MEDICAL DESIGN BRIEFS

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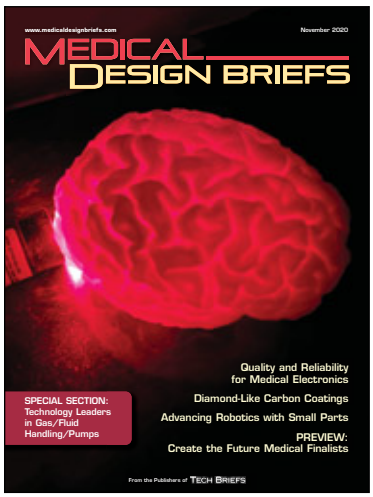

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NEMA 5-15 Standard Cord vs. the NEMA 5-15 Hospital-Grade

Though both cords endure testing, the hospital-grade plug is subjected to the UL 817 Abrupt Removal Test where a 10-lb weight is attached to an inserted plug and then dropped to check for electrical continuity. The standard NEMA 5-15 endures The Abrupt Pull Test where a 2 ½ pound weight is dropped 25 times from the inserted plug.

Only the NEMA 5-15 hospital-grade plugs and receptacles bear the "green dot" which signifies they meet standards UL 817 and CAN/CSA C22.2 no. 21 requirements for Hospital-Grade status.

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Quality and Reliability for Medical Electronics

Diamond-Like Carbon Coatings

Advancing Robotics with Small Parts

PREVIEW: Create the Future Medical Finalists

SPECIAL SECTION: Technology Leaders in Gas/Fluid Handling/Pumps

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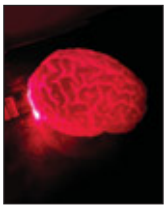


A new tool for medical professionals may help shed more light on tumors in the body and how the brain operates. Purdue University researchers have created a technology that uses optical imaging to better help surgeons map out tumors in the body and help them understand how certain diseases affect activity in the brain. The technology uses contrast in the absorption of light and fluorescent agents that are introduced into the body to find tumors and/or blood vessels within the tissue. The same technology can be used to study neuron activation in the brain, which can help doctors detect diseases such as Parkinson's. To learn more about how the technology improves outcomes for patients, read the article on page 37.

(Credit: Brian Bentz)

Report: Confident Medtech OEMs Proud of Industry Response to Pandemic

The coronavirus pandemic forced medtech companies to go beyond norms and collaborate to overcome critical challenges. According to the 2020 EY medtech report, Pulse of the Industry, many sectors of the industry experienced financial losses, but some — the diagnostics segment, for one — have surged. Moreover, this global crisis can help illuminate the way to a better future for the industry, by demonstrating the need to future-proof business models, strengthen supply chains and ecosystem relationships, and accelerate the progress of digital technology and data, the report says.

"While the financial performance was way down in the first half of 2020, the impact of the medtech industry during this global health crisis has never been greater, from mass producing ventilators, sterilizing equipment, and personal protective equipment to inventing and distributing the rapidly expanding range of diagnostic tests, the industry, collectively, met the challenge of the global pandemic," says Jim Welch, EY Global Medtech Leader. "Medtech's work has saved lives, allowed medical facilities to keep running, enabled patients to be treated in hospitals or at home, and overall made it possible for normal operations to be maintained, while simultaneously also helping health systems, governments, and the general public wage a global health battle on a scale not previously seen this century."

The report also highlights the pandemic's impact on the financial health of the industry. According to the report, due to the high growth of R&D investments and continued investor confidence, the medtech industry is likely to see a quick rebound even as some figures declined.

"COVID-19 had an acute impact on the medtech industry during the second quarter of 2020, delaying or postponing elective surgeries and leading to deferral of revenue," says Arda Ural, PhD, EY Americas Industry Markets Leader, Health Sciences and Wellness. "However, the underlying health of the medtech sector remains robust thanks to its operational performance, continued investor confidence, and resuming M&A activity. The shift toward digitalization, telehealth and remote-operated business models is accelerating as a silver lining to the tragic impact of COVID-19, but executives will have to adapt to operating in a highly uncertain environment in the foreseeable future."

The U.S. medtech industry is resilient. In the coming months, the industry may need to determine how to use this technology and data to streamline the supply chain and aid suppliers in achieving greater production. The industry may also need to accommodate the ongoing reality of travel restrictions between countries and even within the United States and may also need to bring some manufacturing capacity back to the United States or Europe to safeguard the supply base.

Sherrie Trigg
Editor and Director of Medical Content

To download a copy of EY's report, go to ***ey.com/pulse****.*

A Sneak Peek at the Medical 'Create the Future'

The 18th annual "Create the Future" Design Contest for engineers, students, and entrepreneurs worldwide, sponsored by COMSOL, Inc., and Mouser Electronics, drew more than 750 innovative product ideas from engineers and students in 60 countries. Analog Devices and Intel were supporting sponsors, and Zeus sponsored the medical category.

For the first time ever, readers are invited to join us November 10 for a special one-hour presentation as we honor our 2020 Grand Prize Winner, along with the winners in seven categories. Visit ***www.medicaldesignbriefs.com/CTFAwards*** for more information and to register to attend.

This preview introduces the finalists in the Medical Products category. The medical winner and honorable mentions will be featured in the December issue of *Medical Design Briefs*. Entries for all categories can be viewed at ***http://contest.techbriefs.com/ 2020/entries/all.***

Wound Healing Patch

Samarender Nagam Hanumantharao, Carolynn Que, Smitha Rao

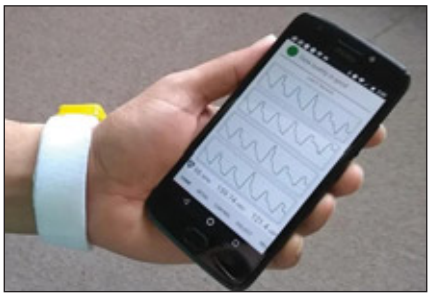
Michigan Tech, Houghton, MI

This novel wound healing patch is designed for use with adhesives or bandages at the wound site. The engineered patches resemble the natural tissue structure found in the body. The structures act as supports for the cells, guide cell growth and alignment, and help in accelerating wound healing, thus reducing scarring and preventing secondary infections. The one-time use patches are optimized for different wound types using polymer materials that are biodegradable, biocompatible, and FDA approved.

In addition to being constructed for specific wound types, they can be customized by size, and they can include drug release over time or antibacterial protection. Once administered, the patches promote cell growth, provide structural support to new tissues, and strengthen the wound bed, thus providing protection from repeated trauma. The patches could significantly reduce healing time in chronic wounds such as diabetic foot ulcers from a year to a few months and improve a patient's overall quality of life.

For more information, visit ***https://contest.techbriefs.com/2020/entries/medical/10784.***

Wearable Continuous Blood Pressure Monitor



Xina Quan

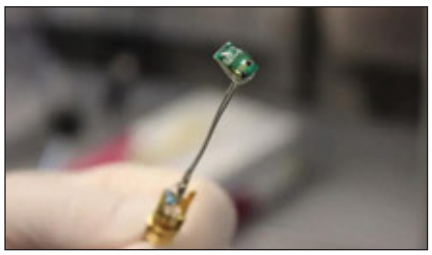
PyrAmes, Cupertino, CA

A comfortable and easy-to-use wearable device has been developed for continuous blood pressure (BP) monitoring and management over long periods of time. The device provides timely data to treat patients at risk of rapid changes in blood pressure that can lead to stroke or multiple organ failure, while removing the pain and risk of the current standards of care at a lower cost and increased patient compliance.

The device uses paper-thin capacitive sensors lightly contacting the skin. The sensors pick up a pulse waveform signal that correlates to arterial blood pressure changes. Artificial intelligence models extract BP values that meet the FDA's accuracy guidelines for noninvasive blood pressure monitoring.

For more information, visit ***https://contest.techbriefs.com/2020/entries/medical/10638.***

Implantable Wireless Pacing System



Mehdi Razavi, MD; Mathews John, MBE; Allison Post, PhD; Aydin Babakhani, PhD

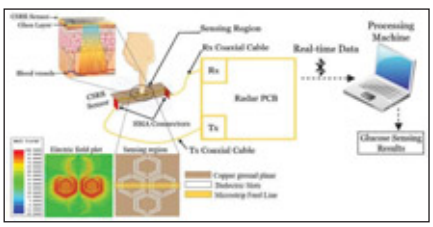
Texas Heart Institute, Houston, TX

Eliminating the need for wires and batteries in ICDs and pacemakers is highly significant. Traditional ICDs and pacemakers send electrical pulses to the heart through wires called *leads*. Leads, however, cannot always be placed where needed, and they are prone to infection and fracture.

This miniaturized implantable wireless, battery-less pacing system (nodes) consists of tiny silicon-based integrated microchips. Each node weighs only about 0.09 g because it requires no internal batteries. Because it can deliver pacing not only to any location but to an unlimited number of locations on the heart, this technology has the potential to deliver imperceptible (painless) defibrillation through sophisticated, coordinated, and targeted multisite pacing bursts.

For more information, visit ***https://contest.techbriefs.com/2020/entries/medical/10608.***

Wearable Blood Glucose Monitor



Ala Eldin Omer, George Shaker, Safieddin Safavi-Naeini

University of Waterloo, Waterloo, Ontario, Canada

A compact low-cost wearable sensing system utilizes microwave sensors and arti-

Sergey Nivens/Shutterstock.com

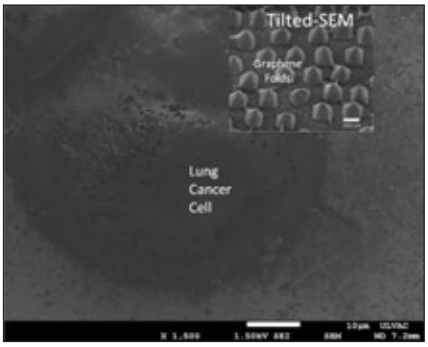
Finalists

ficial intelligence to enable diabetics to noninvasively monitor their blood glucose levels without sampling any fluid outside of the body. The device sends electromagnetic signals of small wavelengths through the finger skin. Signatures of blood glucose levels are reflected in the sensor-scattering responses that are further analyzed to identify the blood glucose levels accurately.

The sensor design incorporates four cells of complementary split ring resonators (CSRRs), arranged in a honey-cell configuration and fabricated on a thin sheet of a dielectric substrate. The CSRR elements are coupled via a planar microstrip-line to a radar board operating in the ISM band 2.4–2.5 GHz. The enhanced design of the CSRR elements intensifies the electric field over the sensing area in the near-field region, thus allowing the sensor to detect small variations in the electromagnetic properties that characterize the varying glucose levels. Therefore, placing the fingertip over the sensing region would consequently perturb the distribution of the highly concentrated electric field.

For more information, visit ***https://contest.techbriefs.com/2020/entries/medical/10764***.

Blood Test for Early Lung Cancer Screening



Owen Liang, Sumita T. Jonak, Brian D'Souza, Abhinav Chandra

UCLA Anderson, Los Angeles, CA

A revolutionary technology enables earlier lung cancer screening to diagnose the disease when it is more treatable. The eXoutcancer system combines a nanochip and a proprietary spectroscopic database derived from a machine learning (ML) algorithm. The biomarker that the device is detecting is called an *exosome.* Cancer cells release a larger quantity of exosomes, which are found throughout various cancer stages. Because the exosome is a routine cellular process, it's found throughout each cancer stage.

A key advantage of the system is the combination of a nanochip and a technique called surface-enhanced Raman spectroscopy (SERS). When a laser is scanned across the chip's surface, any exosome near the nanofeatures gets its signal enhanced, giving the platform the ability to measure at the single exosome level. This translates to extremely high sensitivity and specificity, even at low concentrations. The complex spectroscopic data is parsed out via an ML algorithm to develop this diagnostic fingerprint.

For more information, visit ***https://contest.techbriefs.com/2020/entries/medical/10781***.

Much of the medical market's miniaturization trend is made possible by custom-engineered micro extrusions and enhanced medical-grade silicone elastomers. (Credit: Trelleborg)

Small Innovations Could Help Robotic Surgery Become Big Business

Material and equipment innovations, coupled with the stepped-up collaborative efforts of device manufacturers and their supply partners, continue to advance the development of micro parts and devices used in minimally invasive surgical (MIS) procedures for orthopedic, neurostimulation, and cardio, to name a few disciplines. This article takes a closer look at this trend and how smaller parts and devices will likely play bigger roles in the advancement of robotic surgery and telesurgery, followed by examples of robotic platforms in use at healthcare facilities in the United States and abroad.

Equipment and Material Innovations Drive Development

Much of the medical market's miniaturization trend is made possible by custom-engineered micro extrusions and enhanced medical-grade silicone elastomers. Micro extrusion processing performed below the submillimeter (0.004 in.) range employs highly modified equipment featuring innovations in extrusion head, tool, and screw designs. These innovations have contributed greatly to such advancements as the production of micro extruded, thin-walled tubing down to 0.002 in., and outside and inside diameters down

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to 0.010 and 0.004 in. — potentially contributing to a myriad of MIS procedures.

Such micro extrusion capabilities recently led to the development of a narrow two-layer extrusion for orthopedic applications, with the core serving as an eluting rod while the outer concentric layer controls elution in MIS procedures. This breakthrough was the result of a multiyear collaboration that started with the elution concept; then the testing of concentrations of the additive to determine how it behaves over time; and finally the development of an outer jacket to lengthen and flatten the elution curve. It took many iterations and additional extruder heads to accomplish this complex tubing to ensure precise elution.

