are both highly accessible and available to the consumer. (Credit: Web Industries)

"The growth in digital medical devices will only grow over the next five to ten years as the world becomes more connected and the potential to analyze all that data collected will provide better patient outcomes and hopefully a healthier society," says Warren.

Remote patient monitoring surged after FDA issued a new guidance to help expand the availability and capability of noninvasive remote monitoring devices in March 2020. An increased focus on digital devices for remote use remain part of the landscape.

"Home use devices and testing tools are being seen as critical to the provision of care, and as consumer confidence brings an appreciation for the convenience of these products, there will be a greater emphasis on their development," says Danielle Bradnan, research associate at Lux Research.

"If there's anything we've learned this year, it's that the role of and demand for technologies enabling remote patient monitoring and remote patient care will only increase," says Russ Johannesson, CEO of Glooko, which develops a platform for diabetes management. "For several years, there has been a push toward connected medical devices and data management solutions that enable providers to work with patients remotely. But often, the adoption of this technology has been led by defined segments of healthcare professionals — either inherent technophiles, visionaries driven by what the marriage of technology and medicine offers, or those who've simply had the opportunity to witness what new medtech can do. Accordingly, the adoption of digital health and remote solutions has been increasing over the past couple of decades at a rate that is steady, but not booming," he says.

"With onset of the global pandemic, we've witnessed what happens when demands beyond our control move the reason for adopting technology from what we know it can do to the necessities of what we suddenly need it to do. The drive we've seen to adopt remote technologies is unprecedented, and it extends not only to patient care but also to clinical research," says Johannesson.

Technologies enabling virtual care are expected to expand significantly. "Virtual care is enabled by interoperability, artificial intelligence, and advanced analytics all coming together," says Sonya Denysenko, global digital health director at Frost & Sullivan. "It is exciting to see the growth opportunities and various ecosystems and platforms that will be created between vendors and in partnerships to provide these services going forward. We believe that home health monitoring will continue to expand across the healthcare continuum."

Telehealth was deemed transformative during 2020 as it reduced disease exposure for healthcare workers and patients, preserved scarce supplies of personal protective equipment, and minimized a patient surge on facilities.

"In patient care, with the sudden need to limit medical visits to only the most essential due to safety, we saw primary care office visits in the U.S. drop more than 50 percent, from an average of 117.8 million visits per quarter in Q2 of 2018 and 2019 to just 58.7 million visits in Q2 of this year," adds Johannesson. "By contrast, we witnessed telemedicine increase from just 1.1 percent of primary care visits in 2018–2019 to more than 35 percent of visits in Q2 of 2020.[1] With reimbursement now available for telehealth, this shift is possible because, especially with chronic conditions like diabetes and cardiovascular disease, a large portion of medical visits are consultative and only need a telehealth session — the provider can review data from a patient's connected devices and then confirm or adjust their therapeutic regime. In our own work at Glooko this year, we've seen a 50 percent increase in the use of our remote patient monitoring platform, which provides the diabetes data used in telehealth visits."

Similarly, telehealth shifted many clinical trials to a virtual setting. "Many trials — as many as 80 percent — came to a sudden halt with the arrival of the virus. That's because — out of the same safety concerns that curtailed medical office visits — clinical trial centers had to cease hosting participants on-site for data collection.[2] In response, a

vast number of trials were revived by the use of connected digital products for remote data collection, the use of real-world data and real-world evidence, and the capabilities of modern clinical research platforms, without which most of the impacted trials would still be at a standstill," says Johannesson.

Many OEMs want legacy devices to be modernized with connectivity capabilities. (Credit: Benchmark)

Diagnostics and Point-of-Care Platforms

"COVID has accelerated efforts to bring diagnostic testing closer to the in-home user. There will continue to be a focus on making devices that perform with simplicity and that are both highly accessible and available to the consumer," says Claudio Hanna, business development director, medical, for Web Industries, a contract manufacturing organization (CMO) that provides medical device and PPE manufacturers with precision converting and outsource manufacturing services. "These factors already are playing a role in COVID testing, and they will be critical in fighting future pandemics."

Digital point-of-care testing platforms will play a significant role in the future. These platforms will benefit from leveraging artificial intelligence (AI) and machine learning to drive the next phase of infectious disease point-of-care (POC) testing. "AI transforms the way that results are gathered and analyzed and ultimately delivered in terms of the speed and efficacy to the provider and the patient," notes Denysenko. "It's all about the ability to scale quickly, and platforms like this allow us to do that."

Todd Martensen, vice president, medical technologies sector, at Benchmark, adds that POC testing is one of two major shifts he has already seen in the types of medical devices being developed over the past few years, and says that this trend will certainly continue through the next year.

"The demand for POC is driven by the desire to move more aspects of healthcare out of the clinical setting and closer to patients in their everyday lives. Innovative manufacturing techniques, including microelectronics and automation, are making these devices possible and competitive. The types of devices we're seeing include in-vitro diagnostics, especially those involving microfluidics, as well as mobile imaging and therapeutic devices."

Connected Devices and IoT

Smart, connected devices are on the rise, and the role of these connected devices in the healthcare industry has grown tremendously. "There is greater interest in collecting and providing real-time data from patients to care providers. Medical device manufacturers are including connectivity in all of their new devices, and we've also seen a great deal of OEMs ask for legacy devices to be modernized with connectivity capabilities," says Martensen.

This connectivity will play a crucial role in the future of medical technology. "Connectivity allows for real-time processing of data sets and can immediately provide caregivers and patients answers to problems that need addressing. Connectivity allows for the collection of data sets that facilitate the development of digital biomarkers, which are a key technology for preventative care and early diagnostics," says Bradnan.

Along with the move toward remote patient care and clinical research, experts believe he importance of the IoT and connected devices will only continue to grow. "In diabetes, we see the proliferation of connected devices in the form of glucose meters, continuous glucose monitoring systems, insulin pumps, and even smart insulin pens that are connected," says Johannesson. "Even mainstream consumer fitness and biometrics devices are connected now, and most importantly, healthcare providers are increasingly growing to not just accept but to truly value patient-collected data as an important piece of what goes into shaping their clinical decisions."

Johannesson adds that the proliferation of connected devices, however, is creating some interesting challenges for providers. "Medical technology has proven so effective at helping patients and their providers record and utilize their health data that it's easy for clinical care teams to become overwhelmed with the massive amounts of health data contributed from stand-alone sources. Clinical teams often don't have the time and — until recently — the tools hadn't been developed to help them effectively analyze these data so they could regularly determine the most effective care for their patients," he says.

"To help with this challenge, population health management tools that utilize data analytics have been developed to assist clinicians working in diabetes and other chronic disease states to effectively manage disease in patient populations through aggregating and analyzing patient data. These analytical tools can help clinical teams highlight risk, predict the course of a patient's diabetes, and even intervene before predicted events turn into costly and negative patient health outcomes," says Johannesson.

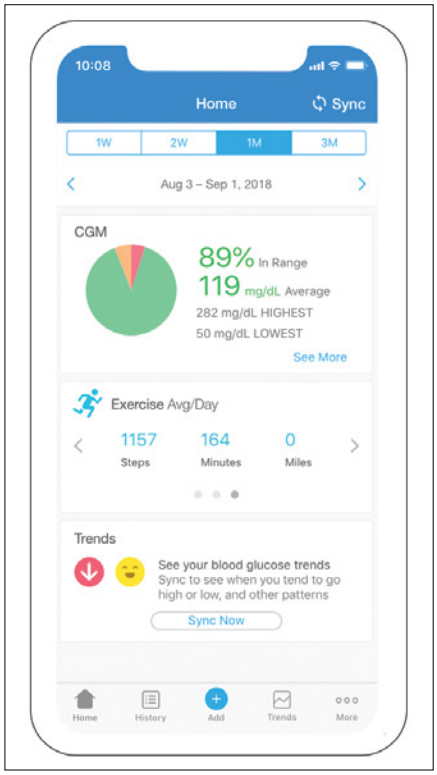
Martensen notes that in addition to device programming, there is now a desire for patients to be able to share clinical information through medical devices with hospitals, caregivers, and insurance providers. "IoMT has taken over the entire ecosystem of medical device development, and OEMs are developing new ways to monitor and collect data on patient health in real-time," says Martensen.

