I-Connect007

NOVEMBER 2018

PCB007 MAGAZINE

MEDICAL INNOVATIONS

PCB007 MAGAZINE

Medical Innovations

Of all the driving forces in the PCB manufacturing marketplace today, one major contributor is medical device technology. Medical device development influences materials, components, manufacturing techniques, and procurement. In this issue, we investigate innovations surrounding the medical sector.

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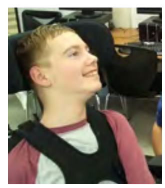

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Medical Devices by the Bucketful

Nolan's Notes

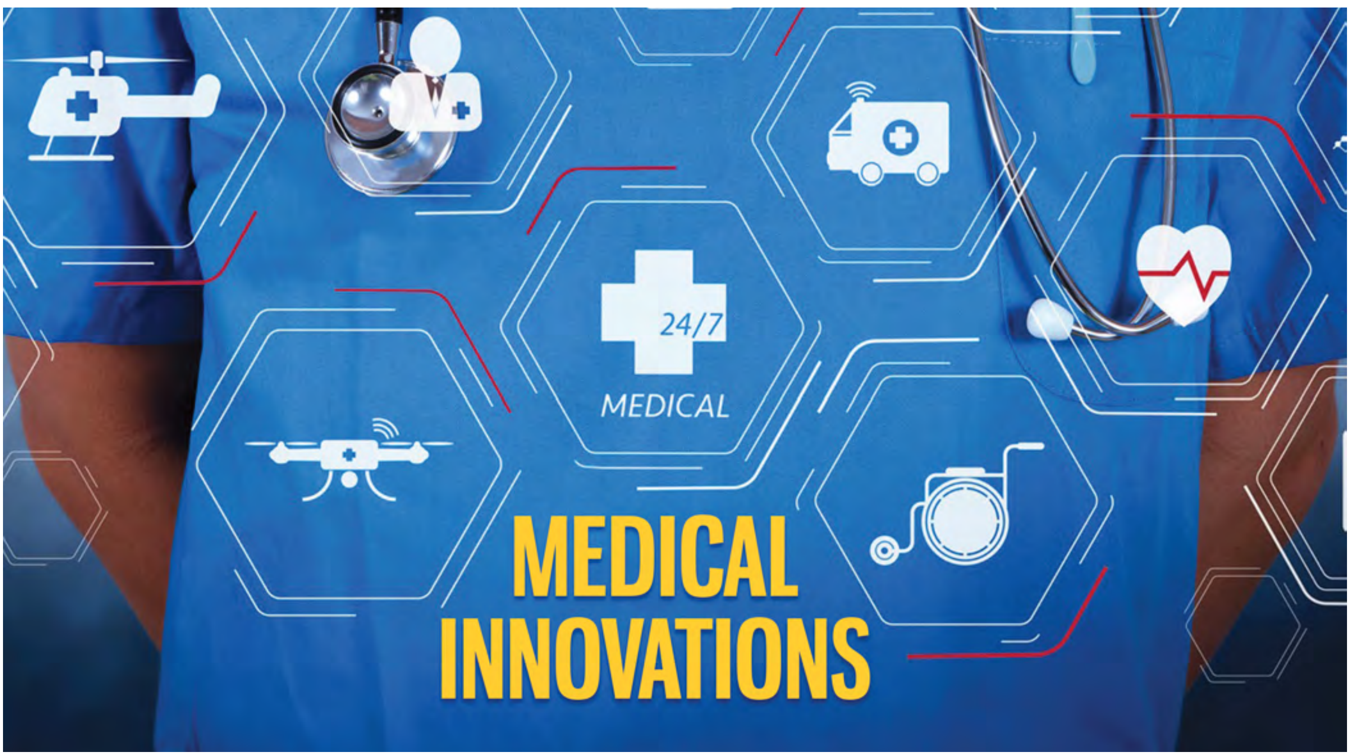
by Nolan Johnson, I-CONNECT007

I'm a bit of a Disney buff—as in Walt Disney himself. I love the parks, and I especially love the studio productions back when Walt still had an influence. Walt had a remarkable and subtle way of driving the social agenda through his films and cartoons. For example, Disney studios produced training films for the United States Army and Navy during World War II—not just for Friday night doubleheaders at the hometown movie theater. But I digress; one of my favorite pieces stars Mickey himself—"The Sorcerer's Apprentice" from Disney's "Fantasia."

For those of you who don't know, the story involves Mickey as a young, inexperienced apprentice to a wizened old wizard. The wizard leaves and the apprentice decides to use a magic spell to animate a broom to finish the apprentice's water-carrying chore. As you can imagine, things got out of hand quickly, and before you know it, there is an entire army of duplicate brooms carrying buckets of water flooding the workshop. Mickey wielded more influence than he could yet control, resulting in unintended—yet severe—consequences in his workplace. The idea to use his skills to automate seemed fine enough; it was his inability to foresee and mitigate the consequences that got him in trouble.

As we put this issue together, Mickey as an apprentice was on my mind precisely because of the unintended consequences of wielding mighty power within the electronics manufacturing industry.

For PCB fabrication, the apprentices are aerospace, automotive, and medical. These three sectors are driving fabrication technology investments. These three sectors are also driv-



ing nearly every part of the electronics supply chain right now from parts specification to component stocking, lead times, testing, and certification. However, the significant market forces of these apprentices affect us all, and human lives are very much on the line with these technologies.

I say this because much of the innovation currently being undertaken will automate even more of our lives. Innovation is a good thing. Cars will soon drive themselves, and our jewelry will report our vital statistics to our doctor's office—until there are unintended consequences.

In this issue, we investigate innovations surrounding the medical sector. PCB design teams drive manufacturer investment through the kinds of fabrication they order, but it is always valuable for a fabrication facility to understand larger or more diverse innovations. If you want to grow your business, you'll need more than just current customers. This issue brings over a dozen articles covering a wide range of new technologies, chips, 3D-printing applications, and more.

But that's not all.

Tara Dunn's column brings us the story of high school students working with advanced electronics manufacturing technologies. Tara and the students challenge us all to continue to flex our imagination and innovate.

Jan Pedersen of the PCB Norsemen goes nuts on IPC medical application standards. Seriously, this column is a must-read to know what the IPC is currently working on regarding medical device standards.

In "The Right Approach," columnist Steve Williams describes a competition to develop medical devices inspired by the iconic Star Trek tricorder. Fifty years after the introduction of the tricorder on U.S. television, we may not have to wait 300 more years to see similar devices.

Running simultaneously with this month's *SMT007 Magazine,* Nolan Johnson's overview article on FDA approval processes, "FDA Approval: A Vital Step in Medical Manufacturing," offers three different perspectives from key players in the medical device space.

Next is our tour of emerging medical technologies, devices, and applications. The work coming out of industry and academia will be what we fabricate for our medical customers in the future, so we give you a glimpse into that technology now.

Following his keynote address at SMTAI in Rosemont, Illinois, "Requirements for Both Cleaning and Coating to Building Medical Hardware," DfR Solutions' Dock Brown sat down with Barry Matties and Happy Holden to discuss failure analysis, predictive software, and "rules versus tools." Find this conversation at "Dock Brown on Succeeding at Failure Analysis."

Michael Carano's column, "Trouble in Your Tank," brings us part two of the art and science of resist stripping.

In a technical article titled "Via Fill and Through-Hole Plating Process with Enhanced TH Microdistribution," the team—including Nicolova, Rodriguez, Feng, Gugliotti, Bowerman, and Watkowski (MacDermid Enthone Electronics Solutions in the U.S.), and Wei (MacDermid Enthone Global Development Application Center in China)—details their work to optimize a new copper process for simultaneously filling via and plating through-holes. Improvements to fabrication reliability improve the fabricator's ability to meet Class 3 medical device requirements.

As a bonus, the PCB007 China Editorial Team brings us a preview interview with representatives from HKPCA (Hong Kong Printed Circuit Association) and IPC (Association Connection Electronics Industries) about the upcoming 2018 HKPCA & IPC Show: "Inspire the Industry, Explore the Infinity."

In the end, the PCB fabrication industry carries the water for major market influencers. As always, we welcome your feedback and experiences in the medical devices sector. **PCB007**

Nolan Johnson is managing editor of *PCB007 Magazine*. Nolan brings 30 years of career experience focused almost entirely on electronics design and manufacturing.
To contact Johnson, click here.

FlexFactor: Imagination and Innovation

Flex Talk

Feature Column by Tara Dunn, OMNI PCB

Take a minute and think back to your high school days. Now that you have thought of some of your best memories and hopefully chuckled only a little, did any of those memories involve conceptualizing a product introduction that utilized a flexible circuit or rigid-flex? I know mine didn't. I didn't give flexible circuitry much thought at all until I interviewed at a flexible circuit manufacturing company after graduating from college. Thankfully, I was hired for that job and my early years in the printed circuit board industry were focused almost exclusively on flex and rigid-flex. One of my favorite phrases to this day came from that time: "Flex is really only limited by your imagination." I am from the generation that saw flexible circuit application ideas take off outside of military and aerospace work. I remember the insulin pump being developed, and medical equipment—such as hearing aids—becoming smaller, lighter, and more portable. Flex technology and the number of flexible circuit applications is advancing at a staggering pace. With the demand for increasingly complex electronics, we see semi-additive processing, modified semi-additive processing, and flexible hybrid electronics technology (among others), advancing rapidly to meet those needs.

Imagine being back in high school and getting introduced to these advanced electronics

Figure 1: A student team from Abraham Lincoln High School in San Jose, California, pitches their product concept, driving technology, and business model to a panel of representatives. (Source: NextFlex)

Figure 2: Students visit Jabil's Blue Sky Center to learn about advanced technologies and applications. (Source: NextFlex)

manufacturing technologies. Then, imagine the opportunity to earn college credit by participating in an entrepreneurial program that challenged you to conceptualize a new product introduction using this technology to solve a human health issue or develop a performance monitoring program where you would pitch your idea in a similar way to the business show "Shark Tank." Wouldn't that be fun!

One exciting program that fosters this type of imagination and creativity in high schools is the NextFlex FlexFactor program. Over the past two years, NextFlex—America's Flexible Hybrid Electronics Institute—has built and scaled an innovative educational program designed to create a pipeline of young people excited about and prepared for the advanced manufacturing careers of tomorrow.

Emily McGrath, deputy director of workforce development at NextFlex, describes the program: "The FlexFactor platform assembles all the actors in the labor market to allow students to visualize their future and understand the educational pathways to make that future a reality. Through an amazing immersion experience, students, schools, higher education, and companies interact and bring advanced technologies and entrepreneurship into the classroom in a project-based learning approach that fits in any class, any subject, anywhere. Students leave the program convinced that they can and should be part of solving the big problems of our time and well into the future."

Through FlexFactor, students are exposed to the vast range of professional opportunities in the advanced manufacturing sector. Skills needed for a career in industry are revealed in a way that is appealing and fun where student teams address a wide range of real-world problems—from cancer treatment and head trauma, to waste management and lunch lines. The conceptualized hardware solutions developed by students often feature an incredible array of revolutionary technologies, including advanced functional fabrics, Internet of Things (IoT) devices, cloud technology, augmented reality, flexible hybrid electronics, and more.

A few fun examples of creative applications utilizing flexible hybrid electronics include Fast Asleep—a small wristband that would fit snug-

Figure 3: Students design, print, and test flexible circuits in NextFlex's cleanroom to learn what it's like to work with next-generation technologies in the advanced manufacturing sector. (Source: NextFlex)

Figure 4: Students visit Jabil's Blue Sky Center to learn about manufacturing processes and careers in the advanced manufacturing sector. (Source: NextFlex)

ly around a baby's arm while sleeping that measures movements, oxygen, and heart rate, allowing parents to rest easier. Another example is the Relieve Sleeve—a pain reliever designed to alleviate joint pain and stiffness associated with rheumatoid arthritis (RA) that administers heat sensations and applies electric pulses tailored to a user's needs. These functions are embedded in a compression sleeve for easy application around joints and muscles. Another creative application is Asthmex—a chest band with a smart patch to detect asthma symptoms and administer medication via an autoinjector, which helps everyone from student athletes to Olympic athletes with asthma to compete.

FlexFactor alumnus Tate Morillo from Willow Glen High School in San Jose, California, worked with his team to conceptualize an implantable glucose monitor for diabetes patients that would alert users in real time to take insulin by pushing notifications to a paired cellphone. The device would be powered by low-flow hydroelectric power harvested from blood flow.

Tate explained, "My impetus for creating such a concept stemmed from first-hand experience with my diabetic father's struggles. Watching him checking his glucose levels as a child scared me, and I felt that there must be a better solution to this problem. Already being a large burden on the individual, diabetes seems to consume the lives of people, controlling how they eat, their energy levels, and the way they must live their lives. As a son, I wanted to do everything in my power to make the way this problem was treated easier, more convenient, and less painful for my father. The most important lesson I learned from FlexFactor was that the youth's ideas should not be ignored, but nurtured. Without influencing the young minds of today, students may never find their passion or become the inventors of tomorrow, thus changing the path of technological development and history."

The program layers onto an existing class and requires students to work in teams to identify a real-world problem, conceptualize an advanced hardware solution, and build a business model around it. At the end of the program, students pitch their ideas "Shark-Tank style" to a panel of representatives, highlighting how they have considered both technical features and market needs to solve the problem they identified. The program's agile framework allows it to work in a wide range of subject areas, including topics like English and fashion design, allowing it to engage new populations of students with the advanced manufacturing sector instead of only students who have already self-selected STEM pathways.

NextFlex launched the pilot of FlexFactor in the fall of 2016 with eight students, and by the end of this semester (fall 2018), they expect to have put roughly 2,100 students through the program across multiple states. FlexFactor's success at engaging young people with the careers of tomorrow has sparked a national expansion of the program, beginning with Lorain Community College in Elyria, Ohio, which launched their first pilot in spring 2018. Colleges and universities leverage the turn-key program to improve engagement with local high school students, increase enrollment in specific education pathways, and achieve regional workforce and economic development objectives.

The ultimate goal of FlexFactor is to create a generation of students who use their critical thinking, creativity, communication, and collaboration skills to create the materials and devices that will address and mitigate the biggest challenges of the future. I have personally had the opportunity to participate in one of the student "pitch days" and was completely impressed with their innovative product ideas, energy, and knowledge of the advanced manufacturing space. If NextFlex ever decides to expand this concept to an adult continuing education program, I may be the first to sign up! **PCB007**

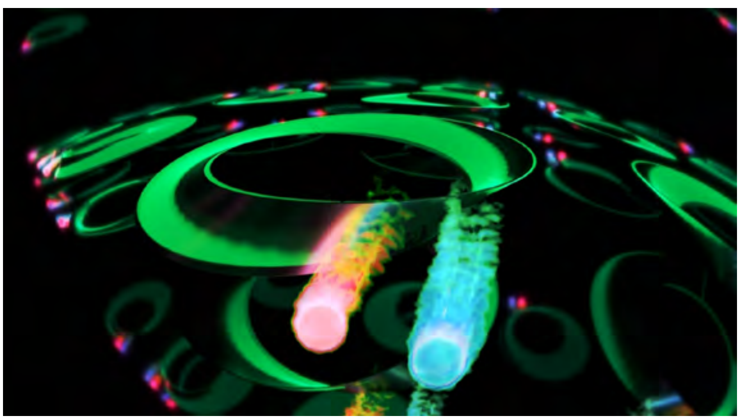
Tara Dunn is the president of Omni PCB, a manufacturer's rep firm specializing in the printed circuit board industry. To read past columns or contact Dunn, click here.

Photons Created at the Edge of a Silicon Chip

by Dina Genkina and Emily Edwards
JOINT QUANTUM INSTITUTE

Researchers at the Joint Quantum Institute (JQI) have demonstrated a new approach that enables different devices to emit nearly identical single photons repeatedly.

Led by JQI Fellow Mohammad Hafezi, the team made a silicon chip that guides light around the device's edge where it is inherently protected against disruptions. In earlier research, Hafezi and colleagues showed that this design could reduce the likelihood of optical signal degradation.



Researchers configure silicon rings on a chip to emit high-quality photons for use in quantum information processing. (Source: JQI)

Their recent paper published in the journal *Nature* explains that the same physics that protects the light along the chip's edge also ensures reliable photon production.

In the experiment, the team used silicon to convert infrared laser light into pairs of differently colored single photons. They injected light into a chip containing an array of minuscule silicon loops and arranged in a way that always allows the light to travel undisturbed around the edge of the chip even if fabrication defects were present. This design not only shields the light from disruptions, but also restricts how single photons form within those edge channels. The loop layout essentially forces each photon pair to be nearly identical to the next regardless of microscopic differences among the rings.

Using this approach, the researchers were able to produce high-quality single-color photons reliably and repeatedly compared to the unpredictable output of traditional chips. Their device also has one unique advantage: "Our chip works at room temperature," says Sunil Mittal, a JQI postdoctoral researcher and lead author of the study, "I don't have to cool it down to cryogenic temperatures, making it a comparatively very simple setup."

The team says this finding could open up a new avenue of research that unites quantum light with photonic devices having built-in protective features.

PCB Standards for Medical Device Applications: A Hard Nut to Crack!

The PCB Norsemen
Feature Column by Jan Pedersen, ELMATICA

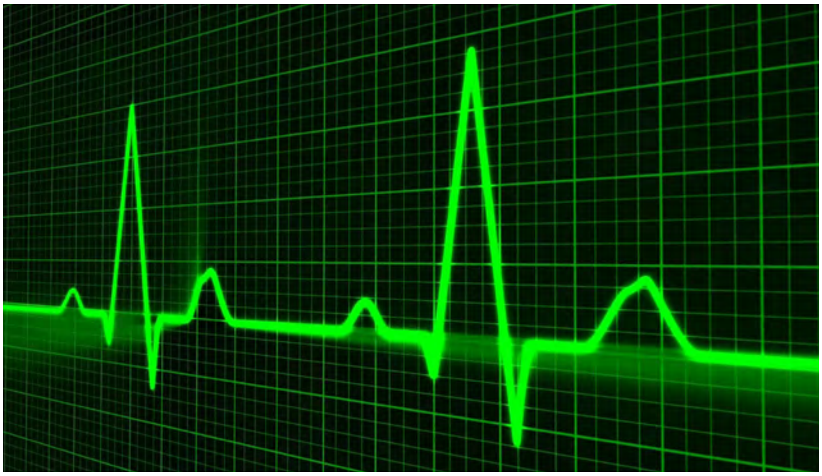
Medical applications must be made by the book with strict standards and can vary in size and technology—from large advanced X-ray machines to robotic arms and microscopic hearing devices or sensors. Applications can also be made for both the exterior and interior of the human body. When you think of the variety of environments medical devices must tolerate, it is not hard to understand that finding one standard to embrace them all is a challenge.

Two years ago, Elmatica initiated a task group for medical applications. IPC accepted the challenge and founded the IPC-6012 and IPC-6013 medical device addendums with me as the chair. With experience from similarities in the automotive addendum, the task group quickly discovered the need for a different approach to the medical addendum.

The purpose of the medical device addendum working group is to determine enhanced IPC standards, such as 6012 and 6013, for fabrication beyond IPC Class III to demonstrate suitability for medical devices and provide a high degree of assurance of the reliability and durability of the PCB.

Reaching Consensus in the Jungle

The task group, which consists of several members from the entire industry, first met at electronica in 2016 and has continuously developed the standardized PCB requirements for medical device applications since then. Is the work exciting? Yes! And is it challenging? Absolutely.



In an industry where failures can be fatal, the development of rigid standards is necessary. My thoughts the entire way, and the idea behind the addendum, was to find a consensus in the jungle of corporate specifications—a common document describing basic PCB requirements for medical device applications. We collected all learnings from developing the addendum for the automotive industry and tried to do the same with medical.

When developing a new standard, experiences from the complete production chain is vital, which is why it is so important to have product owners in the task group. The task group has met on a regular basis to discuss and solve challenges, discover new ones, and sometimes argue before finally agreeing. Working with standards like this often provides the feeling of one step forward, two steps back. It's hard work, but it's important.

When the new standards are approved, manufacturers of PCBs can rely on specific standards for production. The requirements and parameters for building and supplying PCBs for the medical device applications will then increase in reliability and transparency.

In the development of these two standards, we have come to a point where we have agreed on most of the requirements and are ready to write a draft document for each of the two standards for the industry to review. We have recently been working in two subgroups focusing on important segments that soon will be presented for the larger group where a consensus will hopefully be reached.

Rome Was Not Built in a Day

They say that "Rome was not built in a day." Similarly, developing advanced addendums with several parameters to fulfill is not completed by just snapping your fingers either.

After several webinars and meetings, the task group found that addendums in the industry for medical device applications require a different approach than automotive. The demands and specifications that need to be considered are quite different. The challenge is to define what specifications can apply and work for PCBs in both small sensors on and under the skin, to larger medical equipment.

We have identified that PCBs used in several applications—such as implants and hearing aids—have line widths, thicknesses, hole sizes, and other features below current tolerances and limits in today's design, performance, and acceptability standard. Imperfections in the material that in a typical PCB would be acceptable may cause application failures in these products. Volume manufacturers of standard PCBs accept a waiver of IPC's test frequency requirements, while suppliers of these small PCBs must exceed the standards!

IPC Design Producibility Levels

"Micro PCB" is a new term recently used in discussion with members of the IPC TAEC (Technical Activities Executive Committee). We ended up with a completely new terminology, which we now call "design producibility level D." We are pushing IPC design standards (the IPC-2220 series) to be more up to date. This will take time to implement globally within IPC, but thanks to the miniaturization in some medical device applications, these standards will be the first to use the new term.

In the IPC-2220 series, IPC refers to design producibility levels of features, tolerances, measurements, assembly, testing of completion, and verification of the manufacturing

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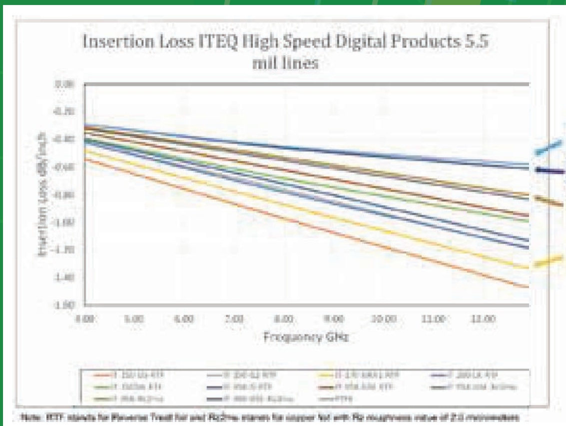

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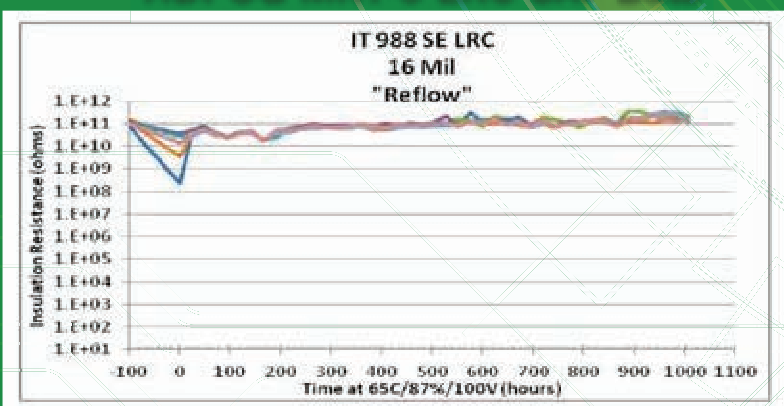
2	216	194 / 199	193	> 60	> 60	417 / 438
3	214	186 / 192	185	> 60	> 60	417 / 442
4	216	193 / 194	184	> 60	> 60	424 / 443
5	217	194 / 199	190	> 60	> 60	418 / 442
6	218	191 / 197	188	> 60	> 60	405 / 436
7	218	190 / 197	194	> 60	> 60	425 / 444

No thermal degradation observable after 7 lamination cycles

HDPUG MRT-6 LRC CAF Data



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process that reflect progressive increases in the sophistication of tooling, materials or processing, and fabrication cost. These levels are:

- Level A: General design producibility (preferred)
- Level B: Moderate design producibility (standard)
- Level C: Least design producibility (reduced)

The new proposed level that was suggested due to the complexity in the PCBs for medical device applications is:

- Level D: Advanced design producibility (exceedingly reduced)

The producibility levels should not be interpreted as a design requirement, but rather as a method of communicating the degree of difficulty.