Another area of medicine driving a reduction in device size limits is neurostimulation, which uses an implantable neurostimulator for brain and nerve stimulation to treat disorders such as epilepsy, Parkinson's, and Tourette syndrome, and spinal-cord stimulation used as chronic-pain therapy. The diameter of extruded tubing used to deliver pain-disrupting electrical signals to the brain or spine commonly meets tolerances of ±0.001 in. Such tolerances are being pushed even further thanks to advancements in quality process control and monitoring systems and the prowess of today's engineering teams.

And when it comes to matters of the heart, cardiac catheterization, a procedure to examine how well a heart is working, requires a thin, hollow tube (catheter) for insertion into a large blood vessel that leads to the heart. The narrower the tube, the less invasive the procedure.

These developments would not be possible without today's platinum-cured silicones, which eliminate the secondary operations associated with their peroxide-cured counterparts, including post-curing to remove by-products, such as volatile organic compounds, while offering faster cure times at lower temperatures.

Not so long ago, cure profiles were tested at 350 °F. Today, materials are cured at 250 °F. These cooler cure temperatures enable better flow, less process variation, and faster cure times. Also, materials cured at lower temperatures enable risk-free bonding to a range of substrates. In the case of cable jacketing for a heart pump, internal components, such as insulators, will not be damaged. And with so many readily available formulations, today's platinum-cured silicones can be formulated to bond with metals used in implants, such as titanium, stainless steel, and nitinol and such plastics as polycarbonate, polyester, and polyetheretherketone, commonly known as PEEK.

Another area driving a reduction in size and tolerances is geometric transition extrusions for wound drains, hemodialysis tubing, and catheters. To accomplish these extrusions, a process by which tool components can be moved to change tubing geometry enables a single lumen to transition to multiple lumens, or split from a multi-lumen tube into two or three single-lumen tubes. Applications include wound drains, off-ration bumps, and discrete ID and OD changes in tubing for catheters.[1]

From Conventional to Robotic to Telesurgery—Stay Tuned

As micro extruded parts and devices continue to shrink in size, and MIS procedures become more common, the surgical skills required for such operations continue to ramp up. While smaller implantable devices are hugely beneficial because they require smaller, less invasive holes, the smaller devices also pose increasingly difficult challenges for even the most skilled human surgeon's hands. So much so that robotic surgeries for a range of surgical implants could one day become the norm.

Recognizing the potential role of robotic surgery, the leaders in this space are stepping up device design efforts with robotic platforms in mind. These companies recognize that while they might be able to invent and develop increasingly sophisticated devices, such innovations require skilled surgeons to successfully implant them. Therefore, robotic-surgery platforms could level the playing field.

There is also an increasing use of robotic platforms at healthcare facilities worldwide. For example, the Golden Jubilee National Hospital in Clydebank, near Glasgow, Scotland, recently announced its use of a Mako robot by Stryker Corp., Kalamazoo, MI, for knee replacement surgery to ensure greater implant accuracy.[2]

At Excelsior Springs Hospital in Excelsior Springs, MO, where a robotic-assisted surgery program relies on the da Vinci Xi Surgical System by Intuitive Surgical Inc., Sunnyvale, CA, Dr. Douglas Desporty, surgeon, sings its praises. "Although I was initially skeptical," he says, "I became fully vested after seeing impressive patient satisfaction results and less need for post-operative narcotics. Not only are general sur-

Micro extrusion processing performed below the submillimeter (0.004 in.) range employs highly modified equipment featuring innovations in extrusion head, tool, and screw designs. (Credit: Trelleborg)

geons embracing the robotic results, other specialists, including urologists and gynecologists, are utilizing the system with similar outcomes."[3]

And at Corindus Vascular Robotics, Inc. in Waltham, MA, a joint project with the Mayo Clinic in Rochester, MN, serves to pretest "telesenting" procedures in hopes that these tests will lead to viable telesurgical procedures. While for now a Mayo Clinic doctor will be in the next room if needed, it is possible that remote procedures with doctors located miles away from the action could become a reality for rural patients without ready access to specialized healthcare.[4]

As innovations in micro extruded parts, implantable devices, and robotic platforms expand the benefits of MIS, interest in robotic surgery soars. According to IDTechEx's recent report, "Innovations in Robotic Surgery 2020–2030," "Investments in companies operating in this space have skyrocketed since 2016, recording an increase of over 300 percent in three years, and total investment to date has reached $1.36 billion."[5]

With such a growth curve, it is safe to say that robotic surgeries are now viable options, and it may not be too long before the same is said of telesurgeries. As this important healthcare chapter unfolds, makers of micro parts and devices will be central to the story.

Stay tuned.

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This article was written by Dan Sanchez, Product Manager, Trelleborg Healthcare & Medical. For more information, visit ***http://info.hotims.com/76509-340.***

Quality and Reliability in the Assembly and Manufacturing of Medical Electronics PCBs

With COVID-19 continuing to rage across the United States and the world, hospitals and medical centers are relying on their medical electronics equipment, including ventilators, to help improve COVID-19 patients' health. EMS providers, contract manufacturers (CMs), and printed circuit board (PCB) fabricators are the strongest link in the supply chain critical for building medical electronics equipment, including ventilators. These PCB companies help design, assemble, and manufacture the PCBs that are at the heart of these life-saving medical instruments.

At this time of urgency, medical electronics OEMs must keep in mind the

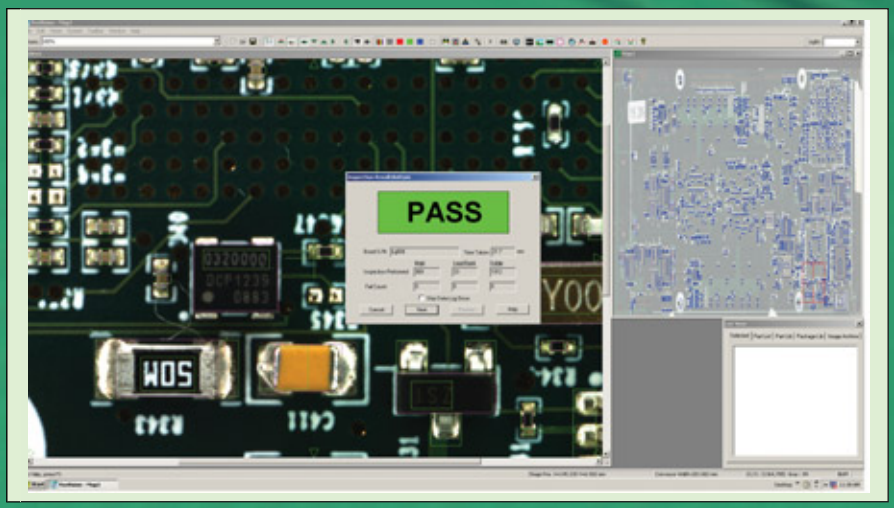

Fig. 1 – An AOI system verifying every component on a PCB and then "passing" the board.

basic, yet critical requirements demanded by all medical electronics products: quality, repeatability, and reliability. This trio of requirements must be completely and conscientiously exercised at layout, fabrication, and assembly.

The ISO 13485 standard and U.S. Federal Food & Drug Administration (FDA) regulations fully support those three requirements. As defined, an EMS provider or CM that has ISO 13485 certification holds the "proof of Quality Management System compliance to the standard involved in the Medical Device industry." Similarly, the tightly controlled FDA approval process requires precise documentation, audits, design capability evaluation, and verification, including clinical trials. For example, this means that when information for a ventilator PCB design is not properly documented, there are flaws in clinical studies, or the design is incorrect or incomplete, then adverse effects arise during PCB assembly, leading to challenges in obtaining FDA approval of the finished device.

No Failures

With that backdrop, medical ventilators and other medical equipment cannot afford failures whether it's in the lab or in the field. The burden is on the EMS provider to ensure that PCBs are designed to be extremely reliable and that they deliver quality time after time.

This means that the EMS or CM must have well-disciplined quality measures throughout the assembly and manufacturing process, such as automated optical inspection (AOI). Figure 1 shows an AOI system verifying every component on a PCB and then "passing" the board. Other quality control (QC) steps include first article inspection (FAI), x-ray, and multiple sets of QC checks along the way.

Therefore, maintaining high-quality manufacturing translates directly into high reliability. The EMS provider or CM must always be checking, evaluating, tweaking, and streamlining that process to make it as strong as possible. With such a stringent manufacturing process, quality and reliability come at a price: an EMS provider must diligently pursue each and every step to ensure that it is attaining quality and the resulting reliability. Here, a highly experienced reliability manager on the assembly floor is a valuable asset to make sure there are no shortcuts, cutting corners, or short-changing each quality step.

These QC steps are all embedded in the process. If manufacturing is run based on a set of disciplined and verified processes, the end result is a ventilator or other medical electronics product that embodies the highest level of quality.

The Role of Experience

Experience is at the crux of manufacturing medical electronics such as ventilators. But along with experience is the need for a continually growing knowledge about electronics engineering. For example, achieving Certified Interconnect Designer (CID) or CID+ certification plays a major part in successfully addressing the complexity of PCB layout, routing, high-speed terminations, impedance control issues, and other related design points.

It's important to understand device packaging dynamics. Advanced medical electronics products like today's conven-

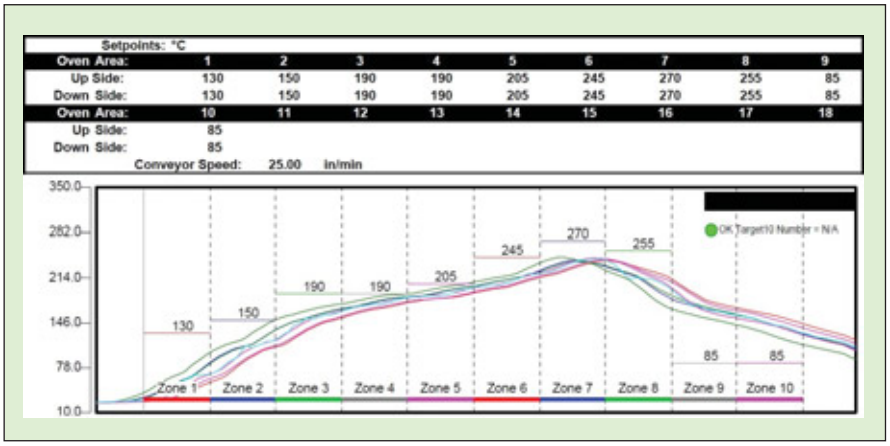

Fig. 2 – A thermal profile records temperatures at different spots on the PCB surface to create custom thermal profile. It includes soak periods in zones 3 to 5; peak temperatures in zones 6,7, and 8; and cool off at zones 9 and 10.

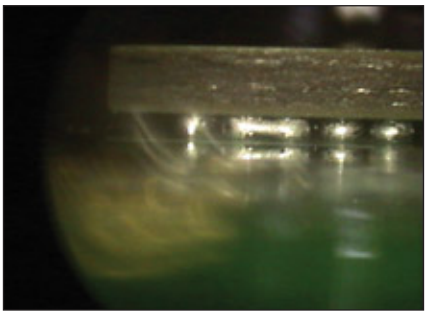

Fig. 3 – If the thermal profile is too hot, bridging results.

An FAI system helps to create the first article board by scanning the image of the whole board, called *a golden board*. Images of other boards are compared with the golden board to ensure that all components are properly placed on the board with correct orientation and polarities.

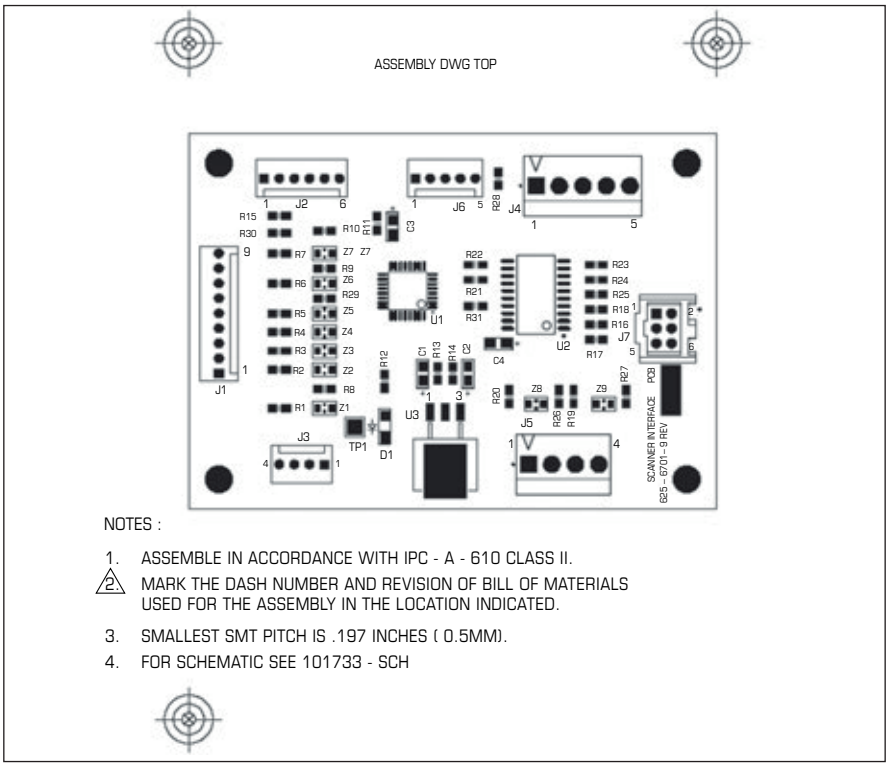

Fig. 4 – Example of a properly created assembly drawing. It can eliminate confusion, answer questions, and reduce board defects.

tional and portable ventilators rely on such state-of-the-art device packaging as package-on-package (PoP), flip chip, land grid arrays (LGAs), and tiny passive device packages such as 0201 and 01005 packages.