Data management and access will be critical to decentralizing diagnostics, adds Hanna. "There already are niche applications for managing confidential financial and other health information, and we will see

an IT segment develop around test results. IoT and connected devices will play critical roles in expanding diagnostics access to the consumer and making both tests and results easier to access globally."

He adds that there will be a consolidation of features and functionality in solutions that deliver this greater diagnostics connectivity. "As with most technologies, we will start with many competing platforms and then see consolidation to a few. It will be similar to choosing whether to have Amazon's Alexa, Google Home, or Apple's Siri. Users will have one home health standard, and all their diagnostic devices and data will flow through that platform," says Hanna.

Warren says he sees IoT's role in medical technology being all about the generation of data, and ultimately harnessing and analyzing all that data to predict better patient outcomes and prevent down time of mission critical equipment within the healthcare environment. However, one area of concern with IoT devices in a healthcare setting is security. "As healthcare embraces IoT, that increases the chances of attack from an outside threat or a ransomware attack. Luckily, medical device manufacturers and software developers are continually developing new ways to prevent these types of situations from happening," he says.



Glooko's remote patient monitoring platform provides diabetes data used in telehealth visits. (Credit: Glooko)

AR, VR, and Increased Collaboration

In medical device development, it's critical to have constant communication between OEMs, partners, and suppliers. The COVID-19 pandemic led many companies to step up collaboration to drive innovation and get products to market more quickly. Tools such as augmented and virtual reality (AR/VR) emerged to help these efforts, and they will likely be part of the product development process in 2021 and beyond.

"A trend that will have a dramatic impact on the future development of medical technology is the cross collaboration of multiple companies to create new product offerings. The lines are blurring between hardware and software vendors as customers are looking for multiple vendors to come together to provide the best solution for their clinicians and patients," says Warren.

He adds that Lenovo is starting to see customers embrace technologies like AR/VR to help facilitate a higher quality of collaboration and training versus a traditional video webinar. "With VR, healthcare workers are able to train and prepare for real-world events all while being in a remote location," says Warren. "VR has been proven to increase trainee engagement and knowledge retention when compared to traditional training environments, while also reducing training time and cost in the process. VR hardware and software companies also have built-in tracking and analytics, which allows institutions to produce a more proficient workforce."

Large medical device manufacturers are global companies and have employees based around the world. Augmented and virtual reality technology can help them collaborate in real time as they develop the next generation of medical technology, he says.

Some collaborations have benefitted everyone as device companies and healthcare developers have focused on core competencies, allowing new solutions to advance quickly. "These synergies will develop further as companies continue to explore new technologies in 2021. But after a period of high growth and close alliances, we will see consolidation in the industry as companies cement their collaborative partnerships," predicts Hanna.

Biosensors and Wearables

Biosensors have emerged as a key technology because of their potential analytical tools used for the detection of an analytic with the assistance of a physiochemical detector, both in wearables and POC diagnostics. According to a report by Market Research Engines, although traditional laboratory techniques yield correct measurements, these area unit extraordinarily time- consuming, complex, expensive and need pre-treatment of the biological sample. By contrast, biosensor-based devices give speedy, on-site and time period watching while not the requirement for sample preparation.

In wearables, these biosensors will see increased use in continuous health monitoring, with the wireless sensors enclosed in bandages or patches or in a body-worn form factor. Biosensors predict the possibility of a patient's worsening clinical condition and also monitor the impact of needed clinical interventions. Sweat, blood, and other biological agents are common analytes that are analyzed.

"I'd say that the largest role that the pandemic has had in this sector has been the acceleration of some technologies. There has never been a greater need for POC and connected devices than there is today as the world grapples with a predominantly digital environment. Overall, the digital transformation going on today will only enhance progress in the medical device industry in the future," says Martensen.

There is no question that COVID-19 has propelled rapid technology advancement and rapid regulatory approval of technologies such as wearables, POC diagnostics, and digital health. "We need these factors to continue beyond COVID-19 and foster the emergence of more essential healthcare solutions, governed by a regulatory establishment that welcomes and supports continuous innovation," says Hanna.

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Powering Up Medtech's Modalities: Top Trends and Design Considerations

We are living in a digitally integrated and connected world. Evidenced by the use of smartphones, smartwatches, and other smart devices, there is no ending this trend. This holds true across many industries and applications, but is especially prevalent within medtech devices — a market that's predicted to reach $432.6 billion by 2025.[1] With the emergence of connected health, medical devices such as wearables are being powered by sensors at an increasing rate, driven in a large part by the impact of the COVID-19 global pandemic and healthcare providers' growing investment in remote monitoring. There's not only an uptick in the adoption of wearable medical technologies, but also in devices that are miniaturized, AI-optimized, and incorporate 3D printing.[2]

Medical device manufacturers are challenged with significantly smaller and lighter weight devices, yet still need to arm them with maximum power and minimum latency. More than ever, they must consider the ever-shrinking real estate of next-generation medical devices across diagnostic, therapeutic, and patient monitoring modalities while keeping patient comfort, convenience, and ease of use as a priority.

Emerging Technology Advances in Connected Device Modalities

Diagnostics, therapeutics, and medical monitoring modalities have set the stage for connected wearable medical devices. Let's take a look at the emerging technology advances within each of these three key connected device modalities, and then

A flat cable design such as Molex's PremoFlex can be folded and bent for wearable applications with space restrictions. (Credit: Molex)

Fig. 1 – Diagnostics, therapeutics, and medical monitoring modalities have set the stage for connected wearable medical devices. (Credit: Molex)

explore the top design considerations that device manufacturers need to integrate moving forward.

Diagnostics — Continuous and Proactive. A patient's medical journey begins with an accurate diagnosis, as it informs subsequent healthcare decisions. Common diagnostic modalities include angiography, ultrasonography, conventional radiography, computed tomography (CT) scan, bone scan, and magnetic resonance imaging (MRI). All of these modes call for large, complex, and expensive systems that require a patient to enter a medical facility with results that can often take several days to receive and with a greater error rate within a hospital setting versus where a patient typically resides.[2]

Medical diagnostic technology is evolving from reactive treatments to prevention and proactive diagnosis of diseases and disorders. As the healthcare system shifts from a fee-for-service to a managed-provider model, there's a greater focus on the quality vs. quantity of care. Furthermore, patients themselves desire more control and insight into their own health management. Next-generation medical diagnostics is a key enabler for these transformations.

However, for diagnostics to play a more significant role in the healthcare process, it must first become more continuous. This movement toward "continuous diagnostics" is made possible by the same innovations that have enabled smartphones and wearable devices. From apps that can replace a stethoscope or monitor the gait of Parkinson's patients, to add-on devices that continuously monitor blood glucose levels (CGM), technology is proving to be indispensable in revolutionizing medical diagnostics.

In addition to implantable sensors made of biocompatible materials, breakthroughs in manufacturing processes now allow for inexpensive and even disposable sensors. Nearly as thin as a sticker, they affix to a patient's skin for continuous monitoring of biosignals through electroencephalograms (EEGs), electrocardiograms (ECGs), pulse oximetry, and galvanic skin response. Data from these sensors can be transmitted using very low power technologies such as near field communications (NFC) to a receiver that a patient can attach to their clothing or wear as a smartwatch. From there, data can be relayed to a physician's portal or directly to the cloud using more powerful wireless technologies such as Bluetooth or Wi-Fi.

Diagnostic devices — along with new types of flexible sensors, artificial intelligence, and energy-harvesting hardware — are coalescing into the foundation that will make continuous medical diagnostics a reality. This trend will soon allow patients to monitor their health 24/7 with the same precision and detail as has historically been possible only with expensive, hospital-grade equipment.