Task Group

Today, PCBs are made to customer requirements rather than following IPC standards and we do not want to continue on this page. There are active 44 members in the task group representing the PCB, electronics manufacturing, and medical industries. The task group is still open to new members. Above all, we need more product owners and people from electronics production for medical device applications to join.

Conclusion

With digitalization, AI, and IoT, the traceability and transparency to how a PCB is produced will be even more important. We must rule out the PCBs that follow the standards to the ones that do not. The day will come when you or someone you know might need a medical device, and you want to make sure it does its job correctly. **PCB007**

Jan Pedersen is a senior technical advisor at Elmatica. To read past columns or contact Pedersen, click here.

Superconductivity Where You Don't Expect It

Scientists at the University of Twente (UT) and the University of Amsterdam have demonstrated a new property of topological materials: the lossless current conduction of bismuth.

In their paper published in the journal *Nature Materials,* researchers demonstrated that the transport and spin of electrons are related in a topological material. Thanks to this property, a non-superconducting material can conduct current without resistance. By applying superconducting electrodes made of niobium to a thin crystal flake of bismuth doped with antimony, a superconducting current flows through the material at a temperature of 10 milli-Kelvin. In a superconductor, paired electrons or Cooper pairs are responsible for conduction.

Majorana quasiparticles also play a major role in this. Further, this property can be observed at the surface and inside the material in the "bulk." This makes the properties less vulnerable to noise or pollution.

The material used, bismuth with a little antimony, continues to surprise. Over the years, it has turned into a model material for electronic properties. While the number of electrons available for conduction in bismuth is so low that it can hardly be called a metal, these electrons move like particles at the speed of light.

For future electronics and quantum computing, 2D materials like graphene appear to be strong candidates. The newly discovered property shows that this doesn't have to be a limiting factor. 3D building blocks might be possible as well, just like in current-day silicon-based electronic devices.

The research was done by the Quantum Transport in Matter (QTM) group, part of University of Twente's MESA+ Institute. The UT scientists closely collaborated with colleagues of the Van der Waals-Zeeman Institute of the University of Amsterdam.

(Source: University of Twente)

Star Trek Inspires Medical Technology: An Update

The Right Approach

Feature Column by Steve Williams, THE RIGHT APPROACH CONSULTING

In the March 2012 issue of *The PCB Magazine*, I wrote "How William Shatner Changed the PCB World." Two short years later, I wrote a follow-up in the December 2014 issue called "Star Trek® Inspires Medical Technology for 2015" with a global competition to develop a modern tricorder for the medical industry. My obsession with all things Star Trek continues with an update on the Qualcomm Tricorder XPRIZE Contest. In April 2017, the top prize winner was named and awarded a $2.5-million prize.

Qualcomm Tricorder XPRIZE Contest

Over 50 years after Dr. Leonard H. "Bones" McCoy of the Starship Enterprise first used a fictional tricorder to scan patients for ailments and anomalies, real-world medical science is turning that science fiction into reality. More than 300 teams from around the world competed in the Qualcomm Tricorder XPRIZE Contest—a Star Trek-inspired challenge—that first launched in January 2012. The goal was to incentivize the development of innovative technologies capable of accurately monitoring a set of medical conditions independent of a healthcare professional or facility.

Rules

There were three rules for the Qualcomm Tricorder XPRIZE Contest:

1. Diagnose a set of 13 prescribed medical conditions
2. Continuously measure five prescribed vital signs
3. Have a positive consumer experience

"The theme of Star Trek is really about what the future is going to be like and the kind of technology we're going to see," said Erik Viirre, technical and medical director of the competi-

Qualcomm Tricorder XPRIZE video.

Figure 1: The winner, Final Frontier Medical Devices, receiving the XPRIZE check.

tion. The interesting takeaway of this competition is that creating a handheld medical laboratory could give us insight into what the next generation of cellphone capabilities might include!

Finalists

A total of 300 teams entered and were thoroughly vetted and reduced to 34 registered teams in the competition, which was further reduced to seven teams with two emerging to compete in the final round. These two finalists were the Taiwanese Dynamical Biomarkers Group and Final Frontier Medical Devices (gotta love the name!) out of the United States.

Dynamical Biomarkers Group of Zhongli City, Taiwan, included a team of physicians, physicists, scientists, engineers, and designers charged. Dr. Chung-Kang Peng of Harvard Medical School founded the team in 2013 and was co-led by Dr. Edward Chang from HTC Corporation's research and healthcare division (a mobile technology company). Their DeepQ tricorder device included four main components: smartphone, vital signs monitoring set, scope set, and blood/urine/breath tests. All subsystems connect to a smartphone app.

The Final Frontier Medical Devices team from Paoli, Pennsylvania, was led by the founders of Basil Leaf Technologies—brothers Dr. Basil Harris, an emergency room physician, and George Harris, a network engineer. They created a portable, consumer-friendly device—DxtER (pronounced "Dexter")—capable of collecting and interpreting large amounts of diagnostic data giving real-time insight into 22 medical conditions.

"It is an impressive achievement for these two teams to advance to the consumer testing stage of the competition with their devices," said Grant Campany, prize lead for the competition, "This stage not only takes us one step closer to transforming a sci-fi vision into a real-world impact, but more importantly, we are another important step closer to bringing a very user-friendly device to consumers around the globe, allowing them to proactively manage their own health in a way that has never been done before."

Winner

And the prize goes to…Final Frontier Medical Devices (Figure 1)! After four years of development, their AI-based engine learned to diagnose medical conditions by integrating information from clinical emergency medicine with data analysis from actual patients. DxtER includes a group of non-invasive sensors designed to collect data about vital signs, body chemistries, and biological functions, which is then synthesized in the device's diagnostic engine to make a quick and accurate assessment (Figure 2).

The Not-So-Final-Frontier

While Bones and his medical crew were the users of tricorder technology in Star Trek, the purpose of this contest is to develop medical diagnostic devices that the average person can use to improve their health. Today, most of us have used some kind of wearable device to monitor our steps, exercise, heart rate, etc. However, as an eight-year-old watching

Figure 2: DxtER, the winning device.

Star Trek with my dad and younger brother in the late 1960s, this wearable technology would have been thought to be crazy. If I have learned anything by being in a technological industry for four decades, it's that something is only crazy until someone does it!

It should be noted that the original Star Trek series that has inspired 50 years of innovation only ran for three seasons! If I didn't double-check it for myself, I wouldn't have believed it. This just goes to show that there is no time constraint for game-changing innovation. I'm not sure "Bones" could ever see a time when a computer could be held in our hands:

Captain Kirk: "Well, Bones, do the new medical facilities meet with your approval?"

Bones McCoy: "They do not. It's like working in a damn computer center!" **PCB007**

Steve Williams is the president of The Right Approach Consulting. To read past columns or contact Williams, click here.

Flexible Sensor Maps Blood-oxygen Levels Anywhere in the Body

A new flexible sensor developed by engineers at the University of California, Berkeley, can map blood-oxygen levels over large areas of skin, tissue, and organs.

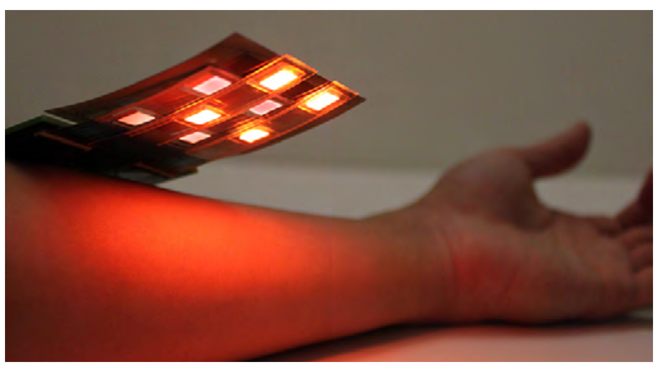
The new sensor is made of organic electronics printed on bendable plastic that molds to the contours of the body. It is built of an array of alternating red and near-infrared organic LEDs and organic photodiodes printed on a flexible material. Unlike fingertip oximeters that are rigid and bulky, it can detect blood-oxygen levels at nine points in a grid and be placed anywhere on the skin. It could potentially be used to map oxygenation of skin grafts or look through the skin to monitor oxygen levels in transplanted organs.

"After transplantation, surgeons want to measure that all parts of an organ are getting oxygen," said Yasser Khan, a graduate student in electrical engineering and computer sciences at UC Berkeley. "If you have one sensor, you have to move it around to measure oxygenation at different locations. With an array, you can know right away if there is a point that is not healing properly."

"All medical applications that use oxygen monitoring could benefit from a wearable sensor," said Ana Claudia Arias, a professor of electrical engineering and computer sciences at UC Berkeley. "Patients with diabetes, respiration diseases, and even sleep apnea could use a sensor that could be worn anywhere to monitor blood-oxygen levels 24/7."

The co-authors on this work are Donggeon Han, Adrien Pierre, Jonathan Ting, Xingchun Wang, and Claire M. Lochner of UC Berkeley, and Gianluca Bovo, Nir Yaacobi-Gross, Chris Newsome, and Richard Wilson of Cambridge Display Technology Ltd.

(Source: UC Berkeley)



Emerging Medical Technologies: What to Watch For

Feature by the I-Connect007 Editorial Team

Hockey great Wayne Gretzky once summed up his success like this: "I skate where the puck is going to be, not where it has been." There is no mistaking that medical electronics are a driving force in PCB fabrication. In this feature, we present a compendium of just a few of the medical and electronic R&D projects currently underway around the globe. We also take a moment to celebrate the life of Ed Bakken—a man who attacked the early days of medical electronics using the same fighting spirit with which Gretzky attacked the puck in his day. Inside this report, we present technology that medical device OEMs will be specifying in the near future and will move fabrication to where it's going to be—not where it has been.

AI Helps Detect Fetal Heart Problems

A research group led by scientists from Japan's RIKEN Center for Advanced Intelligence Project (AIP) has developed a novel system that can automatically detect abnormalities in fetal hearts in real time using artificial intelligence (AI). This technology could help examiners avoid missing severe and complex congenital heart abnormalities that require prompt treatments—leading to early diagnosis and well-planned treatment plans—and could contribute to the development of perinatal or neonatal medicine.

Congenital heart problems can be very serious and account for about 20% of all newborn deaths. An earlier diagnosis of such problems before the baby is born would allow for prompt treatment within a week after birth. This is known to improve the prognosis markedly and why there have been many attempts to develop technology to enable a better diagnosis. However, fetal diagnosis today still depends heavily on observations by experienced examiners using ultrasound imaging. Unfortunately, it is not uncommon for children to be born without having been properly diagnosed.

The rapid development of machine learning in recent years has driven a great interest in its application for medical applications. With machine learning, diagnostic systems will be able to detect diseases more rapidly and accurately. However, this requires the availability of adequate datasets on normal and abnormal subjects for a particular condition. Since congenital heart problems in children are relatively rare, there are no complete datasets. Until now, prediction based on machine learning was not accurate enough for practical use in the clinic.

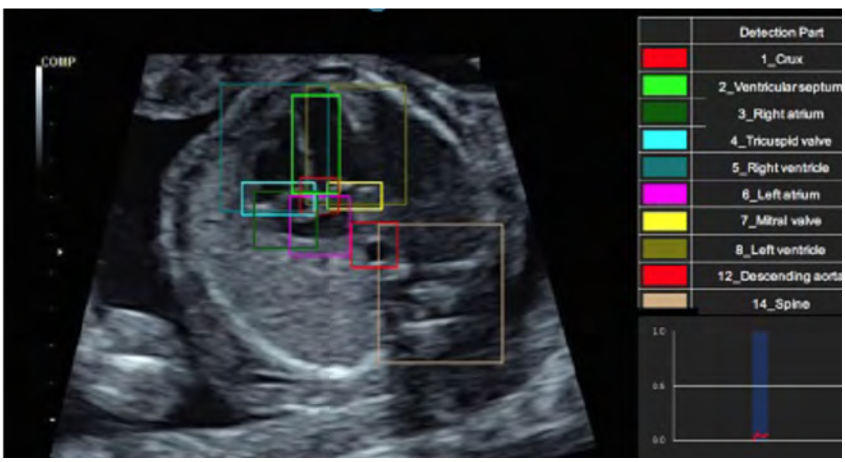


Photo: Heart screening system.

The RIKEN Center AIP-led group, which also involves collaborators from Fujitsu Ltd and Showa University, took on this challenge and has successfully developed a new machine-learn-

ing technology that can accurately predict diseases using relatively small and incomplete datasets.

A set of "teacher" data—from which the AI is to learn—is prepared through annotation—the attachment of meanings of objects—and used to train the object detection system. To develop the current system, the researchers used normal heart images to annotate the correct positions of 18 different parts of the heart and peripheral organs and developed a novel fetal heart screening system that allows the automatic detection of heart abnormalities from ultrasound images. When there are differences between the test and learned data, the system judges that there is an abnormality if the difference is higher than a defined confidence value. The process is quick and can be performed in real time with the results appearing immediately on the examination screen. The system can also help harmonize diagnoses among different hospitals with varying levels of medical expertise or equipment.

The researchers now plan to carry out clinical trials at university hospitals in Japan, adding a larger number of fetal ultrasound images to allow the AI to learn more, improve the screening accuracy, and expand its target. Implementing this system could help correct medical disparities between regions through the training of examiners or by remote diagnosis using cloud-based systems. **PCB007**

Wearable Ultrasound Patch for Blood Pressure Monitoring

A team of researchers led by the University of California San Diego has developed a new wearable ultrasound patch that non-invasively continuously monitors central blood pressure (BP) in major arteries as deep as four centimeters (more than one inch) deep beneath the skin. This could help people detect cardiovascular problems earlier and with greater precision.

In tests, the patch performed as well as some clinical methods to measure BP. Applications include continuous real-time monitoring of changes in BP in patients with heart or lung disease, as well as patients who are critically ill or undergoing surgery. The patch uses ultrasound, so it could potentially be used to non-invasively track other vital signs and physiological signals from places deep inside the body.

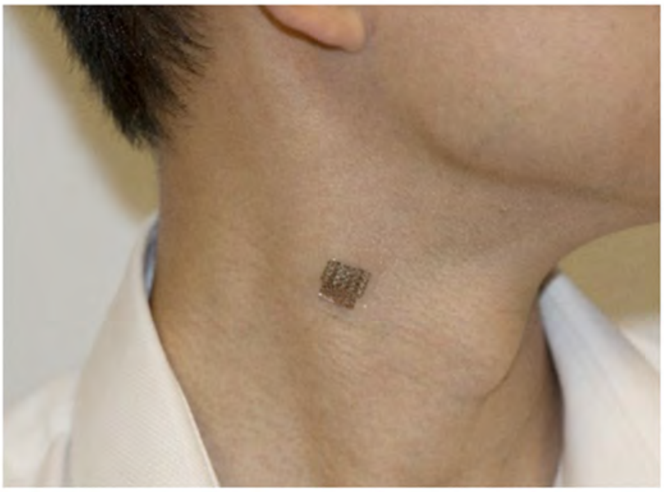
Figure 1: Ultrasound patch on a finger.

"Wearable devices have so far been limited to sensing signals either on the surface of the skin or right beneath it, but this is like seeing just the tip of the iceberg," said Sheng Xu, a professor of nanoengineering at the UC San Diego Jacobs School of Engineering and the corresponding author of the study, "By integrating ultrasound technology into wearables, we can start to capture a whole lot of other signals, biological events, and activities going on way below the surface in a non-invasive manner."

Physicians involved with the study say the technology would be useful in various inpatient procedures. "This has the potential to be a great addition to cardiovascular medicine," said Dr. Brady Huang, a co-author on the paper and radiologist at UC San Diego Health, "In the operating room, especially in complex cardiopulmonary procedures, accurate real-time assessment of central blood pressure is needed, which is where this device has the potential to supplant traditional methods."

Central Blood Pressure Measurement

The device measures central BP, which differs from peripheral BP measured with an in-



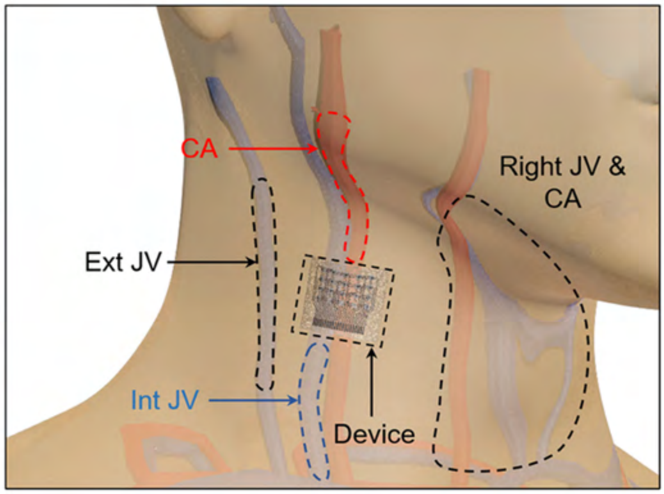


Figure 2: BP patch on a neck.

flatable cuff strapped around the upper arm. Medical experts consider central BP—the pressure in the central blood vessels that sends blood directly from the heart to other major organs throughout the body—more accurate than peripheral BP and better at predicting heart disease.

However, measuring central BP isn't typically done in routine exams. The state-of-the-art clinical method is invasive and involves a catheter to be inserted into a blood vessel in a patient's arm, groin, or neck, and guiding it to the heart. While a non-invasive method exists, it cannot consistently produce accurate readings. It involves holding a pen-like probe called a tonometer on the skin directly above a major blood vessel. To get a good reading, the tonometer must be held steady at just the right angle and with the right amount of pressure each time, but this can vary between tests and different technicians.

"It's highly operator dependent. Even with the proper technique, if you move the tonometer tip just a millimeter off, the data get distorted. And if you push the tonometer down too hard, it will put too much pressure on the vessel, which also affects the data," said co-first author Chonghe Wang, a nanoengineering graduate student at UC San Diego.

Tonometers also require the patient to sit still—which makes continuous monitoring difficult—and are not sensitive enough to get good readings through fatty tissue.

The UC San Diego-led team's alternative—a soft, stretchy ultrasound patch that can be worn on the skin—provides accurate, precise readings of central BP each time, even while the user is moving. The patch can also get a good reading through fatty tissue.

Making Ultrasound Wearable

"A major advance of this work is it transforms ultrasound technology into a wearable platform. This is important because now we can start to do continuous, non-invasive monitoring of major blood vessels deep underneath the skin—not just in shallow tissues," said Wang.

The patch is a thin sheet of silicone elastomer patterned with what's called an island-bridge structure—an array of small electron-

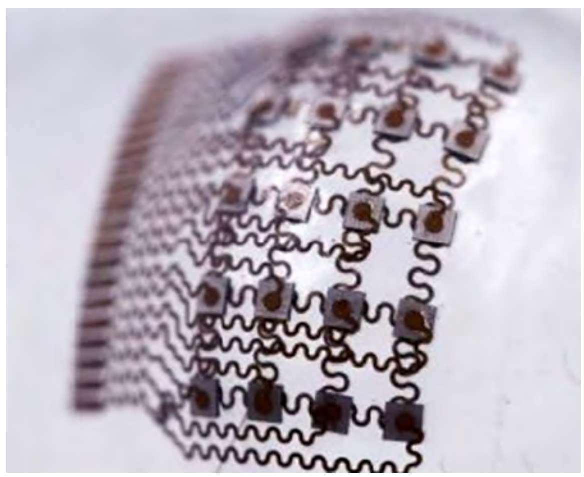


Figure 3: Ultrasound patch islands and bridges.

ic parts connected by spring-shaped wires. Each island contains electrodes and devices called piezoelectric transducers that produce ultrasound waves when electricity passes through them. The bridges connecting them are made of thin, spring-like copper wires. The island-bridge structure allows the entire patch to conform to the skin and stretch, bend, and twist without compromising electronic function.

The patch uses ultrasound waves to continuously record the diameter of a pulsing blood vessel located as deep as four centimeters below the skin. This information then gets translated into a waveform using customized software. Each peak, valley, and notch in the waveform—as well as the overall shape of the waveform—represents a specific activity or event in the heart. These signals provide detailed information to doctors assessing a patient's cardiovascular health. They can also be used to predict heart failure, determine if the blood supply is fine, etc.

Next Steps

Researchers note that the patch still has a long way to go before it reaches clinics. Improvements include integrating a power source, data processing units, and wireless communication capability into the patch.

"Right now, these capabilities have to be delivered by wires from external devices. If we want to move this from benchtop to bedside, we need to put all these components on board," said Xu.

The team is looking to collaborate with experts in data processing and wireless technologies for the next phase of the project.

The paper, "Monitoring of the Central Blood Pressure Waveform via a Conformal Ultrasonic Device," is published in the journal *Nature Biomedical Engineering.* Joint co-authors include Xiaoshi Li, Hongjie Hu, Lin Zhang, Zhenlong Huang, Muyang Lin, Zhuorui Zhang, Zhenan Yin, Hua Gong, Shubha Bhaskaran, Yue Gu, Mitsutoshi Makihata, Yuxuan Guo, Yusheng Lei, Yimu Chen, Yang Li, Tianjiao Zhang, Albert P. Pisano, and Liangfang Zhang (UC San Diego); Chunfeng Wang (Zhengzhou University); and Zeyu Chen and Qifa Zhou (University of Southern California).

This project was supported by the National Institutes of Health and the Center for Wearable Sensors at UC San Diego. PCB007

3D Organ-on-a-chip Could Accelerate Search for New Disease Treatments

Researchers have developed a three-dimensional (3D) organ-on-a-chip that enables continuous real-time monitoring of cells and could be used to develop new treatments for disease while reducing the number of animals used in research.

The device—which incorporates cells inside a 3D transistor made from a soft sponge-like material inspired by native tissue structure—gives scientists the ability to study cells and tissues in new ways. By enabling cells to grow in three dimensions, the device more accurately mimics the way that cells grow in the body.

Led by the University of Cambridge, the researchers say their device could be modified to generate multiple types of organs—such as a liver-on-a-chip or a heart-on-a-chip—ultimately leading to a body-on-a-chip that would simulate how various treatments affect the body as a whole. Their results are reported in the journal *Science Advances.*

Traditionally, biological studies were (and still are) done in Petri dishes where specific types of cells are grown on a flat surface. While many of the medical advances made since the 1950s—including the polio vaccine—have originated in Petri dishes, these two-dimensional (2D) environments do not accurately represent the native 3D environments of human cells and can lead to misleading information and failures of drugs in clinical trials.

Dr. Charalampos Pitsalidis

According to Dr. Róisín Owens from Cambridge's Department of Chemical Engineering and Biotechnology and the study's senior author, while 2D cell models—biological studies traditionally in Petri dishes—have served the scientific community well, research needs to move to 3D cell models to develop the next generation of therapies.

"Three-dimensional cell cultures can help us identify new treatments and know which ones to avoid if we can accurately monitor them," said Dr. Charalampos Pitsalidis, a postdoctoral researcher in the Department of Chemical Engineering & Biotechnology and the study's first author.

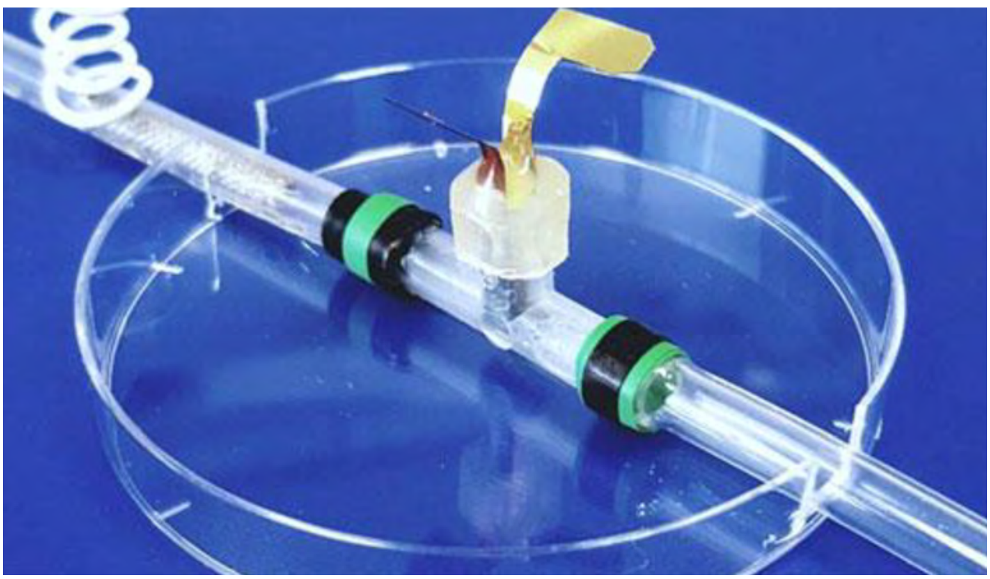
Now, 3D cell and tissue cultures are an emerging field of biomedical research, enabling scientists to study the physiology of human organs and tissues in ways that have not been possible before. However, while these 3D cultures can be generated, a technology that accurately assesses their functionality in real time has not been well-developed.