There are also a number of so-called quality gates that a PCB assembly house has to pass through to maintain ultra-reliability. These gates include complying with the ISO 13485 quality standard. The ISO 13485 medical electronics standard is the equivalent of Mil/Aero J standard for manufacturing. Both demand tight tolerance controls. Medical electronics PCBs have similar, and in some cases, stricter requirements than those used in mil/aero products.

At PCB Assembly

The thermal profile and stencil design and associated solder paste are two prime examples of processes that are critical to maintaining quality and reliability during PCB assembly. In simple terms, a thermal profile is a recipe for preparing a surface-mount (SM) component-populated PCB for the infrared (IR) reflow oven. A particular profile must be correctly designed and implemented for a given medical electronics PCB.

The thermal profile records temperatures under different components on the PCB surface to create a custom thermal profile, which includes three different area segments: soak, peak temperature, and cool-off period. As shown in Figure 2, zones 3, 4 and 5 are soak periods; zones 6, 7, and 8 are peak temperatures; and zones 9 and 10 are cool-off periods.

It is important to note that if the thermal profile is not correct, and the board is not profiled properly, the result will be cold soldered balls on the ball-grid array (BGA), chip-scale package (CSP), and/or quad flat no-lead (QFN) devices. If the thermal profile is too hot, bridging results (see Figure 3). Therefore, if a thermal profile for a given PCB isn't correctly designed, it will either be severely damaged during reflow, or it will incur latent flaws that could cause catastrophic failures at a hospital or healthcare center.

Properly defining a stencil design and associated solder paste dispensing are further examples of the steps critical for maintaining quality and reliability. Using the right paste, correct stencil design, and correct profile eliminates about 75 percent of potential rework and touch-up issues.

Eliminating PCB Defects

Multiple factors must be taken into account to eliminate PCB defects. A comprehensive assembly drawing detailing all necessary assembly processes is a critical first step. For example, process documentation can specify that all components, including BGAs, are to be machine placed, and this documentation can define any rework or engineering change order (ECO) callouts and the use of any special processes. Figure 4 shows an example of a properly created assembly drawing, which can eliminate confusion, answer questions, and reduce board defects.

Assembly processes must also be reliable for repeatability. In this instance, the first article inspection (FAI) is important at the assembly level so that technicians can check for polarities, missing components, and other key issues.

As shown in Figure 5, the system helps to create the first article board by scanning the image of the whole board, called a *golden board*, and then comparing the images of all the other boards with this golden board to ensure that all the components are placed properly on the board with correct orientation and polarities. It is used as a process verification and inspection tool to significantly reduce the

human interface and make the inspection and QC process more reliable, repeatable, and faster by at least 30–50 percent.

During first article pre-reflow inspection — when boards are about to go for reflow — the process can be stopped. It can be changed, however, and a single board or set of two boards as second articles can be run to correct the process. If defects are not caught during the process, they turn up at the end of the process when it can be too late to address them. A shipment could be missed, or rework may be too involved, thus adding time, resources, and extra cost. Planning must also be conducted to determine and document:

- Processes that need to be defined.
- Machines needed.
- ECOs.
- Use of special equipment (e.g., an arbor press for press fit connectors).
- Use of an AOI machine or flying probe tester.

Documentation is also important for technicians in the field who need to read and decipher ECO instructions, which deviate from original build. Likewise, rework instructions, if any, need to clearly state solid quantitative data for measurement and verification purposes, including illustrations, if possible.

At times, instructions can be issued in an assembly drawing to avoid board defects, which could be process-related issues. Also, depending on how progressive an EMS provider is, post reflow x-ray inspection can be specified as part of the process for all BGAs, CSPs, and QFN devices, rather than performing these steps as part of the QC stage of the assembly process. Early intervention enables corrective actions to be taken to prevent board defects such as improper board reflow, poor orientation, wrong thermal profile, and improper flux activation, among other issues.

Lastly, it is essential that an EMS provider or CM always maintains a constant review of its assembly processes and procedures. This ensures that assembly is sustained at the highest levels possible to efficiently produce quality PCBs for ventilators or other medical electronics. Repeatable processes also minimize defects and issues at the QC stage and in the marketplace.

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Silicon doping can be used when a lower coefficient of friction is required for mated or sliding parts. (Credit: Oerlikon Balzers)

Diamond-Like Carbon Coatings for High-Wear Medical Applications

Applying DLC coatings to medical components increases the surface hardness and durability, meaning essential parts are less likely to fail. (Credit: Oerlikon Balzers).

In the universe of wear resistant thin films, diamond-like carbon (DLC) coatings have emerged as the ideal solution for demanding physical applications, such as medical devices and instruments, where components are under high loads or subject to extreme friction, wear, and contact with other parts.

In these types of environments, only the high hardness of a DLC coating — along with a corresponding low coefficient of friction — can prevent parts from pitting, galling, seizing, and ultimately failing in the field. To examine the benefits of DLC coatings for medical applications, this article discusses the advantages of this approach.

Because of the broad range of customizable attributes possible within the category, DLC coatings can play an important role in medical component engineering from the earliest steps of the design process.

A coating is very much a sophisticated design element with highly engineered properties. The properties can be tailored specifically to meet the medical performance requirements of different operating conditions. As such, coatings should not be a design afterthought but rather a critical element of how a component is initially engineered to fully utilize possibilities for maximum system performance.

Hydrogenated Amorphous Carbon Coatings

DLC Coatings are hydrogenated amorphous carbon (a-C:H) coatings, but this categorization can be a misconception. Coatings within the DLC family can be highly engineered based on hydrogen content (hydrogenated or hydrogen-

DLC coatings can play an important role in medical component engineering because they offer a broad range of customizable attributes. (Credit: Oerlikon Balzers)

free), the selection of additional metallic and non-metallic doping elements, the presence of sublayers, and choice of deposition and bonding methods.

Together, these factors can be precisely controlled to create a broad range of thinly applied (typically 1–5 m) DLC coatings with a hardness of 8–80 GPa or higher (diamond is the hardest known material at 70–150 GPa). In addition, the desired coefficient of friction, surface finish, and even application temperature can also be manipulated.

The most widely known DLC coating type, hydrogenated amorphous carbon, is most often applied through a process called *plasma-assisted chemical vapor deposition* (PACVD). This deposition method causes a chemical reaction through plasma excitation and ionization, creating a coating hardness of approximately 15–30 GPa, which is on the lower end of the DLC family. A hydrogenated amorphous carbon coating can be manipulated further through doping, which is a process of adding chemical elements to alter the performance properties. Silicon, oxygen, or metals can all be used as doping elements to achieve different results.

When a lower coefficient of friction is required for mated or sliding parts, or to assist in releasing items from cavities or molds, silicon doping can be a suitable approach. This silicon doping approach creates an a-C:H:Si coating with a coating hardness of 15–20 GPa. With silicon and oxygen-doping, high electrical resistivity and chemical inertness can also be achieved. All of Oerlikon Balzers' DLC coatings, for example, are biocompatible, which makes them an ideal solution for medical instruments.

Hydrogen-Free-Based Coatings

An alternative to hydrogenated DLC coatings is a family of hydrogen-free based coatings that provide even higher hardness along with a very low coefficient of friction. Most hydrogen-free coatings are applied using a method of physical vapor deposition (PVD) by arc evaporation, which produces tetrahedral amorphous carbon, or ta-C. With a high level of tetrahedral bonds (mostly 50–60 percent), substantially higher abrasive wear resistance is achieved compared to a-C:H alternatives.

With a typical hardness up to 60 GPa, ta-C coatings are an excellent choice for components that are exposed to extreme operating forces over the long

ASK THE EXPERT

Ralph Bright, Vice President, Interpower Corporation, Oskaloosa, IA

Ralph Bright is Vice President of marketing at Interpower Corporation. Interpower is the leading supplier of Power System Components in the Medical Device Industry. Ralph holds a BA from William Penn University and a Master's in Business Administration, and he has been in the electronic component industry for over 25 years. He helps customers design, build, and maintain electrical products for worldwide markets, including understanding power system components and the correct means of connecting them.

MDB: What are the requirements for hospital-grade cords for North America?

Ralph Bright: The following briefly describes requirements found within these North American standards — UL 817, CSA C22.2 no. 21, UL 498, and UL 60601-1. For hospital-grade molded-on attachment plugs and connectors, the UL 817 and CSA C22.2 no. 21 requirements are applicable to the following configurations: 5-15, 5-20, 6-15, and 6-20. The blades on the plug shall be of solid brass material, and the grounding pin cannot be easily bent or removed. Both the plug and connector need to be marked "Hospital Grade" with a green dot. Similar requirements are also found in UL 498.

MDB: Are there hospital-grade requirements for power entry modules?

Ralph Bright: Hospital-grade equipment must meet special requirements. Patient-connected medical equipment can be subjected to low-leakage current requirements. The use of a low-leakage filter in the 5 A range at 250 VAC is desirable. In addition, fusing of both line and neutral connectors may be required (i.e., double fusing). Low leakage is achieved in modules with medical-grade filters by removing the y-capacitors (Cy) from between the two signal paths (L and N) and ground, as well as resizing inductor values. Removal of these capacitors drastically reduces leakage current; however, it also has a negative impact on the overall filter performance (insertion loss).

To learn more about Interpower Corporation, read the full-length version of this interview at ***www.medicaldesignbriefs.com/askexpert/1120****.*

Diamond-Like Carbon Coatings

term, including shafts and seals that must work in tribological environments where friction can cause them to overheat and fail.

The challenge historically with hydrogen-free coatings, and with ta-C deposition in particular, is that the application process produces small droplets that contribute to a rougher surface finish. As a result, coating manufacturers must complete secondary polishing processes to smoothen the surface. Because of its hardness, it is a time-consuming and expensive process the requires specialized equipment.

To address this concern, some hydrogen-free DLCs are produced using a filtered cathodic arc deposition method in which an electromagnetic filter removes most droplets. Although this creates a smoother surface, a secondary polishing step is still often required, and process times are longer for the same coating thickness.

Coatings as a Design Element

When an even smoother surface is needed, hydrogen-free DLC coatings can be applied utilizing a proprietary Scalable Pulsed Power Plasma (S3p) technology developed by Oerlikon Balzers. S3p is a unique type of high-power impulse magnetron sputtering (HiPIMS) technology, which can be seen as combining the advantages of the arc evaporation and sputtering methods. The very dense plasma yields hard coatings with high adhesion (at a level comparable to arc evaporation). At the same time, it results in smooth coatings due to the nature of the sputtering process, in which atoms are ejected from a target or source material.

The coating is applied at relatively low temperature, well below 200° C as compared with up to 350° C for other DLC coatings, which enables its application to a much wider panel of materials, effectively bonding to aluminum and steel substrates. Hydrogen-free DLC coatings applied using the S3p process BALIQ CARBOS include medical instruments and other small, precision tools.

At the top end of the scale are diamond coatings applied by a chemical vapor deposition (CVD) process in both micro and nanocrystalline options that are rated at 80–100 GPa. Such coatings are mainly used for highly specialized tools for cutting demanding materials such as carbon-reinforced fiber materials and do not offer the benefit of low friction anymore.

Given the number of variables involved with DLC coatings, it is important that medical OEMs better understand the range of options so they can select the ideal solution for the application while also taking into consideration the economics.

Coatings are effectively an architecture of layers engineered to achieve specific properties. A coating is built layer by layer focused on bonding, hardness, and the surface. Modifying the properties of each creates an extremely wide range of medical surface solutions within the DLC coating family.

By applying DLC coatings to medical components, not only is the surface hardness and durability increased, but essential parts are far less likely to fail, if at all. As a result, maintenance and unexpected downtime is drastically reduced, even in the most demanding medical environments with high friction, wear, and contact pressure.

This article was written by Dr. Florian Rovere, a coatings expert for Oerlikon Balzers, Scchaumburg, IL. For more information, visit ***http://info.hotims.com/76509-342****.*

Single-Use Applications Maximize Biomanufacturing Agility

Biopharmaceutical manufacturing is changing. With the rise of biologics and personalized medicine, the industry is appreciating the single-use manufacturing style. Instead of large-scale production processes, manufacturers are finding it pays to be agile — which is why many are increasingly adopting single-use technologies to turn over new products and batches quickly and efficiently. Single-use technologies utilize disposable bioprocessing equipment in place of traditional stainless steel. By eliminating the time-consuming clean-in-place (CIP) and steam-in-place (SIP) processes between batches, single-use technologies cut down on the costs of labor, materials, and utilities — all while shortening time to market.

These new technologies play a crucial role in the changing biomanufacturing landscape. Fluid control and automation systems and solutions can help processors reap the benefits of single-use products, including reducing product development time, enhancing operator safety, and increasing productivity.

