MEDICAL DESIGN BRIEFS

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Improving Patient Outcomes with MEMS Sensors

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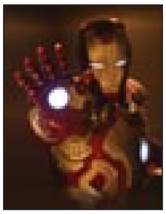
SPECIAL SECTION

Technology Leaders in Materials/Coatings/Adhesives

ON THE COVER



Health trackers are perhaps the most visible expression of the wearables market to the public. But there's growing innovation in more hospital-grade medtech wearables — devices considered less entertainment and more diagnostic or assistive. A number of novel devices made their debut at the 2019 Consumer Electronics such as Samsung's wearable exoskeleton called the Gait Enhancing Mobility System (GEMS), which provides walking assistance and posture correction. While it's not quite an Iron Man-esque flying, armored exoskeleton, it is arguably more useful to the commercial consumer. To learn how to design wearables that span both the digital and physical worlds, read the article on page 6.

(Credit: Sarunyu L/shutterstock.com)

FROM THE EDITOR

Permanently Repealing the Device Tax to Protect Medical Innovation

A new house bill is set to end the medical device tax once and for all. H.R. 2207 was introduced in April — it's goal to permanently repeal the medical device excise tax that was imposed as a provision of the Affordable Care Act in 2010.

"America's medical technology industry is facing a $20 billion tax increase at year-end, when the current medical device tax suspension expires," says Scott Whitaker, president and CEO of the Advanced Medical Technology Association (AdvaMed). Urgent action is essential to protect future medtech innovations that benefit patients and to avoid putting good-paying U.S. jobs at risk."

Whitaker says the House bill, "Protect Medical Innovation Act of 2019" brings us "one step closer to ensuring this innovation-stifling burden on the medtech industry never returns, supporting continued American leadership of this vital industry."

The medical device tax was characterized as "an economically flawed tax," in a report by Alec Fornwalt and Nicole Kaeding of the Tax Foundation, a tax policy nonprofit.

According to Fornwalt and Kaeding, the imposition of the tax "raises prices for consumers, lowers job opportunities, and results in less investment in the industry. Research on the period when the tax was in effect shows that R&D spending decreased, which could lead to less innovation on needed medical devices. The tax has also led to approximately 22,000 fewer jobs from 2013 to 2015."

The bill's lead sponsors are Reps. Ron Kind (D-WI), Jackie Walorski (R-IN), Scott Peters (D-CA), and Richard Hudson (R-NC) and has gathered strong bipartisan support.

"Medical devices and new technologies improve the lives and health of millions of Americans every year. Given that this tax applies to revenues — not profits — it is extremely punitive to medical technology innovators. It's time we permanently repeal this outdated tax on innovation, and support jobs and well-being across the country," said Rep. Kind in a release.

Rep. Peters highlighted the impact to innovation. "Innovation drives progress in healthcare, technology, science, and more, but the medical device tax stifles innovation and passes costs to consumers," he said. He believes the change will fuel startup potential in San Diego and make it easier for these job creators to launch their ventures.

Whitaker noted that while past suspensions of the medical device tax have enabled manufacturers to invest in R&D, infrastructure, and new hiring — which in turn benefits patients and the U.S. economy — these benefits are at risk if nothing is done. "Now that bipartisan legislation to permanently repeal the device tax has been introduced in both the House and Senate, AdvaMed will urge Congress and the administration to act as expeditiously as possible to get rid of the tax once and for all this year," he says.

I have been writing about the need to permanently repeal this excise tax for nearly a decade. Maybe this is our lucky year.

Sherrie Trigg
Editor and Director of Medical Content

Intro Cov ToC

Style Meets Technology in the World of Wearables

> “The goal of wearable computing is to position or contextualize the computer in such a way that the human and computer are inextricably intertwined.”
>
> – Steve Mann

People often talk about thinking “outside the box” but one of the things most exciting in modern technology is being able to design “off the glass” — meaning a piece of technology that isn’t bound to a glass screen with a perimeter of plastic. Thanks to Moore’s Law and cheap computing power, designers can embed technology into items worn on the wrist to monitor your health, or shoes that count your steps, or rings that can store data. Or, if you’re me, 3D printed armor with microprocessor controlled servos to open your visor. Welcome to the world of wearable computing.

Where Did This Crazy Idea Originate?

The idea of having technology that can be worn as an item of clothing is by no means new. The concept goes all the way back to the 1500s when clocks were cutting-edge technology and the ability to wear one on the wrist was so novel that only the Queen of England was privileged enough to own one.

Fast forward to the 1980s, when Steve Mann, an MIT grad and professor at the University of Toronto widely regarded as the father of wearable computing, began experimenting with backpack-mounted computers. With the perpetual advancement of computing power, coupled with near-ubiquitous access to cloud-based data processing, today we now have rings that can track health and watches that can do video teleconferencing. (Here are some wearables startups to keep an eye on: https://www.wareable.com/wearable-tech/the-hottest-wearable-tech-startups-for-2018.)

For designers, this is a very exciting time. Designers are going beyond the flat glass, looking at the physical nature of objects and deciding how to enhance existing affordances with digital intelligence. Mark Weiser, who coined the term *ubiquitous computing,* was talking about creating the “invisible interface”

Images By Sarunyu L/Shutterstock.com, Aleksandr Andrushkiv/Shutterstock.com, and RomanYa/Shutterstock.com

to computers way back in 1994. Now that's become reality as objects and clothing people are already familiar with become that interface.[1]

In his book *Smart Things: Ubiquitous Computing User Experience Design*, Mike Kuniavsky introduced the concept of treating information as a material with properties that we can design with.[2] Just as traditional materials like steel and plastic have properties such as strength and elasticity, Kuniavsky proposes that information can be thought of as having properties such as capability, possibility, and constraint that can influence how we design with it.

Designers can think about how physical phenomena can be translated into information with sensors, how information can be stored to maintain state, and how it can be translated back into the physical world by a vast number of actuator devices. For example, consider a pair of smart gloves that can read the ambient air temperature and activate internal heaters when the temperature falls below a value previously set by the wearer.

A New Challenge for Designers

Our challenge as designers comes in thinking about information, or information processing, as a material property of what we are creating — and incorporating it into whatever we are creating in a way that improves the experience. Information as a material opens up infinite design possibilities, letting us enable new behaviors in previously inert objects.

In the example above, the purpose of gloves is to keep hands warm and dry, so the addition of information processing makes that more effective. Companies from startups to global players are adding information processing in a spectrum of new products.

For instance, Google and Levi's teamed up to make Jacquard, a smart jacket for bike commuters that incorporates conductive threading — literally a material to incorporate information.[3] The left sleeve becomes a touchable surface for interacting with commuter-based services on the wearer's cell phone, letting a rider skip tracks or check time to destination without taking eyes off the road.

Contrast that to the attempts by appliance manufacturers to create a smart refrigerator by basically bolting a screen on the door and adding Wi-Fi. Smart refrigerators (and similar products) haven't gained traction with consumers because the "intelligence" didn't improve the fundamental purpose of the fridge: keep food fresh.

Rather, smart-fridge designers took a "two great tastes that taste great together"

> **"You always wear such nice suits."**
>
> *– General Ross to Tony Stark (The Incredible Hulk, 2008)*

approach, and it didn't work. If manufacturers are going to go to the effort of adding information processing to a fridge, it should deliver value. I'd want the fridge to tell me when I'm out of milk or that the lettuce is going bad, and then add the items to the shopping list on my phone.

Some manufacturers understand this need and are coming up with new products to address it. For instance, there's a smart egg tray that can signal when you're low on eggs. Problem is, reviews are mixed. That means there is still a lot of work to be done in this space.

Wearables for Fitness and Health

Also part of the transformational technological wave, collectively referred to as the Internet of Things (IoT), wearable computers are attracting a following. Many of these devices are geared toward health and wellness, helping people better monitor and maintain a healthy lifestyle.

The most common types of medical wearables are, at their core, data collection devices. These clever bundles of sensors and connectivity amass a wide range of biometric data and make it accessible to users by the associated cloud-based services. Heart rate, blood pressure, hours of sleep per night, and even daily caloric intake are among the metrics that can be gathered, analyzed, and visualized. Sensor capabilities and data collection allow individuals to make better choices about their daily lives. For instance, the Fitbit — perhaps the best-known wearable device — tracks exercise and sleeping patterns.

While Fitbit was early to market, these days the shelves are crowded. There are smart watches, rings, necklaces, jackets, and even shoes, to name but a few, that all integrate with cloud-based systems and help us make better decisions about our diet and exercise levels.

The wearables market is growing at an exponential rate. (Credit: Andrew Babkin, ICS/Boston UX)

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These types of health trackers are perhaps the most visible expression of the wearables market to the public. But there's growing innovation in more hospital-grade medtech wearables — devices considered less entertainment and more diagnostic or assistive.

At the 2019 Consumer Electronics Show (CES), one of the novel wearable devices that debuted was the Dfree from Triple W. The Dfree, which stands for "diaper free," consists of a small sensor that is taped to the user's torso to monitor the wearer's bladder-fullness level. When a preset level is reached, the device sends a notification to the tethered smartphone. Targeted at the elderly and the disabled, this device — life-changing for many users — won the Best of CES award in the Digital Health and Fitness Category.

Short for Gait Enhancing and Motivating System, Samsung's GEMS assists users with walking and can also help them strengthen their muscles and improve their mobility and balance. (Credit: Samsung)

Also making its CES debut this year was Samsung's wearable exoskeleton called the Gait Enhancing Mobility System (GEMS), which provides walking assistance and posture correction. While it's not quite an Iron Man-esque flying, armored exoskeleton, it is arguably more useful to the commercial consumer.

Designing Wearables

Learning how to design wearables will be an exciting challenge for user experience practitioners. Designers need to consider use cases that span both the digital and physical worlds, and figure out how best to meld the two. Information is our new material to build with, as pliable as clay in the hands of talented designers and developers.

Designers already have a pretty good handle on the digital aspects of wearables. If the device has a small screen, many of the same techniques and heuristics that are used to create digital experiences on mobile phones can be applied. However, many wearable devices do not have that screen so their users have to get information from the device in other ways. LEDs, haptics, and even sound can play a part in letting the user know what the device is up to.

Though the interface may differ, a core trait of wearables is that nearly all have some kind of cloud-based service that is an integral part of the user experience. Many devices now come with a companion mobile app that allows users to configure the device and provide much more involved access to the functions of the physical device. Many devices can completely forego any kind of screen by moving complex inputs and output to the companion device. Since the device is pushing data at the smartphone, it's a short step to getting that data over the Internet and making it accessible over the web.

In fact, it can be argued that the service is significantly more important than the device itself. For example, I have a number of devices that I interact with in my daily life that can play music from my personal collection. That collection lives in the Amazon cloud and has grown over the years, and it's the access to that music that is important to me, rather than the physical device that happens to access it. I can always buy another Echo, but losing my collection of college bootlegs would be devastating!

Designing the physical device is a multidisciplinary endeavor because factors of branding, ergonomics, and industrial design must be considered as well as aesthetics and context. A medical device needs to safely provide information or treatment, yes, but it also must do so in a way appropriate for the user. Understanding the psychology of a device — especially one that directly touches a patient — is essential. In terms of context, designers need to ensure that the design accommodates the environment, whether that's the ER, OR, or any other clinical setting.

FDA Takes Notice

Perhaps the most exciting thing about the medical portion of the IoT market involves changes coming to the industry courtesy of the 21st Century Cures Act of 2016. As part of this legislation, the Food and Drug Administration (FDA) has established processes to help reduce the time to market for new medical devices the agency classifies as Class 1, or low-risk, devices.

To provide guidance and help companies that develop medtech navigate this shifting landscape, FDA released "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act." This important document explains some of the agency's current thinking in regard to devices and medical-related software systems. FDA's "Digital Health Innovation Action Plan" document further describes this shift in thinking and outlines a plan that allows nine major companies to become precertified to market these low-risk devices with minimal FDA review.[4] So look for a whole slew of new wearable medtech in the coming months and years.

As the IoT becomes ingrained in modern life, wearables offer convenient and clever ways to improve people's lives, whether by diagnosing illness, providing treatment, or simply by making the user more aware of health-related metrics. As designers, our job is to make that tech appealing and easy to use. This way, everyone gets to feel like a superhero.