"The majority of the cells in our body communicate with each other by electrical signals, so in order to monitor cell cultures in the lab, we need to attach electrodes to them," said Dr. Owens, "However, electrodes are pretty clunky and difficult to attach to cell cultures, so we decided to turn the whole thing on its head and put the cells inside the electrode."

The device that Dr. Owens and her colleagues developed is based on a scaffold of a conducting polymer sponge configured into an electrochemical transistor. The cells are grown within the scaffold, and the entire device is then placed inside a plastic tube through which the necessary nutrients for the cells can flow. The use of the soft sponge electrode instead of a traditional rigid-metal electrode provides a more natural environment for cells and is key to the success of organ-on-a-chip technology in predicting the response of an organ to different stimuli.

Other organ-on-a-chip devices need to be completely taken apart to monitor the function of the cells, but since the Cambridge-led design allows for continuous real-time monitoring, it is possible to carry out longer-term experiments on the effects of various diseases and potential treatments.

"With this system, we can monitor the growth of the tissue and its health in response to external drugs or toxins," said Dr. Pitsalidis, "Apart from toxicology testing, we can also induce a particular disease in the tissue, and study the key mechanisms involved in that disease or discover the right treatments."



3D organ-on-a-chip.

The researchers plan to use their device to develop a gut-on-a-chip and attach it to a brain-on-a-chip to study the relationship between the gut microbiome and brain function as part of the IMBIBE project funded by the European Research Council.

The researchers have filed a patent for the device in France. PCB007

How to Mass Produce Cell-sized Robots

by David L. Chandler,
Massachusetts Institute of Technology

Tiny robots no larger than a cell could be mass-produced using a new method developed by researchers at the Massachusetts Institute of Technology (MIT). The microscopic devices—which the team calls "syncells" (short for synthetic cells)—might eventually be used to search for disease while floating through the bloodstream, or to monitor conditions inside an oil or gas pipeline.

To make such tiny devices in large quantities, the team developed a method called autoperforation to control the natural fracturing process of atomically-thin, brittle materials, directing the fracture lines so that they produce miniscule pockets of a predictable size and shape. Embedded inside these pockets are electronic circuits and materials that can collect, record, and output data.

The novel process is described in a paper published in the journal *Nature Materials* by MIT Professor Michael Strano, postdoc Pingwei Liu, graduate student Albert Liu, and eight others at MIT.

The system uses a two-dimensional (2D) form of carbon called graphene, which forms the outer structure of the tiny syncells. One layer of the material is laid down on a surface, then small dots of a polymer material containing the electronics for the devices are deposited by a sophisticated laboratory version of an inkjet printer. Then, a second layer of graphene is laid on top.

"We discovered that you can use the brittleness," says Strano, who is the Carbon P. Dubbs Professor of Chemical Engineering at MIT. "It's counterintuitive. Before this work, if you told me you could fracture a material to control its shape at the nanoscale, I would have been incredulous."

However, the new system does just that. It controls the fracturing process so that rather than generating random shards of material, like the remains of a broken window, it produces pieces of uniform shape and size. "You can impose a strain field to cause the fracture to be guided, and you can use that for controlled fabrication," Strano says.

When the top layer of graphene is placed over the array of polymer dots, which form round pillar shapes, the places where the graphene drapes over the round edges of the pillars form lines of high strain in the material. As Liu describes it, "Imagine a tablecloth falling slowly down onto the surface of a circular table. One can very easily visualize the developing circular strain toward the table edges, and that's very much analogous to what happens when a flat sheet of graphene folds around these printed polymer pillars."

As a result, the fractures are concentrated along those boundaries, Strano says, "And then something pretty amazing happens—the graphene will completely fracture, but the fracture will be guided around the periphery of the pillar." The result is a neat, round piece of graphene that looks as if it had been cleanly cut out by a microscopic hole punch.

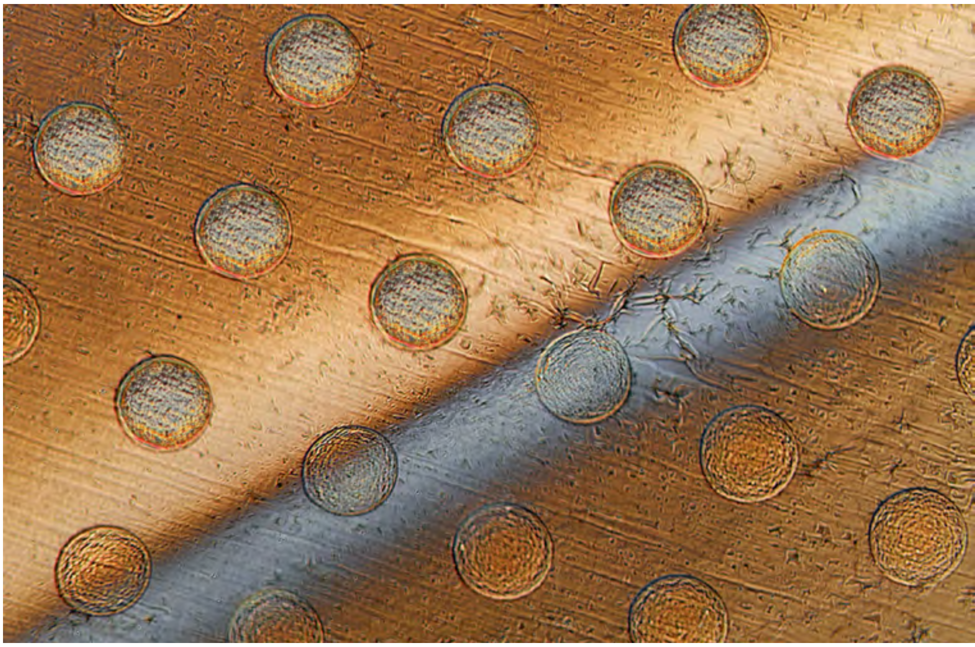
Because there are two layers of graphene above and below the polymer pillars, the two resulting disks adhere at their edges to form something like a tiny pita-bread pocket with the polymer sealed inside. "The advantage here is that this is essentially a single step," Strano says, in contrast to many complex cleanroom steps needed by other processes to try to make microscopic robotic devices.

The researchers have also shown that other 2D materials in addition to graphene, such as molybdenum disulfide and hexagonal boronitride, work just as well.

Cell-like Robots

Ranging in size from that of a human red blood cell—about 10 micrometers across—up to about 10 times that size, these tiny objects "start to look and behave like a living biological cell," according to Strano. "In fact, under a microscope, you could probably convince most people that it is a cell," he says.

This work follows up on earlier research by Strano and his students on developing syncells that could gather information about the chemistry or other properties of their surroundings using sensors on their surface and store the information for later retrieval. For example, injecting a swarm of such particles in one end of a pipeline and retrieving them at the other to gain data about conditions inside it. While the new syncells do not yet have as many capabilities as the earlier ones—which were assembled individually—this work demonstrates a way of easily mass-producing such devices.



Circles on a graphene sheet where the sheet is draped over an array of round posts, creating stresses that will cause these discs to separate from the sheet. The gray bar across the sheet is liquid being used to lift the discs from the surface. (Source: MIT)

Apart from the syncells' potential uses for industrial or biomedical monitoring, the way the tiny devices are made is innovative and has great potential, according to Liu. "This general procedure of using controlled fracture as a production method can be extended across many length scales," he says, "[It could potentially be used with] essentially any 2D materials of choice in principle, allowing future researchers to tailor these atomically-thin surfaces into any desired shape or form for applications in other disciplines."

According to Liu, this is one of the only ways available right now to produce stand-alone integrated microelectronics on a large scale that can function as independent, free-floating devices. Depending on the nature of the electronics inside, the devices could be provided with capabilities for movement, detection of various chemicals or other parameters, and memory storage.

There is a wide range of potential new applications for cell-sized robotic devices, says Strano, who details many possible uses in a book he co-authored with Shawn Walsh, an expert at Army Research Laboratories, on the subject—Robotic Systems and Autonomous Platforms—which is being published by Elsevier Press.

As a demonstration, the team "wrote" the letters M, I, and T into a memory array within a syncell, which stores the information as varying levels of electrical conductivity. This information can then be "read" using an electrical probe, showing that the material can function as a form of electronic memory into which data can be written, read, and erased at will. It can also retain the data without the need for power, allowing information to be collected at a later time. The researchers have demonstrated that the particles are stable over months even when floating in water, which is a harsh solvent for electronics, according to Strano.

"It opens up a whole new toolkit for microfabrication and nanofabrication," he says.

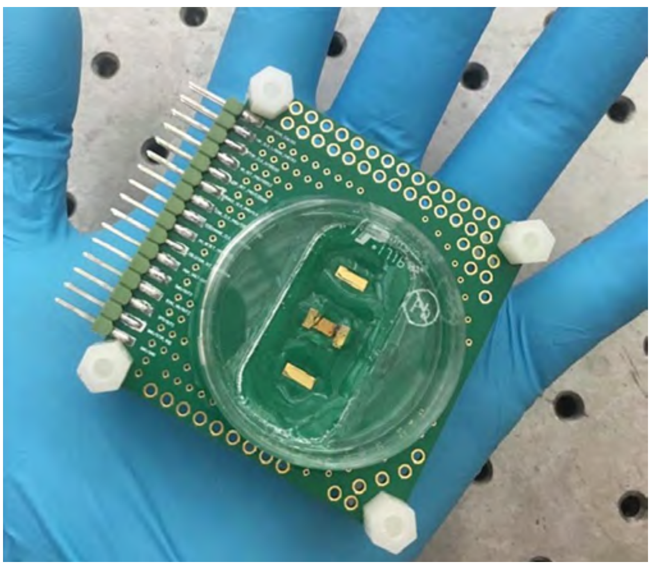
Strano's team also included MIT graduate student Jing Fan Yang; postdocs Daichi Kozawa, Juyao Dong, and Volodomyr Koman; Youngwoo Son, research affiliate Min Hao Wong; Dartmouth College student Max Saccone; and visiting scholar Song Wang. The work was supported by the Air Force Office of Scientific Research, and the Army Research Office through MIT's Institute for Soldier Nanotechnologies. **PCB007**

New Chip Measures Multiple Cellular Responses to Speed Drug Discovery

by Kenna Simmons, Georgia Institute of Technology

Researchers from the Georgia Institute of Technology have designed a cellular interfacing array using low-cost electronics that measures multiple cellular properties and responses in real time. This could enable more potential drugs to be comprehensively tested for efficacy and toxic effects much faster. Hua Wang, associate professor in the School of Electrical and Computer Engineering at Georgia Tech, describes it as "helping us find the golden needle in the haystack."

Pharmaceutical companies use cell-based assays—a combination of living cells and sensor electronics—to measure physiological changes in the cells. That data is used for high-throughput screening (HTS) during drug discovery. In this early phase of drug development, the goal is to identify target pathways and promising chemical compounds that could be developed further and to eliminate those that are ineffective or toxic, by measuring the physiological responses of the cells to each compound. Phenotypic testing of thousands of candidate compounds with the majority failing early allows only the most promising ones develop into drugs and undergo clinical trials where drug failure is much more costly. However, most existing cell-based assays use electronic sensors that can only measure one physiological property at a time and cannot obtain holistic cellular responses.



Built on standard CMOS technologies, the cellular sensing array chip uses a standard 35-mm cell culture dish with the bottom removed to host the cells and expose them to the sensing surface. (Source: Georgia Tech)

That's where the new cellular sensing platform comes in. "The innovation of our technology is that we are able to leverage the advance of nanoelectronic technologies to create cellular interfacing platforms with massively parallel pixels," said Wang, "Within each pixel, we can detect multiple physiological parameters from the same group of cells at the same time."

The experimental quad-modality chip features extracellular or intracellular potential recording, optical detection, cellular impedance measurement, and biphasic current stimulation.

Wang said the new technology offers four advantages over existing platforms:

1. Multimodal sensing: The chip's ability to record multiple parameters on the same cellular sample gives researchers the ability to comprehensively monitor complex cellular responses, uncover the correlations among those parameters, and investigate how they may respond together when exposed to drugs.

2. Large field of view: The platform allows researchers to examine the behavior of cells in a large aggregate to see how they respond collectively at the tissue level.

3. Small spatial resolution: Researchers can look at cells at the tissue level and examine them at single-cell or even sub-cellular resolution.

4. Low-cost platform: The new array platform is built on standard complementary metal oxide semiconductor (CMOS) technologies—which is also used to build computer chips—and can be easily scaled up for mass production.

Wang's team worked closely with Hee Cheol Cho, associate professor and the Urowsky-

Sahr Scholar in Pediatric Bioengineering, whose heart regeneration lab is part of the Wallace Coulter Department of Biomedical Engineering at Georgia Tech and Emory University. They used neonatal rat ventricular myocytes and cardiac fibroblasts to illustrate the multiparametric cell profiling ability of the array for drug screening. The results were published in the Royal Society of Chemistry's journal *Lab on a Chip*.

Monitoring cellular responses in multiphysical domains and holistic multiparametric cellular profiling should also prove beneficial in screening out chemical compounds that could have harmful effects on specific organs, according to Jong Seok Park, a post-doctoral fellow in Wang's lab and a leading author of the study. Many drugs have been withdrawn from the market after discoveries that they had toxic effects on the heart or liver, for example. This platform should enable researchers to comprehensively test for organ toxicity and other side effects at the initial phases of drug discovery.

The experimental chip may be useful for other applications, including personalized medicine (e.g., testing cancer cells from a particular patient). "Patient-to-patient variation is huge, even with the same type of drug," said Wang. The cellular interface array could be used to see which combination of existing drugs would give the best response and find the optimum dose that is most effective with minimum toxicity to healthy cells.

The chip is capable of actuation as well as sensing. In the future, Wang said that cellular data from the chip could be uploaded and processed, and based on that, commands for new actuation or data acquisition could be sent to the chip automatically and wirelessly. He envisions multiple rooms containing culture chambers with millions of chips in fully automated facilities, "automatically doing new drug selection for us," he said.

Beyond these applications, Wang noted the scientific value of the research itself. Integrated circuits and nanoelectronics are some of the most sophisticated technology platforms created by humans. Living cells, on the other hand, are complex products produced through billions of years of natural selection and evolution.

"The central theme of our research is how we can leverage the best platform created by nature with the best platform created by humans," he said. "Can we let them work together to create hybrid systems that achieve capabilities beyond biology only or electronics only systems? The fundamental scientific question we are addressing is how we can let inorganic electronics better interface with organic living cells."

These researchers also participated in the related studies: Doohwan Jung, Adam Wang, Taiyun Chi, Sensen Li, and Moez K. Aziz from the School of Electrical and Computer Engineering at Georgia Tech; and Sandra I. Grijalva and Michael N. Sayegh from the Department of Biomedical Engineering at Emory University.

The research was funded in part by the National Science Foundation CAREER Award and ECCS CCSS Program, National Science Foundation Graduate Research Fellowship (grant numbers DGE-1148903 and DGE-1650044), Office of Naval Research, and Semiconductor Research Corporation SSB roadmap consortium. **PCB007**

Wireless Device Aids Breast Cancer Patient Recovery

by Joanna Wilson, Imperial College London

An international team led by Imperial College London and funded by the Engineering and Physical Sciences Research Council (EPSRC) has developed a wireless bio-patch as part of the Smart Sensing for Surgery project.

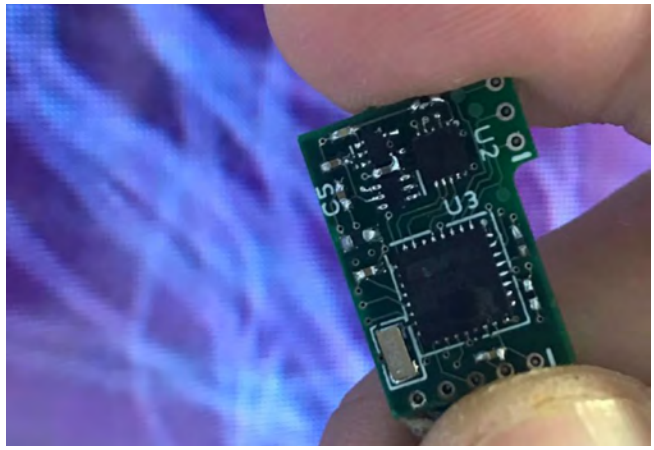
Incorporating 1.8 x 1.1 cm electronics measuring, the bio-patch was attached to patients for 48 hours following breast reconstruction surgery. It successfully performed continuous monitoring of the level of oxygen saturation in transferred tissue—a key indicator of whether there is a risk of reconstruction failure.

"Poor blood supply or failure of breast reconstruction surgery can have a major impact on a breast cancer patient's recovery, prognosis, and mental wellbeing. Clinical signs of failure often occur late, and patients may be returned to the operating room on clinical suspicion," said Professor Guang-Zhong Yang, director of Imperial's Hamlyn Centre and the lead of the Smart Sensing for Surgery project, "Our new bio-patch tackles this problem by providing objective data as an early warning system for medical staff, enabling earlier and simpler interventions, as well as giving patients increased peace of mind."

Breast reconstruction surgery following a mastectomy routinely includes transferring the patient's own tissue to help rebuild the breast. This procedure achieves high success rates, but early detection of possible problems could help to reduce post-surgical complications further and cut surgery failure rates.

Harnessing a technique known as near-infrared spectroscopy (NIRS), the new device safely captures and transmits data using sensors sealed inside fully biocompatible materials. The data is encrypted to ensure security and privacy.

Early trials have opened up the prospect of the bio-patch becoming available for widespread clinical use within two to three years. The project team is currently exploring the scope to secure commercial or National Institute for Health Research (NIHR) support for the next stage of development and commercialization. The device is now being adapted to help monitor conditions such as dementia and chronic obstructive pulmonary disease (COPD).



Imperial College London—The new sensing device can provide early warning of potential failure of breastreconstruction surgery. (Source: Imperial College London—Wireless)

The Smart Sensing for Surgery project has achieved other promising advances, including the development of sensors that can be implanted just under the skin to provide continuous measurement of pulse rate, temperature, and pH balance, and smart catheters or drains enabling problems to be spotted earlier. The project ran from June 2014 to October 2018 and received just over £3 million in EPSRC support. **PCB007**

Electronic Pacemaker Inventor Ed Bakken Passes Away

Earl Bakken, an electronics repairman who created the first wearable external pacemaker and co-founded one of the world's largest medical device companies, Medtronic, passed away on October 21, 2018. He was 94 years old.

Medtronic Chairman and CEO Omar Ishrak, made a statement that Bakken's brilliance and vision have improved the lives of millions of people around the world. "The contributions Earl made to the field of medical technology simply cannot be overstated. His spirit will live on with us as we work to fulfill the mission he wrote nearly 60 years ago—to alleviate pain, restore health, and extend life. Our thoughts and prayers are with the Bakken family during this difficult time," he said.

Bakken founded Medtronic with his brother-in-law Palmer J. Hermundslie in 1949. Before retiring as chairman in 1989, he led Medtronic for 40 years, guiding the company from its humble roots to the world's premier medical technology company.

Born in Columbia Heights, Minnesota, Bakken graduated from high school in 1941 and enlisted in the Army Signal Corps where he served in World War II as a radar instructor. After leaving the army, he attended the University of Minnesota, earning a degree in electrical engineering.

As a graduate student, Bakken worked part-time repairing delicate lab equipment at Northwestern Hospital in Minneapolis. Demand for these services grew, and on April 29, 1949, Bakken and Hermundslie formed a business partnership. They named the company Medtronic with its headquarters in a modified garage in northeast Minneapolis.

Earl Bakken, Medtronic co-founder

While installing and servicing devices used during early open-heart surgeries, Bakken and Hermundslie built relationships with physicians at in the local area. The late C. Walton Lillehei, a young staff surgeon at the time, pioneered procedures to help "blue babies" born with often-lethal heart defects. Following a power outage in the Twin Cities (Minneapolis and St. Paul, Minnesota) that caused the death of an infant, Dr. Lillehei asked Bakken to find a solution.

Bakken responded by building the world's first wearable, transistorized pacemaker. He adapted a circuit described for a transistorized electronic metronome in the magazine Popular Electronics. This milestone is viewed by many as the birth of Medtronic. However, pacemakers were only one product in a growing and increasingly diverse product line.

In 1960, in an effort to more clearly define Medtronic's values and areas of concentration, Bakken wrote Medtronic's mission, which has guided the company and remains unchanged.

In 1994, Bakken moved to the Big Island of Hawaii. As a resident, he was a prominent volunteer and philanthropist. He became Chairman of the Board of Directors of the Five Mountain Medical Community as it developed the North Hawaii Community Hospital. While on the board, he also helped to establish Tutu's House—a community resource center promoting careers, education, and effective health outcomes—and the Kohala Center, a community-based center for research, conservation and education.

In 1975, he founded The Bakken Museum—a nonprofit library, museum, and education center in Minneapolis. The museum is devoted to the history of electricity and magnetism and their uses in science and medicine.

Bakken's passion for philanthropy did not wane in his later years. In 2013, he launched The Bakken Invitation, which honors patients whose lives have been extended thanks to medical technology and who have used this gift of extra life to make an impact through service and volunteerism. Bakken Invitation honorees receive a donation to their cause along with a trip to Hawaii to take part in a special ceremony.

Bakken also was involved in several other philanthropic ventures, including Na Kalai Waa Moku O Hawaii, Friends of the Future, and the Imiloa Astronomy Center of Hawaii.

In December 2007, at age 83, Bakken became the first recipient of an honorary medical degree from the University of Minnesota, recognizing his contributions in the medical field. During his life, he also received honorary doctorates from the Universities of Hawaii, Tulane, and the Albany College of Pharmacy.

In 1981, Bakken received an Outstanding Achievement Award from the University of Minnesota, and his cardiac pacemaker was named one of the 10 most outstanding engineering achievements of the last half century by the National Society of Professional Engineers in 1984. Further, he was named to the Minnesota Inventors Hall of Fame in 1995. In 2014, Bakken received the Lifetime Achievement Award from the Advanced Medical Technology Association. **PCB007**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Supporting the Digital Transformation in Medicine

To prepare computer science students for challenges in the digital medicine area, the Fraunhofer MEVIS Institute for Medical Image Computing—one of the world's leading research centers in digital medicine—and the University of Bremen are now cooperating even more closely in teaching.

Today, digital medicine plays an important role in everyday clinical life in healthcare, diagnosis, surgery, and treatment. The aim of this partnership is for physicians to make the best use of the possibilities offered by big data, artificial intelligence (AI), and image-based medicine.

The new study focus of medical computing in the Faculty of Mathematics and Computer Science at the University of Bremen reflects groundbreaking developments in this field. For example, students gain insights into medical image processing and methods that can help physicians analyze increasingly complex situations. To create a connection to practice, clinic employees also come to the university and are integrated into teaching operations.

Dr. Hans Meine, senior research scientist and computer scientist at MEVIS, explains how medical computing helps to analyse medical images. (Source: MEVIS)

Headed by the physicist Horst Hahn and the physician Ron Kikinis, Fraunhofer MEVIS has been closely associated with the University of Bremen since its beginnings. Today's research center emerged from the Center for Complex Systems and Visualization (CeVis) at the University of Bremen, which was founded in 1992, and similar to the university, is a member of the U Bremen Research Alliance. In addition to the university, the members of the association include 11 non-university research institutes from the region that are financed by state and federal governments. Employees of Fraunhofer MEVIS not only conduct joint research projects with colleagues from the University of Bremen, but have also been active in university teaching for many years.