The G3 Electronic Fieldbus Platform complements the ASCO Series 501 pneumatic valve manifold for easy commissioning and highly distributable I/O. The graphic display for configuration and diagnostics is compatible with various industry-leading communication protocols like Ethernet IP, ProfiNet, DeviceNet, and others. (Credit: Emerson)

The Key to Minimizing Downtime

One of the biggest challenges biomanufacturers face is downtime — something single-use technologies overcome. Generally made from platinum-cured silicone or biopharma-graded plastic, these products are disposed of after each use. As a result, single-use products eliminate the need to clean between batches and have a short changeover period compared to stainless-steel equipment. A line changeover for a stainless-steel bioreactor, for example, can take up to 10 hours for the same product — and up to three weeks for a full product changeover. Compare that to a single-use bioreactor, which only requires a few hours between batches. Because of their quick changeovers, single-use products lead to significantly higher throughput and enable smaller, more efficient batches. They can also decrease a facility's manufacturing footprint, reducing the costs for ventilation, heating, and other utilities.

ASCO 580 CHARM node integrates seamlessly into the DeltaV DCS S-series via Electronic Marshalling — a tightly integrated remote I/O solution for pneumatic valve manifolds. (Credit: Emerson)

It's important to work with fluidic system suppliers that offer fluid automation products — released or in development — that benefit biomanufacturers making this leap from large-scale to single-use production processes. These suppliers combine their product offering — which can include valve automation solutions, air preparation equipment, instrumentation, and integrated solutions — with industry expertise to provide reliable service.

Single-Use Pneumatic Pinch Valve Reduces Install Time and Costs

From valve automation solutions to advanced control systems, a variety of solutions can help get a single-use biomanufacturing operation up and running. Single-use pneumatic pinch valves, for example, achieve process control automation in areas like bioreactor and fermentation tanks, chromatography, tangential flow filter (TFF) skids, and other drug-discovery lab applications. Look for valves with innovative designs, in which the pinch mechanism holds the soft tubing in place, minimizing any disturbances to process media and preventing tube damage over repeated use.

Valve suppliers should always keep user safety at the forefront of product designs. Pinch valves, for example, should include a protection guard that allows operators to safely work around the pinching mechanism, as well as a manual override function that lets operators insert or remove tubing without actuating the valve. In addition to keeping operators safer, this enhanced valve design accelerates setup, reduces costs, and makes unscheduled maintenance easy — all of which are critical to maximizing uptime in single-use applications.

In addition, the right pinch valve makes no contact with process media, features a high life cycle, and provides a reliable pinching force without the need for an electrical connection. It should also resist corrosion due to tube breakage or washdown.

A One-Stop Shop for Process Control Automation. Bear in mind, as the single-use market continues to expand globally, it pays to use a single, global supplier that can deliver a comprehensive fluid control solution. To that end, many suppliers offer a wide range of systems and solutions that enhance product quality, improve reliability, and reduce operating costs in the biomanufacturing sector.

In addition to pinch valves, which overcome many of the issues related to downtime and operator safety in single-use applications, many suppliers offer directional valves, communication protocols, air preparation units, and other technologies — all of which work together seamlessly so device OEMs can focus on what really matters: optimizing their biomanufacturing operation. From design and implementation, to start-up and ongoing technical support, the supplier can help a single-use operation stay competitive in a global economy, enabling the OEM to:

- **Control aggressive fluids with durable valves.** Angle body valves handle aggressive fluids, such as steam, hot water, solvents, and light slurries, in CIP and SIP applications. Air- or water-pressure-operated with a straight-through design, these valves come with advanced accessories, including a signaling box, compact positioner for proportional control, and stroke limiter for even greater precision.
- **Speed time to market with high-performing valve manifolds.** Valve manifolds with modular, flexible designs simplify installation, commissioning, and system integration in single-use applications — reducing engineering costs and speeding time to market. These plug-and-play systems include high flow rates, input/output (I/O) capabilities, compatibility with popular industry protocols, and a pressure shutoff function, which allows individual valves to be replaced without halting the production process — further reducing line downtime and maintenance in single-use applications.
- **Improve valve efficiency with next-generation electronics.** Electronic fieldbus platforms provide pneumatic valve manifolds with fieldbus and Ethernet connectivity, as well as a graphics display for configuration, commissioning, and diagnostics. They allow programmable logic controllers in single-use systems to more efficiently turn valves on and off. They also channel I/O data from sensors, lights, relays, valves, and other I/O devices via various industrial networks.
- **Minimize downtime with quality air-preparation equipment.** Air-preparation devices treat the air quality and pressure in a plant's pneumatic system. Modular filter regulator lubricator (FRL) assemblies with body-to-body clamps facilitate assembly during installation and service, while optional end plates allow the manifold assembly to be quickly removed by loosening screws — keeping downtime to a minimum in single-use systems.
- **Optimize plant performance with advanced control systems.** Distributed control systems (DCS) can improve manufacturing agility in single-use applications by helping meet demands in real time. These easy-to-use automation systems often include a suite of services geared toward simplifying operational complexity and reducing project risk. They also adapt to meet specific biomanufacturing needs — scaling easily without adding complexity.

For single-use batch production, the ASCO Series 273 pneumatic pinch valve features an innovative design that enables better tube retention and prevents breakage or damage to the soft tubing over repeated use — virtually eliminating any disturbance from valve motion to process media unlike other products on the market. (Credit: Emerson)

A Robust, Customized Control Cabinet

In cleanrooms or environments subject to washdown, OEMs need a quick, easy, and space-saving way to protect sensitive electrical and pneumatic components. Already assembled, tested, and ready to install, integrated enclosures ensure corrosion and damage resistance in sensitive installations. These turnkey packages also withstand regular exposure to aggressive cleaning fluids. In addition to biomanufacturing applications, these enclosures are ideal for the life sciences, food and beverage, petrochemical, and packaging industries.

This article was written by Mukta Sharma, Product Marketing Manager, Fluid Control and Pneumatics at Emerson Automation Solutions, St. Louis, MO. For more information, visit ***http://info.hotims.com/76509-343****.*

ASCO Series 290 angle body valves handle various types of fluids in CIP and SIP applications. (Credit: Emerson)

Taking Benchtop Fluid Dispensing to a New Level of Process Control

Pneumatic benchtop fluid dispensers encompass a range of models that can accommodate specific fluid application processes with a wide scope of functionality. The latest benchtop dispensers provide a high degree of process control, capable of dispensing adhesives, solder pastes, and all other assembly fluids with high consistency. Handling fluid dispensing of dots, beads, and fills under a broad range of conditions, these units are equipped with multiple capabilities to refine the dispensing process. Features such as 0–100 psi air pressure regulation, timed-shots, vacuum control to keep thin fluids from dripping, digital time/pressure displays, and electric foot pedals help operators maintain process control.

Dispensing UV-cure adhesive onto a kyphoplasty catheter. (Credit: Nordson EFD)

Fluid Dispensing for Assembly of Life-Critical Components

For more critical dispensing requirements where exceptional process control is needed, like for dispensing applications in the assembly of medical devices and critical electronics components, some benchtop fluid dispensers are designed to deliver a much higher level of precision dispensing. These systems' features can include a) time adjustment as fine as 0.0001 seconds and b) full electronic air pressure regulation for full operator lock-out of dispensing parameters. In these demanding applications, small amounts of adhesives, silicone, and other fluids must be dispensed reliably and accurately in dosage, placement, and repeatability. The precise positioning and quantity of these fluids deposited is crucial to the products' assembly, function, quality, appearance, and viability.

Despite the proliferation of robotics and machine/process interconnectivity via Ethernet and the cloud in virtually all aspects of manufacturing, fluid dispensing for the assembly of medical devices largely remains a semi-automated, pneumatic benchtop process. In most cases, the process requires a technician who holds a syringe barrel filled with fluid, which is connected to a dispenser. Using a foot pedal, the technician dispenses the amount of fluid required, which remains consistent from shot to shot. When the technician points the tip and pushes the foot pedal, the fluid is dispensed, and the dot or line is made.

It is the nature of these medical devices that warrants a more personalized, and manual, fluid dispensing approach in their assembly, compared to employing a more automated, robotic system. Often, the geometry of the parts is too complex to make automation a viable option. Or the production volume is too low to warrant the investment.

Quantum Leap for Benchtop Fluid Dispensing

Because benchtop fluid dispensing has proven to be a highly workable and reliable method for assembly of these products, fluid dispensing manufacturers have routinely improved and refined their systems. Now, pneumatic benchtop fluid dispensing is taking a quantum leap forward in both simplicity and ease of use, and improved process control, to further support the stringent requirements of medical device manufacturers.

These improvements are designed to facilitate easier and more efficient operation of the fluid dispensing process from the operator's perspective and maintain better process control over dispensing parameters to effect more consistent dispensing outcomes.

But these latest changes also bring semi-automated desktop fluid dispensing into a compatibility with Ethernet, the Industrial Internet of Things (IIoT) and the cloud, enabling the potential for more direct machine/process interconnectivity. Although this is particularly beneficial where benchtop fluid dispensing systems are used in combination with robotic dispensing applications, aspects of this enhanced connectivity can be beneficial, right now, to nonrobotic pneumatic benchtop fluid dispensing. In essence, these new improvements enable the benchtop dispense technician to begin to benefit from smart-factory digitization.

For example, fluid dispensing systems incorporating these developments have recently been released by Nordson EFD, under the new UltimusPlus™ line of pneumatic benchtop dispensers. The following provides an overview of unique capabilities integrated into this new fluid-dispense line.

Human Machine Interface (HMI) – Total Touchscreen Control. New to

A barcode scanner allows users to switch between dispensing programs to boost productivity. (Credit: Nordson EFD)

pneumatic benchtop dispensing, these dispensers incorporate HMI touchscreen control for input of dispensing parameters and management of all dispense process functions. This improvement brings with it a new level of usability for operators and production managers. Touchscreen control makes setup significantly faster than it was with analog knobs and push-button controls.

With little need to reference a manual and rarely any software updates to upload, the intuitive large-format screen also prominently displays process information. It simplifies setup and programming, allowing operators to focus on their process. It also reduces setup time for any new fluid dispensing operation.

Automated Pressure Regulation with Full Operator Lock-Out. A key feature of this system is its unique approach to fully automated pressure regulation. Particularly in the assembly of medical devices, it is critical that the fluid dispensing be administered precisely and in the same repeatable pattern on each component with repetitive standardizations.

Typically, pneumatic benchtop fluid dispensers allow the operator to manually adjust the pressure regulation. On this new dispenser, the operator can now be fully locked out from manually adjusting the pressure regulation, as well as other dispense parameters like time and vacuum settings. Without access to an assigned password, the operator cannot change the dispense program parameters, which provides the next level of process control at a lower cost of ownership than was previously possible. This full electronic pressure regulation provides full operator lock-out. It alone enhances dispense quality control by eliminating any process inconsistencies caused by operator-to-operator variability.

Barcode Scanning for Enhanced Process Control. Also new to the world of pneumatic benchtop fluid dispensing is the unique capability to switch between stored dispensing programs using nothing more than a barcode scanner. This allows the operator to change the parameters for a new application without touching process parameters on the screen. The dispenser settings automatically switch when the new program barcode is scanned.

In addition, most medical device components have a unique barcode assigned to them as they move through the production/assembly process to facilitate keeping track of the components throughout production. This system is often utilized by industries other than medical device manufacturing for Six Sigma process controls.

An available option is to scan the lot barcode directly into the dispenser's memory. This is ideal when the factory is processing multiple parts throughout the day. It adds complete part traceability to the long list of benefits of using the barcode scanner.

Memory Programs Store Project Parameters. This dispenser permits the selection of time, pressure, vacuum, and other parameters for fluid dispensing on a specific project, as determined by plant and project requirements. These settings are locked in and stored in the dispenser and can be called up at any time to be run with the associated

Ethernet compatibility supports Smart Factory integration. (Credit: Nordson EFD)

project with a barcode scanner or via the intuitive touchscreen interface. Up to 16 memory programs can be set up and stored in the memory cells of the dispenser.

The days of maintaining dispensing parameters in handwritten spreadsheets and notepads, and manually entering coordinates into the dispenser on subsequent runs is now in the past, greatly reducing the possibility of human error in setting dispensing parameters.

Dispense Log Records Lot Dispensing Data. A digital dispense log automatically records data on dispense parameters — such as dispense time, pressure, vacuum, the number assigned to identify the component part, and the date, day, and time of each dispense cycle. The log can contain up to 10,000 lines of data. It is downloadable manually through the dispenser's USB port.

The dispense log is beneficial to manufacturing processes that require stringent, documented process control, especially in life sciences applications to meet FDA requirements and/or of other global medical device regulatory bodies.

Multiple Shots — Single Dispense Cycle. This is an ergonomic benefit that reduces operator fatigue by minimizing

repetitive movements, allowing multiple shots with a single dispense cycle.

When this function is engaged through the touchscreen, it allows the operator to make multiple deposits with only one cycle initiated, only one press of the foot pedal. This MultiShot™ functionality allows one single dispense cycle to make dozens or hundreds of shots with one single foot pedal press. A pause is programed to occur between each deposit to allow the operator time to position the tip on the next part. Essentially, the exact same shot is executed, based on the exact same settings of time, pressure, and vacuum.

Sleep Mode Reduces Power and Air Consumption. Pneumatic benchtop fluid dispensing consumes both compressed air and power. To reduce both the power and compressed air required by fluid dispensing, this new dispenser integrates a sleep mode functionality. Sleep mode can have significant impact on operating costs for plants using bottled compressed air, such as in cleanrooms in medical device manufacturing, or in facilities operating dozens to hundreds of dispensers.

Flash Drive Program Download. This new dispenser line is also equipped with a USB drive, which not only permits dispense reports to be output onto a flash drive, it also enables distribution of dispense programs into and out of the dispenser. This can considerably cut programming time when multiple dispensers are set up to dispense the exact same parameters on the same parts. One dispenser can be set up with multiple programs, those parameters then output to a flash drive and loaded into the other dispensers, minimizing human error and expediting loading of dispense programs across the factory floor.