Therapeutics — Treatment on Demand. The acceptance of home-use medical monitoring technology is driving the expansion of these devices to also provide therapeutic relief, shifting therapy from the clinic setting to the on-patient ecosystem.

Thanks to smartphones, inexpensive yet consumer-friendly hardware, and ad-vances in next-generation software algorithms, therapies can now be delivered automatically without medical professional intervention. With the advent of the "connected health" movement, patients of the future will be able to receive therapies automatically wherever and whenever they need relief (see Figure 1). The blending of therapeutic and monitoring modalities will give back patients time to live their lives on their own terms instead of living their lives around their treatments.

Therapeutics encompass a vast array of technologies and methodologies. Some therapeutic modalities of note include electrical stimulation, such as transcutaneous electrical nerve stimulation, interferential current, and deep brain stimulation (DBS), which is essentially a "brain pacemaker" for the treatment of Parkinson's and even Alzheimer's patients.

Several cutting-edge advancements are evolving. For example, thermal therapies such as thermotherapy and cryotherapy are useful in treating soft tissue and musculoskeletal injuries. Drug-delivery systems are expected to greatly expand beyond decades-old tech such as insulin pumps and nebulizers. As an example, for those suffering from sleep apnea, CPAP (continuous positive airway pressure) machines have long been the prescribed therapy. Such cumbersome machinery, though, is giving way to implantable technologies, thanks to advances in technology miniaturization and materials science. These same advances will yield new implantable treatments for next-generation pacemakers and neuromodulation therapies. Rounding out the list are therapies based on ultrasound,

lasers, and even robotic hardware for use in surgeries, physical therapy, and at-home senior care.

Telemetry from patient monitoring and therapeutic devices will be transmitted back to their healthcare providers in real time via their smartphone or other wireless connection. Doctors will then remotely tweak each patient's therapy regimen as needed. Finally, more therapies will become noninvasive as well. Percutaneous (the delivery of active ingredients through absorption by the skin), natural-orifice delivery and minimally invasive radiotherapy technologies are primed to make this a reality.

Medical Monitoring — All-in-One Devices. Once a patient is accurately diagnosed and therapeutic treatment is prescribed, medical monitoring is crucial to understand how the body is responding to therapies, to maintain adherence, and to mitigate the effects of a disease or other physical ailment.

From the early days of a mechanical pedometer to a digital smartwatch, today's technologies have begun to integrate more functionality into one device and are of particular value to high-risk patient populations who suffer chronic conditions. For example, wearable ECG monitors and blood pressure monitors also can now track an individual's vitals, storing as many as 100 readings at a time. More sensitive monitoring systems such as a patch that's worn by a patient can gather extensive vitals including heart rate, temperature, and more. Glucose monitoring technology now enables diabetic patients to monitor their blood sugar levels wherever and whenever they need to do so. Newer EKG capabilities of wellness tracking devices allow wearers to detect atrial fibrillation, yielding data that could be a matter of life or death for those with a history of heart problems (see Figure 2).

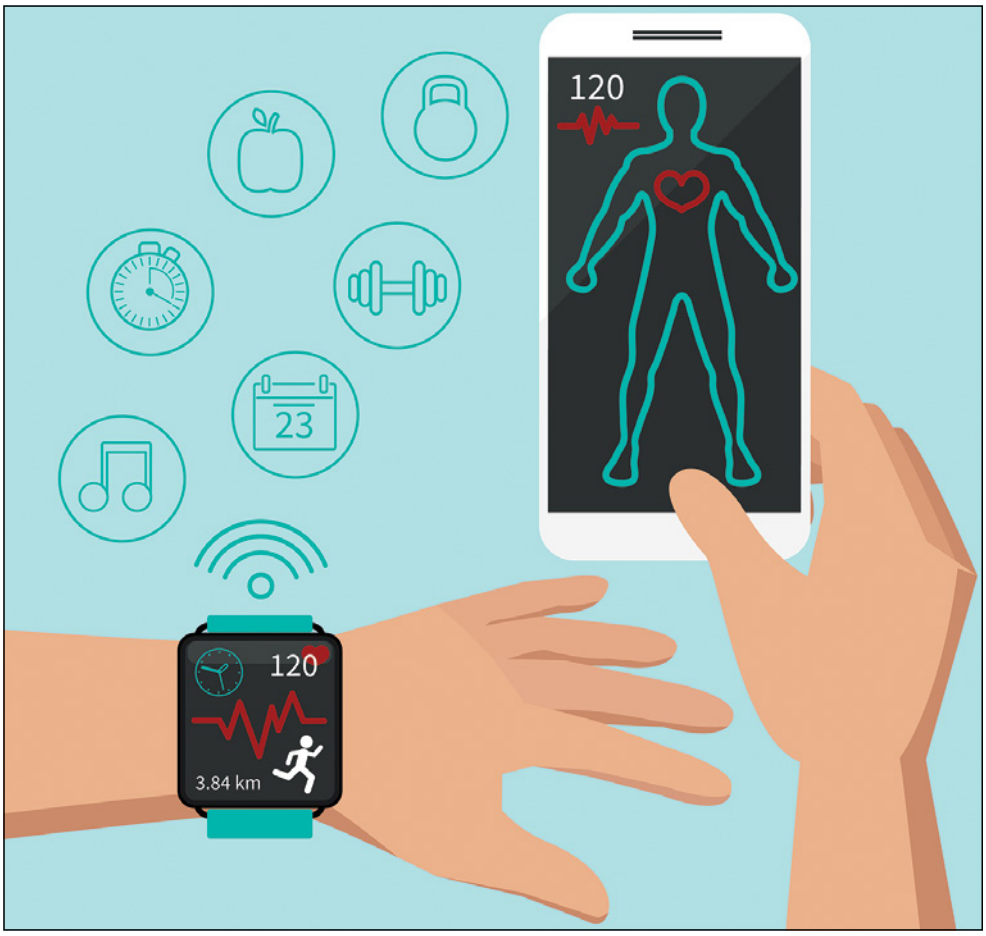


Fig. 2 – Newer EKG capabilities of wellness tracking devices allow wearers to detect atrial fibrillation. (Credit: Molex)