Harvard Professor Kikinis came to Bremen in 2014. Among other things, he heads the medical image computing working group at the Faculty of Mathematics and Computer Science. Professor Matthias Günther, head of the MR (magnetic resonance) physics working group at Fraunhofer MEVIS and professor of physics, has been teaching at the university since 2009. In addition, he conducts research in the laboratory of magnetic resonance tomography, which has been operated jointly with the university since 2011. **PCB007**

Sugar-powered Sensor Detects and Prevents Disease

A cross-disciplinary research team led by Subhanshu Gupta, assistant professor in Washington State University's School of Electrical Engineering and Computer Science, has developed an implantable, biofuel-powered sensor that runs on sugar and can monitor a body's biological signals to detect, prevent, and diagnose diseases. The sensor could also remove the need to prick a finger for testing of certain diseases, such as diabetes.

Professors Su Ha and Alla Kostyukova from the Gene and Linda School of Chemical Engineering and Bioengineering led the design of the biofuel cell. Their work recently was published in the *IEEE Transactions on Circuits and Systems journal.* The research team has demonstrated a unique integration of the biofuel

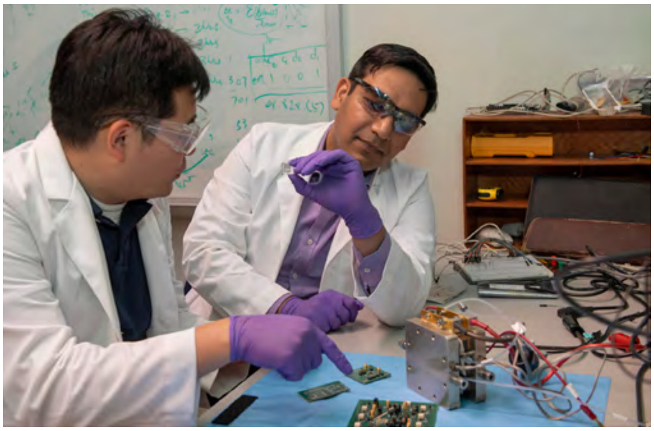


Figure 1: Professor Su Ha (L) and Assistant Professor Subhanshu Gupta (R).

Figure 2: Researchers examine a biofuel cell.

cell with electronics to process physiological and biochemical signals with high sensitivity.

The electronics in the sensor use state-of-the-art design and fabrication to consume only a few microwatts of power while being highly sensitive. Coupling these electronics with the biofuel cell makes it more efficient than traditional battery-powered devices, according to Gupta. Since it relies on body glucose, the sensor's electronics can be powered indefinitely. For example, the sensor could run on sugar produced just under the skin.

Gupta said that unlike commonly used lithium-ion batteries, the biofuel cell is also completely non-toxic, making it more promising as an implant for humans. It is also more stable and sensitive than conventional biofuel cells. Further, the researchers say their sensor could be manufactured cheaply through mass production by leveraging economies of scale.

While the sensors have been tested in the lab, the researchers are hoping to test and demonstrate them in blood capillaries, which will require regulatory approval. The researchers are also working on further improving and increasing the power output of their biofuel cell.

The research team also included Yuehe Lin and Annie Du from the School of Mechanical and Materials Engineering, and Martin Schiavenato with Walden University (formerly with WSU's College of Nursing).

A WSU Grand Challenges seed grant funded the project to develop the sensor. **PCB007**

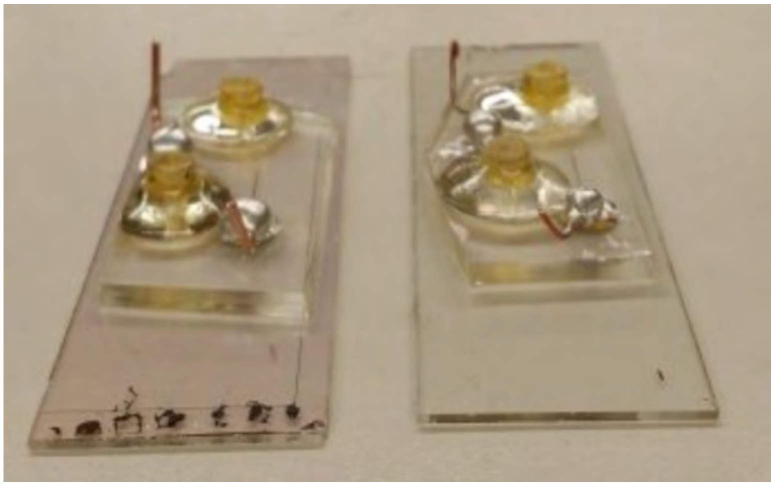
Researchers Develop Clear and Biocompatible Lab-on-a-chip

by Allison Mills, Michigan Technological University

A team from Michigan Technological University studying chemical engineering, electrical engineering, and materials science streamlined the design of microfluidic devices to be see-through to observe their inner workings. Using hair-thin tunnels and equally tiny electrodes, these devices funnel fluids through an electric current to sort cells, find diseases, and run diagnostic tests.

The problem is that biological samples are not inert—they are charged and ready to interact. When fluids come into contact with microdevice electrodes, tiny explosions can happen. However, exploding red blood cells caused by an ion imbalance that bursts cell membranes in a process called lysis defeat the point of testing blood sugar levels or types. In other tests, like those for cancer or infectious disease, messing with sample chemistry can lead to false negatives or positives. Interactions between samples and electrodes (Faradaic reactions) can be an unwanted side effect in microfluidics.

To preserve the integrity of samples and maintain a transparent surface to observe what's going on inside the device, Michigan Tech engineers detail how thin hafnium oxide layers act like a cellphone screen protector for microdevices. Their work was recently published in the journal *Thin Solid Films.*



Hafnium oxide coats the left device and provides both sample protection and optical transparency to help improve the study of microfluidic medical devices.

Designing a Lab-on-a-chip

Jeana Collins, lecturer of chemical engineering at Michigan Tech, is the first author on the paper. She explains how the lab-on-a-chip uses a process called dielectrophoresis. "The dielectrophoretic response is a movement," she says, "And how can you tell it moved? By watching it move."

Collins goes on to explain that a non-uniform electric field from the electrodes interacts with the charge on the particles or cells in a sample, causing them to migrate. Many biological lab-on-a-chip devices rely on this kind of electrical response.

"As chemical engineers, we deal more with the fluidics side," Collins says, adding that the electronics are also key and a blood glucose meter is a prime example, "You have the blood—that's your fluid—and it goes in, you have a test done, then you get a digital readout. So, it's a combination of fluidics and electronics."

Even though a commercialized lab-on-a-chip like a glucose meter is covered, Collins and other engineers need to see what's going on to get a clear picture under a microscope. That's why hafnium oxide, which leaves only a slight hue, is useful in their microdevice design development.

Also, the technology does not apply to a single device. Because of its simplicity, the hafnium oxide layer works with many electrode designs, maintains a consistent dielectric constant of 20.32, and is hemocompatible, meaning it minimizes the Faradaic reactions that can cause cell lysis and fewer red blood cells explode when they come near the electrodes.

Collins and her team tested three different thicknesses of hafnium oxide—58, 127, and 239 nanometers. They found that depending on the deposition time—6.5, 13, or 20 minutes—the grain size and structure can be tweaked for the needs of specific devices. The only potential issue would be for fluorescence-based microdevices because the hafnium oxide does interfere with certain wavelengths. However, the layer's optical transparency makes it a good solution for many biological lab-on-a-chip tests.

The project's success is directly tied to the team's complementary skills. By bringing together chemical engineers, electrical engineers, and materials scientists in the Michigan Tech Microfabrication Shared User Facility, they were able to push the boundaries of all their fields.

"Microdevice design has tended toward increasing levels of complexity where each level of complexity increases the probability of failure," says Adrienne Minerick, dean of the School of Technology, professor of chemical engineering, and Collins' doctoral adviser. "Simple solutions—while challenging to find—can provide robust, failure-resistant solutions for a wide range of applications. We explored numerous polymeric and inorganic films."

The other co-authors include Hector Moncada Hernandez, Sanaz Habibi, and Zhichao Wang from the Department of Chemical Engineering; and Chito Kendrick, Nupur Bihari, and Paul Bergstrom from the Department of Electrical and Computer Engineering. **PCB007**

3D Bioprinting Artificial Blood Vessels and Organ Tissues

by Trent Knoss, University of Colorado Boulder

University of Colorado Boulder engineers have developed a 3D printing technique that allows for localized control of an object's firmness, opening up new biomedical avenues that could one day include artificial arteries and organ tissue.

The study outlines a layer-by-layer printing method that features fine-grain, programmable control over rigidity, allowing researchers to mimic the complex geometry of blood vessels that are highly structured, yet must remain pliable. The paper was published in the journal *Nature Communications.*

The findings could one day lead to better, more personalized treatments for those suffering from hypertension and other vascular diseases.

"The idea was to add independent mechanical properties to 3D structures that can mimic the body's natural tissue," said Xiaobo Yin, an associate professor in CU Boulder's Department of Mechanical Engineering and the senior author of the study, "This technology allows us to create microstructures that can be customized for disease models."

Hardened blood vessels are associated with cardiovascular disease, but engineering a solution for viable artery and tissue replacement has historically proven challenging. To overcome these hurdles, the researchers found a unique way to take advantage of oxygen's role in setting the final form of a 3D-printed structure.

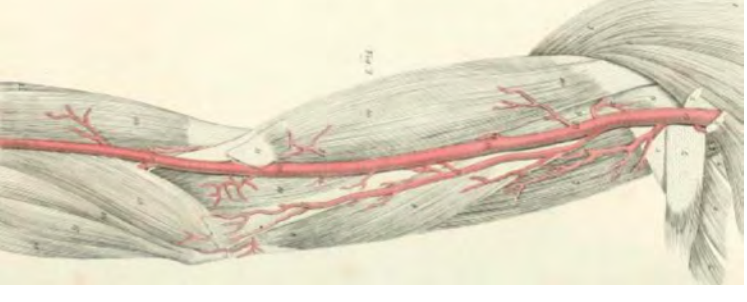


Photo: A new 3D printing technique could lead to new biomedical opportunities. (Source: UC Boulder)

Yonghui Ding, a postdoctoral researcher in mechanical engineering and the lead author of the study, said oxygen usually causes incomplete curing. "Here, we utilize a layer that allows a fixed rate of oxygen permeation," he said.

By keeping tight control over oxygen migration and its subsequent light exposure, the researchers have the freedom to control which areas of an object are solidified to be harder or softer all while keeping the overall geometry the same. "This is a profound development, and an encouraging first step toward our goal of creating structures that function as a healthy cell should," Ding said.

As a demonstration, the researchers printed three versions of a simple structure: a top beam supported by two rods. The structures were identical in shape, size, and materials, but printed with three variations in rod rigidity: soft-soft, hard-soft, and hard-hard. The harder rods supported the top beam while the softer rods allowed it to fully or partially collapse.

The researchers repeated the feat with a small Chinese warrior figure, printing it so that the outer layers remained hard while the interior remained soft, leaving the warrior with a tough exterior and a tender heart, so to speak.

The tabletop-sized printer is currently capable of working with biomaterials down to a size of 10 microns, or about one-tenth the width of a human hair. The researchers are optimistic that future studies will help improve the capabilities even further.

"The challenge is to create an even finer scale for the chemical reactions," said Yin, "But we see tremendous opportunity ahead for this technology and the potential for artificial tissue fabrication."

Additional co-authors of the new study include Hang Yin, Yao Zhai, and Associate Professor Wei Tan of mechanical engineering. The National Science Foundation and the National Institutes of Health provided funding for the research. **PCB007**

Low-temperature Solder Gaining Ground

At the recent SMTA International Conference in Rosemont, Illinois, one notable topic seeing increased interest in the industry is the board reliability of low-temperature solder (LTS). LTS is gaining attention for multiple reasons, including lower power consumption, less warpage, higher assembly yields, and a possible path to more complex assemblies. Presently, much work is being performed to compare the reliability of LTS with the conventional SAC (tin-silver-copper) alloy. Some of that work was presented at the conference.

iNEMI's investigations of third-generation lead-free alloys presented by Richard Coyle showed that such alloys provide significantly better high-reliability accelerated thermal cycling (ATC) performance than traditional SAC alloy, in one case, doubling 0/100°C characteristic life. Among these alloys was an indium-containing SAC alloy that one might consider to be an LTS (202–206°C liquidus). A homogenous assembly of this alloy in which the paste and solder ball alloys are the same had equal to or better characteristic life as a homogeneous SAC alloy in 0/100°C, 40/125°C, and -55/125°C ATC; however, it had earlier first failure in -55/125°C ATC [1].

In a paper reporting the potential of what is considered to be true LTS for enterprise computing and automotive electronics, Paul Wang and his team at Mitac point out that backward compatibility will be important. Their ATC testing is not complete, but they reported that their mixed assembly using tin-bismuth LTS paste (130–140°C liquidus) and SAC solder balls (Figure 1) is exhibiting earlier failures in -40/100°C ATC than their homogenous LTS assembly [2]. Other work reported this year by Satyajit Walwadkar et al. at Intel investigates the use of a novel method to determine the mechanical fatigue performance of solder using only a single solder joint corroborates what Wang reported. Joints made with tin-bismuth LTS pastes (140–150°C liquidus) and SAC405 solder balls did not perform as well as their homogeneous SAC joint [3].

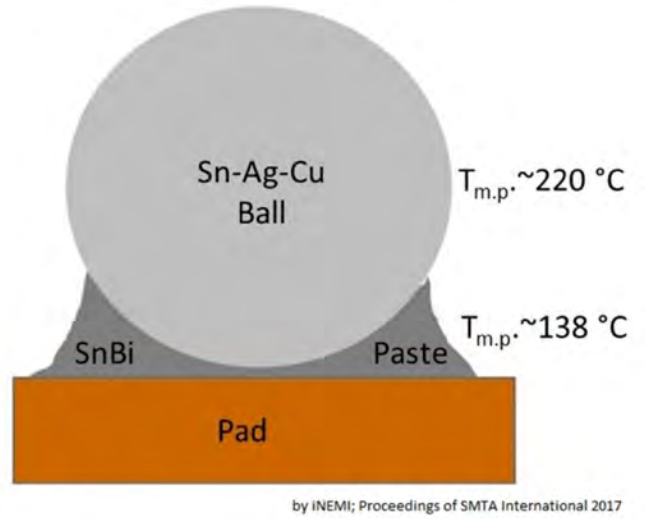


Figure 1: Mixed assembly with SAC ball and LTS paste.

Wang expressed concern that tin-bismuth LTS alloys, being more brittle, would not perform as well in mechanical shock testing. That concern was shown to be well-founded by results reported in another iNEMI paper by Jagadeesh Radhakrishnan et al. Tin-bismuth LTS (liquidus 125–139°C) exhibited a significantly lower drop in test performance compared to SAC305. The iNEMI team also looked at improving performance using solder pastes that create a polymeric reinforcement referred to by some as a polymer collar. The reinforcement improved drop performance, but it could not match the baseline performance of SAC [4]. In their paper, Wang suggested that an edgebond adhesive might be used to enhance drop test performance. Figure 2 illustrates how such an adhesive would be used.

Using an edgebond adhesive to enhance mechanical shock performance raises the concern over what effect such an adhesive would have on board level reliability. That matter was investigated and reported on by Professor Taekyu Lee of Portland State University. A mixed assembly—in this case, SAC305 paste with an LTS ball (197°C liquidus)—exhibited poorer -40/125°C ATC performance than the homogeneous SAC assembly. Lee's team looked into the use of a reworkable edgebond adhesive and found that the ATC performance of the mixed

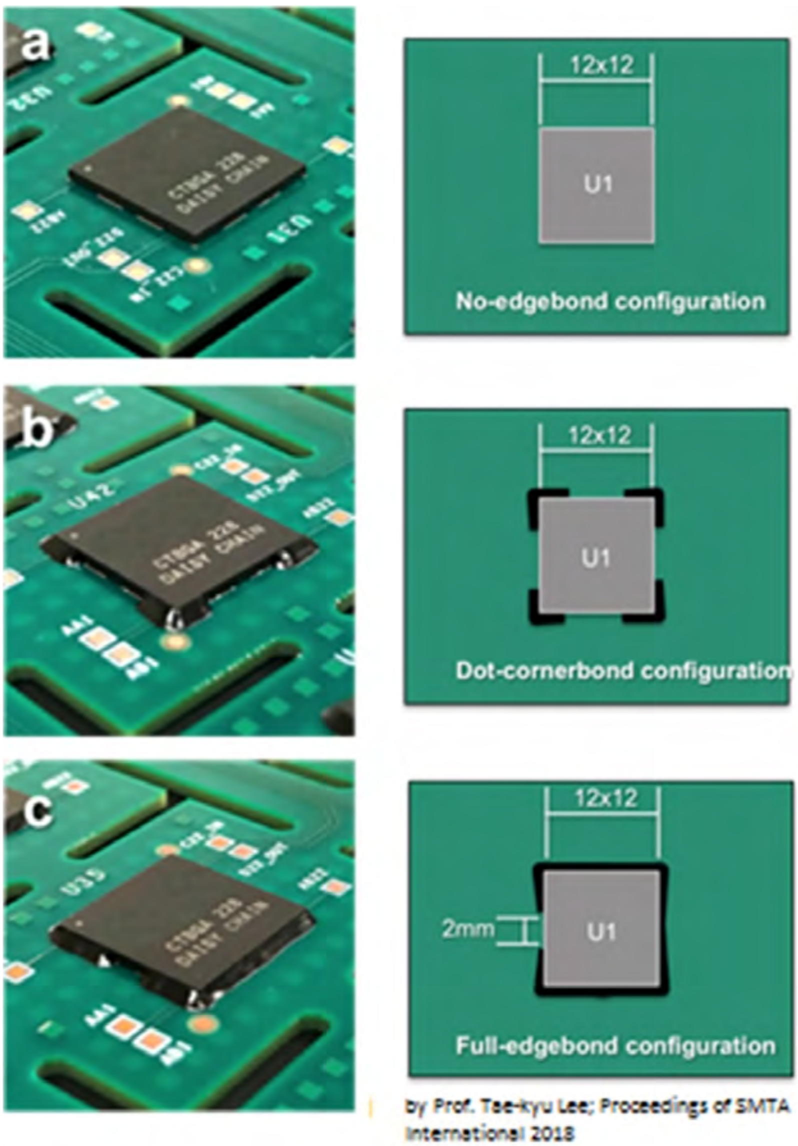


Figure 2: BGAs with and without edgebond adhesive.

assembly with adhesive significantly exceeded that of the homogeneous assembly without adhesive [5]. An edgebond adhesive could be considered to enhance mechanical shock or drop test performance without damaging ATC performance, and as a way to enhance the ATC performance of LTS mixed-alloy assemblies and that of other ATC-challenged assemblies.

Much additional work is needed in the development and investigation of LTS alloys. Among other things, the iNEMI team suggests working to better understand the root cause of the interfacial cracking that they observed in ATC, and proposes the utilization of methods in lieu of scanning electron microscopy (SEM) to identify other phases that appear to be present in the alloys. Their team investigating mechanical shock performance hopes to correlate bismuth mixing and other solder-joint morphology, as well as the extent of polymer reinforcement with drop test results.

Meanwhile, Wang's team plans to push their ATC tests out further and plans to perform drop tests on mixed-alloy assemblies. Having demonstrated that an appropriate reworkable edgebond adhesive will not damage ATC performance and might even enhance it, Lee and his collaborators would like to investigate the use of such an adhesive for enhancing mechanical shock performance of LTS assemblies. Walwadkar and colleagues at Intel—having developed and validated a quick-turn test method—look forward to screening large sets of alloys (LTS or otherwise) for fatigue performance. **PCB007**

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**Editor's Note: All references are from SMTA International 2018 proceedings (October 14-18).*

FDA Approvals: Clearing the Hurdles

Feature by Nolan Johnson
I-CONNECT007

Manufacturers of medical electronics have their work cut out for them. These products have to pass approval by the Food and Drug Administration (FDA) in addition to getting the nod from more typical entities such as Underwriters Laboratories (UL) and Conformité Européene (CE, also known as European Conformity). Most medical device developers will admit that achieving FDA approval can be a big hurdle on the way to new product introduction (NPI).

The need to gain FDA approval may seem daunting. Approvals differ depending on so many different variables: classification, new technology or incremental improvement on existing products, and so much more.

Michael Lynch, quality manager at Libra Industries in Mentor, Ohio, offered a brief explanation of FDA device classifications.

"Everything is risk-based. The FDA uses three main regulatory classes to group medical devices: Class I, Class II, and Class III. Class I devices require the lowest level of regulatory control because they present the lowest level of risk in the form of a low probability of causing injury if they don't work properly. Class I devices are not used to sustain life," said Lynch.

"Class II devices require a higher level of assurance that they will perform without causing harm to the patient than Class I," he continued. "If a Class II device fails, there is a low risk of causing serious injury to the patient. Blood pressure monitoring equipment is a typical example of a Class II device. Though, because patients and staff may be depending upon these devices for feedback, Class II devices are designed and constructed to a high level of assurance that the device will work properly. Class III includes critical care and life support. A malfunction in a Class III device can cause serious injury or death."

Based on the class of the product different pathways, objective evidence and requirements may be necessary. For example, one often-mentioned FDA clearance is Section 510(k) of the Food, Drug, and Cosmetic Act. According to the FDA code of federal regulation, Section

510(k) "requires device manufacturers… to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as premarket notification—also called PMN, or simply 510(k). The premarket notification allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories." The 510(k) process could be considered one of the more well-known approval processes for medical products.

But there are other paths that a design team could follow to complete FDA approval successfully, all of which are worth exploring. We'll look at examples from two new companies: 2C Tech and Project Vive.

Project Vive is a Pennsylvania-based bootstrapped startup creating the VozBox, an affordable, portable, durable communication device for people who have lost the ability to speak. 2C Tech's (Irvine, California) product—although not strictly electronic—delivers an electrical stimulus to the patient's retina. Both products enhance a patient's sensory control in various ways and take different paths through the FDA approval process.

Strict R&D at 2C Tech

2C Tech has been developing a quantum dot (QD) technology that helps patients with degenerative retinal disease to see. The quantum dots are semiconductor crystalline structures a few nanometers in size. These quantum dots are injected into the retina where they absorb light and create an electric signal that the retina will recognize as a single wavelength. In essence, the patient achieves increased clarity in their monochromatic vision.

Jim Taylor, 2C Tech CEO, observed, "Most medical devices progress by 'evolutionary steps' rather than whole new concepts. If the innovators decided they had a way to make a better implantable defibrillator, for example, then a lot of the groundwork and pathway have already been pioneered; the task then is to innovate while leveraging that prior experience."

The 2C Tech technology may be extremely passive in its function, but it is injected into the patient's tissues, making FDA classification of the technology trickier. Classification can have a dramatic impact on the development cycle for a medical product.

Figure 1: Aaron, a 16-year-old with cerebral palsy, is a product tester for ProjectVive. Here a VozBox is being installed with a knee switch to allow Aaron to control the device.

"Just recently, the FDA determined that the 2C Tech technology can be categorized as a medical device and not a drug," stated Astrid Berthe, VP of quality assurance and regulatory affairs for 2C Tech.

Moreover, 2C Tech has been working with the FDA to use early feasibility studies as a pathway to approval. Early feasibility studies are a formalized FDA testing pathway intended to prove the concept of new technology. When discussing how long it would take to go from classification to initial human testing, Berthe said, "Under this classification as a device rather than a drug, we could be conducting our first human early feasibility study within 12 months. Under a drug classification, it would have been much longer—years longer."

Jim Taylor

Project Vive: No Approval Needed

Not every product will need to follow the path to FDA approval. Some devices may be specifically designed for medical patients but are not medical in-and-of themselves.

Mary Elizabeth McCulloch is the founder of Project Vive, a bootstrapped startup creating the affordable, portable, durable VozBox. Her customers and beta testers, for example, might have ALS, cerebral palsy, traumatic brain injuries, etc. These are people whose challenge isn't with thinking, but with communicating and being heard.