Smart Factory Integration. For robotics applications, this dispenser smoothly integrates with Smart Factory Industry 4.0 initiatives, encompassing Ethernet, machine-to-machine technology, IIoT, edge computing, and the cloud. The dispense cycle can be initiated by a centralized, customer-site-specific programmable logic controller (PLC) as part of a large, in-line operation. When the production line needs to move from making one type of part to another, the PLC will remotely trigger the dispenser to change the program and dispense a different deposit pattern.

This dispenser was designed to not only meet the most stringent fluid dispensing needs of today's highly precise medical device requirements, but also to embody the essential components to integrate with the ongoing evolution of the Smart Factory. But ultimately, this new fluid dispenser represents a quantum leap where it matters most — ease of use and greatly enhanced process control.

This article was written by Vlad Konopelko, Global Product Manager, Nordson EFD, East Providence, RI. For more information, visit ***http://info.hotims.com/76509-344.***

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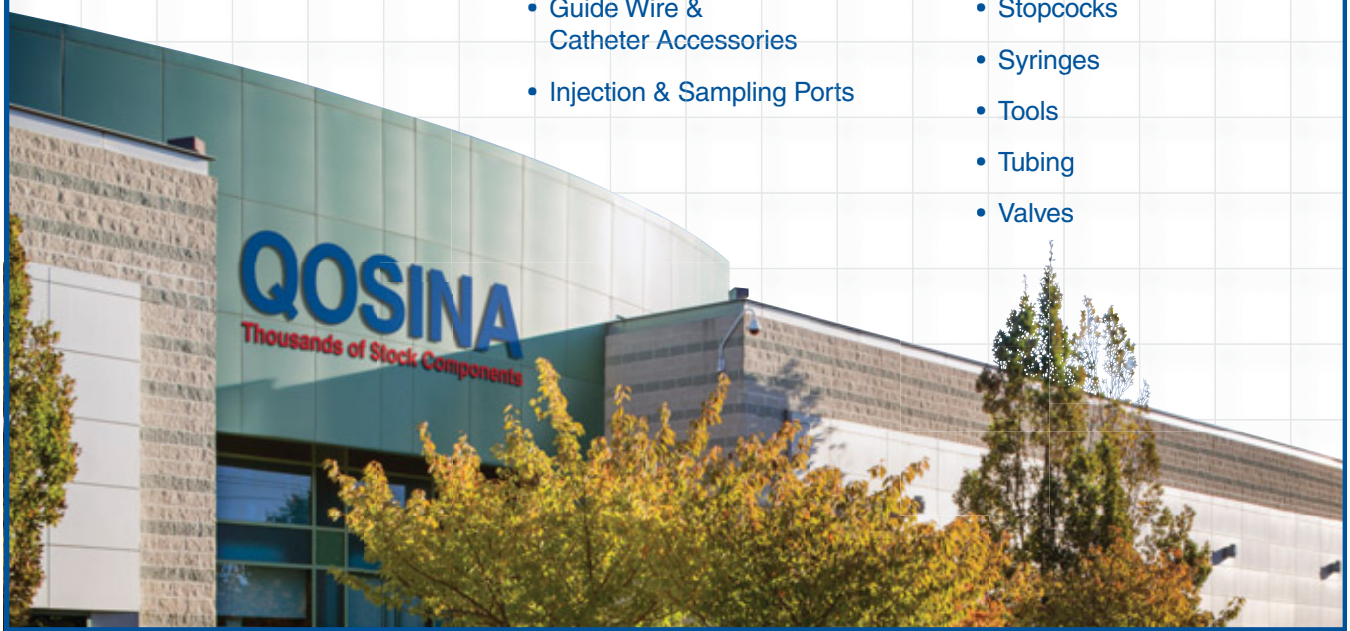

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Company Description

Halkey-Roberts manufactures plastic components and subassemblies used in disposable medical devices, including flow devices, medical valves, needle-free valves, catheter and tracheal tube valves, tubing clamps, closures, and hand pumps.

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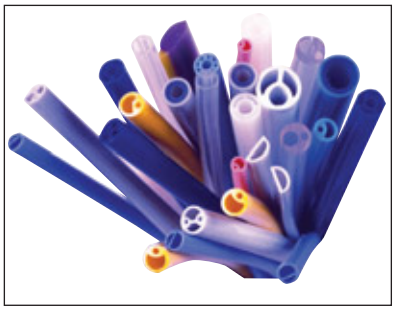
Company Description



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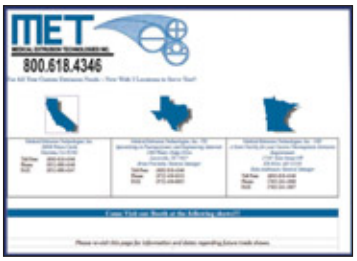

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R&D ROUNDUP

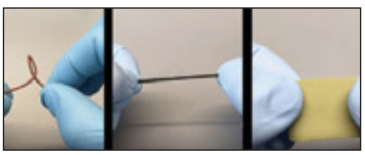
A novel layer helps the metallic components of the sensor bond to print sensors directly on human skin. (Credit: Ling Zhang/Penn State and Cheng Land/Harbin Institute of Technology)

Wearable Sensors Printed Directly on Skin with No Heat

Researchers have printed sensors directly on human skin without the use of heat. The fabrication technique uses a novel sintering aid layer to enable direct printing for on-body sensors. By adding a nanoparticle to the mix, the silver particles sinter at a lower temperature of about 212 °F (100 °C). The room-temperature sintering aid layer consists of polyvinyl alcohol paste — the main ingredient in peelable face masks — and calcium carbonate — which comprises eggshells. The layer reduces printing surface roughness and allows for an ultrathin layer of metal patterns that can bend and fold while maintaining electromechanical capabilities. When the sensor is printed, the researchers use an air blower, such as a hair dryer set on cool, to remove the water that is used as a solvent in the ink.

The sensors can precisely and continuously capture temperature, humidity, blood oxygen levels, and heart performance signals. The researchers also linked the on-body sensors into a network with wireless transmission capabilities to monitor the combination of signals as they progress.

For more information, visit ***www.medicaldesignbriefs.com/roundup/1120/sensors***.



The elasticity of a biodegradable, metal-ion elastomer is demonstrated. (Credit: Cornell University)

Metal-Ion Breakthrough Leads to New Biomaterials

Engineers have developed a new framework that makes elastomer design a modular process, allowing for the mixing and matching of different metals with a single polymer. They incorporated copper into a vascular graft because of its role in inducing angiogenesis — the process by which new blood vessels grow from existing ones.

The key breakthrough was crosslinking the polymer with copper ions using chelating ligands (molecules that tightly bind a metal ion using two or more bonds). Because one ligand can bind multiple metal ions, it can yield a wide range of mechanical properties — such as stiffness and toughness — as well as biomedical properties. They engineered six unique elastomers using one polymer and six different metals, and then made a seventh elastomer using a calcium-magnesium mix. It was the first time anyone had demonstrated a biodegradable metal-ion elastomer. The team also performed mechanical and biocompatibility experiments on their elastomers, testing for the materials' stress, strain, and ability to be used with living tissue.

For more information, visit ***www.medicaldesignbriefs.com/roundup/1120/biomaterials***.

Prof. Sungwon Lee shows his hand with the tiny micro supercapacitor stuck on the skin near his wrist. (Credit: DGIST)

Tiny Energy Storage Power for Wearable Skin Sensors

Researchers have fabricated tiny energy storage devices that can effectively power flexible and wearable skin sensors along with other electronic devices, paving the way toward remote medical monitoring and diagnoses and wearable devices.

A key for success is spraying a specific amount of graphene ink onto flexible substrates at a specific angle and temperature. Graphene is a promising material for improving their energy storage, as graphene electrodes are highly porous and so provide a larger surface area for the necessary electrostatic reactions to occur. They sprayed 10 ml of graphene ink at a 45° angle and 80 °C temperature onto a flexible substrate. This led to the formation of porous, multilayered electrodes.

The micro supercapacitor is 23 µm thin and retains its mechanical stability after 10,000 bends. It can store around 8.4 µF of charge per square centimeter and has a power density of about 1.13 kW per kg. The team demonstrated that it could be used in wearable devices that adhere to the skin.

For more information, visit ***www.medicaldesignbriefs.com/roundup/1120/skin***.

3D printing of tiny, transparent conducting fibers could be used to make devices that can smell and hear. (Credit: University of Cambridge)

3D Printed 'Invisible' Fibers Can Sense Breath, Sound, and Cells

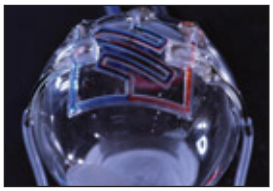
Researchers have used 3D printing to make electronic fibers, each 100 times thinner than a human hair, to create non-contact, wearable, portable respiratory sensors. The low-cost sensors are highly sensitive and can be attached to a mobile phone to collect breath pattern information, sound, and images at the same time.

The fiber sensor was used to test the amount of breath moisture leaked through a face covering for respiratory conditions such as normal breathing, rapid breathing, and simulated coughing. While the fiber sensor has not been designed to detect viral particles, since scientific evidence increasingly points to the fact that viral particles such as coronavirus can be transmitted through respiratory droplets and aerosols, measuring the amount and direction of breath moisture that leaks through different types of face coverings could act an indicator in the protection weak points.

The 3D printed the composite fibers are made from silver and/or semiconducting polymers. This fiber printing technique creates a core-shell fiber structure, with a high-purity conducting fiber core wrapped by a thin protective polymer sheath.

The team is looking to develop this fiber-printing technique for a number of multi-functional sensors, which could potentially detect more breath species for mobile health monitoring, or for biomachine interface applications.

For more information, visit ***www.medicaldesignbriefs.com/roundup/1120/fibers***.



3D printed microfluidic channels on a curved surface. (Credit: McAlpine Group, University of Minnesota)

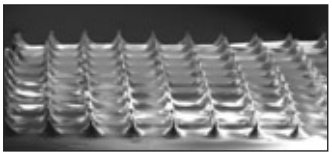
3D Printed Unique Micro-Scale Fluid Channels Made for Medical Testing

Researchers have 3D printed unique fluid channels at the micron scale that could automate production of diagnostics, sensors, and assays used for a variety of medical tests and other applications. The team is the first to 3D print these structures on a curved surface, providing the initial step for someday printing them directly on the skin for real-time sensing of bodily fluids.

The team used a custom-built 3D printer to directly print the microfluidic channels on a surface in an open lab environment. The channels are about 300 µm in diameter. The team showed that the fluid flow through the channels could be controlled, pumped, and redirected using a series of valves.

Printing these microfluidic channels outside of a cleanroom setting could provide for robotic-based automation and portability in producing these devices. For the first time, the researchers were also able to print microfluidics directly onto a curved surface. In addition, they integrated them with electronic sensors for lab-on-a-chip sensing capabilities.

For more information, visit ***www.medicaldesignbriefs.com/roundup/1120/microfluidics****.*



The biodegradable microneedle patch delivers gene therapy applications. (Credit: Terasaki Institute)

Microneedle Patch Delivers Gene Therapy

An ideal gene delivery approach must be able to deliver the genetic material without producing inflammation or toxicity in the body and should be able to penetrate the skin layer effectively. A research team has recently published an approach based on microneedles that meets these challenges.

The microneedles are made of a biocompatible material mixed with nanoparticles containing therapeutic genes. This mixture can be molded into a microneedle patch array for application to the skin. The microneedles are biodegradable, so once they have penetrated the skin, they will release the nanoparticles upon needle degradation. Moreover, the timing and sustainability of this release can be controlled by adjustments in the biomaterial preparation.

The development of these microneedles illustrates the potential for similar gene delivery systems to provide a more effective way to treat skin and other cancers, skin-related cosmetic needs, or diseases such as psoriasis and muscular dystrophy. It can even be used as a method for vaccine delivery against such diseases as skin or breast cancer, influenza, or COVID-19.

For more information, visit ***www.medicaldesignbriefs.com/roundup/1120/microneedle.***

Switch-Mode Power Supply (SMPS) Emissions Filtering: Attenuation vs. Leakage Trade-Off

This relationship is important to understand when developing the end system.

TT Electronics
Abercynon, UK

High-frequency electron spin resonance spectrometers hold the future promise of more closely analyzing fusion peptide structure and function in the current coronavirus.

The AC/DC power converter is often the sole interface between a piece of equipment and a building's electrical installation, which is in turn connected to any number of other off-line systems. It is also the element separating the hazardous high voltage mains from user-facing safety extra low voltage (SELV) networks. Accordingly, AC/DC power converters fall under a great deal of regulatory scrutiny, with mandates ranging from energy efficiency to safety to electromagnetic immunity and emissions. The requirements of each regulatory authority can often spawn contradictions in the resulting engineered solutions.

The design of a power system for medical devices demonstrates the issue, as designers face a prominent trade-off between the attenuation of electromagnetic emissions and the reduction of leakage currents. This relationship is important to understand not only when designing or modifying the power converter, but also when developing the end system — which may have additional mains-connected networks or strenuous touch current constraints for downstream applied parts.

High efficiency power conversion is achieved fundamentally via the deployment of a switch-mode topology. With respect to time, large changes in voltage and current at the circuit's switching nodes generate an abundance of harmonic content that can easily couple back onto the mains or onto output cabling from which the energy can radiate in space. IEC 60601-1-2:2014 (Ed. 4) imposes strict limits on the escape of this energy. Often, in a switch mode power supply (SMPS) design, the effective solution is to provide a low impedance return path to low potential for the high frequency currents, shunting them away from the device's input and output (I/O) ports. These paths are often composed simply of Y-capacitors that couple the line and neutral conductors to earth ground and/or Y-capacitors that bridge the primary and secondary returns.