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This article was written by Jeff LeBlanc, Director of User Experience for both Boston UX and ICS, Waltham, MA. For more information, visit ***http://info.hotims.com/72993-340.***

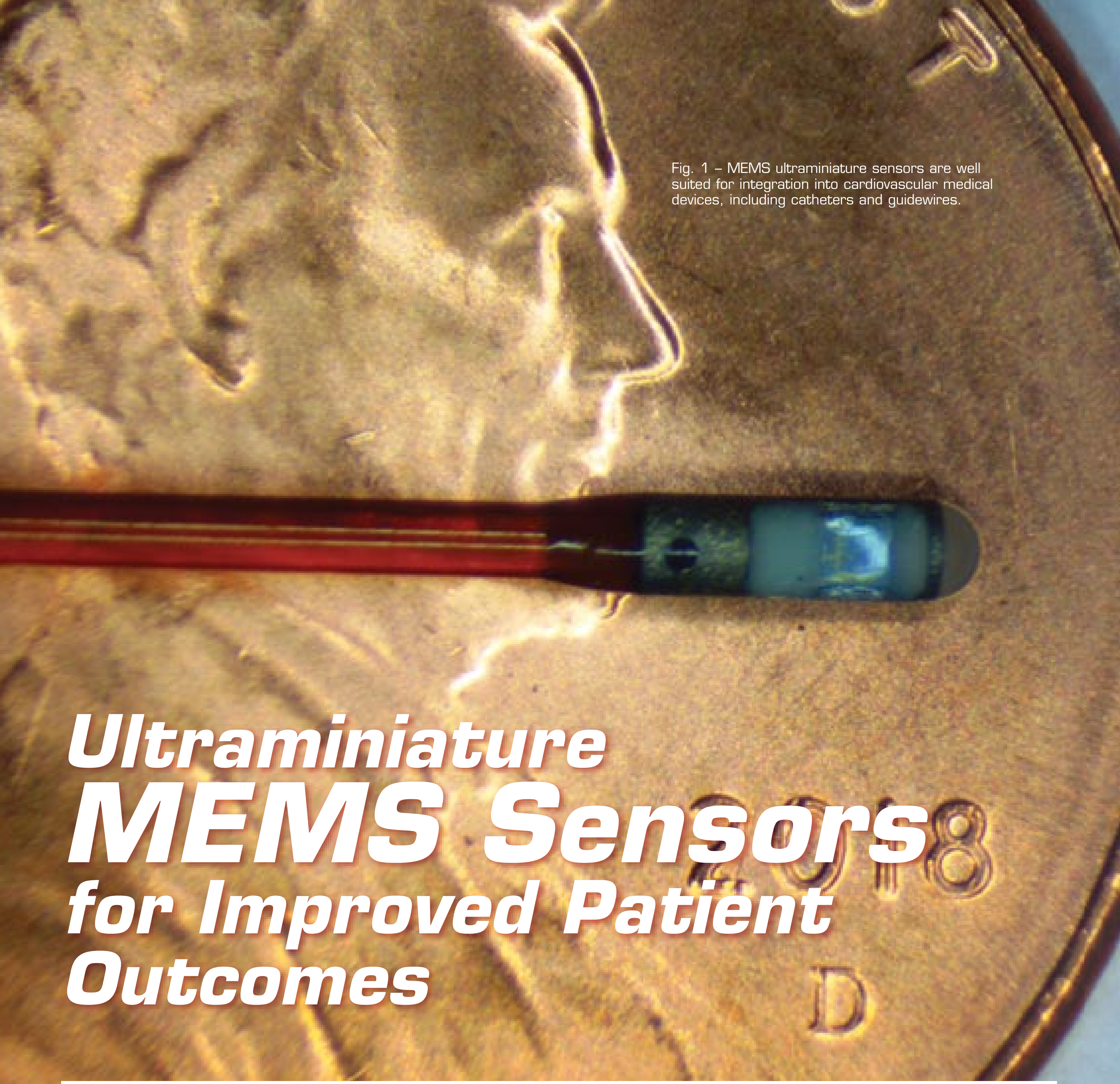


Fig. 1 – MEMS ultraminiature sensors are well suited for integration into cardiovascular medical devices, including catheters and guidewires.

Ultraminiature MEMS Sensors for Improved Patient Outcomes

Ultraminiature sensors (<1 mm in size) enable instrumentation of medical devices in order to advance monitoring capabilities, deliver new insight into complex cardiovascular cases, and optimize targeted treatment therapies. These high-performance medically proven sensors can advance medical devices with real-time monitoring capabilities with less invasive access and more reliable results. Whether integrated directly into an existing medical device or added to a complementary delivery system or procedural accessory, ultraminiature sensors can enable new revenue streams by increasing reimbursement opportunities or adding a new component to an existing sales channel.

MEMS Technology

Ultraminiature sensors are enabled by microelectromechanical systems (MEMS) technology, which integrates sensors or actuators, and sometimes its readout electronics, into a single, tiny silicon chip. Used in applications as varied as aerospace, oil exploration, and automobiles, MEMS sensors are proven for challenging environmental conditions such as within the human body.

MEMS sensors have been developed to measure a wide variety of phenomena, including pressure, acceleration, sound, ultrasound, fluid flow, temperature, light, and many others. Moreover, many types of MEMS actuators have also been developed, including micropumps, tweezers, electrodes, ultrasonic stimulators, and more. These sensors and actuators can be combined into a single device to stimulate and understand the object of observation in multiple ways.

Ultraminiature Sensor Applications

An example of a MEMS sensor used in medical applications is the pressure sensor. As small as 0.25 mm on a side, MEMS pressure sensors offer a highly accurate and reliable method for measuring pressure in situ in various clinical conditions including heart failure, brain injury, airway obstruction, compartment syndrome, and spinal tumor pressures. Novel drug delivery, neuromodulation, and cardiac assist devices can also benefit from integration of high-fidelity pressure sensors. Sensors can provide closed-loop feedback, enabling increased device responsiveness and improved therapy outcomes, reducing facility costs and increasing the device value proposition.

Medical specialties that benefit from pressure sensor-enabled medical devices include:

- Cardiology.
- Critical and emergency care.
- Oncology.
- Pulmonology.
- Neurocritical care.
- Ophthalmology.

Highlight on Sensors within Cardiac Guidewires and Catheter-Based Devices

MEMS ultraminiature sensors are well suited for integration into cardiovascular medical devices, including catheters and guidewires. For example, a device made by Millar can be seen in Figure 1. Understanding changes in pressure within the human circulatory system supports diagnostic decisions and reveals information about disease severity. With sensors on board, catheter-based devices provide a robust tool to navigate difficult paths in the human vasculature. Because pressure may be measured at the desired location only, this technology does not suffer from damping and resonance effects of fluid-filled measurement lines. Catheters incorporating MEMS sensors provide a more accurate measurement of pressure gradients — for example, across a heart valve to assess disease — and can diagnose and monitor conditions like congestive heart failure and hypertension.

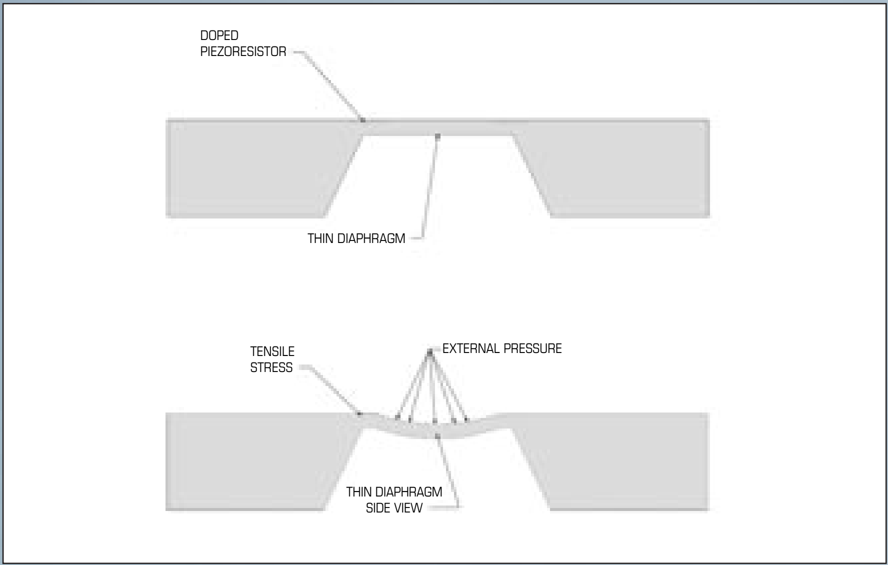


Fig. 2 – A MEMS sensor converts pressure signals into electrical signals by having implanted small strain gages, called piezoresistors, in a thin silicon membrane.

A MEMS pressure sensor operates by converting pressure signals into electrical signals by having implanted small strain gages, called piezoresistors, in a thin silicon membrane (see Figure 2). As pressure deflects the membrane, it creates mechanical strain. The piezoresistors, in turn, convert mechanical strain into a change in electrical resistance. Using a Wheatstone bridge, the electrical resistance can then be read out as a change in voltage.

The interface electronics are fairly simple and can connect to commercially available monitors and leverage existing device circuitry. This reduces system complexity, lowers overall project costs and increases speed to market.

Challenges

Biocompatible encapsulation and integration of the sensor are critical to the performance of the sensor and ultimately, the medical device. While sensor specs may meet the requirements of the medical device usage and application, improper sensor encapsulation could result in higher drift and lower accuracy of pressure measurements. Furthermore, sensors from the same wafer can vary slightly in performance and require compensation circuitry that effectively corrects for any manufacturing differences in the sensor signal.

There are also unique challenges to consider during electrical interconnect and attachment to the sensor. Miniature sensors require working with small wires, such as 50 AWG, and must be handled carefully to avoid breakage and increasing manufacturing cost.

Integration into guidewires introduces added challenges to both sensor integration and sensor selection. Due to the small sizes required to navigate the coronary arteries of the heart, adding a MEMS pressure sensor to an existing guidewire or designing a new guidewire that incorporates a sensor requires specialized capability and MEMS manufacturing knowledge. The unique guidewire construction limits real estate for sensor wires, vent tubes and sensor housings. As a result, selecting the right sensor design at the start of the project can improve project success.

Testing for biocompatibility and electrical leakage or fluid ingress in initial stages can ensure a higher rate of success for future preclinical studies and for long-term commercialization. These are included in the rigorous testing and validation protocols for compliance to the IEC 60601 and AAMI BP-22 standards.

Finally, in comparison with consumer electronics, biomedical devices have lower annual unit volume, but higher per unit value. Due to the nature of their manufacture, MEMS sensors pose businesses challenges when manufacturing volumes less than one million units per year. The correct partners and vendors can create a supply chain to meet the needs of low-volume, high-value specialty medical devices.

Similar to working with an experienced architect and builder to build a home, working with an experienced development group for both the MEMS sensor and its integration into a medical device can reduce timelines, cost, and risk.

Conclusion

The applications for ultraminiature MEMS pressure sensors are numerous. MEMS sensors can provide significant improvements to the medical understanding of existing patient conditions, increase therapy efficacy and increase device capability. This can be achieved without the need to develop a new high-cost interface circuit or standalone device, further reducing barriers to rapid market adoption of the MEMS enabled device.

Ultraminiature sensors also create the potential to combine multiple sensor modalities into one super device or procedure kit. The integration of a MEMS sensor can provide real time feedback on therapy efficacy, thereby reducing long term costs for end users. The addition of a new MEMS enabled device to a product kit can enable new revenue streams to existing sales channels by delivering capability that is not enhanced by sensing capabilities.

Ultimately, capitalizing on the potential of MEMS pressure sensors requires challenging many of the assumptions involved in the original device development and an increased awareness of the total procedure in which the device is utilized. As more large medical device companies acquire compatible technologies to complement their existing devices and sales channels, new combined innovative devices may become the next step in advanced device development.

This article was written by Charles Chung, PhD, a MEMS devices and microsystems expert at A.M. Fitzgerald & Associates, LLC, Burlingame, CA, and Michelle Sanders, Director of Marketing at Millar, Inc., Houston, TX. Contact: ccc@amfitzgerald.com or partner@millaroem.com. For more information on AM Fitzgerald, visit ***http://info.hotims.com/72993-342*** *and for more information on Millar, visit* ***http://info.hotims.com/72993-347****.*

Design for Manufacturability Improves Articulating Instrument Development

For articulating instrument components, for example, it is important to consider the number of times a tube must articulate. (Credit: MICRO)

Precision in surgery is paramount. Surgeons rely on a variety of handheld instruments, and they increasingly want tools that can aid in accessing hard-to-reach areas in the body where tip and positional control need to be seamless.