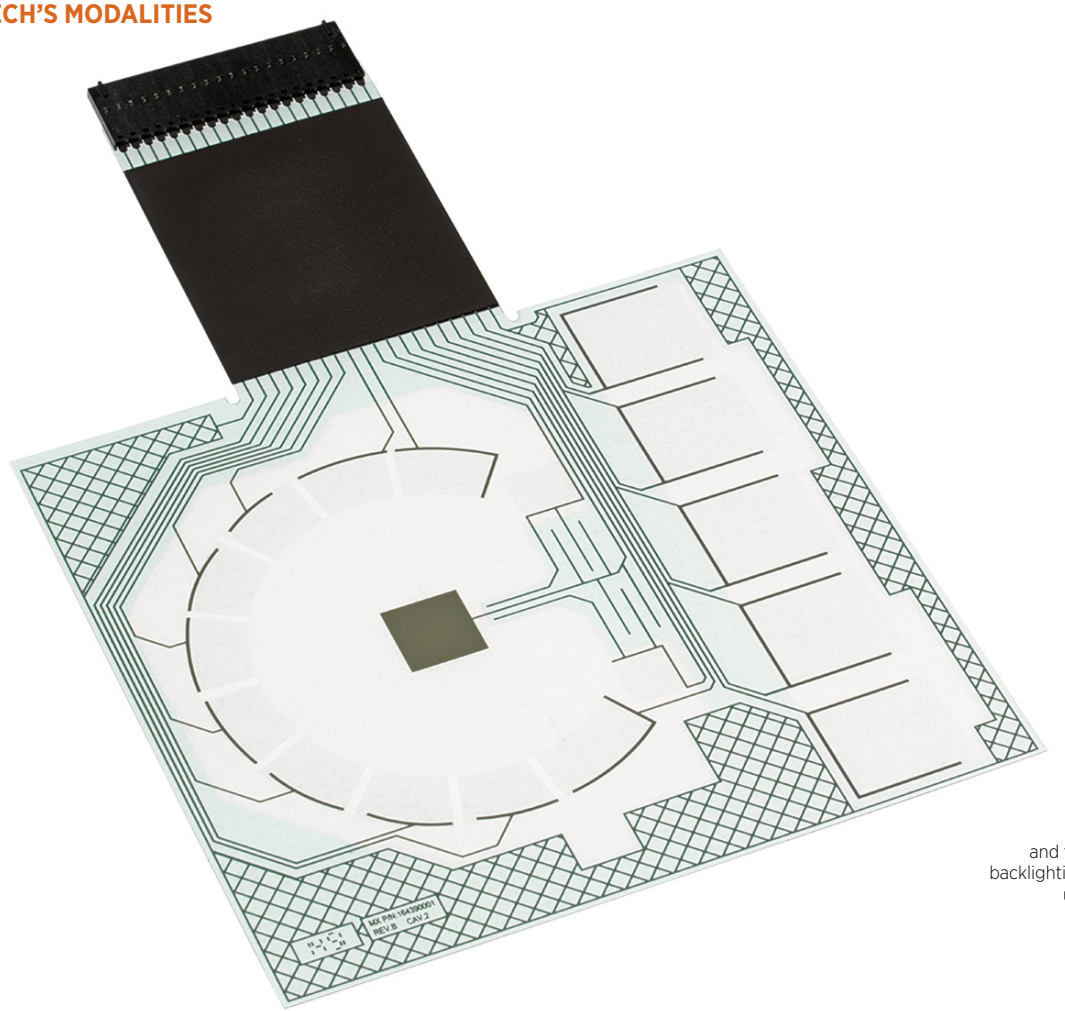
The advancement of biosensor technology unleashes patients from bulky devices by being cableless, wireless and incredibly lightweight — all in a low-cost, easy-to-use, and disposable form factor. Flexible circuitry, low-power sensors, and printed antennas allow convenient and comfortable medical monitoring hardware to be affixed to or even implanted in a patient. The monitoring hardware can even leverage a smartphone or other wireless Internet access as a gateway to cloud-based services where data from a patient's health monitoring device can be stored.

Top Three Design Considerations for Medical Devices

New developments in medical device technology that support diagnostic, therapeutic, and medical monitoring modalities are clearly poised to be game changers for the connected health ecosystem.

Medical device manufacturers will be increasingly tasked with designing low-profile devices that are flexible, light, and comfortable while transmitting real-time data between patients and healthcare providers. In order to address obstacles that may hinder transmission of life-saving data, designers must consider optimizing space for components amid the increasing miniaturization of devices. They must address how to power those devices with limited printed circuit board capacity while simultaneously boosting signal integrity. Here are three top design considerations to take into account:

1. *Component and space optimization.* When monitoring patient data outside of a hospital setting, on-patient wearables should be more compact compared to large, bulky medical devices. Because these wearables are smaller, tinier components are necessary to maintain power delivery and allow for enabling technologies such as sensors to be integrated into the device. Given the reduced footprint, designers must consider optimizing space as board real estate becomes more constrained. Given newer micro-connectors that are currently on the market as well as others that can be customized, designers are able to address these space limitations. Another way to bypass the modularity of space constraints is by utilizing flexible



Clear conductive sensors such as the Molex PEDOT offer flexibility and translucent circuits, enabling keypad backlighting on curved surfaces for capacitive user interface panels. (Credit: Molex)

circuitry to allow for miniaturized components for increased functionality of the device.

2. *Flexible circuitry integration.* Devices are becoming more feature-rich, despite their shrinking size and footprint. The complex electronic systems needed for a medical device's functionality also need to accommodate added components that link a patient-friendly interface with a real-time data connection to the healthcare pro-vider. Such technologies include circuitry to the patient's body to capture deeper and better monitoring results. One option device for designers to consider are flexible printed circuits (FPCs) and associated cables and connectors. This proves to be a great advantage because their light, flexible, and smaller design meets the stringent criteria for wearable medical devices. In addition, antennas can be printed onto the substrate of a flexible circuit to transmit vital signals or biometrics in a noninvasive, continuous, and inexpensive manner.

3. *Maximum power and high signal integrity.* Medical device designers should consider low-profile wire-to-board and flex-to-board options when powering medical devices. As the purpose for enabling medical monitoring devices is to relay patient data quickly to a healthcare provider, power and signal are of utmost importance to ensure seamless delivery. Power-to-board solutions can enable a device's functionality by carrying currents of up to 15 A. Board connections are now being offered with higher circuit counts of 60, 80, and 100 circuits, which is becoming more popular as data is transmitted between connection points in a small form factor. High-performing board-to-board and FPC connectors with multiple grounding points help to ensure the highest level of signal reliability within the connectors, thus allowing for up-to-the-minute information and data relays.

Conclusion

Medtech devices have become smaller over this last decade, and the advancements in connected technology are just beginning. Healthcare providers are always looking to support their patients in a non-invasive manner with minimal downtime and maximum comfort, and medical device manufacturers are, too. They are making these goals a reality by engineering new devices that are not only small and lightweight, but also smart, safe and reliable. There's more to come in this space, and design considerations will continue to be pushed toward continuous innovation and improvement.

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The Future of Remote Cardiac Device Monitoring

Millions of Americans with irregular heart rhythms are leading full lives today, thanks to Medtronic implanted cardiac devices and remote monitoring capabilities — including implantable cardioverter defibrillators (ICDs), which Carol Malnati was instrumental in developing as a product development engineer earlier in her career.

An active and honored member of the Society of Women Engineers, today Malnati is vice president, Cardiac Implantables Technology Development Center at Medtronic, where she leads R&D and engineering efforts for the Cardiac Rhythm businesses. Medtronic is among the world's largest medical technology, services, and solutions companies — alleviating pain, restoring health, and extending life for millions.

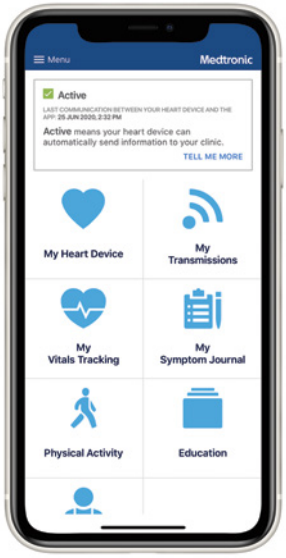
In 2020, we saw a flood of medical news on the growing use of telemedicine — and more specifically, how cardiac arrhythmia patients were relying on remote monitoring technologies during the pandemic. Was the pandemic a catalyst for this technology?

We saw a dramatic jump in usage of our remote monitoring solutions for cardiac devices. The majority of our implantable electronic heart devices are supported by advanced Internet-based remote monitoring technology. And, our remote monitoring capabilities were a game changer for patients and healthcare providers during the global pandemic because these solutions enabled routine device checks to be completed remotely from the patients' homes rather than requiring them to come into the clinic and potentially be exposed to the coronavirus.

Specifically, in 2020, we saw a 116 percent increase in CareLink Express mobile placements. CareLink Express mobile uses a tablet to check a patient's cardiac device in a variety of healthcare settings (e.g., emergency rooms, operating rooms, procedural areas, hospital nursing floors). The COVID-19 pandemic created a skyrocketing usage of remote monitoring, with more than 1,700 new patients being added to our CareLink Internet-based remote monitoring network each day.

We saw this as a moment — for physicians and patients — that underscored the value of digital healthcare. In the case of remote cardiac monitoring, it meant being able to record timely device and physiologic data — and to send that data securely over the Internet to the patient's healthcare team. It not only kept countless cardiac patients out of the ER and helped them avoid in-person clinic visits, but it also helped limit use of personal protective equipment (PPE) and freed up hospital beds for critical-care patients.