These capacitive channels, however, also provide a potential path for hazardous currents (leakage currents) to flow to earth ground, or secondary during normal operation. The amount of leakage current to earth is tightly limited for medical applications according to IEC 60601-1, and leakage currents to secondary can exceed limits for any applied parts which may be powered from the secondary network. In the event that a suitable path to earth potential is interrupted, and a human body instead becomes the most suitable path, excessive leakage currents could be lethal. Thus, a trade-off is borne whereby the power system designer aims to shunt away as much high-frequency (HF) energy as possible from I/O ports, without allowing excessive hazardous currents to flow in these same paths.

A common implication of this trade-off is that leakage currents for off-the-shelf AC/DC power supplies are driven to approach the limits dictated by safety standards; this provides maximum emissions margins, leaving room for conducted and radiated energy contributions from the downstream system. The consequence is that it may not be feasible for the system to include other mains-connected networks including any additional external filtering, or even a second off-line converter. If additional mains-connected networks are required, and those networks would act to contribute to the total leakage current in the system, alternative approaches to mitigation of electromagnetic interference (EMI) may be necessary to allow for an increase in the impedance of the shunt paths.

HF attenuation can always be achieved with series inductive reactances rather than with shunt capacitive reactances. In practice, most off-line AC/DC converters incorporate optimized multi-order filters with both series and shunt elements, but if leakage currents are to be reduced, it is always an option to augment the size of the magnetics to offset decreases in shunt capacitance. As a result, the power converter becomes larger, heavier, and more expensive. If system level interactions necessitate the addition of external filtering, the nature of the noise (common code vs. differential mode) should be carefully characterized, and any additional shunts should be deployed judiciously, with careful regard to existing leakage current magnitudes.

A better approach may be to target the HF noise at its source, primarily semi-conductor state transitions. A well-designed

SMPS will incorporate effective snubbers around switching elements to reduce voltage transition rates, and as a result reduce the overall harmonic content of the switching waveform. Control of parasitic capacitances between primary and secondary, stemming from optical signal isolators and interwinding capacitances in the isolation transformer, lead to a reduced need for decoupling. If radio-frequency (RF) energy is conducted back from the downstream networks to the SMPS, chokes on interconnecting cables can also help to reduce observed emissions levels.

One might consider deploying a modern resonant topology with zero-voltage (ZVS) or zero-current soft (ZCS) switching. Forcing semiconductor state transitions to occur at natural zero-crossings can drastically reduce or potentially eliminate harmonic-rich voltage and/or current waveform discontinuities. These modern topologies provide many additional benefits in power density and energy efficiency.

Given the natural contradiction between commonplace EMI mitigation design techniques and safety requirements for leakage currents, and how tightly both of these SMPS artifacts are regulated in the medical industry, thorough consideration should be given to the EMI/leakage trade-off when deploying low-leakage systems or systems with multiple mains-connected networks. Good SMPS design practices and modern power conversion topologies can make navigating the trade-off less burdensome, boost design margins, and reduce time to market.

This article was written by Dylan Howes, Engineering Manager, TT Electronics, Abercynon, UK. He can be reached at Dylan.Howes@ttelectronics.com. For more information, visit ***http://info.hotims.com/76509-345.***

Improved Electrosurgical Grounding Pad Prevents Patient Skin Burn during Electrosurgery

A specially designed grounding plate uses integrated heat removal components.

ScientificRFA
Sammamish, WA

The high-power electrosurgical and radiofrequency (RF) ablation devices that apply a high level of RF current to the patient for extended periods can increase the risk of patient skin burns at the grounding pad's attachment site. Safety measures that have been proven effective using traditional electrosurgical procedures may not be sufficient to prevent grounding pad burns when used in procedures that require any combination of high current, long activation times and the use of conductive fluids (e.g., saline) for irrigation or distention.[1]

The problem is that some of the new electrosurgical devices and surgical

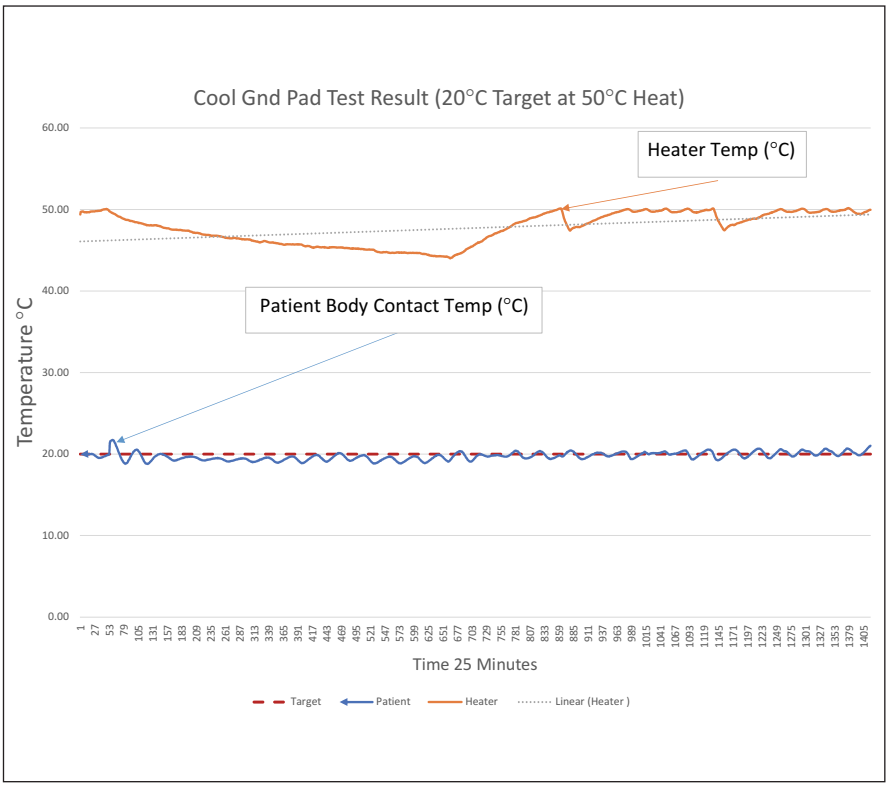


Fig. 1 – Test result data chart at 50 °C applied heat and 20 °C target temperature setting.

techniques can produce higher current levels than an AAMI-HF-18 compliant grounding pad can safely withstand, significantly increasing the risk of a burn at the grounding pad site. According to the AAMI HF-18 standard, an adult grounding pad should be designed to safely carry a current load of 500 mA for continuous period of 60 seconds. In order to pass the AAMI HF-18 performance test, an adult grounding pad must safely carry twice this amount of power, i.e., 700 mA for continuous period of 60 seconds (note: 700 mA double the power of 500 mA according to the power equation P=I2*R). However, some of the newer radiofrequency devices can deliver current levels of 1000–2000 mA for few minutes or up to 20 minutes and longer. Under these conditions, an AAMI HF-18 compliant grounding pad may not safely and effectively disperse the current, resulting in a patient burn at the site of the grounding pad.

A grounding pad must not heat the patient's skin in excess of 6 °C during the tissue ablation or electrosurgical procedure according to AAMI HF-18

standard. The RF current return is usually concentrated around the edges of grounding pad (edge effect), causing excessive heating at the highest current densities. A temperature of 45 °C will burn the skin. Since human skin is usually 30–33 °C, a burn will not occur until the pad causes a temperature rise of 12 °C. In order to provide a thermal safety margin, the skin under the pad should remain much cooler than this during electrosurgery.[2] Second- or third-degree patient burns from grounding pads are not uncommon. The Cool Grounding pad technology described here will ultimately eliminate the skin burn complication at any RF power level and will work with existing RF generators and grounding pads in the market.

The concept is based on the design idea published June 2011 on the *Tech Briefs* Create the Future design contest site.[3] Unlike standard grounding pad in use today, it regulates the patient's body temperature precisely at the grounding attachment site to a safe level, as well as monitoring the grounding pad's RF current return for safety and contact quality. It consists of a specially designed grounding plate with integrated heat removal components such as thermoelectric cooling devices (TEC), which can transfer heat from one side of the device to the other. A matrix of temperature sensors such as medical-grade thermocouples are equally spaced and embedded into the grounding pad or assembled on a separate thin plate. The image shown depicts the conceptual design and a working prototype of the Cool Grounding Pad.

Conceptual (above) and working prototype (below) of the Cool Grounding Pad. (Credit: ScientificRFA)

Controlling Mechanism

An FPGA temperature controlling mechanism with mathematical algorithm such as PID (proportional integral derivative) was developed to control and regulate the grounding pad's surface temperature precisely within AAMI HF-18 standard. The modular design of the controlling system can be integrated into the new RF generator design or can operate as a standalone system working with existing RF generators in the market.

The controller can support multiple grounding pads simultaneously and monitors the grounding contact quality as well. Figure 1 shows the test result data chart collected at 50 °C heat applied to the edges of the grounding pad with a target temperature setting of 20 °C in a half-hour time period. Benefits of the device include the following:

- Solves the excessive heating problem causing patient severe skin burns, especially with higher power RF generators and electrosurgical units.
- Works with existing RFA generators and electrosurgical units in the market.
- Works with existing grounding pads in the market.
- Offers modularity and flexible programmability that allow for many possible scenarios, including customized mathematical algorithms developed by the doctors and specialists.
- Provides data logging and saving with analysis capabilities.
- Communicates with the RF generator through serial or I2C port, e.g., emergency shutdown of the generator because of malfunction, open ground, or excessive temperature of the pad, etc.

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2. "3M Universal Electrosurgical Pad (Electrical and Thermographic Performance)," 3M.
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This article was written by Mike Nasab, ScientificRFA. For information about licensing the technology, contact. info@ScientificRFA.com. For more information, visit ***http://info.hotims.com/76509-346.*** *A video of the technology is available at* ***https://www.youtube.com/watch?v=u6OOxzY3z74.***

Lego-Inspired Bone and Soft Tissue Repair with Tiny, 3D Printed Bricks

Flea-sized, hollow blocks can be filled with materials that improve healing.

OHSU
Portland, OR

Tiny, 3D printed bricks have been designed to heal broken bones — and could one day lead to lab-made organs for human transplant.

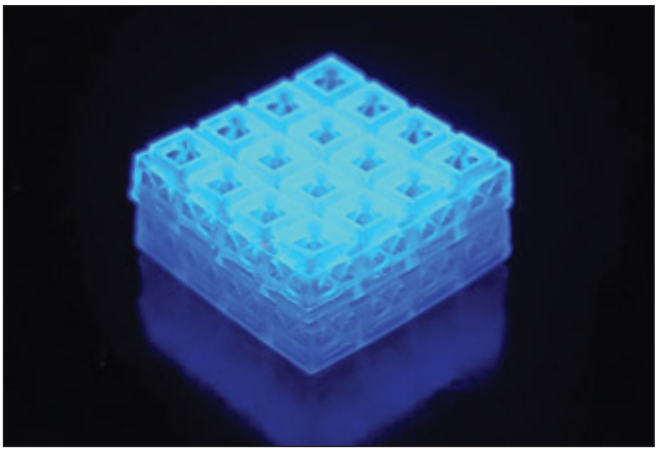
Inspired by Lego blocks, the small, hollow bricks serve as scaffolding onto which both hard and soft tissue can regrow better than today's standard regeneration methods, according to new research published in *Advanced Materials*.[1] Each brick is 1.5 mm cubed, or roughly the size of a small flea.

"Our patent-pending scaffolding is easy to use; it can be stacked together like Legos and placed in thousands of different configurations to match the complexity and size of almost any situation," says Luiz Bertassoni, PhD, who led the technology's development and is an associate professor in the OHSU School of Dentistry and an associate professor of biomedical engineering in the OHSU School of Medicine.

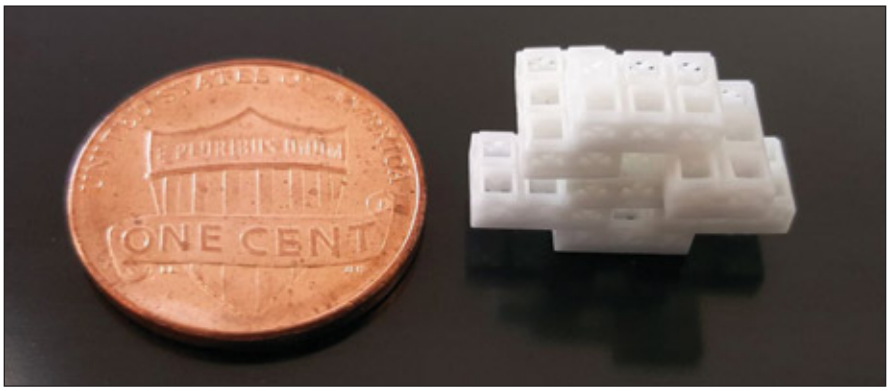
Bertassoni partnered with colleagues from OHSU, University of Oregon, New York University, and Mahidol University in Thailand to develop and evaluate the technology.

When stacked together, the microcages are designed to repair broken bones better than today's methods. Orthopedic surgeons typically repair more complex bone fractures by implanting metal rods or plates to stabilize the bone and then inserting biocompatible scaffolding materials packed with powders or pastes that promote healing.