Articulating instruments that offer greater bend, flex, and reach over rigid tools are being embraced by surgeons for laparoscopic, endoscopic, and arthroscopic minimally invasive procedures where incisions are small and challenging to navigate. Articulating instruments provide more natural dexterity and can help reduce shoulder, arm, and hand fatigue during surgery.

Manufacturing components for these handheld articulating instruments that offer multiple functionalities can be challenging if design planning is not well executed from the start. A host of factors must be considered before a design can be manufactured efficiently, yielding both a high return on investment and positive patient results.

Take Time with Design

Medical device designers often find themselves in pressured situations related to cost, time, and other factors and may dismiss manufacturing considerations early on during the design phase. It's essential to ensure that a product can be manufactured effectively as early as possible in the design phase, before product development is initiated. Failing to properly account for manufacturability can be detrimental, especially for devices that have more sophisticated features and require greater attention to detail, leading to significant cost inefficiencies and possible product failure. Once the manufacturing process has begun, going back to make design revisions can be counterproductive and costly, often resulting in development and production delays.

To prevent such pitfalls, all devices should undergo a process known as design for manufacturability (DFM). This process, which can be combined with lean manufacturing or Six Sigma, entails extensive design review that ensures every product design is optimized for production. DFM is critical because it enables potential problems to be identified early and addressed in a timely fashion during the design phase. It strives to minimize and simplify the number of steps required to manufacture the product. This approach can save time and money, and it can prevent wasted resources in the long run.

Asking the Correct Questions

Understanding the application and subsequently asking the correct questions is key to applying DFM to any component design. For articulating instrument components, for example, it is important to consider the number of times a tube must articulate, the degree of articulation, and the constraints on the design from interactions with the human anatomy.

These considerations will drive initial material selection, laser cut geometry, and the need for post processing to achieve the desired metallurgical properties. Once these questions are answered, DFM can be applied to refine the design to strike the balance between functional requirements of the instrument such as grasping and dissecting and manufacturing capabilities such as laser cutting, molding, or machining.

Selecting the Optimal Material

Material selection during the DFM process is something that the contract manufacturer can guide the OEM product designer through. Not all stainless steels, for example, are created equal, and the specifics of how the tubing is fabricated, shaped, and processed can have a great impact on the function of an articulated instrument.

Finite element analysis and simulation can be used to analyze stress concentrators and determine the fatigue and work hardening that the articulated elements will be exposed to, thus enabling the engineer to understand potential conditions and optimize the design. Understanding these factors and the requirements for assembly will determine the required grade and chemical composition of the material.

Refining the Cut Geometry

In laser cutting, the laser itself is only a means to melt the base material in a localized area. The actual material removal takes place from the high pressure assist gas being used to literally blow away the molten material. This high-pressure gas is also the means by which the shape that is cut is removed from the workpiece. This is where the design of the articulation geometry comes into play. Imagine the difference between cutting a square and cutting a barbell shape where there is a significant difference between the widest part of the cut and the smallest part of the cut.

The square is very likely to be easily flushed away with the high-pressure gas, but the barbell shape has the potential to lock in place. This "slug" could then be welded onto the part from the laser depositing molten material from another cut, or worse, it could cause a crash in the machine and lead to accelerated wear of the cutting nozzle. The other important consideration is the economics of the operation. Choosing a simpler geometry helps avoid costly rework and manual operations required to remove troublesome laser slag and difficult-to-remove material slugs.

Execution and Development

Along with component DFM, process execution is equally important to yielding a profitable and capable operation. Partnering with a contract manufacturer that implements DFM can make this significantly easier. Lessons learned are applied to important parameters in the cutting process such as optimal pierce locations, nozzle geometry, and cut paths. The cut path and how a particular cut is divided into individual segments

can also have a great effect on the stability of the process. For example, there are techniques that can be employed to increase the likelihood of a slug being removed without greatly increasing the complexity of the process.

Many of these techniques, however, can potentially increase piece part price because they usually require additional cycle time to break a cut into smaller sections, therefore minimizing the impact of the cut geometry on the slug removal potential. This is why there is such an emphasis on DFM being considered as early as possible in the product design cycle for articulating instrument components. Because most articulating instruments have a large number of individual cuts for their overall length, even small changes in cut geometry to articulation windows will add significant cycle time. Understanding and accounting for this mitigation is essential to profitability.

Developing an efficient design is crucial to keeping costs manageable and return on investment high. This is especially true for components and devices that require sophisticated features and intricate designs such as articulating instruments. DFM helps to achieve the best possible cost to repeatably produce a functional product that will pass all necessary approvals to reach the marketplace.

This article was written by Steve Jacobsen, Process Development Engineering Manager at MICRO, Somerset, NJ. For more information, visit ***http://info.hotims.com/72993-341***.

Articulating instruments offer greater bend, flex, and reach over rigid tools for laparoscopic, endoscopic, and arthroscopic minimally invasive procedures. (Credit: MICRO)

Functional PVD Coatings Improve Medical Device Performance and Life

OEMs are looking to move beyond aesthetics by applying titanium nitride and other innovative PVD coatings to improve wear resistance and other properties.

As the medical device industry continues to grow rapidly, manufacturers must contend with a variety of challenges if they wish to differentiate products in a highly competitive market. With this in mind, greater emphasis is being placed on the functional coatings that are applied to stainless steel, titanium, and other substrates of critical medical devices from implants to scalpels, needle drivers, bone saws, and reamers.

When manufacturers first began coating instruments, the primary purpose was to improve the aesthetics of instruments and improve identification during surgery. Titanium nitride, with its easily recognizable gold color, quickly became the coating of choice for this purpose.

However, OEMs are now looking to move beyond aesthetics by applying titanium nitride and other innovative physical vapor deposition (PVD) coatings to improve wear resistance, reduce galling between sliding component, increase lubricity, and even help retain sharp edges on cutting instruments.

These same coatings can also deliver other important functional benefits, such as providing antiglare surface for bright operating rooms, antimicrobial properties, and antifouling in the presence of blood and tissue. In some cases, it can even potentially turn devices into multiple re-use items such as with laparoscopic instruments.

Coatings for Medical Devices

One option medical device manufacturers often consider for adding functional value to medical devices is medical-grade polytetrafluoroethylene (PTFE). Although this type of coating is known for its low coefficient of friction, it is not recommended for high load applications because it is relatively soft and can wear away or experience micro-fracturing under high loads.

Another alternative is anodization, an electrolytic process that coats the metal substrate. Unfortunately, it is impossible to effectively anodize stainless steel without losing wear resistance and durability, which is a significant disadvantage.

Moreover, anodization can form a layer of rust on the stainless steel, causing it to corrode. For this reason, anodization is typically only used on aluminum or titanium. This limits the range of medical devices that can utilize this type of coating.

Physical Vapor Deposition

To overcome these challenges, medical device manufacturers are increasingly turning to PVD, a process that describes a variety of vacuum deposition methods that can be used to produce extremely hard, thin coatings on stainless steel, titanium, ceramics, and other advanced materials.

These coatings provide a unique combination of extreme surface hardness, low friction coefficient, and anticorrosion properties. The coatings also have the advantage of being thin, typically 1–4 μm. This feature, in conjunction with close tolerancing, means that the component retains its form, fit, and dimensions after coating without the need for remachining.

Introduced into the medical device industry nearly 20 years ago, PVD coatings like titanium nitride (TiN) are extremely hard (2,200–2,400 Vickers) coatings that provide excellent wear resistance. However, despite its functional properties, the first medical instruments used the coating as a decorative, high-end finish.

Initially, the industry was looking for ways to differentiate instruments aesthetically and for identification purposes, and titanium nitride was as a solution for that. To this day, it is the highest volume PVD coating used in the medical device industry. Oerlikon Balzers, for example, has been producing specialized PVD coatings for more than 70 years. The company offers coating services at more than 140 coating centers worldwide, including 16 locations throughout the United States.

The orthopedic industry was the first medical segment to realize the functional strengths of PVD coatings, as applied to surgical instruments supplied with implants. The surgical instruments coated included items such as reamers, drills, taps, and broaches.

Given its widespread use, titanium nitride is well established in the medical device industry. This is supported by a vast quantity of literature and testing that supports the biocompatibility of the coating, and many precedents with FDA.

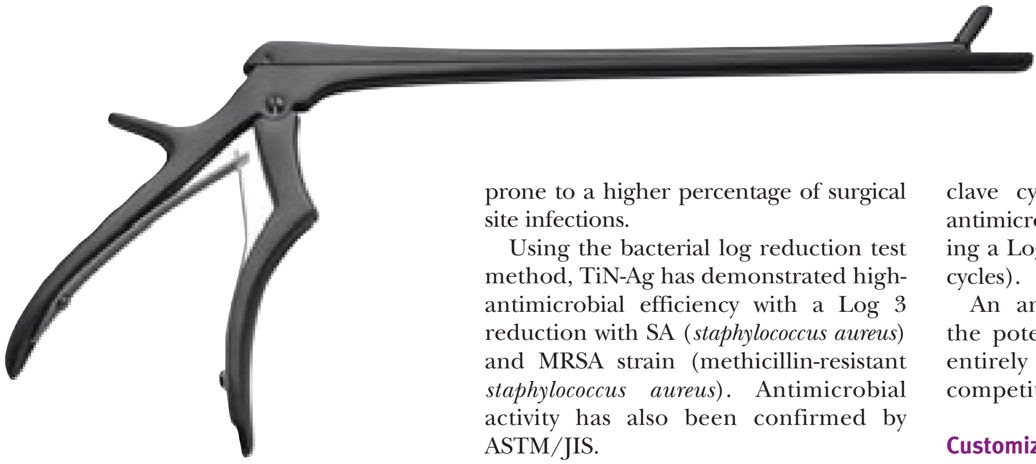
As a result, other PVD coatings like diamond-like-carbon (DLC) and aluminum titanium nitride (AlTiN) have gained widespread acceptance — particularly for coating stainless steel. This is significant because there are few surface treatments that can be applied to stainless steel while still providing the desired functional properties.

DLC coatings provide an ideal combination of low coefficient of friction like PTFE, but with the hardness of a ceramic. The coating has good functional properties, including excellent wear resistance, lubricity, corrosion resistance, antisticking, and antifouling.

The DLC coating even improves sharp edge retention of surgical instruments extending the service life of the instrument considerably. As an added benefit, cleaner cuts help surgical incisions heal more quickly, reducing patient recovery time.

In addition to their low coefficient of friction and wear resistance, PVD coatings may eliminate the need for lubrication, functioning even under dry running conditions. This is particularly useful for the pneumatic components of powered instruments such as surgical bone saws or for the implantation and removal of intramedullary nails.

Surgeons that must perform under the harsh glare of operating room lighting have also found PVD coatings useful for its antiglare properties. For example, Oerlikon Balzers' Balinit® DLC Medical and Balinit® C (a WC/C ductile carbide carbon of the DLC family) are black or



Device manufacturers must consider whether the coating solution they choose should contain antimicrobial properties.

dark grey, enabling surgeons to work faster and with greater comfort in bright operating rooms.

Antimicrobial Properties

Another important factor that device manufacturers must consider is whether the coating solution they choose contains antimicrobial properties. Invasive surgical instruments circumvent the body's natural lines of defense. Therefore, it is critical that instruments' surfaces are antimicrobial whenever possible to reduce the incidence of infection. Oerlikon Balzers' titanium nitride (TiN-Ag) coatings, which are doped with silver and have a film thickness of approximately 2 µm, were specifically designed to address this issue and are one of the only types of coatings that offer this antimicrobial protection.

Silver-doped titanium nitride is especially useful in trauma applications in which there are a lot of open wounds. These may require medium- to short-term implantation of devices and, subsequently, are prone to a higher percentage of surgical site infections.

Using the bacterial log reduction test method, TiN-Ag has demonstrated high-antimicrobial efficiency with a Log 3 reduction with SA (*staphylococcus aureus*) and MRSA strain (methicillin-resistant *staphylococcus aureus*). Antimicrobial activity has also been confirmed by ASTM/JIS.

In addition, when tested using the cytotoxicity testing method (ISO 10993-5), TiN-Ag has shown no cytotoxic effect. Oerlikon Balzers' TiN-Ag coatings, in particular, are specially certified under the MEM Elution method, 72 hours (according to US FDA 21 CFR Part 58).

Nevertheless, regardless of a coating's antimicrobial and biocompatibility properties, it is, ultimately, worthless if it delaminates from the surface of a part after going through the thermal cycling of an autoclave cycle.

With that in mind, the TiN-Ag coating was designed to withstand multiple autoclave cycles without influencing the antimicrobial activity itself (demonstrating a Log 3 reduction after 50 autoclave cycles).