Today, not only can we receive data on patients' cardiac functions, but we can actually reprogram some device settings from afar, such as for patients who are undergoing MRI scans, as well as remotely reprogramming our newest insertable cardiac monitor (ICM), called LINQ II™. This means we can provide technical support without having our field personnel in the same room — again, reducing exposure and saving valuable time for patients and healthcare providers.



From the perspective of a product development engineer, would you say it's been a steady evolution of the technology design and applications to get to this point?

Looking back on the past few decades of our development process, it seems inevitable that we'd have remote monitoring systems that are this functional, intuitive, and reliable today. But you could say there were three primary make-or-break technology developments that paved the way: 1) access to the internet and eventual cloud connectivity, 2) the proliferation of consumer electronics and Bluetooth communication technology, and 3) advances in sensors and diagnostic technology.

In parallel with these advances, we also benefited from refinements in microelectronic circuitry, increased speed of data transmission, and a recognition of the importance of user-experience design. Medtronic continuously fueled progress by investing in specialized engineering expertise in systems architecture, software design, and human factors.

The first technology enabler — the Internet — allowed patients' devices to be remotely monitored. And even in the 1990s, long before Google was a household name, we had a bold vision of managing cardiac device patients utilizing the Internet. We began working with the FCC in 1999 to dedicate a frequency band for medical device transmissions, known as MICS in the U.S. and MICS/MEDS elsewhere in the world. We also built a secure back-end system to protect patient health information, clinician-facing websites and in-home patient monitors.

By 2002, we had launched our first cardiac remote monitoring system in the U.S., called the CareLink network, and within a few years began seeing significant gains in patient adherence and health outcomes.

The second technology advance was around the proliferation of consumer electronics, which meant we could finally meet patients where they were — instead of requiring them to come to the clinic or hospital. Bluetooth® technology and modern mobile consumer electronics were still in development when we identified the need to pivot from our proprietary telemetry to an open, but protected, platform.

But the first iteration of Bluetooth wasn't well-suited to medical applications; it didn't meet our security standards, and it drained batteries too quickly. That prompted our engineers to develop something we called BlueSync™, which uses a low-energy form of Bluetooth and solved both of those problems.

After rigorous testing for reliability and security in real-world conditions, we implemented BlueSync across our entire family of implant-able devices, which required a complete changeout in electronics and firmware and a whole new mechanical package. Now more than 365,000 patients across 35 countries experience the ease of BlueSync monitoring.

What direction are you seeing in remote monitoring technology today?

It was a huge breakthrough for patients in 2017 when we could monitor their pacemakers via smartphone, instead of a bedside monitor. Today, 25 percent of patients use their smartphones and a Medtronic app as their heart monitor. And with app-based monitoring comes significant increases in patient adherence to their doctor's guidelines — we saw an increase from 77 percent to 95 percent when they switched to the mobile app from bedside monitors.

Because smartphone technology is constantly advancing — along with consumer expectations for simpler, more convenient, more intuitive experiences — we are continuously upgrading our patient mobile app. Now the app-based monitoring is available to patients across the entire cardiac device portfolio.

And the third technology milestone for remote cardiac monitoring was the development of a new generation of sensors, data, and diagnostics. Our investments in research, technology, and product development allowed us to develop new physiologic sensors and apply predictive analytics.

In 2014, we launched our first miniaturized insertable cardiac monitor, the Reveal LINQ™ICM. Now in its fifth generation, this device is inserted under the skin and monitors the heartbeat. Medtronic ICMs leverage a sophisticated, precise atrial fibrillation detection algorithm, deep miniaturization, and link to a mobile management and monitoring service. The advanced technology is producing more exact data – patients are 4.3 times more likely to reach a suspected atrial fibrillation diagnosis with a Medtronic ICM in 12 months compared to a one-time 30-day monitor.

Can you sum up what these engineering advances mean to the average cardiac device user today?

In a word, this technology means freedom. Freedom for patients to get on with their lives, knowing they can have remote connectivity of their pacemaker or defibrillator's operation to their healthcare provider through these technologies. The patient has basic visibility to their device just by checking an app on their smartphone, for example. With advanced technology widely available — more than 1.5 million patients monitored — patients can expect this type of freedom in their healthcare experiences. Beyond that, the precision, reliability, and personalization of these remote monitoring devices means greater peace of mind — so reassuring to heart patients.

Does the current technology ecosystem give any clues as to what's next for remote cardiac monitoring?

We're seeing a wider variety of remote monitoring technology — from wearables to new smartphone apps — now available to monitor, diagnose and/or treat diverse health conditions, due to COVID-19. Likewise, I'm confident we'll see increasingly convenient and personalized solutions for more people with a variety of heart conditions — solutions that are integrated across patient and physician platforms and devices, for more meaningful and accessible insights into a range of physiologic factors.

Along the way, our growing mastery of user-experience and patient-centric focus design will continue to simplify and improve the way we interact with these devices as well. And finally, as our predictive analytics grow, these technologies should be able to better forecast potential heart health problems. And with our rapidly aging population — and heart disease now the #2 cause of death in the U.S. after COVID-19 — that could be life-changing for millions.

Sherrie Trigg, Editor and Director of Medical Content

NEXT→GEN POC Diagnostics:

Electronic Measurement Technology Driven by Global Demand for COVID-19 Testing

The in-vitro diagnostic (IVD) home point-of-care (POC) product landscape will look very different over the coming years as new products to detect the COVID-19 virus are launched. It is driven in part by FDA's Emergency Use Authorization (EUA), which fast-tracks the traditional 510(k) process so that COVID testing can be as ubiquitous as measuring your temperature.

And $157 million has already been distributed by the Biomedical Advanced Research Development Agency (BARDA) to support the development of more than 40 COVID-19 diagnostic products. Some of those products are targeted for POC use cases versus laboratory testing. Many new companies entering the market are planning a diagnostic roadmap of capabilities beyond their entry point of COVID-19 testing.

IVD and POC Defined

"In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body" compared with in-vivo products, which perform the same but within the human body as defined by the FDA. According to FDA, "POC testing means that results are delivered to patients in the patient care settings, like hospitals, urgent

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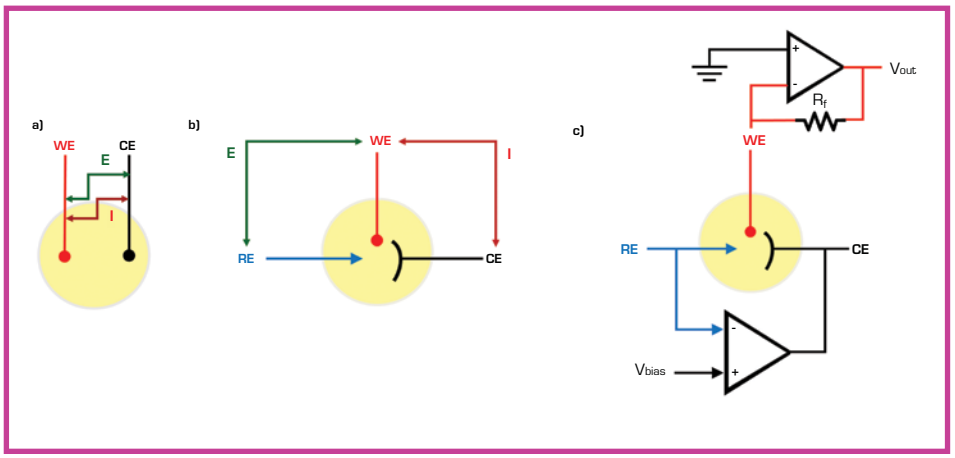

Fig 1 – Current and potential in a two-electrode system (a) and in a three-electrode system (b), and the schematic of a potentiostat control circuit (c).

care centers, and emergency rooms, instead of samples being sent to a laboratory."