"Our device does not need to be FDA approved; I didn't know that for the first few years," said McCulloch. "I thought that I was going to have to spend a lot of money and time. Then, I learned that a lot of medical devices don't need FDA approval."

McCulloch's product is based on a souped-up, ruggedized tablet platform with a variety of peripherals to allow users to control the device: buttons; vision tracking, joysticks, etc.

McCulloch said, "A lot of times—particularly in the ALS community—the process is to apply to get a device. When the devices cost $10,000 to $16,000, it can be hard to be accepted; communication devices are only approved if they're medically necessary. Sometimes insurance won't cover it at all. And if they do, approvals can take two to four months. For someone who has a degenerative disability, if they can't buy a $10,000 device out of pocket, then by the time they get their device, their abilities have already changed so much that some people can't even use that device.

Medicare and Medicaid will cover devices like ours, but we would have to lock the device functionality. Medicare and Medicaid won't cover anything that's not a dedicated speech-generation device used exclusively for communication. With ours, you can access the internet, App Store, and play games."

To McCulloch, that's the whole point of her device.

"We're going for a device people can buy out of pocket. Buy it now and start trying things early on," McCulloch stated. "Medical approvals typically require an 80% speech impairment, as in 'unintelligible.' You can't even get an assistive device until you get to that point? Instead of making this fit into the insurance system, we're making a device that individuals can buy on their own, which is more accessible for them."

Because the VozBox is not physically changing anything about the user, the device does nothing medical to the user. "It's a communication device, just like your cellphone," added McCulloch. "They're just using an alternate access method." VozBox would need a more thorough FDA approval, according to McCulloch, if "it would be in a medical context, such as a hospital or patient treatment setting with some type of medical intervention."

Including FDA Approvals in the Design Phase

In Libra's role as a contract manufacturer, Lynch and his team work closely with the original equipment manufacturers (OEMs) to verify the appropriate levels of reliability and testing required as a device moves up the clas-


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sifications. Higher reliability performance is critical as the classes get higher, so design and manufacturing requirements become more stringent as well. Lynch said, "At Libra, we're the contract manufacturer with a little 'm'; the OEM is the manufacturer with the big 'M.' Between these two groups, success requires a lot of communication between the little m and the big M."

Michael Lynch

The baseline guidelines for manufacturing medical devices, according to Lynch, is 21 CFR part 820—Good Manufacturing Practices for Medical Devices. "This guideline is required for all medical devices," said Lynch, "Everything Class II requires a higher level of reliability than Class I." Lynch added that this reliability often is achieved through design: choice of components, design for manufacturing (DFM) discipline, and design for testability (DFT).

"Class III merely continues the trend toward even higher reliability. A Class III device cannot have a failure because it sustains life," Lynch continued. "Class III also requires clinical testing and a premarket approval."

Understandably, testing requirements increase as a device moves up the classifications. DFT becomes much more important, as does test coverage. Virtually every component on the bill of materials (BOM) requires scrutiny for performance, reliability, and availability.

Lynch gave an example: "We were working with a recent medical device that included an ethernet connector. Originally, the BOM called out a $1 connector. We found in testing that the original connector demonstrated a 2% connection failure rate when the cable was inserted at an angle. By changing to a $3 ethernet connector, we found that the tighter tolerances and different design eliminated the at-angle connection failures. That $3 connector would be the proper level of reliability for a Class III device, but that $1 connector may be acceptable for a Class II device."

Lynch continued, "The point is that each component should be subjected to close performance scrutiny."

Advice from Both Entrepreneurs

It is clear that a key to successfully bringing a new medical technology product to market depends on learning the boundaries around any required FDA approval and making it a part of the design and specification process.

Taylor said, "You can never be too soon," with the question of when to bring the FDA into the discussion with the designers.

How did McCulloch conduct her research? "I learned by going to trade shows and expos and talking with people who had devices similar to mine," she explained. "That's the quickest way. When we went to ATIA—the Assistive Technology International Association—they had products there that were similar to ours, and they said, 'You don't need to get this FDA approved.'"

2C Tech's seminal technical development, according to Taylor, came out of "an idea to pursue a better approach to electrical stimulation of the retina than the artificial retina (implantable chip), and better than other similar prostheses under development. Research on that idea led to the identification of QDs as a possible concept." This sort of breakthrough R&D, coupled with implantation into the body, increases the amount of testing involved in ultimately approving the product.

The FDA suggests following these process steps premarket:

1. Classify your device because it will help you plan your design for appropriate levels of reliability, manufacturability, and testability
2. Choose the correct premarket submission and know your path to market so you can fund your project appropriately
3. Prepare the appropriate information for your premarket submission to the FDA
4. Send your premarket submission to the FDA and interact with staff during the review
5. Complete the establishment registration and device listing

Mary Elizabeth McCulloch

For designers moving into the medical or assistive technologies space, McCulloch advised, "There are a lot of policies, and they're always changing. I would encourage anyone to start reaching out early. There are people in the medical-legal space that know this legislation like the back of their hand. They can tell you why you would want FDA approval or why you wouldn't. Sometimes, it's a little bit of a toss-up on which way to go. How is your device classified? How are you going to label it? If Project Vive were targeting the hospital market, FDA approval would be a good idea, but we're not targeting hospitals. We're targeting the daily quality of life for someone just trying to go about their day."

However, 2C Tech's in-depth R&D approach elicits a different response. "The world of medical devices is drastically different today than it was only 10–15 years ago. Controlled clinical trials and proof of both safety and efficacy are now routinely required even for non-invasive diagnostics, and implantable devices take that to a whole different level of intensity, scrutiny, and complexity," stated Taylor.

"If anything, we're in the therapeutic device section more than a medical device," said McCulloch. "But that is the essence of an assistive medical device, isn't it?"

Taylor's comments contrasted McCulloch's on this topic: "If the innovation is groundbreaking, as is the case with 2C Tech, then the pioneering work is critical, challenging, and potentially very time-consuming."

If you're developing a medical device, find out early in the process whether or not your product requires FDA approval. As always, communication is king, and this is especially true in the medical segment. **PCB007**

KYZEN's Forsythe Discusses Gap in Cleaning Knowledge

At SMTA International 2018, Tom Forsythe, executive vice president of KYZEN Corporation, busts myths around "how clean is clean?" He discusses the increasing cleaning challenges as devices become denser and form factors become even smaller, and how these trends are driving the need for cleaning and causing a gap in cleaning knowledge. Forsythe also speaks about their new products in data collection and monitoring software for cleaning equipment.


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Electronics Industry News and Market Highlights

UVA Faculty Work to Advance the Internet of Things ▶

The "Internet of Things" needs energy-efficient hardware, some of which may come from research developed at the University of Virginia School of Engineering and Applied Science's affiliate of the MIST Center.

Spinning the Light: The World's Smallest Optical Gyroscope ▶

Gyroscopes are devices that help vehicles, drones, and wearable and handheld electronic devices know their orientation in three-dimensional space. They are commonplace in just about every bit of technology we rely on every day.

Robotic Process Automation Market Worth $3B by 2025 ▶

The global market is estimated to expand at a CAGR of 31.1% during the forecast period. Different organizations in different sectors are increasingly challenged by the growing market competition due to shift in technology and changing consumer preferences.

Global Automotive 3D Printing Market to Reach $2.7B by 2023 ▶

As per the report, the global automotive 3D printing market was valued at $930.2 million in 2017 and is projected to reach $2.73 billion by 2023, growing at a CAGR of 19.7% from 2017 to 2023.

Semiconductor Sales Up 15% YoY in August ▶

The Semiconductor Industry Association (SIA) has reported that worldwide sales of semiconductors reached $40.16 billion for the month of August 2018, an increase of 14.9% compared to August last year.

Lockheed Martin Provides Energy Resiliency Solutions to Support U.S. Army Operations ▶

Lockheed Martin is providing energy storage capabilities to support the U.S. Army's efforts to enhance its base resiliency, preserving power in the event of natural disasters, cyber-attacks or shutdowns.

Ultra-Light Gloves Let Users 'Touch' Virtual Objects ▶

Scientists from EPFL and ETH Zurich have developed an ultra-light glove—weighing less than 8 grams per finger—that enables users to feel and manipulate virtual objects. Their system provides extremely realistic haptic feedback and could run on a battery, allowing for unparalleled freedom of movement.

NASA Looking to Tiny Technology for Big Payoffs ▶

NASA is advancing technology that could use large amounts of nanoscale materials to launch lighter rockets and spacecraft than ever before. The super-lightweight aerospace composites (SAC) project seeks to scale up the manufacturing and use of high-strength carbon nanotube composite materials.

The Race to Build a Quantum Computer ▶

Tasks that take billions of years done in just minutes. That's the quantum revolution coming to computing and it's set to transform our whole society.

Dock Brown on Succeeding at Failure Analysis

Interview by Barry Matties and Happy Holden
I-CONNECT007

Dock Brown of DfR Solutions gave a keynote speech at SMTAI, "Requirements for Both Cleaning and Coating to Building Medical Hardware." Barry Matties and Happy Holden sat down with Dock to discuss the current trends he sees in failure analysis, the concept of "rules versus tools," and how predictive engineering software used early in the design cycle can help predict failures in components and microvias and drive cost down.

Barry Matties: Dock, can you just tell us a little bit about what DfR Solutions does?

Dock Brown: DfR Solutions is an international reliability consulting firm. There are basically three aspects to the technical portion of our business. We do 1,200–1,300 failure analyses a year. The value proposition that we offer to our clients is that we have a whole suite of on-staff Ph.D. material science folks. These people are experts in chemistry, physics, and metals. What we try to do first is to understand the customer's problem because most of the time, they don't just want a quick cross-section in a picture—they want us to get to the root cause of the root cause of the root cause.

We first try to thoroughly understand the problem or set of problems the customer is facing, and then when we acquire the samples, we treat those very gingerly. We make sure that we have damaged and exemplary sample because oftentimes, you want to do an A/B comparison between the two. Then, we do a very careful disassembly or cross-section; we do non-destructive kinds of things first. Usually, you can see the issue there, and even if you can't see the problem non-destructively, it will help you focus in on it. For example, if you have a 600-ball ball grid array (BGA) with an issue, we can't afford to cross-section every single one of those little guys; we have to focus on the ones that are most likely to be problematic. Once we get down to the failure in the BGA ball, where is that fracture occurring—is it in the metallization or the ball itself, or is it even a pad cratering kind of issue?

The second part of our business is that we sell a software package called Sherlock that does reliability physics analysis. We're applying mathematical modeling to all the various complex material structures that are involved in any kind of electronics applications. You have, in the case of a circuit board, polymers, metals, ceramics, etc. All of these materials

have very different properties, such as stress and strain properties, fracture mechanics, etc.

The Sherlock software can model all that. We combine the modeling with the failure analysis work to do what the people in the automotive industry, for example, are calling "shift left." This is instead of waiting until the last portion of the product development cycle where you're doing low-rate initial production, and then verification validation qualification testing—if you discover problems there, it's very expensive. What the shift left means is that they try to do pre-failure analysis and reliability physics modeling right at the schematic capture and board layout portion of the design development sequence.

> **What the shift left means is that they try to do pre-failure analysis and reliability physics modeling right at the schematic capture and board layout portion of the design development sequence.**

Matties: Predictive engineering, basically.

Brown: Exactly. We can model all those stresses, strains, and ruptured things you're looking for while it's still in software. If you're going to have problems, you want to find those early. In the early part of my career, I worked at Rocket Research Corporation, which made rocket engines for satellites and things like that. The watchword there was if you had a problem, where and when do you want to find it? Do you want to find it when it shows up or when it blows up? In the rocket business, sometimes blowing up is literal. That's an analogy for the solution set that we're trying to offer people nowadays. You can do that shift left kind of thing and find the problem when it shows up, as opposed to when it blows up in testing.

Matties: That's a new shift in thinking though. Do you see more companies looking for this?

Brown: More and more people are looking at it because it's a heck of a lot less expensive. You find issues earlier, and time is money. That's particularly true in the case of automotive. The automotive industry is working on new standards, not only for the circuit board applications, but also within the integrated circuits themselves. As geometries are shrinking in the integrated circuits, as well as at the board level, the CMOS properties inside memory elements and processors are not as long-lived as they used to be.

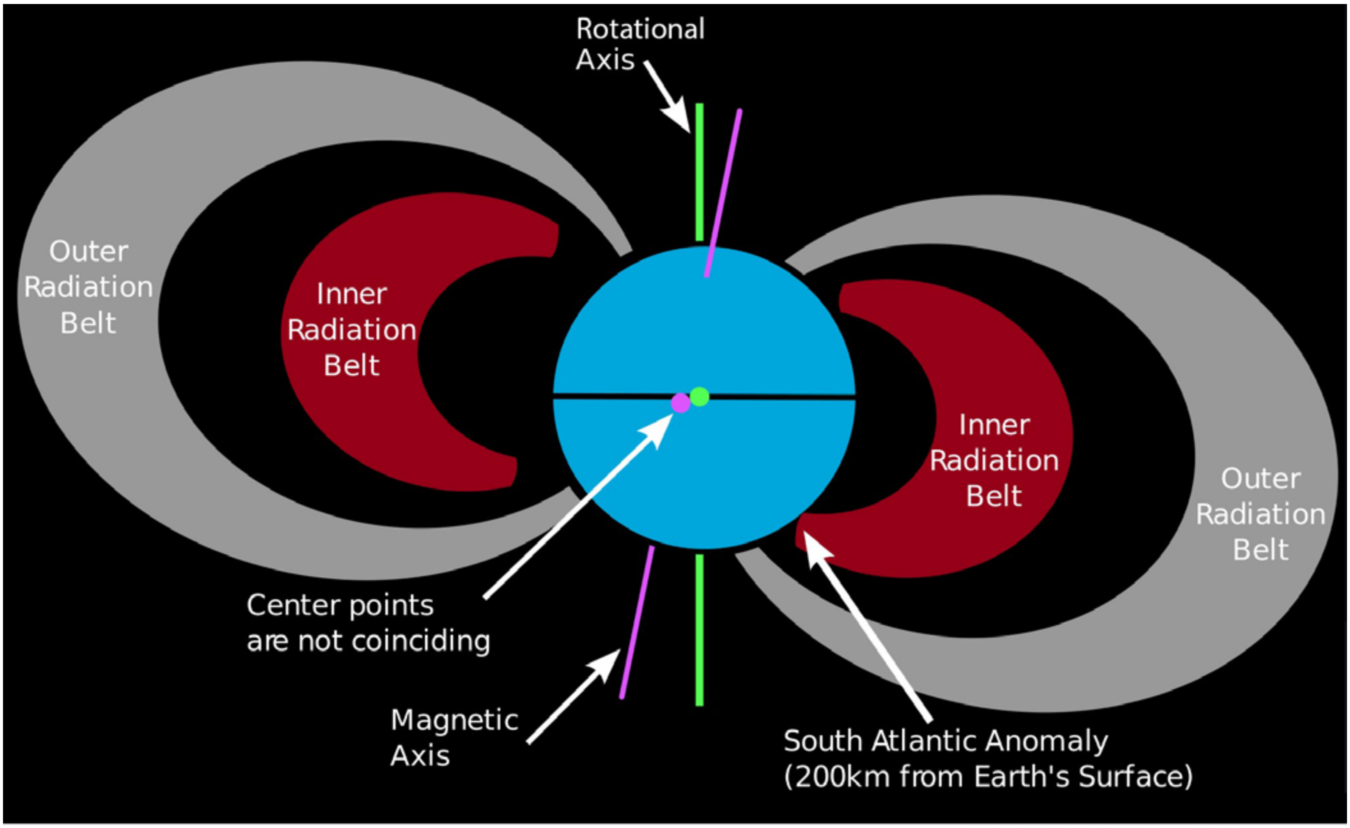
In the old days, people would say, "It's not a tube anymore, it's a transistor—it's all solid state; nothing moves, and nothing will break." What we're finding is those geometries are shrinking in integrated circuits, then at the atomic level, things really do move. We can now model that movement mathematically—for example, electromigration in the metallization of the integrated circuit. If semiconductor manufacturers are going to have a problem with electromigration, we can help them figure that out before they go with the production. In the case of end users in automotive, which is such a harsh environment, if you're going to have those kinds of issues, you want to be able to figure that out.

Matties: Obviously, it's driven by the cost of failure, right? The higher the cost, the more likely they are to look at it on the front end?

Brown: It's also the consequence of failure.

Matties: That's part of the cost, for sure. As technology changes, I would think that you're seeing new types of failures. What trends and failures are you seeing?

Brown: One of the big surprises for all of us was a presentation at the SMTA Pan Pacific Microelectronics Symposium about three years ago.



Marko Markovic, Wikimedia Commons

Some scientists at RESRI and IMS in Europe were looking at what was going on with the radiation effects in COTS integrated circuits. For a long time, that wasn't that big of a deal because most applications are terrestrial rather than up in the air. We have the atmosphere protecting us, and in this particular presentation, what the folks from Europe showed was an aircraft was transiting the South Atlantic Anomaly.

The South Atlantic Anomaly is an area on the earth's surface where the level of cosmic radiation is quite a bit higher, and it has to do with how the Van Allen belt twists. The Van Allen belt is this ionizing belt that shields and screens earth from cosmic radiation. There's a small twist to the belt, and the South Atlantic just off the coast of Brazil has a much higher total of ionizing radiation nodes than any place else on the surface of the planet. There was an airplane that was transiting through that area, and there was a disruption in the flight control system; thankfully, they were able to recover, and the only thing that happened was some overhead bins popped. This is another area that people are becoming increasingly concerned about. As those geometries in processors and memories shrink, they become more susceptible to those single events.

Happy Holden: I'm surprised with the number of Army, Navy, and military contractors that have shown up at our meetings, including SpaceX and a few others, that are having failures and aren't sure what's caused them. That's why we're having this workshop today. Has anybody contacted you on the failure problem we're having with microvias and stacked vias?

Brown: Our Sherlock software does an excellent job of modeling those properties of the microvias. What we're seeing both in reliability failure analyses and cross-sectioning after failure is if the construction of the microvia configuration is done correctly, those microvia feedthroughs can actually be more reliable than a plated via for plated through-holes.

Holden: That's what we expect, but we're not getting that.

Brown: What we see in the modeling and laboratory is that when people stack up microvias, they can actually be less reliable than plated through-holes. The kind of design configuration that seems to work better is one where if you have to go a long distance through a board, you go a little way, shoot over on the internal layer, go down a little bit, and shoot over through another spot. As I mentioned earlier, these material configurations in today's boards are extremely complex structures. They have all of those different properties of polymers and metals and things like that, so yes, you can model the behavior of those microvias and then see what kinds of failures are anticipated.

When we initially tried to validate this reliability physics package about 10 years ago, we had some struggles with that validation process. We wanted a high correlation between what the model was showing and what we could demonstrate either in the field or laboratory with temperature cycling or shock vibration. What we discovered was that the material properties of the polymers, for example, in the prepreg and laminates in the board, weren't precisely per the manufacturer's datasheets. There were changes in the modulus of elasticity, in the X, Y, Z, and coefficient of thermal expansion (CTE) that didn't match up exactly with the manufacturer's datasheets. When we were going through the validation phase, part of the software development process was to match up those real-world physical constants with the way that they really play out inside board structures, rather than what's on the datasheet for just a polymer layer.

Holden: Nobody has gone to DfR yet with this because we think we have a containment process, so if the coupons pass, they'll assemble the boards, but we haven't figured out how to find the root cause. As many as 40% of the boards are being returned. They're failing the containment process, which is expensive for the fabricator and for schedules and timelines. We have dozens of theories about why it is, but no real hard evidence.

Matties: Thanks for your time today, Dock. Is there anything that we haven't talked about that you feel we should share with the industry?

Brown: One of the things that I would like to see a broader spreading of the knowledge that engineering is as much as art as it is a science, which is one of the things I talk about in my design for excellence classes at both SMTAI and IPC APEX EXPO. Part of engineering being an art means that as engineers, we are called upon to develop good intuitions as well as good analytical programs. Analyses and computer simulations are expensive. You can't analyze everything, so the art part of that comes in knowing when to deploy more expensive modeling techniques, and when you can allow your intuition to take place.

Back to the example of automotive; for instance, there were design rules that people of various industries applied in the old days. The origin of those design rules for temperature cycling was a relatively smooth diurnal day-night cycle where things gradually heat up in the morning, get hot around 4:00 p.m., and cool off at night. The next morning, you go through that same thing in a gentle once-a-day diurnal cycle. What some of the people in automotive are now discovering is that infotainment products that are in the cabin of the automobile are seeing temperature cycling profiles that are dramatically different.

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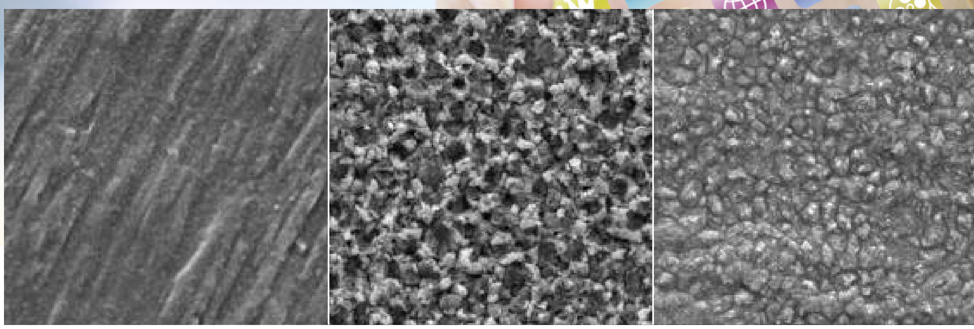

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Let's say you live in Phoenix, Arizona. You grab the kids in the morning and take them to school. Then, you pick them up, take them out to the soccer game, park the car in the sun, and when the soccer game is over, you turn the air conditioning up full blast and drive them off to an ice cream place. You take them in for some ice cream and a hamburger while the car sits in the sun and gets all hot. You come back out, throw on the AC on full blast again, drive to the grocery store—you see where I'm going with this.

There's no longer a gentle one-per-day cycle; The cycles occur at an extremely rapid rate with multiple cycles—four, five, six, or seven—per day for the electronics inside the cabin of an automobile. It's not a smooth ramp rate; it's very jagged, which exercises the solder joints even more. What we've been able to show in our modeling work is that modest changes in the X and Y CTEs of the circuit board—for example, going from a 16 to a 13—can double the life of solder joints for certain BGA parts.

Holden: Would you call this intuition a skill?

Brown: It's to be aware that your intuition, for example, would realize that a modest change in X, Y, and CTE of a board wouldn't make all that much a difference in the life of a solder joint. In fact, it makes two times the difference. For an infotainment automobile manufacturer, that could mean the difference between meeting the requirements of the top automotive customer and failing.

Holden: I'm interested in the essential skills that you have to develop after college, or the things that they don't teach you in college but are still essential. If we step back into something more basic, how would you define the skill of intuition of the artistic part of engineering?

Brown: I'll leave you with this final thought, which is rules versus tools. In the old days, we had design rules. We had a separate set of design rules for medical, avionics, industrial, automotive, and consumer products. Those worked very well when the change of pace was more sedate; today, with shrinking geometries and shorter development lifetimes, we need to make the transition from rules to tools. There's a variety of tools out there—our Sherlock reliability physics modeling software is only one—but it's up to design engineers to know what rule and tool to apply under different circumstances.

Holden: I think I've found another skill—rules versus tools.

Matties: Thank you so much for spending time sharing your wisdom with us, Dock. We greatly appreciate that.

Brown: My pleasure. **PCB007**

Army Research Paves the Way for Designer Materials

Scientists Dr. David Baker and Dr. Joshua McClure from the U.S. Army Research Laboratory (ARL)—in collaboration with Professor Marina Leite and Dr. Chen Gong at the University of Maryland and Professor Alexandre Rocha at the Universidade Estadual Paulista in Brazil—have developed new designer materials with a broad range of capabilities to enhance the power of soldier devices used on the battlefield.

Focused on the control of optical and plasmonic properties of gold and silver alloys by changing alloy chemical composition, their research titled "Band Structure Engineering by Alloying for Photonics" was recently featured in the journal *Advanced Optical Materials.*

The research focused on combining experimental and theoretical efforts to elucidate the alloyed material's electronic structure with direct implications for the optical behavior. According to the researchers, the insights gained enable one to tune the optical dispersion and light-harvesting capability of these materials, which can outperform systems made of individual elements like gold.