An antimicrobial PVD coating has the potential to take a product to an entirely different level compared to its competition.

Customized Solutions

To further differentiate products, medical device manufacturers often require even more customized surface coatings.

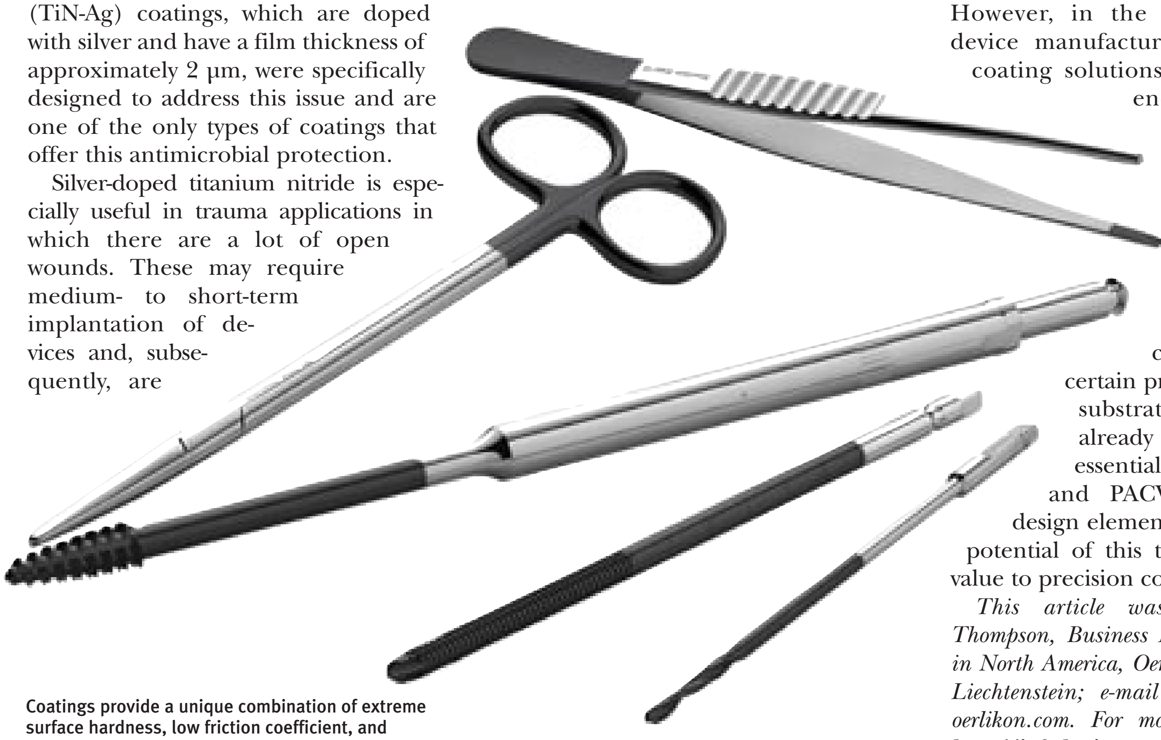
For this, companies often offer R&D capabilities to tailor coating solutions to meet unique requirements. In addition to coating thickness and hardness, properties such as structure, chemical, temperature resistance, and adhesion can be precisely controlled.

Conclusion

In a perfect world, medical OEMs would look into PVD coatings early in the design phase of new products. However, in the real world, many device manufacturers seek out PVD coating solutions only after experiencing excessive wear, high friction, and other issues in early engineering builds.

OEMs often seek out a coating expert late in the design phase looking for a coating solution when certain properties such as the substrate material may already be locked in. It is essential to think about PVD and PACVD coatings as a design element to fully unlock the potential of this technology and add value to precision components.

This article was written by Matt Thompson, Business Development Manager in North America, Oerlikon Balzers, Balzers, Liechtenstein; e-mail balzers.components@oerlikon.com. For more information, visit ***http://info.hotims.com/72993-343.***



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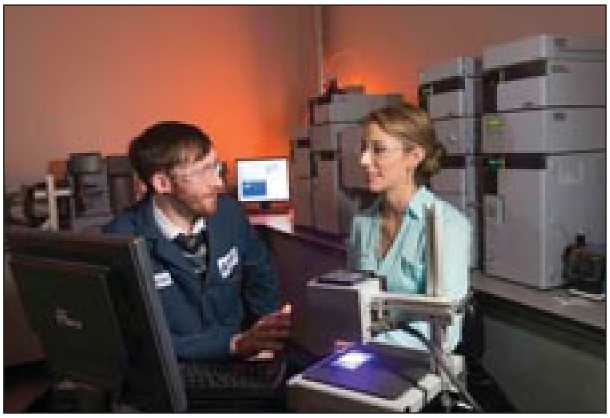

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Intro Cov ToC

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Company Description

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- Advanced Packaging
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Company Description

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Target Markets

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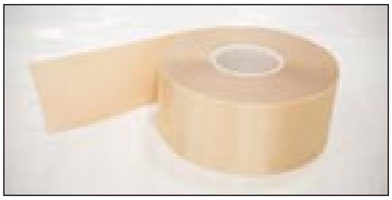
- Wearable Device
- Ostomy & Incontinence Care
- Transdermal Drug Delivery
- General Fixation
- In-Vitro Diagnostics



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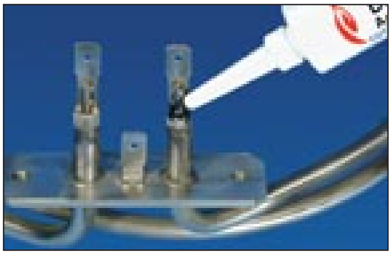

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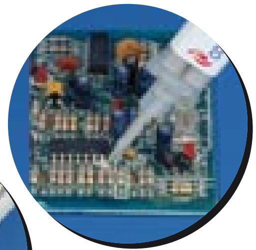

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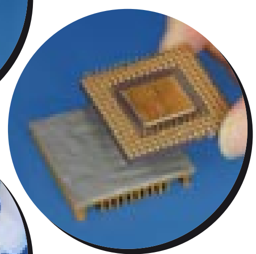

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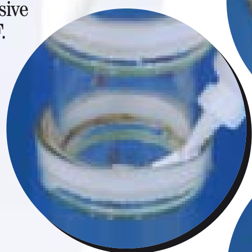

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R&D ROUNDUP

A baby wearing two of the patches developed by the team. (Credit: University of Illinois)

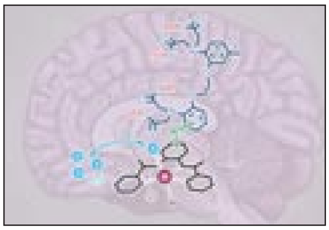
Patch Improves Care for NICU Babies

When a baby is placed into a neonatal intensive care unit (NICU), its vitals are continuously recorded through electrodes placed on the skin with wires attached to monitoring platforms. Researchers are working to replace the wires with a patch that would allow parents to hold their little one while it's being monitored.

Data is collected through two separate patches on each neonate, generally on the child's back and then either their chest or foot. Since there are multiple data streams, the information must be synchronized before it can be processed and streamed to the monitors. The patch must also allow staff to observe the skin in addition to allowing for x-rays and magnetic resonance images to be taken.

The devices were deployed at the Lori Children Hospital in Chicago on NICU patients whose parents agreed to the research. To make sure they were getting accurate measurements, the patches were placed on neonates who were also hooked up to the conventional wired system to compare the data readings. The patients involved in the research were also surrounded by nurses, neonatologists, and dermatologists to ensure that everything ran smoothly.

*For more information, visit **www.medicaldesignbriefs.com/roundup/0519/patch**.*



An MRI contrast agent can detect calcium within neurons, allowing brain activity to be tracked. (Credit: MIT)

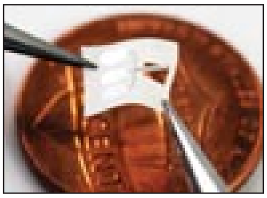
MRI Sensor Can Image Activity Deep Within the Brain

A new way to image calcium activity is based on magnetic resonance imaging (MRI) and allows them researchers to peer much deeper into the brain. Using this technique, they can track signaling processes inside the neurons of living animals, enabling them to link neural activity with specific behaviors.

The researchers used building blocks that can pass through the cell membrane. The contrast agent contains manganese, a metal that interacts weakly with magnetic fields, bound to an organic compound that can penetrate cell membranes. This complex also contains a calcium-binding arm called a *chelator*.

Once inside the cell, if calcium levels are low, the calcium chelator binds weakly to the manganese atom, shielding the manganese from MRI detection. When calcium flows into the cell, the chelator binds to the calcium and releases the manganese, which makes the contrast agent appear brighter in an MRI image.

*For more information, visit **www.medicaldesignbriefs.com/roundup/0519/brain**.*



An implantable sensor has the speed and precision for tracking a brain chemical known to be elevated in certain brain diseases and after a spinal cord injury. (Credit: Purdue University image/Tran Nguyen)

Implant Tracks Rogue Brain Chemicals

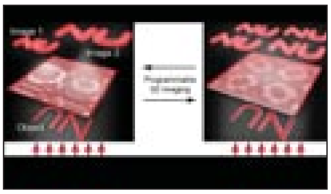
Engineers have built a tiny, flexible sensor that is faster and more precise than past attempts at tracking this chemical, called glutamate. The sensor, an implantable device on the spinal cord, is primarily a research tool for testing in animal models but could find future clinical use as a way to monitor whether a drug for neurotrauma or brain disease is working.

The technique allows researchers to rapidly change the size, shape, and orientation of the sensors and then test in animal models without having to go through the more expensive process of microfabrication.

Measuring levels in vivo would help researchers to study how spinal cord injuries happen, as well as how brain diseases develop.

The researchers implanted the device into the spinal cord of an animal model and then injured the cord to observe a spike. The device captured the spike immediately, whereas for current devices, researchers have had to wait 30 minutes to get data after damaging the spinal cord.

*For more information, visit **www.medicaldesignbriefs.com/roundup/0519/implant.***



During a single imaging session, the device can evolve from a single-focus lens to a multi-focal lens that can produce more than one image at any programmable 3D position. (Credit: Northwestern University)

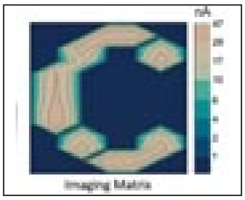
Tiny Optical Elements for Miniature Endoscopes

A research team has developed tiny optical elements from metal nanoparticles and a polymer that one day could replace traditional refractive lenses to realize portable imaging systems and optoelectronic devices.

The flat and versatile lens, a type of metalens, has a thickness 100 times smaller than the width of a human hair. The team built their lenses out of an array of cylindrical silver nanoparticles and a layer of polymer patterned into blocks on top of the metal array. By simply controlling the arrangement of the polymer patterns, the nanoparticle array could direct visible light to any targeted focal points without needing to change the nanoparticle structures.

This scalable method enables different lens structures to be made in one step of erasing and writing, with no noticeable degradation in nanoscale features after multiple erase-and-write cycles. The technique that can reshape any preformed polymer pattern into any desirable pattern using soft masks made from elastomers.

*For more information, visit **www.medicaldesignbriefs.com/roundup/0519/optical.***



The high sensitivity was proven using shadow masks. (Credit: Macmillan Publishers Limited, part of Springer Nature)

Molecular Device Uses Novel OPT Arrays

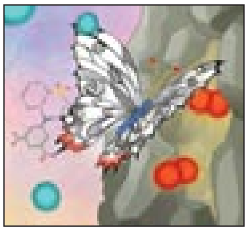
Converting light into electrical signals is essential for a number of future applications including imaging, optical communication, and biomedical sensing. Researchers have developed a new molecular device that can detect light and translate it with high efficiency to detectable electronical current.

Phototransistors are important electronic building units for capturing and converting light into electrical signals. For applications such as foldable electronic devices, organic phototransistors (OPTs) are attractive because of their flexibility, low cost, light weight, ease of large-area processing, and precise molecular engineering.

Researchers have developed a novel thin-film OPT array. Their approach is based on a small-molecule — 2, 6-diphenylanthracene (DPA) — which has a strong fluorescence anthracene as the semiconducting core and phenyl groups at 2 and 6 positions of anthracene to balance the mobility and optoelectronic properties.