Optical vs. Electrochemical Test Techniques

IVD POC products available today like glucose meters or pregnancy test kits will soon share "shelf space" with start-ups offering novel sensors and meters using nasal swabs, saliva, urine, sweat, and blood. These new IVD products will use the latest in sensor technologies, ultra low power analog, precision mixed-signal, and digital processing, and they will be highly portable, including using biocompatible enclosures for wearable applications. They will also harness the enormous computing power of smartphones and the cloud.

The two basic measurement techniques for IVD POC home testing are optical and electrochemical (EC). Pregnancy test kits, for example, detect human chorionic gonadotropin (hCG) in urine. Urine is placed on the end of the nitrocellulose strip and flows; hCG binds with dyed mobile antibodies and is captured using fixed antibodies to produce a color line that LEDs and photodiodes will detect. Glucose test strips require a very small drop of blood at the tip of the strip where the chemical enzymes are stored.

Technique	Working principle	Advantages	Application areas
Cyclic Voltammetry	Linear potential ramps, current recorded	Shape often characteristic, fast, quantitative signal	Fundamental research, characterization
Square Wave Voltammetry	Potential pulses superimposed on a linear ramp, current difference between right before the pulse and the end of the pulse	Sensitive, overcomes diffusion limitation, quantitative signal	Quantitative measurements
Open Circuit Potentiometry	Zero current, potential is measured	Noninvasive, quantitative signal	Corrosion research, ion-selective electrodes
Electrochemical Impedance Spectroscopy	AC potential applied, impedance and phase shift from AC current calculated	Very interface-sensitive, label-free detection	Coatings, corrosion, battery research, label-free biosensors

Table 1. Different electrochemical techniques enable precise potential control and current measurement for the detection of many substances.

An electrical connection is made from the meter to the test zone on the strip to allow a voltage stimulus and measurement, whereas a system using nitrocellulose strips only requires a simple mechanical interface like a light pipe to focus the LED signal on the strip and capture the reflected signal on the photodiode. This article focuses on the more widely used POC electrochemical measurement technique. Future articles will address optical techniques.

EC Measurement Background

In every household, two-terminal batteries are the most common example of a dc power supply. They are used for flashlights, mobile phones, clocks, etc. A well-known EC application is the electrolysis of compounds. A common industrial example is the chlor-alkali process where the salt (NaCl) and water (H_2O) in saltwater are split into chlorine (Cl_2), hydrogen (H_2), and sodium hydroxide (NaOH).

The disadvantage of two-terminal EC applications is that it is not possible to investigate a single electrode and thus a single event (see Figure 1). The current flows through the anode (electrode where oxidation happens) and the cathode (electrode where reduction takes place). So, both these electrodes influence the measured current and the current-limiting process cannot be determined. This is especially an issue in analytical chemistry. Another issue is concentration polarization. This is the effect of an electrode changing its environment and thus its potential during an electrochemical reaction. For most electroanalytical methods, a potentiostat is required (see Figure 2). A potentiostat uses three electrodes and a feedback loop to control the potential and measure the current flowing at just one of these electrodes, the working electrode. The potential will be measured to a fixed reference point and thus a lot of information about the event happening at the working electrode can be gathered.

Why not just two electrodes? One reason is that the potential of the working electrode cannot be measures against a fixed point when there are only two electrodes. Imagine a two-electrode system that consists of the already mentioned working electrode, and the electrode, whose potential should be the fixed reference point, is the reference electrode.

In this case, a certain potential is applied between these electrodes and an electrochemical reaction happens at the working electrode, but since the circuit needs to be closed and current needs to flow, a reaction that is inverse to the reaction at the working electrode must occur; that is, if an oxidation occurs at the working electrode, a reduction must take place at the reference electrode. If a current flows at a constant potential, an electrochemical reaction must happen according to Faraday's law.

The change of the solution surrounding the reference electrode, due to a flowing current, leads to a change of the potential that is supposed to be the fixed reference point. But the current flow cannot be limited through the reference electrode (RE), because all limitations should be caused by the desired process to investigate; that is, the process at the working electrode (WE).

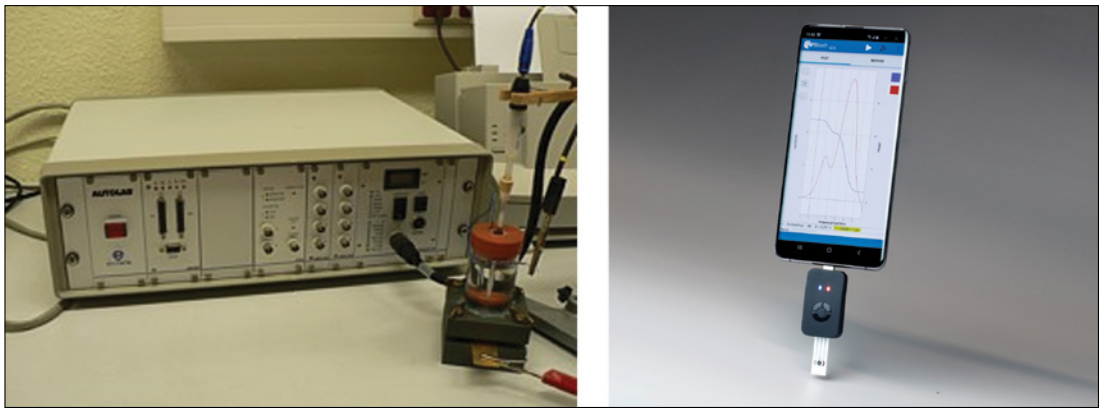

Fig. 2 – Desktop potentiostat (left) from the 1990s and handheld potentiostat (right) from 2020. (Left photo courtesy of University of Rostock – Institute for Electronic Appliances and Circuits)

The solution for this problem is a third electrode. At this counter electrode (CE), also known as auxiliary electrode, the counter-reaction to the working electrode's reactions takes place. The current is flowing between the working and the counter electrode. The potential is controlled between the working electrode and reference electrode. The potential between the counter electrode and reference electrode is adjusted in such a way that the current flowing through the working electrode at a certain potential between working and reference electrode is satisfied.

This technology allows the use of many different electrochemical techniques like cyclic voltammetry, square wave voltammetry, open circuit potential measurements, etc. (see Table 1). The precise potential control and current measurement allow the detection of many substances. This has led to many lab-based quantitative measurements. It is not always possible to wait for a laboratory or to ship samples. On-site POC measurements, especially during the pandemic, have become very important.

Electroanalysis, the detection of substances by electrochemistry, offers many options to quantitatively determine different substances and species, but for many years potentiostats were lab bound (see Figure 3). Now the newest generation of compact potentiostats offered by PalmSens, for example, with expertise in instrument design, including hardware, firmware, and software offer potentiostat systems with high precision, portability, programmability, and low cost.

The compact and ready-to-use potentiostats like the Sensit Smart, are capable of common electrochemical techniques and advanced techniques like electrochemical impedance spectroscopy (EIS). While having the size of a common glucose meter, these devices offer more functionalities and are more versatile.

EIS is a very interface-sensitive technique, which allows among other applications label-free detection of biomolecules for example DNA.1 It is no surprise that in 2021 these compact potentiostats were also used for different SARS-CoV-2 detection systems.2–5 While the academic world reacted swiftly and developed many new detection methods for SARS-CoV-2, the translation of the proof of principles into a commercial product is a challenging task. Developing a dedicated device including electronics design, firmware, and software requires a team of specialized staff and time.

Commercial solutions that support this translation are available as well. The development can be accelerated by using potentiostat modules. Instead of designing your own potentiostats and firmware, potentiostat modules provide the electrochemical methods of the measurement system. Another option is to use modular potentiostats, which can be changed into an individual product with just a few customizations. The simplest version of such a solution is just exchanging the logo on the device. More advanced solutions allow modification of the electrode connection, as well as offering battery and Bluetooth options and customized keypads. Such turnkey electronic design services allow having prototypes of a reader within a few months (see Figure 4).