(Source: U.S. Army Research Laboratory)

The Art and Science of Resist Stripping, Part 2

Trouble in Your Tank

by Michael Carano, RBP CHEMICAL TECHNOLOGY

In Part 1 of this series on resist stripping, I presented some of the basics related to resist stripping chemistry. The pH curves of the performance of generic resist strippers were used to illustrate stripping behavior during the process as well as the best method to control the stripping process.

In Part 2, I will focus on some additional performance properties of the resist stripping, such as:

- "Cleanliness" of stripping
- Size of stripper skins (i.e., the stripped particles)
- Tarnishing of the copper surface
- Attack/activation of tin or tin-lead etch resists (this will be explored in a future column)

Dry Film Resist Complexities

Before delving into the bullet points listed above, it would be a good idea to get an understanding of resist technology in general. Photoresist is a complex mix of chemicals. Photoresists are commonly composed of acrylic resins, polyvinyl cinnamates, diazo compounds, phenol-formaldehydes, or other similar film-forming materials. Photoresists can be applied dry or wet to a substrate. After the exposure process of step, the photoresist-covered copper-clad laminate sandwich goes through the developing step. The entire panel is exposed to carbonate-based chemistry, which reacts with and dissolves the unexposed portions of the photoresist. The exposed portions of the photoresist do not react with the carbonate-based developer chemistry. What is left behind is the

desired circuit pattern atop the laminate. Bare (uncovered) copper (foil) remains in the areas where the unexposed photoresist was removed. Thus, a later step is the not-so-trivial job of removing the exposed resist. This is far from simple and requires a thoughtful evaluation of process parameters and resist stripping formulations.

Cleanliness: Removing All the Exposed Resist

What exactly does that mean? For most, this means an efficient and rapid removal of the exposed resist from the panels. One may conclude that cleanliness and resist stripper particle size are related. This includes dislodging and removing the exposed resist from tight spaces (more critical today for HDI designs) as well as any resist that may be trapped under an over-plated trace or pad.

One performance attribute of resist stripping technology is the ability of the chemistry to break down the exposed resist in small particles. As the resist stripper attacks the backbone, the resist will release from the copper surface and break into particles of various sizes. The particles must be small enough to be dislodged from recessed resist channels between pattern-plated features. This is especially important if the resist pattern is "over-plated" (i.e., the plating has mushroomed over the resist and makes it even more difficult for the resist particle to escape). There is also the notion that the resist should have some degree of solubility in the stripper, so that a thin residue of resist left on the copper after the initial breakup of the resist matrix into flakes will dissolve later in the stripping cycle to leave a clean surface.

It is noteworthy that various resists will react differently when they come into contact with the particular resist stripping formulation.

Size of Stripped Particles

To enable a smooth operating resist stripping operation, remove the resist as small particles or chips. As one may surmise from Figure 1, different photoresist composition strips in various particle sizes at different speeds in numerous resist stripping formulations will lead to varying results. Further, the initial size of the stripped particles reduces under the impact of sprays. However, not all resists have the same propensity to break up under a given spray impact. Fortunately, one can manipulate the particle size (within limits) by selecting the stripper chemistry, temperature, and concentration (Figure 2).

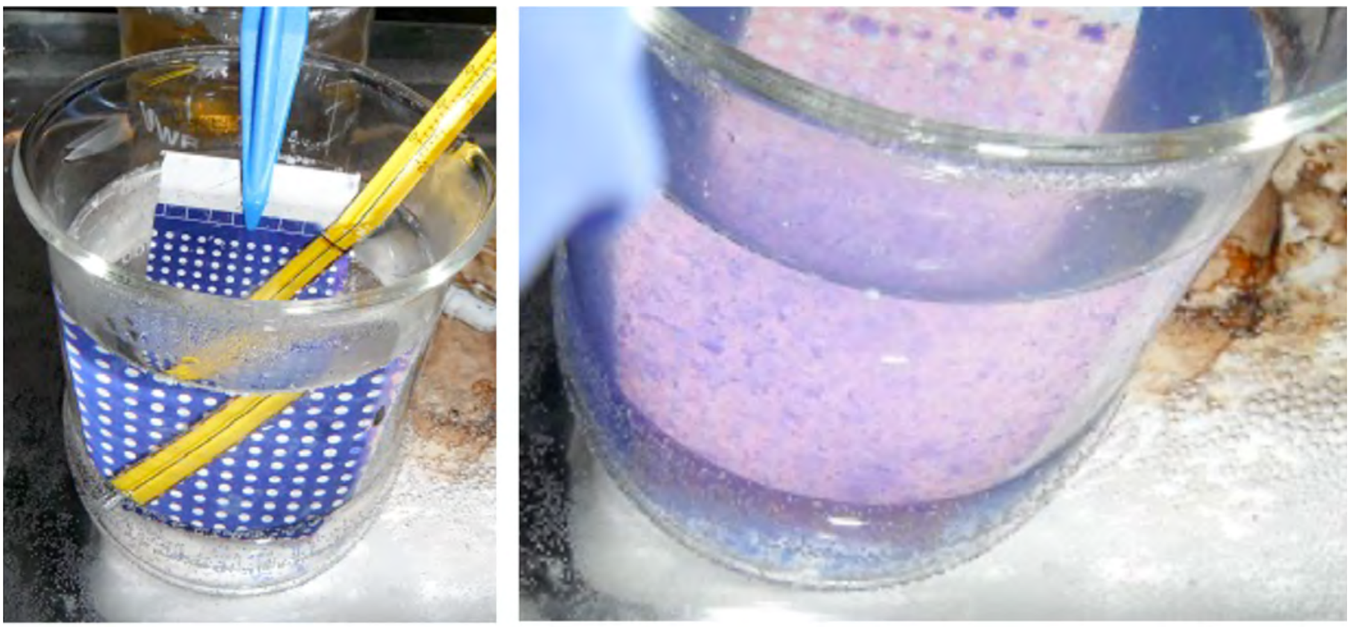


Figure 1: Commercially available resist (L) versus a second (R). Under the same resist stripping conditions, the right resist strips much faster and more completely in the given time.

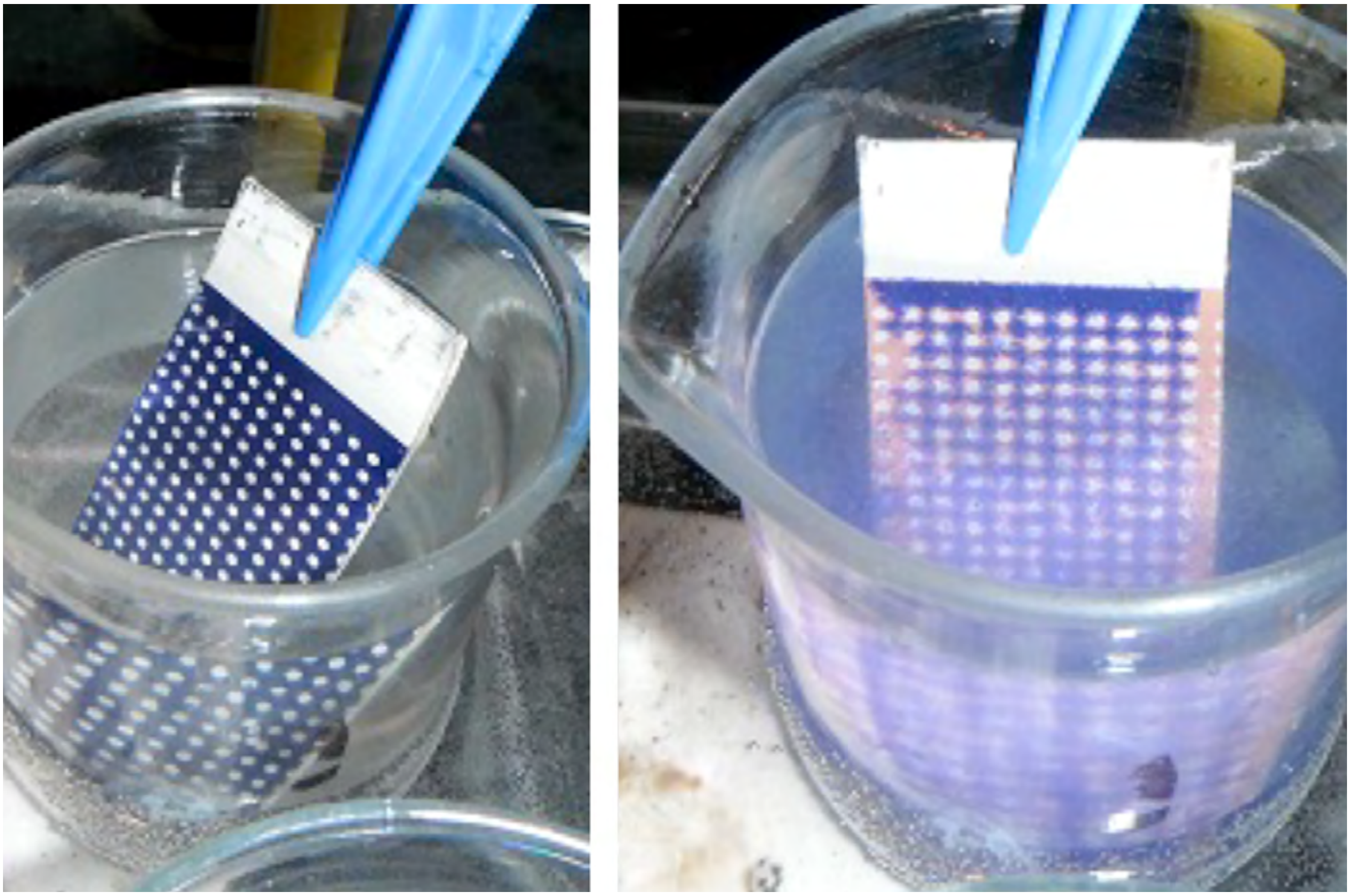


Figure 2: Same photoresist in each beaker, but two different resist stripper formulations (right shows more effective resist removal).

While attempting to enhance resist stripping for those more difficult to remove resists, here is a word of caution. Manipulating dwell times, concentrations, and operating temperatures will have adverse effects on metal etch resist attack, copper darkening, and potentially higher cost. This is where different resist stripping formulations should be evaluated.

Tarnishing of the Copper Surface

A second part of the cleanliness equation is the stripping process must leave the copper surface free of any staining, tarnishing, or any other cosmetic issues. High-pH resist stripping formulations tend to oxidize the bare copper. It is critical that most resist stripper formulations contain effective compounds to prevent oxidation. In addition, certain additives within the resist formulation itself can leave stains on the copper. These additives are dye precursors used to cause a color change during exposure. These dyes can form complexes with the copper surface. Thus, these stained complexes are difficult to remove. If this is an issue, the fabricator must ensure that the resist stripping formulation contains solvents to break that bond and leave the copper surface clean.

Conclusion

Yes, there is some art to the resist stripping operation. However, it is more about the science. In a future column, I will present process control methods for resist stripping as well as dive into additional troublesome activities related to the process. **PCB007**

Michael Carano is VP of technology and business development for RBP Chemical Technology. To read past columns or contact Carano, click here.

MilAero007 Highlights

Standard of Excellence: Working for the Future–Partnering with PCB Vendors on Innovative Technology ▶

The true test of the vendor-customer relationship comes when you need innovative PCBs—boards that are not easily found in the common marketplace and are so technologically advanced that they require your designers and suppliers to work together to go where neither has before.

UVA Faculty Work to Advance the Internet of Things ▶

The "Internet of Things" needs energy-efficient hardware, some of which may come from research developed at the University of Virginia School of Engineering and Applied Science's affiliate of the MIST Center.

Are Megatrends Putting Your Product at Megarisk? ▶

It took 38 years for radio to get 50 million users, television made it in 13 years, Internet in four, iPod in three, and Facebook in only two years. What these numbers mean to our industry is the need to create electronics at blazing speeds that we haven't seen before. But how will it affect reliability? Read on.

IPC's John Mitchell Comments on New NAFTA Deal ▶

IPC's John Mitchell extends his congratulations and appreciation to the governments of the U.S., Mexico and Canada for their many months of tireless negotiations on a new trilateral trade agreement.

Cadence: Bullish on AI ▶

David White has been involved with artificial intelligence research for almost 30 years. Now, David is the senior group director of R&D for Cadence Design Systems, and I knew we'd have to speak with him for this issue on AI. In a recent interview, we discussed his decades of work in AI, Cadence's research into AI and machine learning, and what he believes AI could mean for the EDA tools of the future.

Volunteers Honored for Contributions to IPC, Electronics Industry ▶

IPC—Association Connecting Electronics Industries presented Committee Leadership, Special Recognition and Distinguished Committee Service Awards on October 15 at IPC's Fall Standards Development Committee Meetings in Rosemont, Illinois.

Defense Speak Interpreted: Defense Electronic Supply Chain Issues ▶

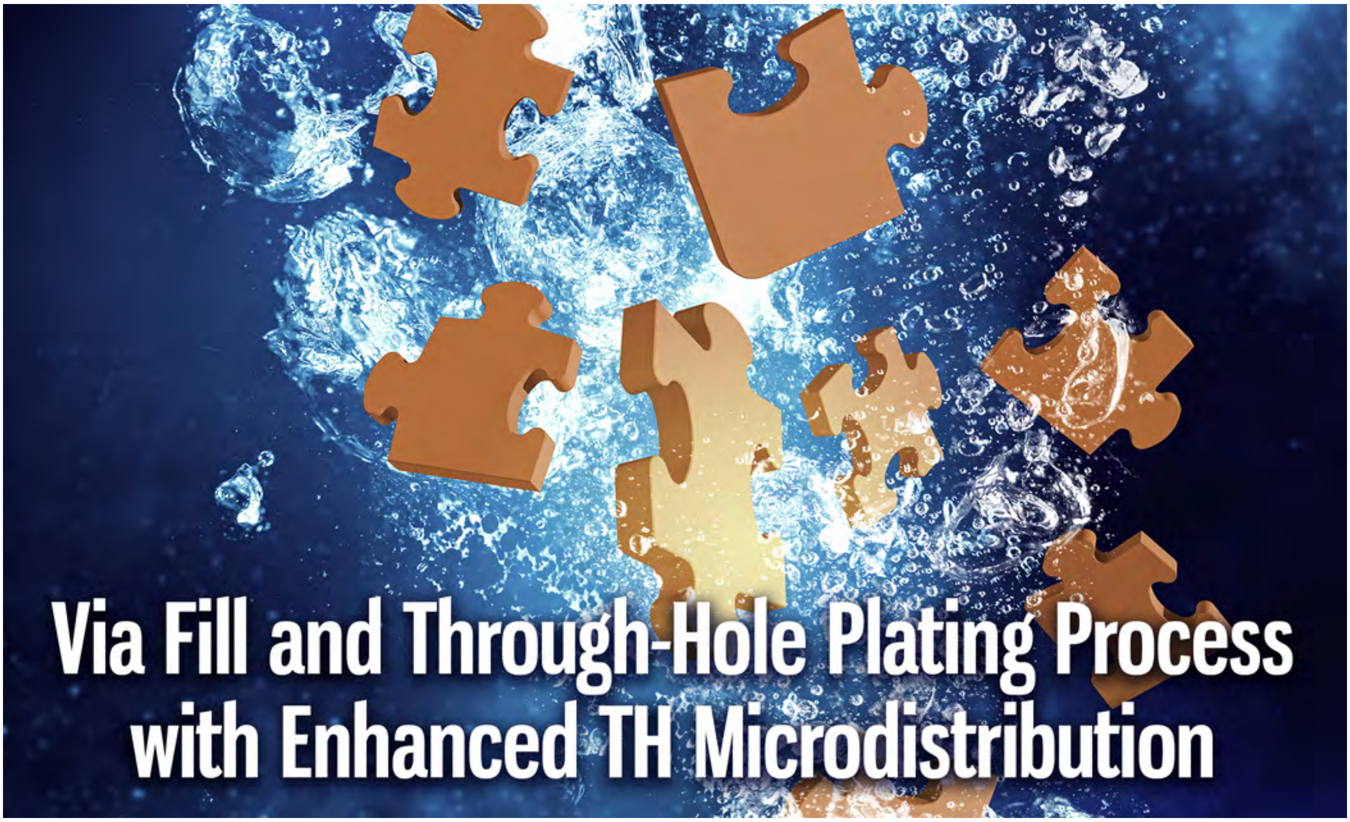
On October 5, 2018, the Department of Defense (DoD) highlighted issues with the release of the 146-page report "Assessing and Strengthening the Manufacturing and Defense Industrial Base and Supply Chain Resiliency of the United States" from President Donald J. Trump.

RF/Microwave eBook: Beneficial Tool for Engineers ▶

Released earlier this year, hundreds of engineers and other readers interested in PCB design have downloaded *The Printed Circuit Designer's Guide to… Fundamentals of RF/Microwave PCBs* micro eBook.

Raytheon, Saab Demonstrating New Guided Carl-Gustaf Munition for US Army ▶

Raytheon Company and Swedish aerospace and defense firm Saab are demonstrating a new guided munition for the Carl-Gustaf man-portable, shoulder-launched weapon system under a U.S. Army contract.



Via Fill and Through-Hole Plating Process with Enhanced TH Microdistribution

Article by Maria Nikolova, Confesol Rodriguez, Kesheng Feng, Carmichael Gugliotti, William Bowerman, Jim Watkowski and Bob Wei
MACDERMID ENTHONE

Introduction

Electroplating copper solutions are used in many industrial applications, such as anti-corrosion and decorative coatings, and in the electronics industry for the manufacturing of electronic devices. Aqueous sulfuric acid copper baths are particularly useful for the fabrication of printed circuit boards (PCBs) and semiconductors. Copper, having better electrical conductivity than any metal except silver, is the metal of choice since copper metallization allows for smaller features application. Interconnect features are features such as blind microvias (BMV), trenches, and through-holes (THs) that are formed in a dielectric substrate. They are metallized, preferably with copper, to render the interconnect electrically conductive. During circuit fabrication, copper is electroplated over selected portions of the surface of the PCB, into blind vias and trenches and onto the walls of THs passing between the surfaces of the circuit board base material. The walls of the THs are metallized to provide conductivity between the circuit layers of the PCB. The conductive deposits should be of a uniform plating thickness. Vias and trenches provide conductive connections between circuit board innerlayers. For semiconductor fabrication, copper is electrodeposited over a surface of a wafer with various features such as vias and trenches. Copper-filled vias and trenches ensure a good conductivity between the semiconductor device layers. Thus, in many PCB and semiconductor fabrication processes, electroplating has been adopted by the industry as the primary deposition means for copper metallization [1–2].

The trend of portability combined with increased functionality of electronic devices has driven the miniaturization of PCBs. Smaller device sizes and increased circuit density require decreasing the dimensions of interconnect features and increasing their density. The conventional multilayer PCBs with TH interconnects are not always the optimal solution. Sequential build-up technologies that utilize blind vias have been developed for high-densi-

ty interconnect (HDI). Maximizing via filling, while minimizing the surface copper thickness and deposit thickness variation, presents difficulties for the manufacturers, especially when the PCBs contain both THs and blind micro vias (BMVs). It is most desirable to obtain a good throwing power in electrodeposition processes. Particularly in the TH plating of PCBs, a uniform distribution of deposited copper is demanded including inside the holes on hole walls. In general, copper plating processes that provide good via fill and better leveling of the deposit across the substrate surface tend to worsen the throwing power of the electroplating bath. In the fabrication of reliable PCBs, via filling, and plated through-holes (PTH) with various aspect ratios (ARs) at the same time, in the same electrolyte is highly challenging for the manufacturers.

The purpose of this work was to optimize a recently developed innovative copper process for simultaneously filling vias and PTHs with a minimal surface thickness. The process was evaluated in a wide variety of conditions to collect information on its capabilities. The effect of inorganic components and organic additives concentrations and the influence of the plating parameters on the plating process performance in terms of throwing power and via filling were determined. A series of copper electroplating solutions were evaluated. THs with various diameters/ARs in boards up to 1.6 mm were measured.

Both insoluble and soluble anode applications were considered. Filling of through-via-holes in core layers of HDI and integrated-circuit (IC) substrates in a one-step DC process was also studied. Panel plating as well as pattern plating for vertical plating applications, including vertical continuous plating (VCP) equipment, were included in the experiments. The mechanical properties of plated copper deposits, tensile stress, and elongation were measured, and the thermal characteristics were evaluated.

Acid Copper Plating Process

A typical copper plating solution contains copper sulfate, sulfuric acid, chloride ions, and organic additives that control the deposition process and the quality of the plated coatings [3–8]. Solutions that provide good via filling and leveling of the copper deposits usually are characterized by low polarization and presence of leveling agents. High-copper, low-acid base electrolytes in a virgin makeup solution (VMS) are used. The brighteners are adsorbed at low-current-density areas of the cathode surface, accelerating the process, while the levelers are adsorbed at the most negatively charged areas, thus slowing the deposition rate there. Meanwhile, high throwing power (TP) is achieved in low-copper, high-acid baths. The throwing power of an electroplating bath depends on solution conductivity, electrodeposition kinetics (the slope of the polarization curve, the higher and better the TP min), cell geometry, and temperature.

The innovative plating process is an advanced, direct current acid copper system offering simultaneously via filling and TH plating [9]. The plating is uniform over the cathode surface, and no TH thin knee or slope is observed around the THs. Key features include filling BMV up to 5 x 4 mils with a low dimple size, and any layer build-up applications (Figure 1). Figure 2 shows a typical plating in the bath at 20 amperes per square foot (ASF). Surface copper thickness is 18–20 microns and the surface appearance is bright. The process is compatible with direct metallization or electroless copper. The low total organic carbon (TOC) system has an extremely long life, and it is easily maintained; all organic additives can be analyzed by cyclic voltammetric stripping (CVS).

Process Optimization

The capabilities of the innovative plating copper process for via filling (VF) and PTHs were studied as a wide range of plating conditions were tested. Factors included organic additive concentrations, inorganic components concentrations, and plating parameters. Large ranges of the additive concentrations were tested (i.e., wetter: 5–15 ml/L, brightener 0.5–4.5 ml/L, and leveler 5-25 ml/L). Current densities applied were 10, 20, and 30 ASF.

Figure 1: Any layer build.

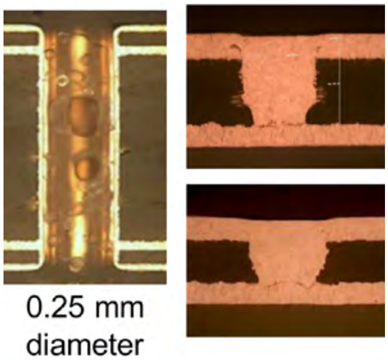


Figure 2: PTHs (0.8-mm panel) and filling vias (20 ASF, 60 minutes).

Figure 3: Plating cell (8.5 liters), knife agitation, and eductor spray.

Optimization was performed in terms of enhancing TH microdistribution, including for thicker panels, up to 1.6 mm (TH ARs up to 6.4:1), via filling (minimal dimple size, void-free filling), while keeping a low surface copper thickness. TH microdistribution is given as throwing power (TP) min and TH corner plating is characterized by TP knee[9].

- TP min = Ave. Cu thickness in the TH center / Ave. Cu surface thickness %
- TP knee = Ave. Cu thickness at TH corners / Ave. Cu surface thickness %

Tests were completed in an 8.5-liter cell (Figure 3) with 200-liter pilot tanks. Insoluble anodes were used. They allow for higher applicable current densities, easy maintenance, and a uniform copper surface distribution. Each bath was made up, dummy-plated for 2 AH/L, analyzed, adjusted to correct additive levels, and then the test panel was plated. Each test panel went through a pre-clean cycle of a two-minute acid cleaner, two-minute rinse, two-minute 10% sulfuric acid before the plating in the Process A bath.

Results and Discussion

Through-Hole Plating: Effect of Concentration Levels and CD Influence on Throwing Power

Results shown are for a basic electrolyte (VMS) containing 250 g/L $CuSO_4 \cdot 5H_2O$, 50 g/L sulfuric acid and 45–50 ppm chloride. An increase in brightener resulted in an increase in throw power. The wetter and leveler did not show a clear trend. When increasing current density, the throw power decreased in all cases. The tests showed that there was a strong interaction between the brightener and leveler concentrations in the electroplating bath. Examples are shown in Figures 4 and 5, TP min as a function of organic additive concentrations and current density (CD.)