The fabricated small-molecule OPT device shows high photosensitivity, photoresponsivity, and detectivity. The reported values are said to be superior to state-of-the-art OPTs. The researchers believe that DPA offers great opportunity for applications such as sensor technology or data transfer.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0519/dpa****.*



Butterfly-shaped ligands were the key to designing a material that can selectively absorb and store different gas molecules. (Credit: Izumi Mindy Takamiya)

Temperature-Controlled Materials

Researchers have designed a temperature-controllable copper-based material for sieving or storing different kinds of gases. The rationale used to design the material could act as a blueprint for developing nanoporous materials with a wide variety of applications, including medical.

They designed a porous coordination polymer that was formed of copper atoms linked by butterfly-shaped ligands made from isophthalic acid and phenothiazine-5,5-dioxide. The resultant material was comprised of tiny nanocages, each with eight protruding channels. At very low temperatures, the channels connecting the nanocages were so narrow that they were effectively closed. As the temperature was increased, the channels opened more and more, allowing gas molecules to move between the cages.

The team found that a gas could move or become locked within the material depending on the size of the gas's molecules and how wide the material's channels were at a given temperature. They also found that the material adsorbed a gas at high temperatures and held it in when ambient temperatures were applied, effectively storing the gas.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0519/material.***

Reliable Structures and Wearable Systems Call for Multiphysics Simulation

Numerical simulation optimizes semiconductor solutions for healthcare.

COMSOL, Burlington, MA

The increasing demand for miniaturized electronics and Internet of Things (IoT) devices has created new challenges for the specialists who design microdevices such as actuators, controllers, drivers, sensors, and transmitters. From responsive equipment and wearable monitors to energy efficient lighting in the office and automation in the factory, engineers need to bridge the microscopic components of semiconductors and our macroscopic world with reliable and innovative products. This shift has inspired engineers to find new solutions by exploring their ideas in the virtual world of numerical simulation.

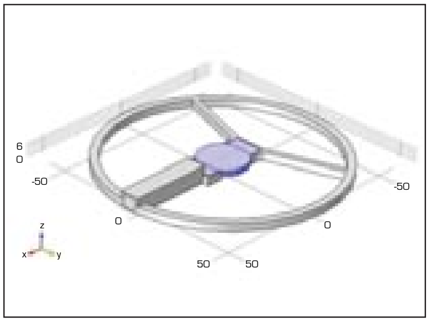


Fig. 1 – Geometry of the embedded structural health monitoring sensor. The sensing part is highlighted in blue.

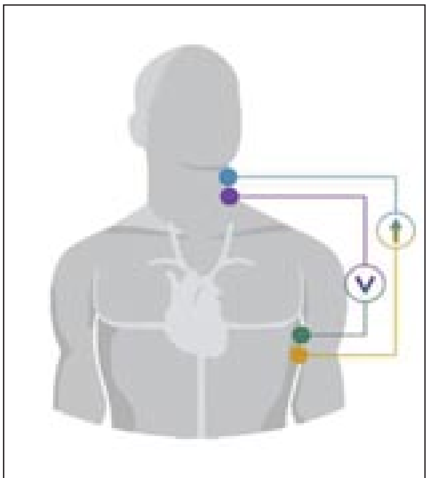


Fig. 2 – Technique used to measure the bio-impedance of an organ.

STMicroelectronics, a leader in designing and manufacturing semiconductor solutions, employs 7500 individuals in the area of research and development (R&D). Lucia Zullino, technology R&D engineer at STMicroelectronics explains their efforts. "In our field we need to analyze very small structures and understand their interaction with large packages in different configurations over a wide range of environments and applications," she says.

For semiconductor manufacturers, the choice of material and design is critical. This is where simulation plays an important role in the evaluation of materials and performance parameters. "Much of our work is done through the COMSOL Multiphysics software, which we use to validate hypotheses and to optimize products," explains Zullino. "There are about 30 users within STMicroelectronics, and although we belong to different departments and work in various locations, we are continually building and sharing knowledge about mathematical modeling techniques used in several projects."

Multiphysics Simulation for Research and Product Design

Simulation is used to understand multiphysics interactions at every stage of the development process for several products. A few examples include: optimizing an epitaxial reactor for faster wafer production, controlling reactant flow distortion in the wet etching process, and investigating the interaction between die and package at the microscopic level. In addition to design and manufacturing of microchips, engineers at STMicroelectronics work on the design of miniaturized actuators such as micromirrors used in recognition technologies that require optics and cameras.

Simulation was also used in another actuator-related project to investigate printheads and compare the effectiveness of two different working principles: displacement of ink through pressure-generated bubbles or using a membrane actuated by a PZT a ceramic material made of lead zirconate titanate. Through this work the researchers were able to determine that

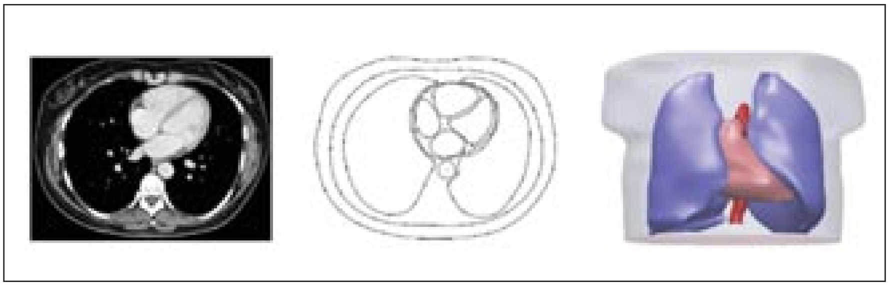


Fig. 3 – 3D model created from computed tomography (CT) images (left), postprocessed with CAD tools (middle), and then interpolated to generate the volumes (right) needed for the analysis.

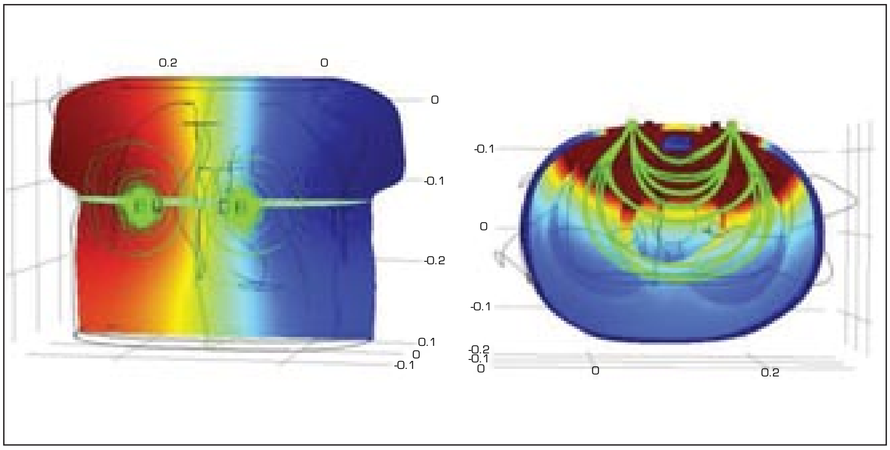


Fig. 4 – Simulation results showing the electric voltage and current distribution in a human torso.

the thin-film piezo printhead offers better compatibility with a wide variety of inks, higher printing speed, superior print output quality, and extended printhead lifetime.

Sensing Concrete Health

Governments and businesses have been implementing various sensor technologies to monitor the performance of concrete for years. In one development project simulation was used to analyze the properties of concrete and predict the capacity of an embedded sensor (see Figure 1) to monitor age-related changes and relay a signal to the surface. This structural health monitoring (SHM) system has already been deployed in Italy. It is being used on various structures to assess the health of concrete and log damage following any unexpected stress that may impact the structural integrity and reliability of the system.

Wearable Medical Monitoring

Over the years, STMicroelectronics has developed many healthcare applications. In one prototype project, a patch was designed to measure the bioimpedance of an organ, such as the heart, inside the human body (see Figure 2). Working from medical imaging of human organs, researchers created a 3D model (see Figure 3) to run an AC/DC simulation in the frequency domain (see Figure 4) and assess the effect of the

Fig. 5 – Comparison between measured and simulated bioimpedance values (left) for different electrode shapes and positions (right).

Intro Cov ToC

electrode shape and position on the measured physiological parameters.

The simulation results they obtained (see Figure 5) correlated closely with real-life measurements and enabled the development of a wearable configurable patch capable of indicating physiological changes. These sensors will enable doctors monitoring various heart conditions to get real-time data to provide patients with the best care using the latest technology.

"Through simulation we have learned a lot about potential problems, and we have gotten better at optimizing semiconductors for the outside world. Simulation now drives product design, both for internal and external customers," comments Zullino. She and her colleagues see opportunities to continue using multiphysics simulation in all aspects of development. She shared that studies on humidity inside packaging and the potential for corrosion are already in progress.

"We can assess materials and structures more quickly and screen for the best ones, which means less time spent on trials, better technical decisions, and quicker business decisions," concludes Zullino. "Compared to physical testing, we can implement new solutions and verify them at zero cost. Simulation is one of the key tools that drives innovation."

For more information, visit ***http://info.hotims.com/72993-345.***

'Origami' Diagnostic Device Offers Affordable Malaria Diagnoses

Simple folded sheets of waxed paper could help bring affordable tests for malaria.

University of Glasgow
Glasgow, Scotland

In a new paper published in the *journal Proceedings of the National Academy of Sciences*, researchers from universities in Scotland and China, working together with the Ministry of Health in Uganda, describe for the first time how origami-style folded paper, prepared with a printer and a hot plate, has helped detect malaria with 98 percent sensitivity in infected participants from two primary schools in Uganda.

Malaria is one of the world's leading causes of illness and death, affecting more than 219 million people in 90 countries around the globe, and killing 435,000 people in 2017 alone.

A significant issue for arresting and reversing the spread of the disease is diagnosing it in people who are infected but who do not display any symptoms, a problem that can only be addressed by widespread field tests. However, current tests, which rely on a process known as polymerase chain reaction (PCR), can only be carried out under laboratory conditions, making them unsuited for use in remote locations.

The team, led by researchers from the University of Glasgow in partnership with Shanghai Jiao Tong University and the Ministry of Health in Uganda, have developed a new approach to diagnostics. It uses paper to prepare patient samples for a different type of detection process known as loop-mediated isothermal amplification, or LAMP, which is more portable and better suited for use in the field.

The origami platform uses a commercially available printer to coat the paper in patterns made from water-resistant wax, which is then melted on a hotplate, bonding the wax to the paper.

A blood sample taken from a patient via finger prick is placed on in a channel in the wax, then the paper is folded, directing the sample into a narrow channel and then three small chambers which the LAMP machine uses to test the samples' DNA for evidence of *Plasmodium falciparum*, the mosquito-borne parasitic species that causes malaria. The test can be completed on-site in less than 50 minutes.

Prof. Jonathan Cooper of the University of Glasgow's School of Engineering is the paper's lead author. He says, "We tested our approach with volunteers from two primary schools in the Mayuge and Apac districts in Uganda. We took samples from 67 school children, under strict ethical approval, and ran diagnostic tests in the field using optical microscopy techniques, the gold standard method in these low-resource settings, a commercial rapid diagnostic procedure known as a lateral flow test and our LAMP approach. We also carried out PCR back in Glasgow, on samples collected in the field.

The approach was tested with volunteers from two primary schools in the Mayuge and Apac districts in Uganda. (Credit: University of Glasgow)

"Our diagnostic approach correctly diagnosed malaria in 98 percent of the infected samples we tested, markedly more sensitive than both the microscopy and lateral flow tests, which delivered 86 percent and 83 percent, respectively.

"It's a very encouraging result which suggests that our paper-based LAMP diagnostics could help deliver better, faster, more effective testing for malaria infections in areas which are currently underserved by available diagnostic techniques."

Dr. Julien Reboud of the University of Glasgow's School of Engineering played a key role in developing the new diagnostic technique.

"These are challenging environments for any test of this type, with no access to the kinds of refrigeration, special equipment, and training that more traditional diagnostic procedures require, so it's very encouraging that the diagnostic techniques we've developed have proven to be so sensitive and reliable," says Reboud.

"With malaria infections on the increase in 13 affected countries according to a World Health Organization report released last year, it's vital that new forms of diagnosis reach the people who need them, and we're committed to developing our approach to paper-based LAMP diagnostics further after this encouraging study."

The team's paper, titled "Paper-based Microfluidics for Diagnosing Malaria in Low Resource Rural Environments," was published in *PNAS*. The research was supported by funding from the UK Global Challenges Research Fund, the Scottish Funding Council, and the Engineering and Physical Sciences Research Council (EPSRC).