IVD System Architecture

Let's take a closer look at what's in the box of a typical EC system and the trade-offs needed when creating a requirements document for a new meter design. System power management is typically a good starting point in any new design (see Figure 5). The number of tests a meter will need to perform, along with the timing, voltages, and currents of those tests and communication (wired/wireless/display/sound) will define the capacity requirements for the battery.

Many home glucose meters on the market today use 3 V CR2032 batteries, as they are small and provide sufficient power of 250 mAHr to support up to a year of daily testing with each test lasting less than 5 seconds. For example, if the system electronics consume 10 mA over 5 seconds (0.00138Hr), then each test draws 0.0138 mAHr, which supports 250 mAHr/0.0138 mAHr = 18,000 tests before replacing the battery. However, if the electrochemical test takes tens of seconds or even minutes and the electrochemical reaction requires higher currents, then much higher capacity batteries must be employed, which increases the enclosure volume, weight, and cost. Rechargeable batteries are an option, but time-sensitive testing to address immediate treatment decisions for home use typically avoids rechargeable batteries.

In such cases, stand-alone potentiostat modules like the EmStat Pico are ideal for the analog front-end function. On-chip sequencers and deep ADC FIFOs allow the analog front end to operate while the processor is shut down, thus saving power. High-speed analog-to-digital conversion enables duty cycling of the front-end measurement system to reduce power consumption. In addition to the battery capacity, it is important to consider the voltage requirements

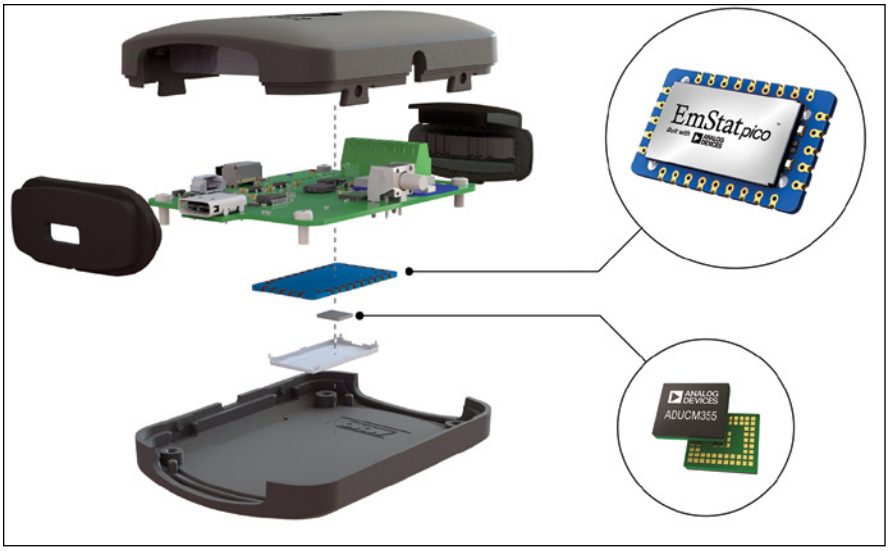

Figure 3: The electrochemistry chip ADuCM355 by Analog Devices is part of the EmStat Pico potentiostat module, which was used to build the handheld, Bluetooth operated potentiostat Sensit BT.

Fig. 4 – Potentiostat module on a development board (left), modular potentiostat (middle, right)
Another reason for long development times is software development. Potentiostat modules often have specialized firmware and Software Development Kits (SDK) which allow writing simple user interfaces in a short amount of time, because the communication with potentiostat itself is simplified. The software developer is in full control without learning the details on a circuitry level.

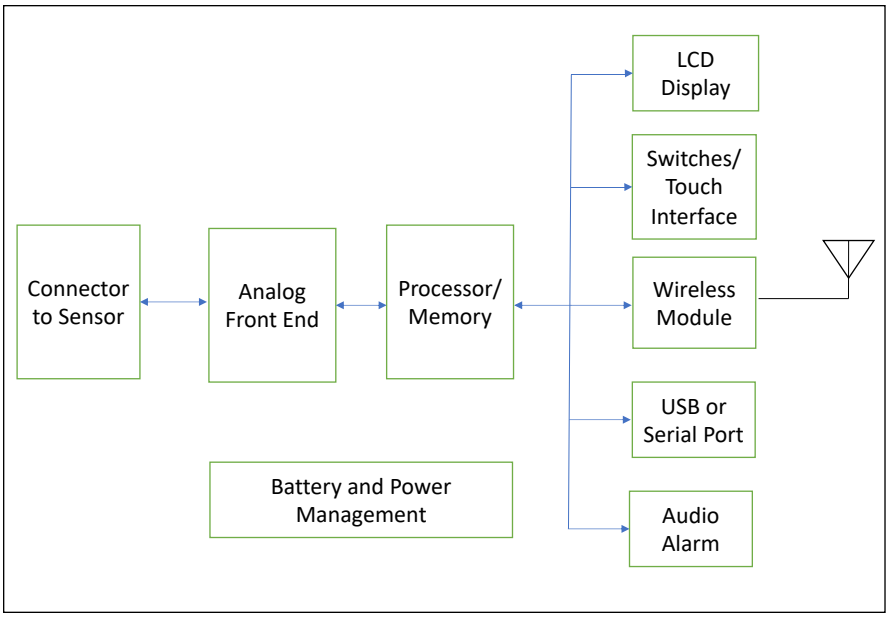

Fig. 5 – Block diagram of an IVD system.

for each block. High-precision, wide dynamic range analog circuits may require boost circuits and LDOs to ensure clean stable supply voltages to the measurement front end.

Conclusion

POC devices to diagnose viruses, joint infections, or nutrient deficiencies, for example, are here to stay. They will become smaller, cheaper, produced in high volume, and more versatile. As competition increases, proven measurement technologies and system design expertise will be a competitive advantage and speed time to market. PalmSens, for example, delivers tested market-ready potentiostats or calibrated potentiostat modules to integrate into hardware, while Tri-Star Design offers turnkey certified product design and development services with expertise in high precision, low-power wireless systems. Both companies are official partners of Analog Devices.

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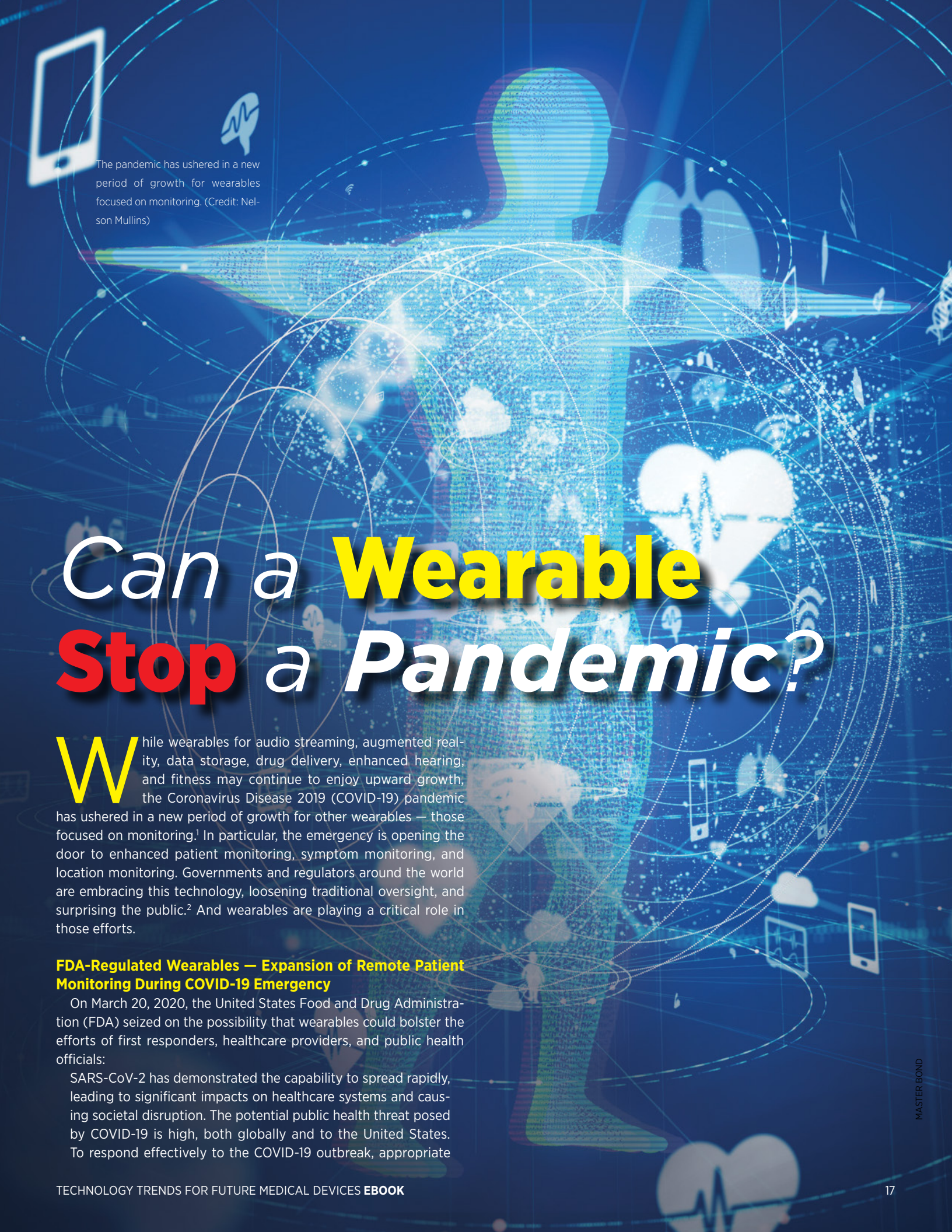