A unique advantage of this new scaffolding system is that its hollow blocks can be filled with small amounts of gel containing various growth factors that are precisely placed closest to where they are needed. The study found growth factor-filled blocks placed near repaired rat bones led to about three times more blood vessel growth than conventional scaffolding material.



Researchers have developed a tiny, 3D printed technology that can be assembled like Lego blocks and help repair broken bones and soft tissue. (Credit: OHSU)



Each brick is 1.5 mm cubed, or roughly the size of a small flea. (Credit: OHSU)

"The 3D printed microcage technology improves healing by stimulating the right type of cells to grow in the right place, and at the right time," says study co-author Ramesh Subbiah, PhD, a postdoctoral scholar in Bertassoni's OHSU lab who specializes in growth factor delivery. "Different growth factors can be placed inside each block, enabling us to more precisely and quickly repair tissue."

The small devices are modular and can be assembled to fit into almost any space. When piecing together block segments containing four layers of four-bricks-by-four bricks, the researchers estimate more than 29,000 different configurations can be created.

Bertassoni and colleagues also imagine their 3D printed technology could be used to heal bones that have to be cut out for cancer treatment, for spinal fusion procedures and to build up weakened jaw bones ahead of a dental implant. And, by changing the composition of the technology's 3D printed materials, they envision it could also be used to build or repair soft tissues. With significantly more research, they hope the modular microcage approach could even be used to make organs for transplant.

Bertassoni and his team will further explore the microcages' performance in bone repair. They plan to test the technology's ability to repair more complex bone fractures in rats or larger animals.

This research was supported by National Institute of Dental and Craniofacial Research (R01DE026170, 3R01DE026170-03S1), National Center for Advancing Translational Sciences (UL1TR002369), Michigan-Pittsburgh-Wyss Resource Center's Regenerative Medicine Resource Center and OHSU Fellowship for Diversity and Inclusion in Research.

Reference

1. Christina Hipfinger, et al., "3D printing of microgel-loaded modular Lego-like microcages as instructive scaffolds for tissue engineering," *Advanced Materials*, July 23, 2020, DOI:10.1002/adma.202001736.

This article was written by Franny White, OHSU. For more information, visit ***https://news.ohsu.edu.***

Tiny Devices Promise New Horizon for Medical Imaging

This form of radiation does not damage living tissues.

University of Strathclyde Glasgow, Scotland

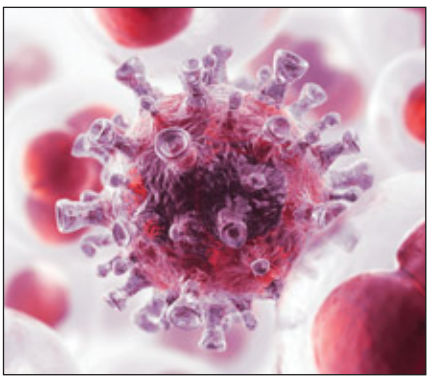
Miniature devices that could be developed into safe, high-resolution imaging technology, with uses such as helping doctors identify potentially deadly cancers and treat them early, have been created in research involving the University of Strathclyde.

The devices use terahertz radiation, which can penetrate through materials such as plastics, wood, and skin. This form of radiation, which falls between infrared and microwaves in the electromagnetic spectrum, does not damage living tissues as other forms such as x-rays can.

The devices are made from nanowires 100 times thinner than a human hair. They could be used in new, safe imaging technology with far higher resolution than current ultrasound devices used to detect small tumors.

A team of researchers from Strathclyde's Institute of Photonics, in the university's department of physics, developed a highly accurate micro-assembly technique to allow the construction of a 3D lattice of nanowire devices. The team used a specialized "transfer printing" micro-assembly system to print semiconductor nanowire structures, with nanoscale accuracy, in orthogonal patterns onto metal antenna structures.

The study, published in the journal *Science*, is the result of a collaboration between Strathclyde, the University of Oxford, and the Australian National University (ANU), based in Canberra.



Miniature devices could be developed into safe, high-resolution imaging technology to help doctors identify potentially deadly cancers. (Credit: University of Strathclyde)

Professor Martin Dawson, one of Strathclyde's lead researchers on the project, say, "It is very exciting to see this collaborative work with our close colleagues at Oxford and ANU published in a journal as prestigious as *Science*. We have developed novel capabilities for printing of semiconductor nanostructures and microstructures at Strathclyde over the past few years and, combined with ANU's leading ability to grow semiconductor nanowires and Oxford's advanced light detection concepts this has led to very exciting results.

"It has been a pleasure to partner with our colleagues in this work and we look forward to further leading-edge results from the collaboration."

Dr. Antonio Hurtado, a senior lecturer in Strathclyde's Institute of Photonics, who is also part of Strathclyde's lead team, says, "Building the THz detection systems was a great challenge that required the development at Strathclyde of extremely precise nanofabrication processes.

"These permitted us to use the semiconductor nanowires from ANU as 'building blocks' for their sequential integration in the 3D THz detectors designed at Oxford, whilst keeping the nanometric accuracy needed to assemble the systems. This has been a great combination of capability and a fantastic collaboration between the different teams involved in this work."

Other terahertz radiation systems, such as those used in airport security scanners, are based on simple intensity detection. However, improved imaging techniques can be implemented by making use of the fact that terahertz radiation, like all electromagnetic waves, contains polarization information — the direction of the electromagnetic fields as they propagate through space.

The orientation of the nanowires in the device allows terahertz radiation with different polarizations to be measured independently and given the compact device area, paves the way for future on-chip imaging systems.

For more information, visit ***https://www.strath.ac.uk.***

Patches Detect When a Viral Disease Is About to Get Worse

Sensing patch detects increased biomarkers in bodily fluids.

EPFL
Lausanne, Switzerland

Just before a viral illness such as the flu or COVID-19 worsens, bodies start producing more inflammatory biomarkers, and the concentrations of these biomarkers in bodily fluids increases. Therefore by continuously monitoring these biomarker concentrations on our skin's surface, doctors can spot such turns for the worse and act immediately, preventing complications and saving lives.

A microfluidic path brings the biofluids toward the chip. (Credit: EPFL)

That's the idea behind the latest development work being done at Xsensio, which has just been granted CHF 1.8 million by the European Innovation Council (EIC) to adapt its Lab-on-Skin™ technology so that it will detect biomarkers specific to viral inflammations. Only 36 of the 1,400 funding applications were selected for the EIC's two-year funding program, intended to support the fight against COVID-19.

Simultaneous and Continuous Biomarker Measurements

"Our highly miniaturized Lab-on-Skin technology means we can create biomarker-sensing patches that operate continuously, which could be an important element in the future of healthcare," says Esmeralda Megally, Xsensio CEO. While existing wearable health-monitoring systems measure only physical signs, Xsensio's system gives immediate readings of biochemical indicators — the same indicators that are currently analyzed in blood samples sent to a lab.

The Lab-on-Skin patches each contain a tiny computer chip (just 5 mm on a side) that could hold thousands of miniature sensors coated with different biochemicals depending on the type of biomarker to be detected: proteins, electrolytes, metabolites, or specific compounds. The bodily fluid collected by the patch is carried to the sensors via capillary action through a microfluidic system. The results of the patches' analyses are immediately sent by Bluetooth to a smartphone app where patients and their doctors or, in some cases, athletes and their coaches, can view and store them. The miniaturized components require very little energy thanks to their structure; depending on the application, they can run anywhere from one day to one week.

Xsensio's engineers developed the miniaturization technology in association with EPFL's Nanolab. The patches' small size, along with their ability to accommodate different biochemical surfaces, means the Lab-on-Chip system is modulable and can be used in a variety of monitoring situations. Xsensio had already developed other applications for its wearable technology under an EU research project on analytics for high-level athletes and an 18-month joint R&D project with one of the world's 10 largest biopharma companies.

"Over the next two years, we will work on developing sensors specifically for viral inflammations and on configuring our system so that the data it generates are reliable enough to be used in medical applications," says Megally. "We made a strategic decision to orient our development work towards the medical industry, with its high standards for reliability and accuracy. That said, our system could also be used for broader healthcare applications like connected watches."

Xsensio was founded in 2014 and will soon move into EPFL's Innovation Park. The firm plans to take full advantage of two key trends that are set to grow: connected healthcare and miniaturized, flexible electronics that can be worn on the skin.

This article was written by Cécilia Carron, EPFL. For more information, visit ***https://actu.epfl.ch/****. A video of the technology is available at* ***https://www.youtube.com/watch?time_continue=26&v=rFcw7RLFdK8&feature=emb_logo.***

Optical Imaging Technology May Help Surgeons Better Treat Cancer, Brain Diseases

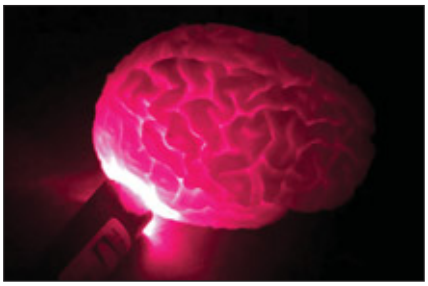
Optical imaging helps surgeons map out tumors.

Purdue University
West Lafayette, IN

A new tool for medical professionals may help shed more light on tumors in the body and how the brain operates.

Purdue University researchers created technology that uses optical imaging to better help surgeons map out tumors in the body and help them understand how certain diseases affect activity in the brain. The work is published in the journal *IEEE Transactions on Medical Imaging*.

"We are using light to extract new information from tissue to inform doctors and assist them in designing and carrying out surgeries to remove tumors," says Brian Bentz, a Purdue alumnus, who worked on the technology with Kevin Webb, a professor of electrical and computer engineering at Purdue. "It is a localization method where our technology helps the surgeon pinpoint precise information about the depth and location of tumors. Such information is not easily accessible with current technologies."



Light travels through tissue like gas from a leaky pipe diffuses to fill a room. This allows illumination and interrogation of structures within the tissue. Through modeling and inversion algorithms, the size, shape, and location of tumors and blood vessels can be determined. (Credit: Brian Bentz)

The Purdue technology uses contrast in the absorption of light and fluorescent agents that are introduced into the body to find tumors and/or blood vessels within the tissue. The same technology can be used to study neuron activation in the brain, which can help doctors detect diseases such as Parkinson's.

Bentz says the Purdue technology overcomes one of the major challenges with fluorescence imaging — the light becomes highly scattered and that limits the information that a surgeon receives.

"Our technology aims to provide more detailed information about tumors for surgeons and neuron activity in the brain, both of which can improve outcomes for patients," Bentz says.

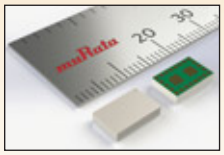
The innovators are working with the Purdue Research Foundation Office of Technology Commercialization to patent the technology. The researchers are looking for partners to continue testing and developing their technology.

This article was written Chris Adam, Purdue University. For more information on licensing and other opportunities, contact D.H.R. Sarma at OTC at dhrsarma@prf.org. For more information, visit ***https:// www.purdue.edu***.

NEW PRODUCTS AND SERVICES

PRODUCT OF THE MONTH

MEDICAL DESIGN BRIEFS 2020 Product of the Year Finalist



MICS Radio Module

Murata, Smyrna, GA, has released a Type 1RM ultra-small Medical Implant Communication System (MICS) band radio module. The LBAA0PC1RMH298 is designed for use in devices with data-intensive wireless capabilities that are used to diagnose, monitor, report, and provide warnings in support of human life. Typical applications include insulin, drug, and baclofen pumps as well as arrhythmia and bladder monitors. Measuring just 8.6 × 5.6 × 1.7 mm, this module discretely bundles several technological components and ICs into one miniatured package to deliver a communication range up to 2 m, an ultra-low current consumption of 0.2 µA sleep state, and a 128 kbps data rate.

For Free Info Visit http://info.hotims.com/76509-347

Product Focus: Manufacturing/Assembly Equipment

SMT Assembly Services

Z-Axis, Phelps, NY, has launched a new product introduction (NPI) line for surface mount technology (SMT) printed circuit board (PCB) assembly at its contract design and electronics manufacturing center near Rochester, NY. The separate NPI line allows the company to run prototype jobs without impacting the schedule on its two SMT production lines. It can also be used for quick-turn production builds to accommodate last-minute requests from existing customers. The NPI line features two recently updated Mycronic MY9E pick-and-place machines and a Speedline MPM/SPM semi-automated stencil printer.

For Free Info Visit http://info.hotims.com/76509-348

Walk-In Tubing Oven

An inert atmosphere walk-in oven from Grieve, Round Lake, IL, can be used for annealing polyurethane tubing at the customer's facility. No. 1038 is a 500 °F (260 °C) oven that measures 60 × 72 × 84 in. A 4200 CFM, 3-HP recirculating blower provides vertical downward airflow to the workload. The oven has 6 in. insulated walls and an aluminized steel exterior with a Type 304, 2B finish stainless steel interior. It also includes a pressure regulator, flow meter, pressure gauge, inner oven walls sealing directly against ½ in. thick silicone rubber door seal, and more.

For Free Info Visit http://info.hotims.com/76509-350

Plug and Produce Linear Motion

Bosch Rexroth, Saint Joseph, MI, offers digital engineering tools and configurators, which are designed to significantly simplify design processes for linear motion technology. Intelligent technology includes everything from the vertical integration with additional features such as software and electronics to the targeted use of sensors in the company's linear motion components. For example, the Smart Function Kit for pressing and joining applications is a modular subsystem consisting of mechanics, electrics, and software. Features include intuitive commissioning and process configuration with no programming knowledge required for either.