For more information, visit ***www.gla.ac.uk/news****.*

Why Reel-to-Reel Molding Might Be Right for Medical Components

A reel-to-reel method for electronics manufacturing eliminates waste and error for reduced costs. Here's how.

Weiss-Aug, East Hanover, NJ

Reel-to-reel insert molding can prove a more efficient process for design engineers when it comes to lowering assembly costs. The process is best suited for products that require dimensional stability and need to function in harsh environments, such as drug-delivery device parts and components.

How It Works

Reel-to-reel insert overmolding combines two technologies: stamping and molding.

In the reel-to-reel process, stamped components or frames arrive from the stamper in continuous form on a disposable cardboard, Masonite, plastic, or other type of reel. The base material of the stamped frame can be any material — copper or nickel-based alloys are the most common.

The perforated, continuous strip resembles a movie film. Perforations, known as *pilot holes*, advance the coiled sheet and locate the metal strip in the progressive die. The accuracy of the relationship between the mold's cavity and the pilot hole guarantee that the plastic detail always remains in the right place. The pilot hole also helps ensure the correct alignment of components in any subsequent manufacturing operation, such as forming, bending, soldering, welding, or assembly.

Technicians mount the stamped, reeled-up frame onto a pay-out reel (uncoiled), which feeds into the molding machine. Like the feeding motion in the die, the frame advances through the mold after each molding cycle. Here, the feeding unit on the punch press is usually mounted on the beginning of the progressive die and pushes the strips through the die.

This arrangement is opposite in the molding process, where the feeding unit mounts at the end of the mold, and the strip is pulled through the mold. Molding can take place in a horizontal or vertical molding machine. Following the molding process, the frame rolls back onto a reel, and the part is ready for any secondary operation or shipment to the customer.

Reel Improvements

The reel-to-reel system saves money by eliminating waste and reducing processing hours, as well as minimizing the need for additional equipment and manpower. It also enables improved designs and lower up-front costs. Because the device developer receives a continually molded and oriented product, less sophisticated assembly tooling is required.

It decreases up-front tooling costs compared with shuttle or rotary molding. Reel-to-reel requires only one “A” and one “B” side mold, whereas rotary or shuttle molding can require multiple “B” sides. Further, the process employs vertical molding, which is lower in cost for hourly machine rates and part costs because the press is less expensive and has a smaller footprint.

Reel-to-reel also offers savings in terms of reducing operating needs and material waste. No operators are required to place stamped inserts into the mold cavity or assemble them into load bars. And the single continuous frame eliminates the need (and cost) of a robot or other delivery system. The continuous, unattended operation ensures consistent, repeatable cycle times, with a high-quality product result.

Flash and mold damage is practically eliminated because components are placed accurately, automatically. Medical device parts can be expensive and can be made from expensive alloys, such as gold, for plating. The process doesn’t waste gold in the stamped contact area of electronic components.

Finished parts fit onto a single reel, ensuring an economical, safe way to package and transport components.

Higher output gives the engineer greater latitude in designing a product, especially when two strips are fed into a mold. The tolerances achievable in reel-to-reel are the same as for any other type of insert molding and are limited only by the resin selected (as far as plastic part dimensions are concerned) and what the blank tolerances of the strip can be maintained. Typically, the thinner the metal used, the greater the accuracy between plastic and metal. For some liquid crystal polymer resins, the accuracy can be in the 0.01 mm range.

Best Practices

While reel-to-reel offers significant savings and flexibility, it is important to consider a few design and operation matters. Keep in mind that the part needs to fit the application; otherwise, the process will require more metal to make the same part. The geometry of the part should also fit the process — the carrier strip may not allow movements for undercut features.

Be sure to monitor the strip position during the cycle. The tool can get damaged if the strip position goes over a shutoff. Likewise, have a process in place to monitor part quality coming out of the tool, particularly if a secondary process is in line and the parts are high value. A technician must be able to stop and fix an issue before making a ton of scrap. With these simple requirements, reel-to-reel can offer a variety of advantages for medical devices.

This article was written by Armand Pagano, Mold Design Manager/CNC Lead at Weiss-Aug Co., East Hanover, NJ. For more information, visit ***http://info.hotims.com/72993-346***.

Encapsulated Nanoparticles Offer Promise for Biomedical Applications

Semiconductor nanocrystals have been efficiently encapsulated into polymers and offer great stability in terms of their optical properties and fluorescence control.

University of Basque Country, Vizcaya, Spain

The Polymerization Process Research Group of the Polymat Institute of the UPV/EHU–University of the Basque Country has efficiently encapsulated semiconductor nanocrystals or quantum dots of various sizes into polymer particles. Great stability in terms of their optical properties and good fluorescence control when combining different quantum dots have been achieved. The possible applicability of these materials as sensors of volatile organic compounds has also been explored.

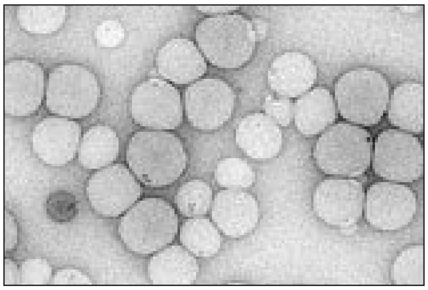
Nanotechnology and nanoscience are disciplines in which minute molecular structures with special physical and chemical properties are designed, manufactured and studied. One of the types of particles that are studied in these disciplines are quantum dots; they are semiconductor nanocrystals, which ranges between 2 and 10 nm and which have excellent optical and electronic properties. Worthy of mention is the fact that they emit light in different colors depending on their size. In other words, "the emission wavelength is varied just by varying the size of the nanocrystal, without modifying its composition," explains Alicia de San Luis, a Polymat researcher and author of a paper on this work.

The properties of quantum dots render them potentially useful for a range of applications, including detection in biomedicine. Yet, "their drawbacks also need to be taken into consideration: they are difficult to handle owing to their small size, and are toxic, given that the quantum dots of higher quality mostly consist of heavy metals," she says.

To get the most out of the excellent optical properties of these nanoparticles, while not forgetting the toxicity problems they have, at the UPV/EHU's Polymat Institute of Research, they have managed to efficiently encapsulate commercial quantum dots into polymer particles dispersed in water while maintaining the fluorescence of the quantum dots over long periods of time. "The main aim was to encapsulate the quantum dots into slightly larger polymer particles to protect them and, at the same time, be able to handle them without them losing their properties," as the author of the research pointed out. "We have implemented a simple method yielding good results: polymer particles with fluorescence stable over a minimum of nine months," she adds.

Different Combinations and Applications

Having achieved the first aim, "the second step was to encapsulate combinations of quantum dots of varying sizes to create a bar code that could be used for multiple detection in biological systems," she explains. That way they managed to control the fluorescence of these combinations, since by using quantum dots that emit at different wavelengths, "their signals can be detected simultaneously without one being superimposed on another one." This could be useful for biomedical detection because there is a possibility of modifying the surface of the polymer particle with different analytes (or different antibodies or antigens). In the researcher's view, "it is a pretty powerful, straightforward, fast detection technique. Most labs have a fluorometer and, what is more, one would not have to wait several days to process the sample."



Microscopic image of quantum dots (dark points) encapsulated in polymer particles (Credit: Dr. Mariano Barrado/UPV/EHU)

They also explored the combining of quantum dots with other inorganic nanoparticles (CeO_2) by co-encapsulating them into the same polymer particles. In this study, they were able to see an increase in the emission of fluorescence during the time they were exposed to sunlight.

Finally, they tackled the possible applicability of a range of synthesized combinations, such as optical and electrical sensors of volatile organic compounds (VOCs) by producing nanofibers and subsequently putting them in contact with VOCs. This part of the research is being carried out in collaboration with Tecnalia. "In this case we are working on fluorescence as well as on conductivity measurements of the nanofibers," says de San Luis.

This research was conducted by Alicia de San Luis-González as part of her PhD thesis at the UPV/EHU's Polymat Institute of Research. The thesis, entitled "Nanostructured polymeric aqueous dispersions containing quantum dots," was supervised by Jose Ramon Leiza, professor of the UPV/EHU's Faculty of Chemistry and director of Polymat, and by María Paulis, tenured lecturer at the UPV/EHU's Faculty of Chemistry. The final part of the work is being conducted in collaboration with Tecnalia.

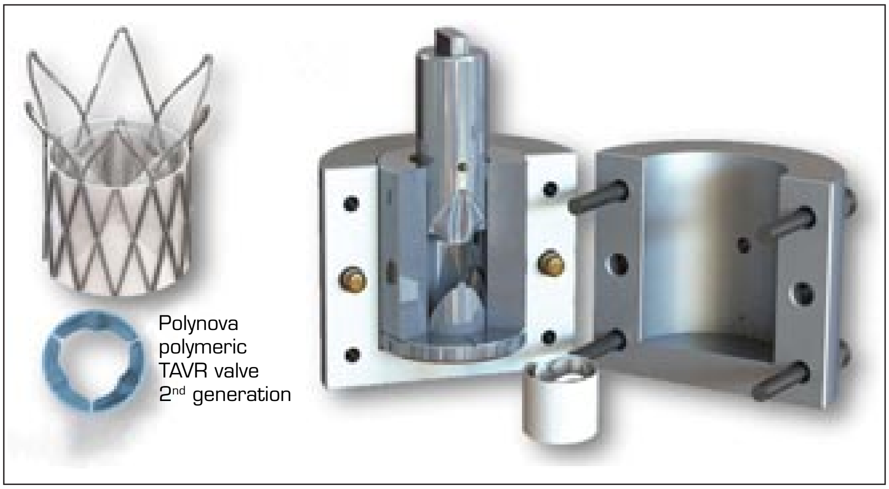
For more information, visit ***www.ehu.eus***.

New Polymer Heart Valves Improve Patient Outcomes

Polymer valves refined by computer simulations aim to reduce costs and improve minimally invasive procedures.

NIBIB, Bethesda, MD

NIBIB-funded engineers are designing and testing aortic heart valve replacements made of polymers rather than animal heart tissues. The goal is to optimize performance of these valves in an effort to improve outcomes and enable increased use of a minimally invasive method for valve replacement over the current practice of open-heart surgery.



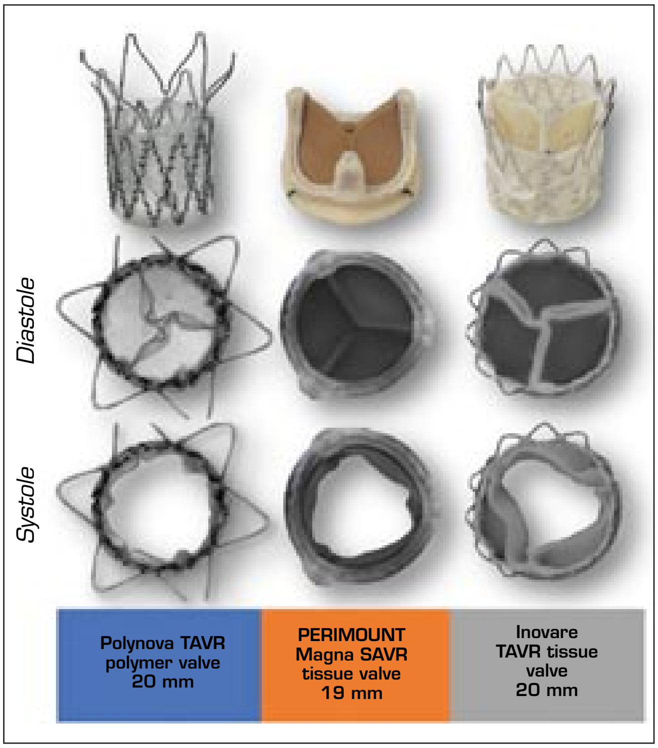
New aortic heart valve made of polymers instead of animal tissues (left). Compression injection mold used to make new valve allows mass production of valves at reduced cost (right). (Credit: Rotman, et al. *Ann Biomed Eng*, Jan 2019: Springer Nature.)

Aortic stenosis occurs when the aortic valve of the heart does not open fully as a result of Calcific Aortic Valve Disease (CAVD). CAVD is caused by calcium build up on the valve and can lead to heart failure. The condition affects more than 2.5 million people over the age of 75 in the United States. For years, the valves have been replaced through open heart surgery: surgical aortic valve replacement (SAVR). However, increasingly, older patients who cannot tolerate surgery have been treated with a minimally invasive procedure: transcatheter aortic valve replacement (TAVR), where a new valve compressed into a catheter is guided through a blood vessel and expanded on top of the diseased valve.