The pandemic has ushered in a new period of growth for wearables focused on monitoring. (Credit: Nelson Mullins)

Can a Wearable Stop a Pandemic?

While wearables for audio streaming, augmented reality, data storage, drug delivery, enhanced hearing, and fitness may continue to enjoy upward growth, the Coronavirus Disease 2019 (COVID-19) pandemic has ushered in a new period of growth for other wearables — those focused on monitoring.[1] In particular, the emergency is opening the door to enhanced patient monitoring, symptom monitoring, and location monitoring. Governments and regulators around the world are embracing this technology, loosening traditional oversight, and surprising the public.[2] And wearables are playing a critical role in those efforts.

FDA-Regulated Wearables — Expansion of Remote Patient Monitoring During COVID-19 Emergency

On March 20, 2020, the United States Food and Drug Administration (FDA) seized on the possibility that wearables could bolster the efforts of first responders, healthcare providers, and public health officials:

> SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, appropriate

MASTER BOND

Using a clinically accurate multi-vital sign wearable wristband and real-time analytics, the loop system is a game changing tool for providers serving COPD patient populations. (Credit: Spry)

> clinical management and infection control in conjunction with implementation of community mitigation efforts are critical. FDA...will help address these urgent public health concerns by helping to expand the availability of remote patient monitoring devices. Modified use of these devices may increase access to important patient physiological data without the need for in-office or in-hospital services during the COVID-19 public health emergency. Increased utilization of non-invasive remote patient monitoring may ease burdens on hospitals and other healthcare facilities and reduce the risk of exposure for patients and health care providers to SARS-CoV-2.[3]

To fight the spread of the virus, FDA decided that it would not require manufacturers to overcome the usual hurdles to modify certain indications, claims, functionality, or hardware or software of previously cleared non-invasive remote monitoring devices used to support patient monitoring.[4]

By reducing the regulatory burden in order to expedite enhanced patient monitoring, FDA is allowing devices, such as the wearable Loop Signal wearable by Spry Health, to make specific claims related to COVID-19, without going through the 510(k) process to receive clearance to target a new disease state. FDA's decision eliminates the costs of both potential testing that could have been required and the months-long process of submitting and receiving FDA marketing authorization.

Additionally, it allows companies to put their products into immediate service in the fight against the pandemic. For example, Spry Health has been able to pivot from promoting the wearable as a system that measures and records arterial oxygen saturation, heart rate, and respiration rate for adult patients at home, to promoting it immediately for "reducing hospital visits and improving home monitoring of patients confirmed, suspected, or at-risk for COVID-19."[5,6]

FDA has indicated that the new policy "is limited to the duration of the emergency."[7] Companies moving forward with expanded uses can gather data during this emergency phase to support future 510(k) applications, to understand patient and healthcare provider preferences, and to evaluate market acceptance. When the emergency ends, companies may be able to use this data to stay on the market for the expanded use during the pendency of the 510(k) process.

Monitoring for Public Health and Welfare

FDA has been disinclined to exercise regulatory authority over a variety of apps, software, and wearables, noting that it generally does not regulate products that are intended to track locations or contacts associated with public health surveillance because these products generally do not meet the definition of a medical device in the Federal Food, Drug & Cosmetic Act...The FDA also does not regulate general purpose location tracking, contact tracking, journaling, scheduling, or related functions. By stepping back, FDA believes that it is allowing innovation to accelerate in the public health space.[8]

Innovators appear to agree. In March, Scripps Translational Research Institute, working with CareEvolution, launched the DETECT health study that is using wearables to track COVID-19, among other fast-spreading viral illnesses.[9] In the study, subjects will allow their wearable devices, including an Apple Watch, Fitbit, or Garmin, to track heart rate, sleep, and activity levels and share that information with the investigators. These wearables are well-suited to measuring resting heart rate. While that information can help users understand fitness levels, it also provides critical data regarding infections. Specifically, "[w]hen your heart beats faster than usual, it can mean that you're coming down with a cold, flu, coronavirus, or other viral infection."[9]

The COVID-19 data that can be tracked on wearables is diminished if the users experience low satisfaction or compliance rates. Thus, related growth areas may include comfort and user interface improvements, and long-lasting wearables. Long-lasting wearables, in particular, is likely to encourage power innovations.[10] Additionally, advances in geofencing could assist in pinpointing virus hot spots and, even, future patients zero.

Wearables at the Intersection of Monitoring, Privacy, and Security

Particularly in the context of wearables for monitoring, generational differences introduce different concerns and preferences. For example, Generation Z may demand more privacy protection than Millennials.[11] These demands, along with concerns about protected health information stored on and transmitted from health monitoring wearables, may lead to device security and encryption technology innovations. Companies developing wearables for monitoring that

will collect and share protected health information should consider potential issues concerning compliance with the HIPAA Security Rule. For wearables subject to FDA regulatory oversight that add wireless and/or Bluetooth capability, FDA guidance directs manufacturers to develop controls that "assure device cybersecurity and maintain device functionality and safety." To develop and maintain the cybersecurity controls, manufacturers may find helpful information in FDA's "Content for Premarket Submissions for Management of Cybersecurity in Medical Devices" and "Postmarket Management of Cybersecurity in Medical Devices."[12–14]

Fighting the Virus and Protecting What is Yours

Just because you may embrace the opportunity for your wearable to help fight COVID-19, that does not mean that you have to ignore the intellectual property related to your product. Wearables and the technology covering them are part of a crowded field. Do your research, including a clearance search, domestically and globally, to understand existing patent protections and to uncover gaps that your invention may fill. Determine whether your wearable will involve standard essential patents and licensing requirements on FRAND terms. Remember that design counts too, and explore the possibility of design patents, trademarks, and trade dress protection. Check to see whether copyright protection may cover software elements.

Conclusion

Wearables for monitoring are having a moment. During this period, patients, healthcare providers, public health professionals, researchers, and governments may become accustomed to having access to increased volume, velocity, and variety of data from wearables. After we move through the current COVID-19 reality, it will be interesting to see whether there is a consensus that the state of emergency has ended or if the desire to prevent the next pandemic, and retain access to all of the data generated by wearables, will cause the war against COVID-19 to continue long after the surge.

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