For Free Info Visit http://info.hotims.com/76509-349

Machine Vision Camera

Omron, Hoffman Estates, IL, has launched a complete machine vision package that can be easily installed on PC-based systems. The new FJ2 cameras feature state-of-the-art complementary metal oxide semiconductor (CMOS) sensors, frame rates as fast as 282 frames per second (FPS), and resolutions ranging from 0.4 up to 5 MP in both monochrome and color versions. The camera's GigE interface provides power and communication via a single Ethernet cable as well as an I/O port. This meets the challenges in situations when Power over Ethernet (PoE) isn't an option or when additional I/O access is required. It allows up to 16 cameras to be connected to a single system.

For Free Info Visit http://info.hotims.com/76509-351

Electromechanical Actuator

Thomson Industries, Radford, VA, has launched a compact electromechanical actuator that retains all of the intelligence built into its larger counterparts. Factory automation applications can benefit from the compact Electrak® MD actuator with up to 2 kN of force, advanced onboard electronics, and J1939 CAN Bus support. Onboard intelligence enhances overall performance and eliminates space consumption by keeping any external equipment like encoders and switches within the actuator housing. It features feedback on position, J1939 CAN bus communication, low-current switching (PLC compatibility), and end-of-stroke indication output.

For Free Info Visit http://info.hotims.com/76509-352

Microprocessor

Renesas, Tokyo, Japan, has released a series of microprocessors (MPUs) that feature a dynamically reconfigurable processor (DRP-AI), the company's vision-optimized artificial intelligence (AI) accelerator. The first product in the RZ/V series, the RZ/V2M, is designed to deliver a combination of real-time AI inference and excellent power efficiency in embedded devices. The RZ/V2M realizes power consumption as low as 4W (typical), which eliminates the need for heat sinks and cooling fans, greatly simplifying heat dissipation measures. The MPU features an imaging signal processor (ISP) capable of processing high-resolution 4K pixels at 30 frames per second.

For Free Info Visit http://info.hotims.com/76509-354

Sleep Tracking Sensor

A sleep tracking sensor from TE Connectivity, Anaheim, CA, monitors vital signs including respiratory rate, heart rate, and other parameters like body motion and bed exit. It requires no external power or bias voltage and enables continuous monitoring without disturbing the user. The sensor is manufactured with PVDF film, and when placed onto a mattress, it monitors vital signs and provides comprehensive sleep data for more precise sleep quality analysis. The noncontact sleep sensor can be combined with a bedside sleep monitor, smartphone, and Web-based app to help track and better understand sleep patterns and create personalized feedback and suggestions to help improve sleep.

For Free Info Visit http://info.hotims.com/76509-353

Display Mount

Southco, Concordville, PA, has extended its line of positioning technology solutions with an entry-level display arm that offers a robust, configurable display mounting solution. The AV B30 adjustable arm (B Series) offers a simplified mounting solution for static applications where displays only need to be moved into a single stationary position, or where frequent repositioning is not required. The adjustable arm allows end users to manually adjust the height and orientation of monitors and screens. Constructed of engineered aluminum castings for optimum performance, the display mount includes integrated wire management covers and minimal joints for easy cleaning.

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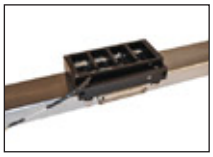
Stepper Motor



Single-axis linear stepper motors from H2W Technologies, Santa Clarita, CA, are ideal for high-speed open loop positioning applications. The motors can perform at speeds of up to 80 in./sec (2 m/sec) and strokes of up to 68 in. (1.7 m). Linear stepper motors are capable of very precise position, velocity, and acceleration control when coupled with a micro-stepping drive and indexer. The moving assembly is supported by magnetically preloaded air bearings that are embedded in the active surface of the forcer.

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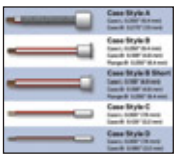

Temperature Sensors

A new line of miniature bearing embedment temperature sensors is available from Minco, Minneapolis, MN. The S7 and TC7 sensors commonly monitor the metal temperature of bearings in rotating equipment — the most reliable indicator of bearing condition — to give early warning of oil film breakdown before costly failures occur. Moreover, the sensor leads can be configured with either stainless steel feedthrough tubes or elastomer filled cables to block oil from wicking out of the machine housing along the lead wires.

For Free Info Visit http://info.hotims.com/76509-359

Mandrels and Fine Wire

Applied Plastics, Norwood, MA, offers PTFE coated mandrels and fine wire to the advanced catheter market. The company is adding international shipping capability to its online store to enable international customers to procure and receive PTFE coated mandrels faster. The online store features in stock, PTFE Natural® coated stainless steel mandrels and wires with diameters ranging from 0.007 to 0.070 in. Product ships within 24 hours of order and includes a certificate of compliance.

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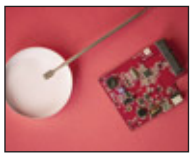
PRODUCT SPOTLIGHT

CLAD METAL MEDICAL WIRE

Anomet Products manufactures clad metal medical wire combining high-strength, highly conductive, biocompatible, and radiopaque alloys into one material "system" with a complete metallurgical bond between layers. Typical wire combinations include 316LVM, Gold, MP35N, Nitinol, Palladium, Platinum, Silver, Tantalum, Titanium, and others. Customized composite wire solutions to meet your unique wire challenges. www.anometproducts.com/content/medical-materials.

Anomet Products

Free Info at http://info.hotims.com/76509-784



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www.medicaldesignbriefs.com/techleaders19

NEW PRODUCTS AND SERVICES

Miniature AC Servomotors

Nippon Pulse, Radford, VA, has introduced a new series of high-performance micro direct-drive (MDD) AC servomotors. Each MDD motor comes with a built-in high-performance encoder (either absolute or incremental) that enables direct fine positioning. The compact motors can bear large loads through a robust bearing arrangement and can deliver increased torque due to their high-energy magnets and power-dense winding technology. The cleanroom-ready motors also feature a ripple-reducing design. The motors are available in frame sizes as small as 13 mm and as large as 70 mm and can support hollow shaft structures.

For Free Info Visit http://info.hotims.com/76509-360

Medical Displays

TRU-Vu Monitors, Arlington Heights, IL, has introduced a new 21.5 in medical display.The new MMZB-21.5G-X medical display features 1920 × 1080 full HD resolution. The display certified to the latest UL and IEC 60601-1-2 4th Edition regulations. It offers a variety of digital video inputs (HDMI, DVI, DisplayPort), as well as a touch screen option. The monitor has a zero-bezel enclosure design, and the four corners of the display are rounded. A single sheet of glass covers the entire front of the display to maximizes safety and hygiene. The front face is rated IP 65 splash proof.

For Free Info Visit http://info.hotims.com/76509-363

Antibacterial Wrench

Technology Services Inc., Glencoe, MO, has released a new version of its multifunctional wrench. The spark-free, antibacterial universal wrench is designed to make handling cylinders easier and safer. Applications include opening or closing cylinder caps, tightening or releasing regulator valve CGA fittings, opening and closing cylinder valve wheels, and opening or closing cylinders for welding gases. One end features a ratchet disk with pins. Its unidirectional operation prevents any excessive torque when used for closing a cylinder. The other end of the wrench has two unique crevices, designed specifically for Type E home healthcare cylinders and Type MC welding cylinders.

For Free Info Visit http://info.hotims.com/76509-361

Fanless Power Supplies

Advanced Energy Industries, Inc., Fort Collins, CO, has released a fanless power supply series that eliminates acoustic noise and vibration for medical applications. The Excelsys CS1000 delivers up to 1000 W with no fans. The convection cooled power supplies provide conversion efficiencies of up to 94 percent, as well as a 24 W bias supply voltage of 5 or 12 V. They are available with 24- or 48-V single outputs and operate off universal AC input voltage of 90 to 264 VAC.

For Free Info Visit http://info.hotims.com/76509-362

Power Supply

A new series of 2 × 3 in. footprint open frame AC/DC power supplies is available from TRACO Power Supplies, San Jose, CA. The TPI 125 provides 125 W of power in a compact package and consists of five single output models providing 12/15/24/36/48 VDC (adjustable –20/+10 percent). The series complies with the ErP directive (< 0.3 W no load power consumption) and Class B EMC limits. Industrial-grade components and advanced thermal management techniques give the power supply a high reliability (790 k hours per MIL-HDBK-217F) and make it an ideal solution for demanding, space-critical applications.

For Free Info Visit http://info.hotims.com/76509-364

IoT Software

Thirdwayv, Irvine, CA, has added a new solution to its family of connectivity and security-by-design building blocks for deploying mission-critical commercial and enterprise Internet of Things (IoT) applications. The SeamlessConnect solution ensures that IoT devices can continuously send and receive data from the cloud. Designed to improve connectivity of an IoT system, it can be implemented either through a software development kit for creating an app or through a reference design for developing gateway hardware. Both implementations can be deployed together or on a standalone basis.

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November 2020, Volume 10, Number 11.

MEDICAL DESIGN BRIEFS

Pot of Gold Engineered to Help with Early Disease Detection

The University of Queensland
Brisbane St. Lucia, Australia

University of Queensland researchers have developed biosensors that use nanoengineered porous gold that more effectively detect early signs of disease, improving patient outcomes.

Most diagnostic methods use costly materials and are time consuming and expensive to run, but PhD candidate Mostafa Masud and research supervisors Professor Yusuke Yamauchi and Dr. MD Shahriar Hossain have developed a cheaper, faster, and ultrasensitive biosensor for point-of-care testing.

Masud says the most exciting thing about the project was that it broke through some of the current limitations associated with early detection of diseases.

"This new diagnostic technique allows for direct detection of disease-specific miRNA, which wasn't previously possible," he says.

"This is especially important for patients at an early stage of a disease such as cancer, who do not have detectable amounts of other biomarkers, but may have a detectable quantity of exosomal miRNA biomarker.

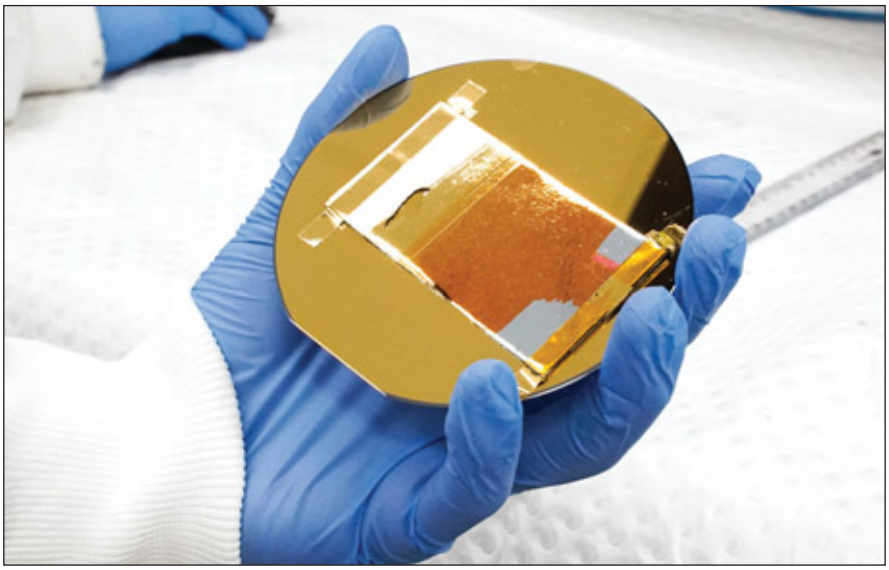
How It Works

The platform was nanoengineered by the team to read samples of blood, urine, saliva, or plasma through a surface covered in a gold film, which has millions of tiny pores.

The method used to create these highly engineered porous films has been published in the journal *Nature Protocols* following 15 years of research, ushering in a new era of opportunity for nanoporous materials research and technology development.

The team is continuing to develop this platform and plans for it to be available to medical practitioners in the next five years.

"Doctors will be able to use our platform to take a small fluid sample from a patient and test for diseases instantly, for around one quarter of the cost of other diagnostic techniques," Yamauchi says.



The biosensors use nanoengineered porous gold to more effectively detect early signs of disease. (Credit: University of Queensland)

Dr. MD Shahriar Hossain, Mostafa Masud, and Prof. Yusuke Yamauchi have developed a cheaper, faster, and ultrasensitive biosensor for point-of-care testing. (Credit: University of Queensland)

The researchers say the technology would be easy to use and particularly useful in remote locations and developing countries where rapid and early diagnostics were critical, especially in the case of viral infections.

This research was funded as an Australian Research Council Discovery Project and published in the journals *Biosensor and Bioelectronics* and *Chemical Society Reviews*.

For more information, visit ***www.uq.edu.au***.

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Molon was Founded by E.F. Moloney in 1954. Previous to establishing Molon Corporation, E.F. Moloney founded Comar Electric Company in 1942. Comar specialized in relay manufacturing, producing electrical components which were used in the Apollo space mission.

Molon remains privately owned and operated by Earle F. Moloney, Chairman of the Board and President. Prior to becoming Chairman of the Board for Molon Corporation, Earle F. Moloney founded Moloney Coachbuilders in 1968, the world's largest manufacturer of limousines. He later purchased Lehmann-Peterson, the pioneer in developing armored security vehicles, serving 5 U.S. Presidents.

Other technological innovations and industry advancements under the Bally/Moloney nameplate were: Bally Vending, which developed the first freshly brewed coffee from a vending machine, and Lion Manufacturing, another Moloney company, who produced the first remote controlled television.

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