As the TAVR procedure and the design of the TAVR valves continues to be improved, more doctors and patients are opting for TAVR over surgery because the minimally-invasive nature of the procedure enables a dramatically decreased recovery time. Recovery from SAVR takes several months, while TAVR patients are typically out of the hospital and able to function normally within a few days.

However, the increase in use of TAVR in younger patients raises a serious issue of the durability of the valves as they are now expected to function for many more years in the patients' bodies. Longer-term studies of TAVR procedures have identified potential degeneration and leakage problems with tissue-based valves currently used for TAVR.

Led by NIBIB grantee Danny Bluestein, PhD, professor of biomedical engineering, Stony Brook University, NY, a team of experts in the dynamics of



The Polynova polymer valve at left was compared with the two animal tissue valves while opening and closing during pulses of blood-like fluid. (Credit: Rotman, et al. *Ann Biomed Eng*, Jan 2019: Springer Nature.)

blood flow in the cardiovascular system has designed and laboratory tested an experimental polymer TAVR valve. The group hopes that the use of polymers will overcome some of the problems with long-term use of tissue valves, improving the procedure and outcomes so that it can be reliably offered to more patients of all ages, reducing the need for open heart surgery.

"We are able to test the valves in the early stages of development using computer models and with mechanical devices that mimic the heart pumping blood through the valve," says Bluestein. "Our test systems and computer simulations allow us to evaluate a polymer valve and identify specific structural issues affecting performance. Then, we can make the necessary changes, for example in the shape, flexibility, or other aspects of the polymer that would mitigate problems and increase efficiency."

Bluestein explains that a key advantage of working with polymers is that unlike tissues, their shape and properties can be changed, allowing problems with devices to be rectified before moving into expensive animal testing.

Testing the New Polymer TAVR Valve

The prototype valve was developed in a collaboration between Stony Brook University and Polynova Cardiovascular Inc., Stony Brook, NY. The valve is a TAVR version of a Polynova polymeric valve designed for surgical aortic valve replacement (SAVR). The valve was made by placing pellets of the raw polymer into a mold under heat and pressure for one hour using compression molding. The ability to make valves with molds would allow for mass production and reduced costs compared to animal tissue valves.

The experimental Polynova valve was compared with tests on two valves that are currently in use in patients, the Perimount

SAVR used in open heart surgery and the Inovare TAVR used in the minimally invasive procedure. Both are animal tissue valves. Hydrodynamic tests evaluated how the valves perform as an imitation blood fluid is pumped through them at the same rate as a heartbeat.

In the baseline test, fluid was pumped through the valves to observe how well the valves opened. The size of the opening when the fluid is pumped through is called the effective orifice area (EOA). A large EOA as well as a more rounded EOA indicates the best performance. The EOA of the polymer valve was both larger and more rounded than both the SAVR and TAVR tissue valves.

For the second test, the valves were mounted in a 3D printed model of the aorta of an actual patient. In both tests, changes in fluid pressure as it passed through each valve were measured. For all three valves, performance dropped slightly in the patient-specific test compared to the mechanical device used in the first test. This was expected because the variation in the patient's anatomy puts various pressures on all the valves resulting in shape changes and a slightly less efficient flow. Nonetheless, there were only slight differences between valves in terms of performance in both test environments, which were insignificant.

The final test measured the activation of platelets as they flow through each valve. Platelets are the tiny vesicles in the blood that cause blood clots to form when activated. The Bluestein group has focused on developing implanted valves and heart pumps that are designed to reduce clotting. These implants can cause perturbations in blood flow that activates the platelets and initiates the clotting cascade, which increases the formation of blood clots and the risk of stroke. The results of the clotting tests indicated that the polymer valve was the least likely to activate platelets.

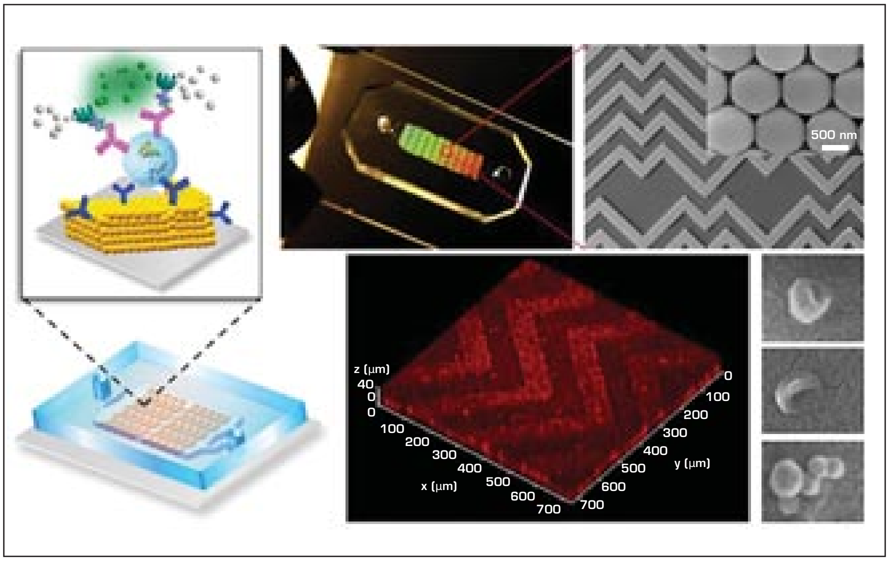
The work was published in the January 2019 issue of the *Annals of Biomedical Engineering*. This project was supported by National Institute of Biomedical Imaging and Bioengineering Quantum Award Phase II-U01EB012487, the National Heart Lung and Blood Institute grant STTR R41-HL134418, and the Center for Biotechnology: a New York State Center for Advanced Technology, New York State Department of Economic Development.

For more information, visit ***www.nibib.nih.gov.***

Breakthrough Lab-on-a-Chip Detects Cancer Faster, Cheaper, Less Invasively

The ultrasensitive diagnostic device uses a droplet of blood or plasma.

University of Kansas
Lawrence, KS



The new lab-on-a-chip's key innovation is a 3D nanoengineering method that mixes and senses biological elements based on a herringbone pattern commonly found in nature, pushing exosomes into contact with the chip's sensing surface much more efficiently in a process called *mass transfer*. (Credit: Yong Zeng)

A new ultrasensitive diagnostic device invented by researchers at the University of Kansas, The University of Kansas Cancer Center, and KU Medical Center could allow doctors to detect cancer quickly from a droplet of blood or plasma, leading to timelier interventions and better outcomes for patients.

The lab-on-a-chip for liquid biopsy analysis, reported in *Nature Biomedical Engineering*, detects exosomes — tiny parcels of biological information produced by tumor cells to stimulate tumor growth or metastasize.

"Historically, people thought exosomes were like 'trash bags' that cells could use to dump unwanted cellular contents," says lead author Yong Zeng, Docking Family Scholar and associate professor of chemistry at KU. "But in the past decade, scientists realized they were quite useful for sending messages to recipient cells and communicating molecular information important in many biological functions. Basically, tumors send out exosomes packaging active molecules that mirror the biological features of the parental cells. While all cells produce exosomes, tumor cells are really active compared to normal cells."

The new lab-on-a-chip's key innovation is a 3D nanoengineering method that mixes and senses biological elements based on a herringbone pattern commonly found in nature, pushing exosomes into contact with the chip's sensing surface much more efficiently in a process called *mass transfer*.

"People have developed smart ideas to improve mass transfer in microscale channels, but when particles are moving closer to the sensor surface, they're separated by a small gap of liquid that creates increasing hydrodynamic resistance," Zeng says. "Here, we developed a

3D nanoporous herringbone structure that can drain the liquid in that gap to bring the particles in hard contact with the surface where probes can recognize and capture them."

Zeng compared the chip's nanopores to a million little kitchen sinks: "If you have a sink filled with water and many balls floating on the surface, how do you get all the balls in contact with the bottom of the sink where sensors could analyze them? The easiest way is to drain the water."

To develop and test the pioneering microfluidic device, Zeng teamed with a tumor-biomarker expert and KU Cancer Center Deputy Director Andrew Godwin at the KU Medical Center's Department of Pathology & Laboratory Medicine, as well as graduate student Ashley Tetlow in Godwin's Biomarker Discovery Lab. The collaborators tested the chip's design using clinical samples from ovarian cancer patients, finding the chip could detect the presence of cancer in a minuscule amount of plasma.

"Our collaborative studies continue to bear fruit and advance an area crucial in cancer research and patient care — namely, innovative tools for early detection," says Godwin, who serves as Chancellor's Distinguished Chair and Endowed Professor in Biomedical Sciences and professor and director of molecular oncology, pathology and laboratory medicine at KU Medical Center. "This area of study is especially important for cancers such as ovarian, given the vast majority of women are diagnosed at an advanced stage when, sadly, the disease is for the most part incurable."

What's more, the new microfluidic chips developed at KU would be cheaper and easier to make than comparable designs, allowing for wider and less-costly testing for patients.

"What we created here is a 3D nanopatterning method without the need for any fancy nanofabrication equipment — an undergraduate or even a high school student can do it in my lab," Zeng says. "This is so simple and low cost that it has great potential to translate into clinical settings. We've been collaborating with Dr. Godwin and other research labs at The KU Cancer Center and the molecular biosciences department to further explore the translational applications of the technology."

According to Zeng, with the microfluidic chip's design now proven using ovarian cancer as a model, the chip could be useful in detecting a host of other diseases.

"Now, we're looking at cell-culture models, animal models, and also clinical patient samples, so we are truly doing some translational research to move the device from the lab setting to more clinical applications," he says. "Almost all mammalian cells release exosomes, so the application is not just limited to ovarian cancer or any one type of cancer. We're working with people to look at neurodegenerative diseases, breast and colorectal cancers, for example."

On KU's Lawrence campus, Zeng worked with a team including postdoctoral fellow Peng Zhang, graduate student Xin Zhou in the Department of Chemistry, as well as Mei He, KU assistant professor of chemistry and chemical engineering.

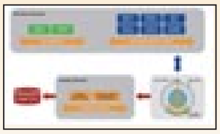
This research was supported by grants from National Institutes of Health, including a joint R21 (CA1806846) and a R33 (CA214333) grant between Zeng and Godwin and the KU Cancer Center's Biospecimen Repository Core Facility, funded in part by a National Cancer Institute Cancer Center Support Grant (P30 CA168524).

*For more information, contact Brendan Lynch, **blynch@ku.edu**, or visit **www.ehu.eus**.*

NEW PRODUCTS AND SERVICES

PRODUCT OF THE MONTH

Medical-Grade Connectivity Framework



Real-Time Innovations (RTI), Sunnyvale, CA, has added a variety of new capabilities to its connectivity software, RTI Connext DDS. Based on the Data Distribution Standard™ (DDS), this release addresses critical design challenges faced in developing secure, interoperable medical devices for healthcare systems of the future. RTI Connext 6 provides syntactic interoperability to lay a foundation for standards-based semantic (i.e., data model) interoperability in the future. It ensures a secure system according to governing regulatory bodies, provides access to real-time patient data from a variety of near patient medical devices, and enables connected health solutions to scale to thousands of nodes, providing critical infrastructure for device manufacturers and providers.

For Free Info Visit http://info.hotims.com/72993-348

Product Focus: Fluid Handling

Peristaltic Fill/Finish System

Watson-Marlow Fluid Technology Group, Cornwall, UK, has unveiled a new highly accurate peristaltic fill/finish system. A wide variety of modules are available for the Flexicon FPC60 system, allowing users to create their own bespoke filling solution to suit small-batch applications. The modules include vial infeed, filling, stoppering, capping, auto-reject, gas purging, and product outfeed. Capable of handling vial sizes between 2R and 100H, the system's unique servo-driven auto adjustment allows for minimal tools and quicker set-up between batches. When supplied with in-line check weighing, it offers dynamic prime, no-intervention initial calibration, and dynamic recalibration.

For Free Info Visit http://info.hotims.com/72993-349

Sterile Connectors

A line of connectors ideal for providing easy sterile connections for small-flow applications is available from Qosina, Ronkonkoma, NY. These connectors are also suitable for use in nonsterile environments. AseptiQuik® G and S Series have a genderless design, which allows them to mate universally, simplifying system integration. Their intuitive, three-step flip-click-pull function promotes reliable execution, reducing the risk of operator error. The robust construction eliminates the need for clamps, fixtures, or tube welders, and the integrated pull-tab covers maintain sterility and ensure simultaneous removal of both membranes.