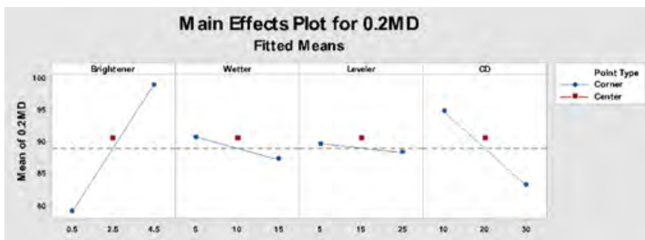


Figure 4: Main effect plot for a 0.20-mm diameter TH in a 0.8-mm panel.

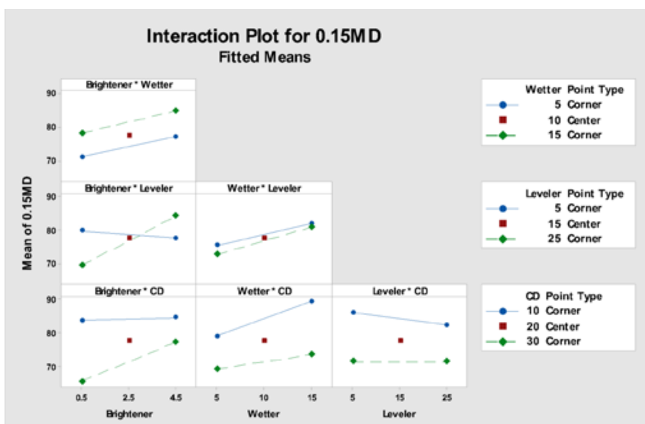


Figure 5: Interaction plot for a 0.15-mm diameter TH in a 0.8-mm panel (AR = 5.3).

Via Fill: Concentration Levels Effect and CD Influence on Via Dimple

It was established that an increase in brightener concentration led to an increase in dimple size. The wetter showed a minimal effect on dimple depth. Leveler results are inconclusive, although in most of the cases increasing the leveler concentration affected via filling, usually increasing via dimple. Increase in current density showed an increase of dimple size for 3 x 3 vias and a decrease in dimple size for larger size vias (Figures 6–8).

A high concentration of organic additives and 10 ASF showed the best plating results. The optimization model could minimize and maximize throwing power and via dimple size. Enhanced TH microdistribution was achieved under optimal conditions for maximum throwing power: high brightener and leveler concentrations, low CD, 10 ASF. A current density of 30 ASF caused cavities in 3 x 3 and 4 x 4 vias, in some cases. Experiments were designed to run under the conditions of the minimum and maximum dimple size and minimum and maximum throwing power:

- Max dimple (no voids inside the vias): 4.5 ml/l brightener, 5.0 ml/l wetter, 25.0 ml/l leveler, 10 ASF
- Max throw power: 4.5 ml/L brightener, 15.0 ml/l wetter, 25.0 ml/l leveler, 10 ASF
- Min dimple (no voids inside the vias): 2.5 ml/l brightener, 10.0 ml/l wetter, 15.0 ml/l leveler, 20 ASF
- Min throw power: 0.5 ml/L brightener, 5.0 ml/l wetter, 25.0 ml/l leveler, 30 ASF

The minimum dimple condition shows a large improvement from maximum dimple conditions; large differentiation. The maximum throw power percentage showed improvement from the minimum condition, but not considerable; small differentiation (Figure 9).

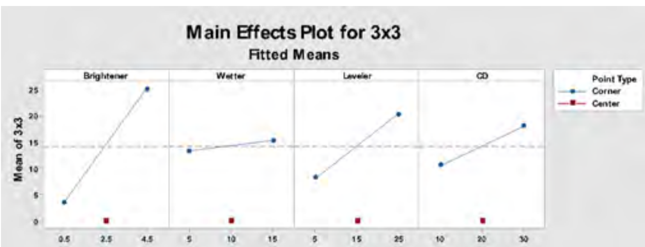


Figure 6: Main effect plot 3 x 3 (75 x 75 mm); via dimple as a function of brightener, wetter, leveler, and CD.

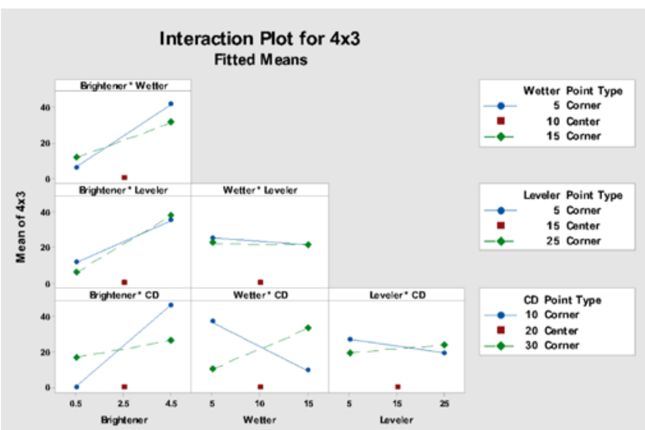


Figure 7: Interaction plot for 4 x 3 (100 x 75 mm) vias.

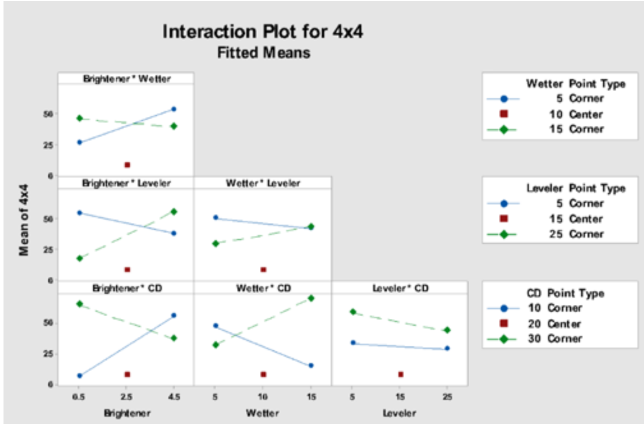


Figure 8: Interaction plot for 4 x 4 (100 x 100 mm) vias.

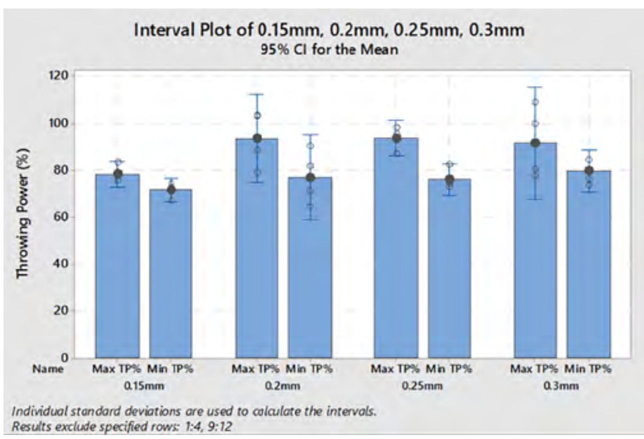


Figure 9: Throwing power interval plot of various sizes THs at min and max TP% conditions.

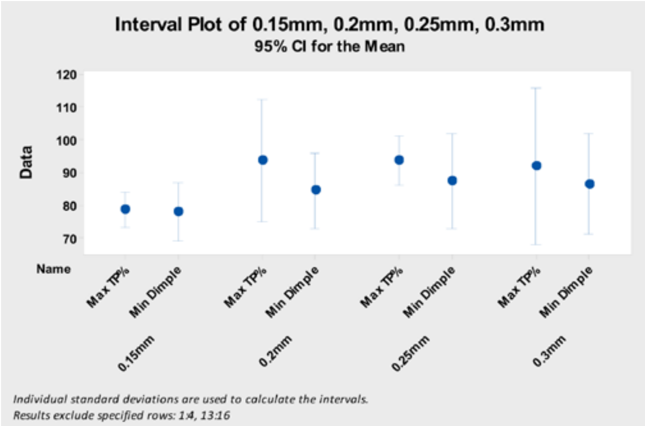


Figure 10: Throwing power interval plot of various sizes THs at optimum conditions.

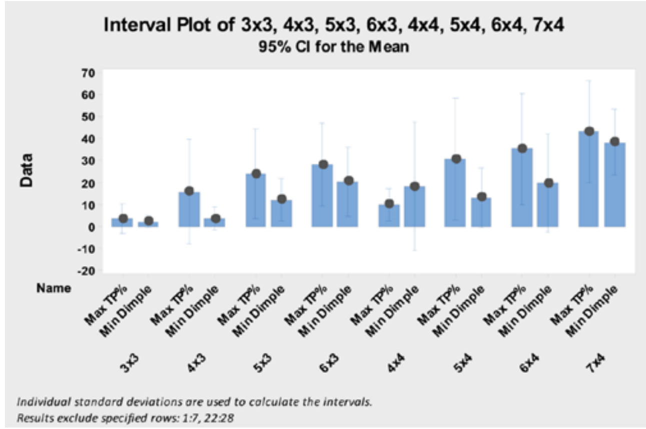


Figure 11: Via dimple interval plot of various sizes vias at optimum conditions.

Comparing maximum throw power and minimum dimple conditions (two ideal conditions) resulted in a better tradeoff by targeting minimal dimple. Throwing power varies much less between the maximum TP condition and minimum dimple condition (Figure 10) than dimple size between the two conditions (Figure 11). The throwing power was reduced slightly when running at optimized dimple conditions (minimum dimple). If dimple size and throwing power are critical, the best compromise is to operate under optimized dimple conditions.

Throwing power and knee thickness increase as the TH AR decreases and the diameter increases, as shown for the 0.8-mm panel in Figure 12.

The industry specification for a throwing power $\geq$75% and knee thickness $\geq$75% could be achieved under proper plating conditions for all sizes THs (0.15, 0.20, 0.25, and 0.30 mm), ARs of up to 5:1 in 0.8-mm panels or thinner 0.4-mm panels. However, the throwing power for thicker panels (1.2 – 1.6 mm) was measured to be below 75%. It usually was about 55–59% for 0.25-mm holes in 1.6-mm panels (AR = 6.4).

Basic Copper Electrolyte (VMS): Enhanced Throwing Power

To improve the throwing power for thicker boards, the inorganic component concentrations in the bath were varied, reducing copper

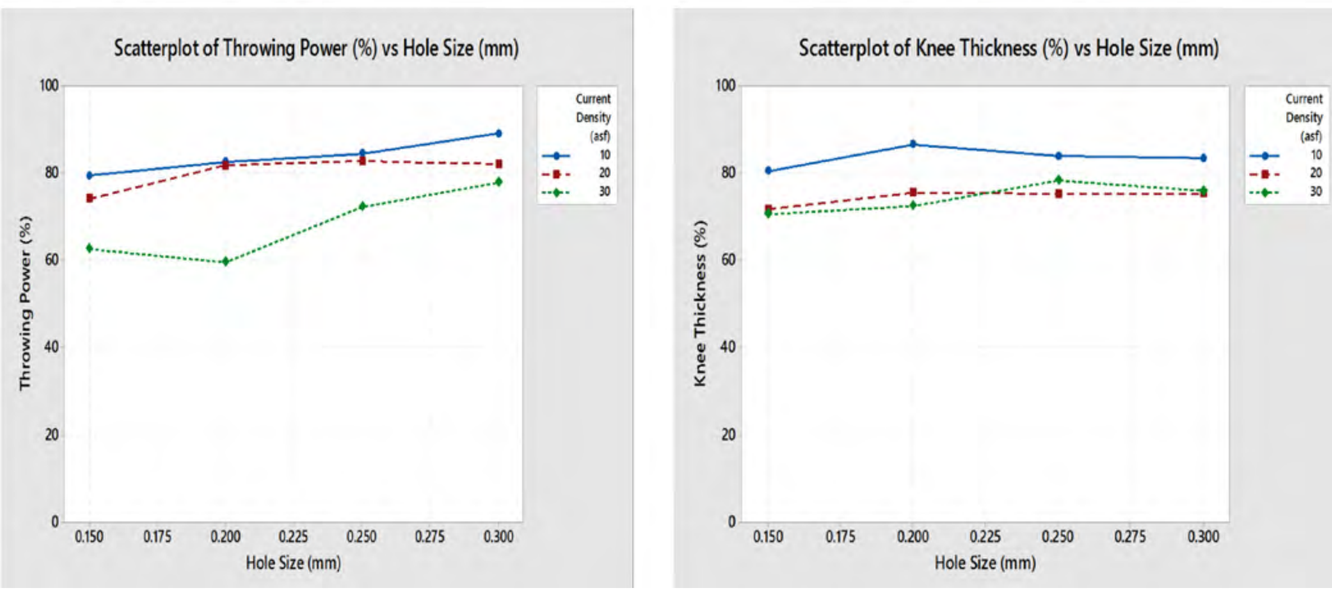
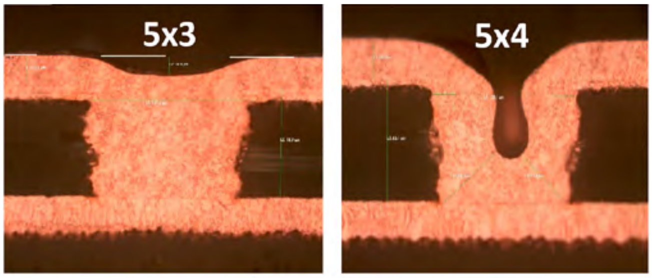


Figure 12: TP min and knee as a function of hole diameter.



TP min	TP knee
78%	89.6%

Figure 13: Plating with reduced copper ion concentration, 0.25-mm diameter TH in a 1.6-mm panel.

ion concentration and increasing the sulfuric acid amount in the bath. Results from plating in a bath with 200 g/L $Cu_2SO_4 \cdot 5H_2O$ and 100 g/L sulfuric acid are shown in Figure 13 (TP min = 78%, TP knee = 86.6% for 0.25-mm TH in a 1.6-mm panel, AR = 6.4:1).

The throwing power was considerably enhanced, TP min = 78% for AR = 6.4:1. The small vias, three mils, are filled up with a dimple < 15 µm. However, the via filling of four-mil vias was adversely affected, as shown in the cross-sections (Figure 13). Still, the thickness of copper plating on 5 x 4 via bottom was > 150% of the surface copper thickness, which met the industry requirements in many cases. More work was done to further improve the via fill, keeping very good throwing power for thicker panels. Tests with different wetter species were run, leading to good results by using a higher Molecular Weight (MW) organic compound. TP min of about 76 – 78% and good via fill for three-mil as well as for four-mil vias were achieved when plating in Process A bath with basic electrolyte (VMS): 180–200 g/L $Cu_2SO_4 \cdot 5H_2O$, sulfuric acid = 80 – 100 g/L; Cl^- = 45–50 ppm. The thickness variation across the cathode surface was improved.

Soluble Anode Application

In many cases, soluble anodes are the preferred choice, especially if copper replenishment presents difficulties. The described process was modified for applications with copper phosphorous anodes. Tests were performed in a large-scale pilot tank. Figure 14 shows the process sequence and the plating tank. Eductor spray and/or air agitation were used; sparger pipes per side were eight with 20 nozzles on each pipe.

Excellent via fill and TH plating were achieved, as shown in Figure 15 using Process B. The plating conditions were 16 ASF, 60 minutes, and eductor flow 100 LPM/side. The surface copper thickness was 18–22 mm, TP min

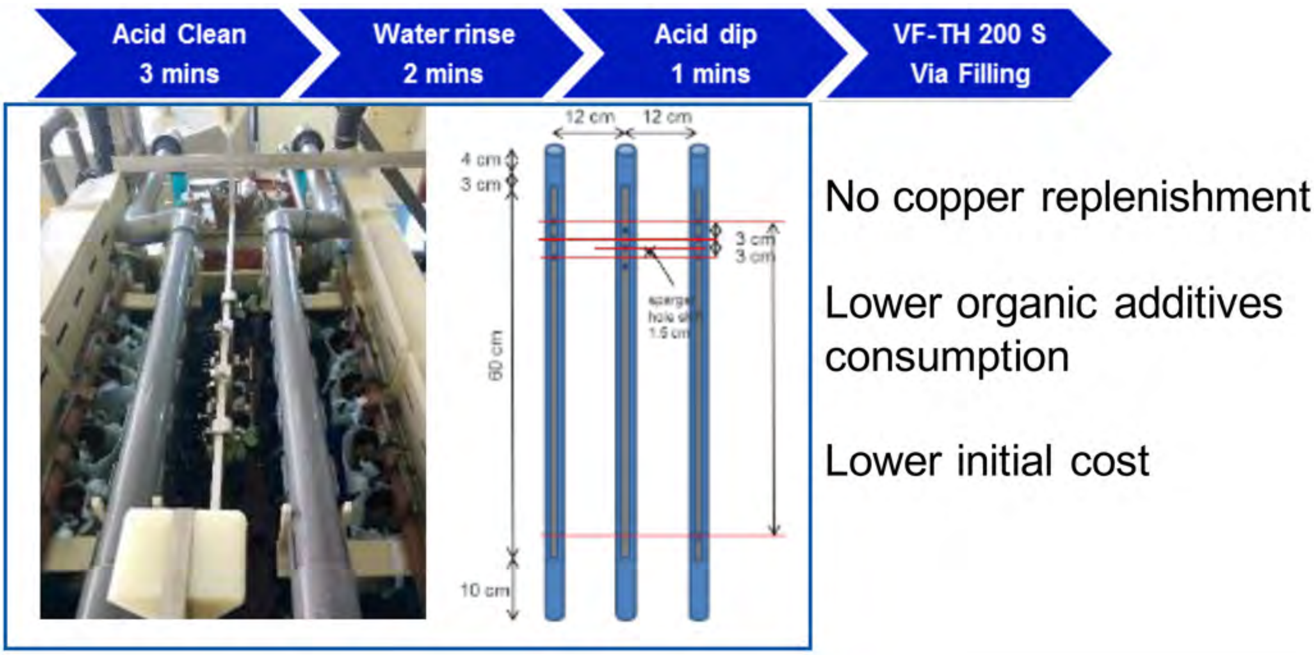


Figure 14: Process sequence (650L tank, soluble anodes, air agitation, and side impingement/eductor flow).

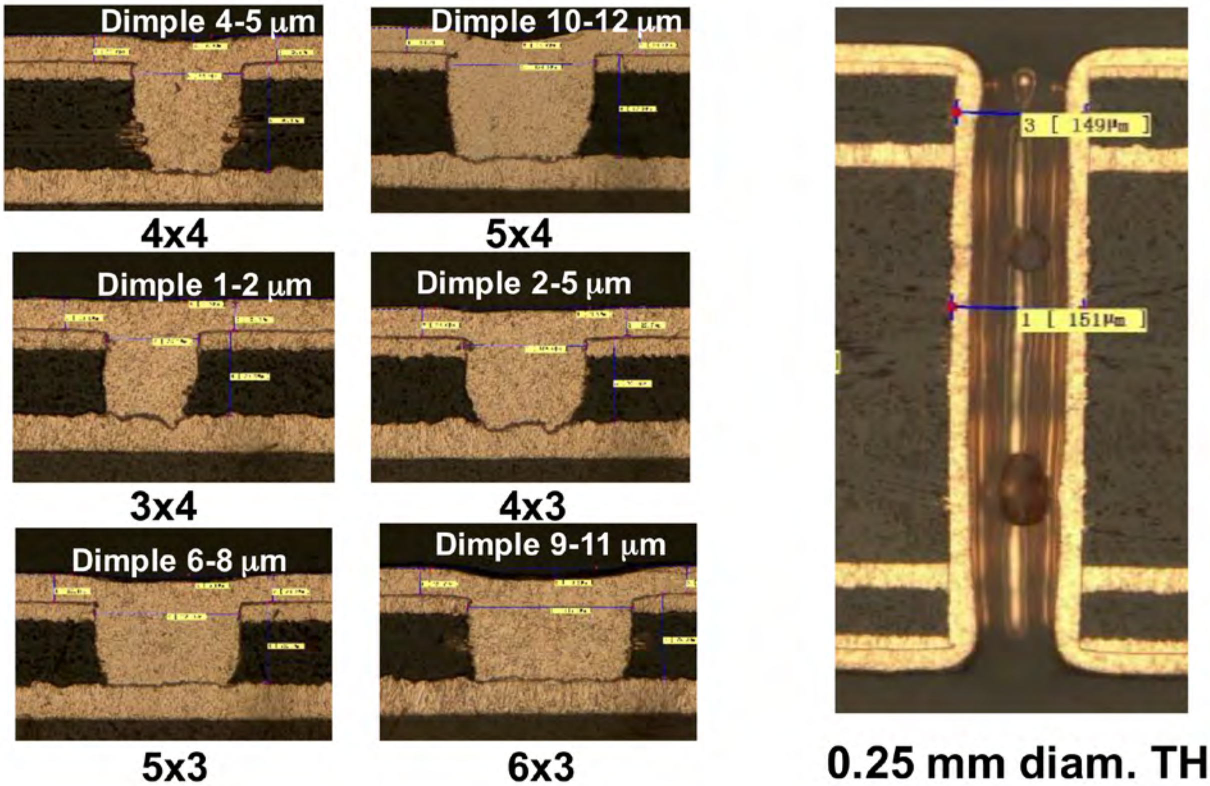


Figure 15: Plating with soluble anodes.

= 93%, TP knee = 86.7% for 0.15-mm TH in a 0.8-mm panel, and AR = 5.3.

A high-flow volume setting (0.8L/nozzle per minute) was recommended to achieve good via fill without void defects for high-AR blind vias. Plating of larger vias, 4 x 4.5 mils and 5 x 5.5 mils, is demonstrated in Figure 16: surface plating thickness 0.85-0.9 mils (21–22.5 mm), dimple < 0.5 mil (12.5 mm). The operating electrolyte is stable, has an extremely long life, and no secondary breakdown product that adversely affects via filling was accumulated in the bath. Plating is consistent across the plated boards (Figure 17).

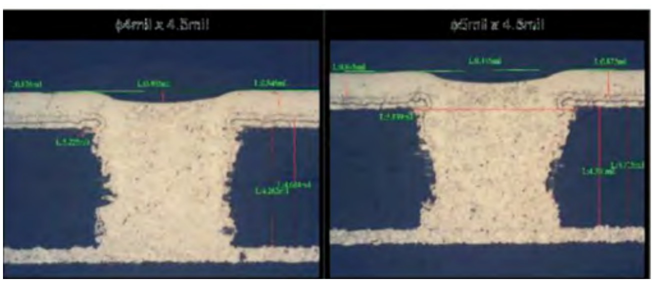


Figure 16: 650L tank, 0.7L/nozzle*min (20 ASF for 65 minutes).

Through-Via-Hole Copper Filling Application

In the manufacturing of multi-functional electronic products, the fabrication of advanced PCBs with HDI is essential. Copper electrodeposition is particularly beneficial to fill through vias in core layers of HDI and IC package substrate. The results from the Process A optimization were used further in developing a process for filling through microvias. The interaction of organic additives as previously discussed is critical in determining the

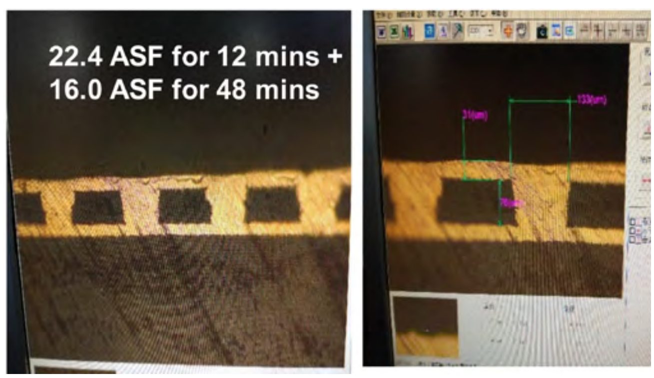


Figure 17: Soluble anodes (22.4 ASF for 12 minutes plus 16 ASF for 48 minutes).

proper conditions for an accelerated filling process and a suppressed deposit growth onto the substrate surface.