For Free Info Visit http://info.hotims.com/72993-350

Electromagnetic Flowmeter

Krohne, Peabody, MA, has released an electromagnetic flowmeter with a biocompatible disposable flow tube. The FLEXMAG 4050 C will not drift over time. It provides a completely stable, direct, and accurate volumetric flow measurement, unaffected by fluid properties such as color or density. The single-use flow path tubes are gamma sterilizable at 25...40 kGy irradiation. All wetted materials comply with FDA/USP Class VI and ISO 10993 and are manufactured in an ISO 13485 certified site within an ISO 7 clean room environment. The tube's full-bore construction is designed for minimal hold-up volume without obstruction.

For Free Info Visit http://info.hotims.com/72993-351

Medical Adhesives

Epoxy Technology, Billerica, MA, has completed ISO 10993 testing of its previously Class VI adhesives, as well as the addition of 12 new medical-device-grade adhesives, extending its MED line of biocompatible products to 23. To date, 14 products have undergone ISO 10993-5 cytotoxicity testing, and nine additional products have undergone even more screening, passing all ISO 10993-4, 5, 6, 10, and 11 testing. Included in testing for EPO-TEK® MED-301 was an extended implantation test, from the normal 2 weeks to 12 weeks, which it passed. This specific optically clear epoxy adhesive is often used for molding header systems on many types of devices including pacemakers, ICDs, and neurostimulators.

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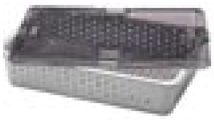
PPSU Material



Solvay, Alpharetta, GA, offers polyphenylsulfone (PPSU) for use in medical equipment. The company's Radel® PPSU was recently chosen by Legacy Medical Solutions to optimize a large-format sterilization tray for surgical instruments. The resin's strength-to-weight ratio and ability to withstand high pH cleaners during repeated sterilization cycles and high-temperature autoclaves were key factors in the decision to utilize the material to improve the design, manufacture, and use of the tray. The tray, which measures (59.7 × 38.1 × 14.2 cm), is comprised of a thermoformed transparent lid and an opaque base tray made from Radel® PPSU resin that secures with a metal clamping system.

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Braze Alloys

Morgan Advanced Materials, Windsor, UK, has improved its braze alloys service to support U.S. customers requiring mission-critical components. The braze alloys are manufactured in configurations specific to customers' requirements. Many applications of braze alloys are used in research and development projects, and information and data is needed quickly for small-run orders. The company has created a dedicated resource to handle inquiries from contract braze houses, while reducing lead times on commonly used alloys. The company can provide precious and nonprecious braze alloys, presintered preforms, and braze inhibitors like Stopyt, which prevents the unwanted flow of molten brazing filler metals.

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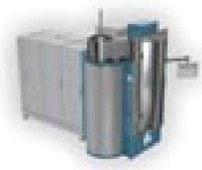
Coating Systems



Vapor Technologies, Inc. (VaporTech), Longmont, CO, has launched a new line of coating machines. The VT-i Series PVD coating machines are designed to meet needs for efficiency, cost-control, product quality, and differentiation. These new systems include the VT-500i™, VT-1000i™, and VT-1500i™ (and 3000i ™) systems. The VT-500i is the most compact machine for small-batch manufacturing operations. The VT-1000i system is a compact, higher capacity system for medium-size operations. The VT-1000i machine, which offers 6x capacity, is a PVD and DLC system for medium-volume applications. The VT-1500i system is designed for high-volume, larger manufacturing operations, while the VT-3000i is an updated version of the VT-3000, with a smaller footprint.

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PRODUCT SPOTLIGHT

CUSTOM AUTOMATION EQUIPMENT

The Arthur G. Russell Company designs automatic assembly equipment for the medical device industry. We specialize in high-speed, mechanical systems designed for products like syringes, blood collection tubes, catheters, and dosage dispensers. AGR's manufacturing process adheres to stringent FDA requirements. http://www.arthurgrussell.com/

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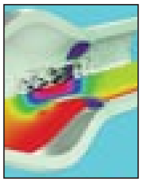

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Master Bond MasterSil 912Med is a single component silicone with a paste viscosity for bonding, sealing and coating medical devices. This non-corrosive, neutral cure compound complies with USP Class VI and ISO 10993-5 specifications. It resists many kinds of sterilization including gamma and other types of radiation, EtO and some types of liquid sterilants. http://www.masterbond.com/tds/mastersil-912med

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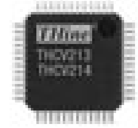
NEW PRODUCTS AND SERVICES

Integrated Circuits



California Eastern Laboratories (CEL), Santa Clara, CA, now offers Tokyo-based THine Electronics integrated circuits (ICs) through CEL's distribution partners. CEL will continue to provide technical support as well as evaluation tools to aid customers' design-ins of THine products. Products include serializer and deserializer ICs deploying LVDS and V-by-One® HS industry standards. The THine product line includes image signal processor ICs and repeater ICs, which reform a high-speed signal to improve its signal quality and enable gigabit serial signal transmission, such as USB3.1 Gen2, PCI Express Gen2, and SATA Gen2, over longer cables. Applications include wearable devices and medical equipment.

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Automated Surface Analysis

An automated solution for evaluating material surfaces is available from BTG Labs, Cincinnati, OH. The Surface Analyst XA is designed to reduce waste, rework, and recalls when poorly prepared substrate surfaces lead to bonding, coating, sealing, painting, or printing failure. The XA delivers real-time surface condition feedback to manufacturers to ensure that adhesion processes will be successful. The unit deposits a highly purified drop of water on a surface and then measures the contact angle. Automating increases the speed and efficiency by completing inspections on multiple surface points on a material surface at rates of up to 5,000 inspections per hour. As a result, it maps a surface across multiple points, ensuring the consistency and uniformity of surface quality.

For Free Info Visit http://info.hotims.com/72993-358

Extrusion Reciprocating Head

Guill Tool, West Warwick, RI, has released a new reciprocating head. The traditional tip-and-die assembly is replaced with a linear reciprocating assembly that changes the tube's profile within a given length. This process is repeated throughout a single extrusion run without interruptions. Cutting capability, in association with the extrusion speed, cuts the finished product to length. Only one extrusion run is needed to produce a finished product, as opposed to multiple extrusion runs with tooling changes along with a manual assembly operation to connect different tubing shapes. The reciprocating head eliminates an assembly operation.

For Free Info Visit http://info.hotims.com/72993-367

Cable and Harness Tester

CAMI Research Inc., Acton, MA, manufactures an automation-ready cable and harness tester for assembly, prototyping, production, and QC of standard or custom wire cables and harnesses. The CableEye tester includes a comprehensive software package that provides test functions, graphic wiring display, connectors database, reporting, data logging, automation scripting, and other features. In addition to being used to automate the test itself, the automation scripting lets users generate and display rich text work instructions with images. Work instructions can be coupled with operator text-to-speech conversion to form a heads-down workstation.

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Power Supplies

Traco Power North America, San Jose, CA, has expanded its TIB series of industrial power supplies. The series now includes the TIB-EX family of 80, 120, 240, and 480 W DIN rail power supplies that are designed for harsh environments. The new TIB-EX models include expanded full load thermal performance, enhanced shock and vibration specifications, and additional outputs of 12 and 48 VDC. They feature 12, 24, and 48 V outputs (–2 ~ +17 percent VADJ Range); high efficiency operation of 88–95 percent; and 150 percent peak power for 4 seconds. They are packaged in a ruggedized metal enclosure.

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Foot Switch Guide

A guide from Steute, Ridgefield, CT, provides answers to frequently answered questions about medical device foot switches. The 24-page downloadable MedFAQ guide addresses advantages of wireless foot switches, medical applications, wireless protocols and specifications, speed of response, and battery life. It also covers custom design capabilities, types of receivers and outputs, and regulatory compliance. A section on safety and security is also included.

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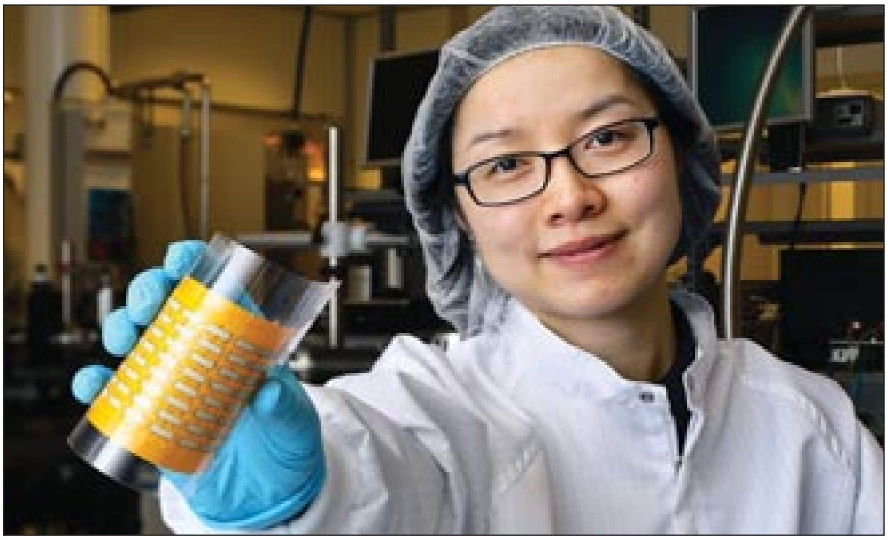
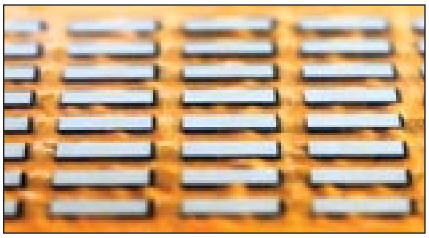
Ultrasensitive Heat Sensor for Wound Healing and Electronic Skin

Linköping University
Linköping, Sweden



Research fellow Dan Zhao with the ultra-sensitive printed sensor (Credit: Peter Holgersson AB)



Ultra-sensitive heat sensor. (Credit: Peter Holgersson AB)

Scientists at the Laboratory of Organic Electronics have developed an ultrasensitive heat sensor that is flexible, transparent, and printable. The results have potential for a wide range of applications including wound healing and electronic skin.

The ultrasensitive heat sensor is based on the fact that certain materials are thermoelectric. The electrons in a thermoelectric material move from the cold side to the warm side when a temperature difference arises between the two sides, and a voltage difference arises. In this present project, however, the researchers have developed a thermoelectric material that uses ions as charge carriers instead of electrons, and the effect is a hundred times larger.

A thermoelectric material that uses electrons can develop 100 µV/K (microvolt per Kelvin), which is to be compared with 10 mV/K from the new material. The signal is thus 100 times stronger, and a small temperature difference produces a strong signal.

The results from the research, carried out by scientists at the Laboratory of Organic Electronics at Linköping University, Chalmers University of Technology, Stuttgart Media University, and the University of Kentucky, have been published in *Nature Communications*.

Dan Zhao, research fellow at Linköping University and one of three principal authors of the article, discovered the new material, an electrolyte that consists of a gel of several ionic polymers. Some of the components are polymers of p-type, in which positively charged ions carry the current. Such polymers are well known from previous work. However, she has also found a highly conductive polymer gel of n-type, in which negatively charged ions carry the current. Very few such materials have been available until now.

First Printed Thermoelectric Module in the World

With the aid of previous results from work with electrolytes for printed electronics, the researchers have now developed the first printed thermoelectric module in the world to use ions as charge carriers. The module consists of linked n- and p-legs, where the number of leg connections determines how strong a signal is produced. The scientists have used screen printing to manufacture a highly sensitive heat sensor, based on the different and complementary polymers. The heat sensor has the ability that convert a tiny temperature difference to a strong signal: a module with 36 connected legs gives 0.333 V for a temperature difference of 1 K.

Researchers Simone Fabiano and Dan Zhao. (Credit: Peter Holgersson AB)

"The material is transparent, soft, and flexible and can be used in a highly sensitive product that can be printed and in this way used on large surfaces. Applications are found within wound healing, where a bandage that shows the progress of the healing process is used, and for electronic skin," says Zhao.

In addition to Zhao, the article in *Nature Communications* has two further principal authors, Simone Fabiano, head of research within organic nanoelectronics and Xavier Crispin, professor in organic electronics, all three of whom work at the Laboratory of Organic Electronics, Campus Norrköping.

The research has been financed by, among other sources, the Knut and Alice Wallenberg Foundation, the Tail of the Sun project, the Swedish Foundation for Strategic Research, the Swedish Research Council, and Vinnova.

This article was written by Monica Westman Svenselius, Linköping University. Contact: Dan Zhao, dan.zhao@liu.se.