The most common thicknesses of the plated boards vary from 60–200 µm and the TH diameters are 45–100 microns. The holes are mechanically or laser drilled, resulting in different hole shapes with different requirements for the filling process. Laser-drilled through-via-holes usually have an X shape since a laser beam is applied from both sides of the substrate. This makes filling easier because the closure of the hole in the middle is easily achieved.

In this study, laser-drilled X-through-via-holes in boards up to 0.150 mm and diameter at the hole opening of 85 – 90 µm were used. Filling capability in terms of dimple size, void formation within the filled hole, and metal distribution on the cathode surface are used as measures to describe the capabilities and effectiveness of the technology.

Tests were run to determine the conditions for the best plating process performance. A high-copper, low sulfuric acid, low chloride concentration electrolyte was the most favorable for hole filling. Voids during X-plating occur easier for smaller TH diameter and higher board thickness. The shape and the drilling quality significantly affect the void occurrence as well. In addition, depending on designs, different pitches on one board increase the difficulty to achieve an acceptable plating uniformity.

Using eductor nozzles, fluid impingement, "knife" cathode movement, low CDs and current, and/or flow ramping resulted in a uniform plating and reduction or complete elimination of the voids within the holes. Examples of void-free performance are shown in Figure 18 (dimple 0 or < 5 µm).

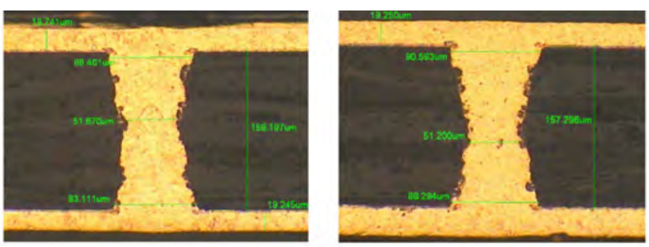


Figure 18: TH fill, thickness 158 µm, diameter at the opening 86–90 µm, middle 52 µm.

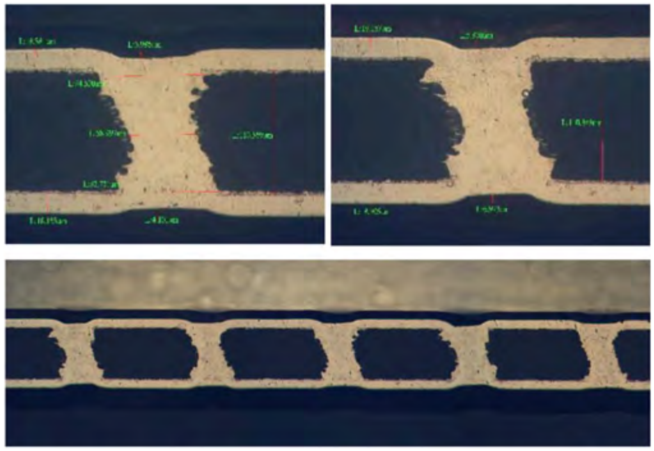


Figure 19: TH fill (30 ASF for 40 minutes).

Figure 19 shows plating results for a substrate thickness = 80 µm, diameter = 60 µm, surface thickness = 18 – 19 µm, and dimple < 10 µm with no voids.

For pattern plate, electroplating uniformity becomes critical. While panel uniformity can be controlled by mechanical parameters like solution flow, usage of insoluble anodes, etc., in pattern plating, the uniformity is mainly determined by usage of proper organic additives that have a significant influence on the surface current distribution. Figure 20 shows pattern TH filling in the innovative copper bath (VCP), 100-µm substrate, through-via-hole diameter of 88 µm at the entrance and51 µm at the hole center, dimple < 2 µm, no voids, and surface copper thickness 20 – 21 µm with uniform and mirror bright surface appearance.

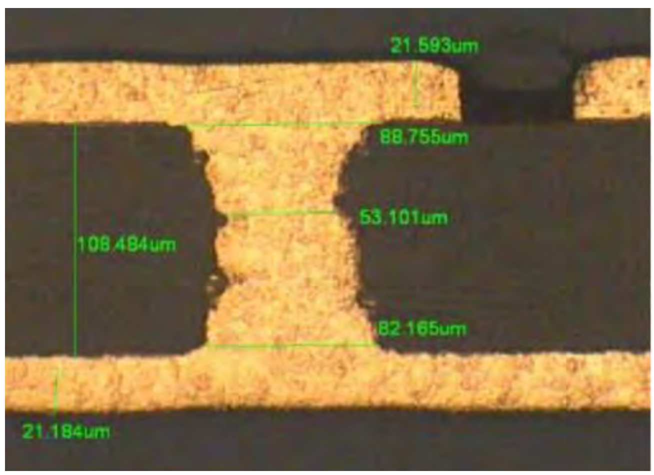


Figure 20: Pattern X-via fill, vertical plating application, 15 ASF, 68 minutes, flow rate = 1 bar/23 min. + 0.2 bar/45 min.

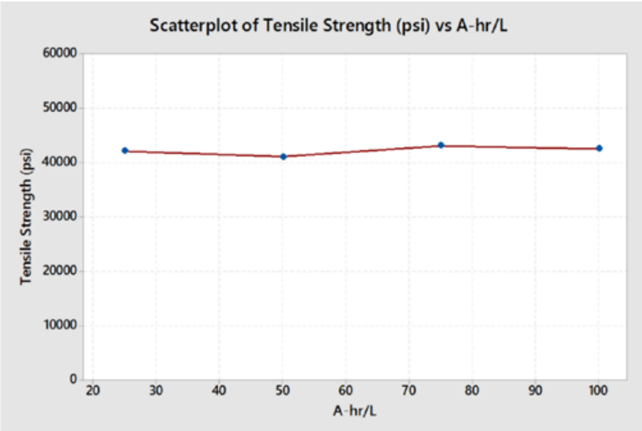


Figure 21: Tensile strength versus bath age (AH/L).

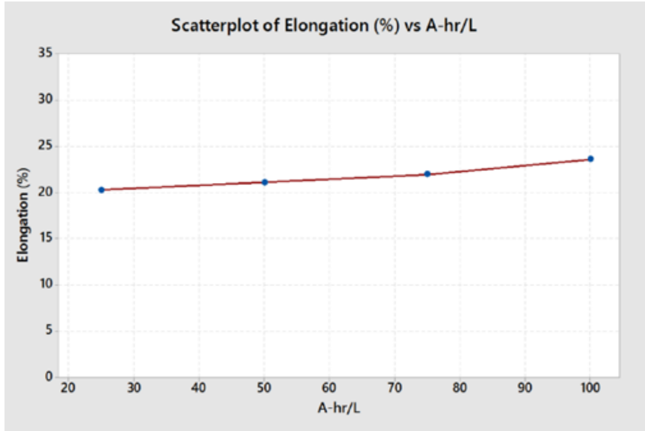


Figure 22: Elongation, percentage versus bath age (AH/L).

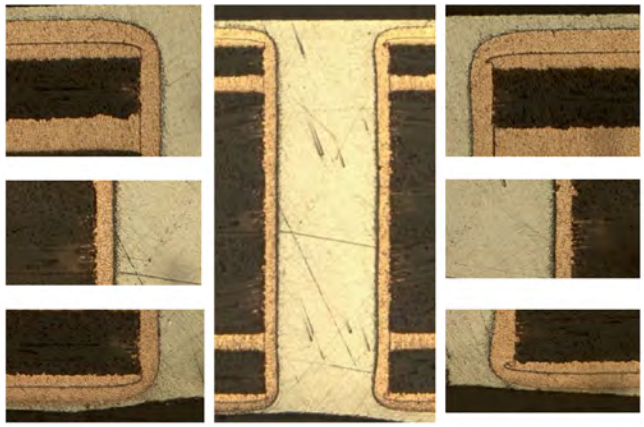


Figure 23: Solder dip test for through holes after six times the solder shock (eductor flow and soluble anodes).

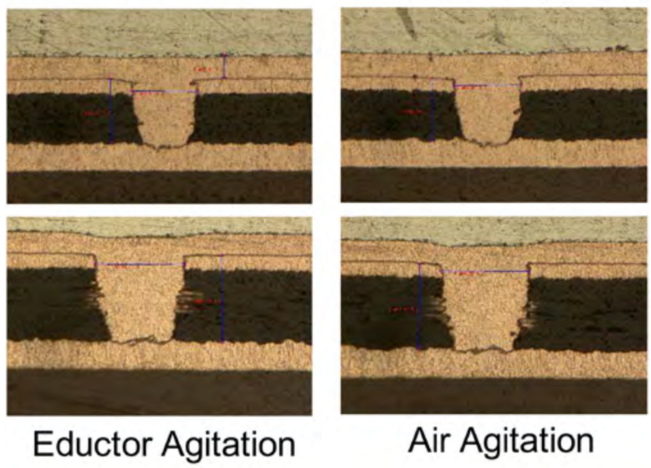


Figure 24: Solder dip test for blind via after six times the solder shock.

By using carefully selected plating conditions with correct organic additives types and their concentrations, electrolyte agitation/solution flow rates and current density, an excellent void-free through-via-hole filling can be achieved. The process is applicable to vertical plating equipment, including VCP. Further optimization is needed to fill through-via-holes without voids in thicker cores (200 µm). Although the preliminary tests for this case showed promising results, more work is needed to confirm and scale up the process.

Properties of Plated Copper Coatings

Tensile Strength and Elongation

Tensile strength and elongation of the plated copper were evaluated per IPC TM-650, 2.4.18.1. Vertical and horizontal pulls were used. Tensile strength ≥42,000 psi and elongation >20% were measured. Tensile strength as a function of the bath age up to 100 AH/L is given in Figure 21, and the elongation results are shown in Figure 22. Plating in a fresh, aged bath met and exceeded IPC specifications.

Reliability

For TH and via reliability, sections were taken, and solder shock resistance testing per IPC TM-650 2.6.8 was performed, with 10-second float at 288°C six times. Tests were run with boards plated in baths with soluble and insoluble anodes. The holes were examined for any defects. No corner cracks, starter cracks, or TH barrel cracks were present under any plating conditions. Figure 23 refers to TH plating and Figure 24 to via fill.

The thermal characteristics of plated copper met the IPC standards and ensured that no failure occurs during the subsequent soldering operations.

Summary

An innovative DC acid copper process for simultaneously filling vias and plating THs was studied in a wide variety of conditions to collect information on its capabilities. The throwing power can be enhanced with optimized physical and chemical plating parameters while keeping very good via fill across a wide range of geometries.

A high-copper, low-acid solution was used for TH ARs up to 5:1 in 0.8-mm panels. The optimization included organic additive concentrations and plating parameters. Conditions of minimum and maximum throwing power and dimple size were determined, and experiments were run under these conditions. A compromise was achieved between plating conditions that favor via fill and those that are beneficial for TH plating.

For thicker panels of 1.6 mm, a TP min = 78% was obtained for 0.25-mm diameter holes and AR = 6.4:1 in a bath containing reduced copper ions concentration and increased acid concentration. Insoluble and soluble anode applications were shown in this article.

Filling through-via-holes in core layers of HDI of the PCB and IC package substrate was discussed. X-through vias, 90 x 150 mm that were filled with <5 microns or zero dimple and no voids or defects were shown. The filling conditions are given. Further work is underway to achieve filling up through-via-holes in thicker cores.

For mechanical properties, tensile strength $\geq$42,000 psi and elongation $>20\%$, as well as the thermal resistance of copper deposited from baths with soluble or insoluble anodes, met and exceeded industry standards thus satisfying the need of a highly reliable copper electroplating process. **PCB007**

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The FDA's Mission to Protect Medical Devices from Cyber-attacks

The threat of cyber-attacks is no longer theoretical. Cybersecurity researchers, often referred to as "white hat hackers" have identified device vulnerabilities in non-clinical, research-based settings. They've shown how bad actors could gain the capability to exploit weaknesses, thereby acquiring access and control of medical devices. The FDA isn't aware of any reports of an unauthorized user exploiting a cybersecurity vulnerability in a medical device that is in use by a patient; however, the risk of such an attack persists. The FDA is working hard to be prepared and responsive when medical device cyber vulnerabilities are identified.

(source: PR Newswire)

Supplier Highlights

Trouble in Your Tank: Understanding Resist Lock-in and Extraneous Copper ▶

It happens when you least expect it. You think you have all the process controls in place to prevent issues after etching, but either copper remains where there should be none or photoresist remains on the copper.

ESI's CapStone FPCB System Delivers Highest Via Drilling Throughput in Industry ▶

Electro Scientific Industries, Inc. announced the availability of its new CapStone flexible printed circuit board laser processing system, which offers 2X throughput improvement over its predecessor for processing blind and through hole vias, the highest in the industry.

RF/Microwave eBook: Beneficial Tool for Engineers ▶

Released earlier this year, hundreds of engineers and other readers interested in PCB design have downloaded *The Printed Circuit Designer's Guide to… Fundamentals of RF/Microwave PCBs* micro eBook.

ITEQ Launches New FR-4 Products for Antenna, LNB Applications ▶

ITEQ Corporation introduces its new IT-8338A and IT-8350A products for use in antenna and LNB applications.

Smartphone Substrate-Like PCBs Will Revolutionize the IC Substrate and PCB Markets ▶

The smartphone is one of the high value-add products that carries a very high demand for miniaturization. Customers expect larger screens, cameras with high resolution, and various other functions, in lighter and thinner phones.

Institute of Circuit Technology Hayling Island Seminar ▶

After an extreme summer heat wave had left trees dehydrated, the leaves were brown and brittle as the great and good of the UK printed circuit board industry crossed the bridge from the mainland of the south coast of England to Hayling Island for the autumn seminar of the Institute of Circuit Technology on September 20, 2018.

Nano Dimension Partners with Productivity Inc.; Expands Reseller Network ▶

Nano Dimension announced a new reseller agreement with Productivity Inc., significantly expanding the company's North American channel partner ecosystem.

MacDermid Enthone to Exhibit and Present at TPCA Show 2018 ▶

MacDermid Enthone Electronics Solutions, a global electronics chemicals process supplier, will exhibit at the TPCA tradeshow and present a technical paper at the IMPACT 2018 Conference, co-located with TPCA in Taipei, October 24–26, 2018.

Atotech to Exhibit and Present at TPCA and IMPACT Conference ▶

Atotech announced its participation at this year's TPCA Show and IMPACT Conference 2018 from October 24 to 26. The company's booth will be prominently located at the TPCA Show floor (booth number K818) and will highlight latest solutions for (a)mSAP, mobile and 5G PCB manufacturing, among several others.

Inspire the Industry, Explore the Infinity:
2018 HKPCA & IPC Show Preview

Article by the PCB007 China Editorial Team

The world's largest circuit board and electronics assembly show—2018 International Printed Circuit & APEX South China Fair (2018 HKPCA & IPC Show)—will be held on December 5–7 at the Shenzhen Convention and Exhibition Center in Shenzhen, China. "Inspire the Industry, Explore the Infinity" will be the theme of this show. The scale of this exhibition is set to break the previous record with approximately 560 exhibitors, 3,100 booths from all over the world, and an exhibition area of more than 60,000 square meters. This will be the biggest show in its history.

Recently, I-Connect007 interviewed the heads of both HKPCA (Hong Kong Printed Circuit Association) and IPC (Association Connection Electronics Industries) and asked them to give our readers a comprehensive introduction to the exhibition and market trends.

HKPCA

PCB007 China: The HKPCA & IPC Show has been here for many years and has become the world's largest industry event. What are the highlights of this year's show?

HKPCA: As one of the world's most influential trading platform for the PCB and EA industry, the HKPCA & IPC Show will continue to bring new highlights with an aim to provide an excellent platform for industry players. The show will return on a record-high scale, and a new hall will be opened (Hall six) in addition to Halls one, two, and four. The 2018 show floor of the venue will showcase the latest innovations from the entire PCB and EA supply chain. Hall six will house over 100 quality materials suppliers from China and overseas who will showcase

their new and innovative products in areas of PCB materials and chemicals, green technology, and more. A wider range of product types and sectors helps visitors conveniently seek quality materials suppliers and offers an efficient one-stop purchasing service.

Based on positive feedback from last year's event, the Hong Kong Pavilion (Hall one) will be expanded with over 100 square meters showcasing PCBs, semiconductor products, and advanced technologies in four different product categories: communication, computers, consumer electronics, and automotive. The pavilion highlights Hong Kong's pivotal role in setting new standards and directions for the PCB industry.

Leading enterprises will exhibit at the fair, to showcase their latest products and solutions, including TTM, Topsearch, Sunshine, Atotech, Harvar, WKK, Schmoll, Process Automation, Dupont, Dow, Hans CNC, C Sun, Topoint, Carl Zeiss, Jadason, Orbotech, Hitachi Chemical, Isola, MacDermid, Rogers, Universal P.C.B., Protek, Joint Stars, World Wide PCB, Boffotto, Guanghua, Farcien, FujiFilm, Zhengye, and more.

The 2018 IPC Hand Soldering and Rework, Repair Competition will enable visitors to observe the highest levels of hand soldering craftsmanship. Further, this year's exhibition will continue to host a wide array of exciting events including the IPC China PCB Design Seminar, welcome dinner, and golf tournament. These activities will be held concurrently to provide industry peers with abundant networking opportunities to foster friendships and strengthen business ties and partnerships in a relaxing environment.

PCB007 China: Is there any correlation between this year's record-breaking show and the development of the entire industry?

HKPCA: In the booth allocation meeting held on July 18–19 in Hong Kong and Shenzhen, feedback was quick with 97% of booth spaces confirmed and sold out, so the industry is developing and doing well. Leading enterprises and new exhibitors will gather at the fair to showcase their latest and most innovative products and solutions. It offers an opportunity for the industry elites to interact with the buyers face-to-face. Also, a total of seven zones will be featured to help visitors locate their areas of interests and effectively reflect industry trends: equipment supplier, smart automation, green, PCB manufacturer, electronic assembly, Japan and Korea, and materials suppliers.

PCB007 China: This year, the PCB industry market has been changing rapidly. Business developments such as expansions, industrial transfers, listings, mergers and acquisitions, and technical cooperation are very active. What new developments and business opportunities do you think there are in the PCB and electronic assembly industry?

HKPCA: With the number of listed companies increasing, the influence of the capital market on our industry is stronger, and mergers and acquisitions will be routine in the future. China, the U.S., Japan, and South Korea have all released 5G commercial news, which is a tremendous opportunity. It is now the final countdown for commercial 5G—a technology that will power the development of IoT, industrial IoT, autonomous vehicles, Internet of Vehicles (IoV), smart cities, augmented and virtual reality (AR and VR), cloud computing, big data, etc. These trends could create a multitrillion-dollar market.

PCB007 China: PCB production technology has developed over many years. What is the hottest topic in the industry that will be in this show, and in which areas do you most hope to see technical breakthroughs? Additionally, what impact do you expect the show will have on the development of the whole industry?

HKPCA: There are two ongoing trends in electronics: light and small-form-factor, and high-speed, high-frequency. These trends will contribute to technological changes in downstream PCBs. Double-sided blind vias, ball grid array (BGA) blind vias, filled vias, multilayer blind vias, and two-step and three-step rigid-

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flex high density interconnect (HDI) PCBs are not that exotic designs now; trace width requirement is 35 µm, and some even require 25 µm. As spacing becomes denser and the data rate of high-speed signals get quicker, the requirement of the trace geometry consistency needs to be better. However, today's technology could not make the copper thickness the same on the surface and in the hole. We hope that there will be new technology that could solve this in the future.

Conferences and forums also cover a wide range of hot topics of this industry including market and technology developments of photosensitive coating in flexible printed circuits (FPCs) and rigid-flex boards, silver catalyst chemistries, using cellphones to manage facility operations, and how to be competitive using enterprise resource planning (ERP), manufacturing execution syetems (MES), advanced parts manufacturing (APM), total productive maintenance (TPM), and warehouse management systems (WMS.) We hope the three-day exhibition and activities will drive the industry forward rapidly.

PCB007 China: What is your opinion on the development of the global PCB industry, and what are your expectations for market development trends in 2019?

IPC: After the adjustments in electronic industry in recent years—developments in smart factories, 5G communication, artificial intelligence (AI), new energy vehicles, autonomous vehicles, and device data interconnections—these trends have emerged, which gives the electronics industry, PCB manufacturers, and electronic assemblers new opportunities to grow. These new opportunities are applications of advanced technology in high-reliability products. How can we seize this opportunity? Do the skills of the workforce, manufacturing capability, and product quality of electronics manufacturing companies meet the requirements of high-reliability products? IPC provides training programs and certification services designed to improve product reliability, and they are very helpful for companies looking to enter the high-reliability market.

PCB007 China: This year, the PCB industry market has been changing rapidly. Business developments such as expansions, industrial transfers, listings, mergers and acquisitions, and technical cooperation are very active. What new developments and business opportunities do you think there are in the PCB and electronic assembly industry?

IPC: High-end electronics manufacturing including 5G, IoT, cloud computing, new energy vehicles, autonomous vehicles, smart manufacturing, automation, and military and aerospace (milaero) will be the top opportunities for the next few years.

PCB007 China: The theme of this show is "Inspire the Industry, Explore the Infinity," and the scale of the show will surpass previous ones. Do you think that PCB production technology is still advancing, and if so, what technological breakthroughs would you like to see the most? Will the organizer help with technical exchanges and promotions?

IPC: PCBs are switching from mass production to low-volume, high-mix production. In this transition, productivity and yield will drop. CFX (Connected Factory Exchange) technology can help enterprises achieve this low-volume, high-mix requirement with low costs. CFX technology also improves the efficiency of the supply chain. CFX is a basic standard that is the realization of data acquisition, transmission, exchange, analysis, modeling, and control of Industry 4.0. IPC has joined hands with the world's leading equipment, software, and original equipment manufacturer (OEM) companies to develop the IPC CFX-2591 standard collaboratively, and has exhibited the CFX demonstration successfully. We will also work together with experts to discuss CFX technology at the IPC WorksAsia conference, and invite

the U.K. made the keynote for a telecommunications conference in Dongguan. These technical exchanges promoted mutual learning between local and foreign experts.

To help domestic companies to realize the importance of employee skills training and continuous education, IPC has been holding the hand soldering competition for ten years. This year, five competitions were held in China. It was revised in response to the high-end manufacturing needs to add rework. The podiums of China will be going to the United States to compete in the World Championship. This competition has trained a large number of highly skilled shop floor workers for domestic milaero, aviation, communication, automotive, medical, industrial, etc. As first-pass yield improves, companies are aware that continuous education is crucial and they will benefit from it.

Today, smart manufacturing has become a hot concept to invest in. IPC has gathered many international experts to take the lead in developing the CFX standard. During the 2018 LEAP show in Munich, the CFX demo line was launched with 16 exhibitors from China for the first time. CFX provides a unified international standard and realizes smart factory data collection, transmission, exchange, and control between equipment and machines that are of different manufacturers at a low cost. Now, as the demand for high-end manufacturing of BGA and flex technology are increasing, IPC has reacted in a timely manner by developing the "IPC-7095 Design and Assembly Process Implementation for BGAs," "IPC-6013 Qualification and Performance Specification for Flexible/Rigid-Flexible Printed Boards," and new services such as aerospace and aviation training. **PCB007**

more companies to join the CFX demo production line to showcase the Industry 4.0 paradigm.

PCB007 China: Regarding IPC standards promotion and training programs, what are the plans for this year's activities?

IPC: With the Industry 4.0 and Made in China 2025 (MIC 2025) strategic plan in place driven by growing market trends, high-end electronic assembling and manufacturing are getting better opportunities to grow. Whether Chinese electronics manufacturing companies can make full use of this opportunity depends on the application of advanced technology, training, and process and production management.

To help Chinese companies improve their high-end electronic manufacturing, IPC utilizes their world-leading standards technology, advanced processes, and technical resources to invite domestic and foreign milaero, automotive electronics, and software experts to China for technical exchanges. For example, we invited Continental and GM gurus to participate in the automotive electronics conference in Shanghai and Shenzhen. Moreover, experts from NASA and IPC headquarters attended the aerospace and aviation conferences in Shanghai, Beijing, and Xi'an, and experts from

Editor Picks from PCB007

1 EPTE Newsletter: Taiwan Electronics are Heating Up (Figuratively) ▶


Dominique Numakura

Dominique Numakura considers electronics manufacturing in Taiwan to be the barometer for the global consumer electronics industry. Market trends can be predicted by analyzing shipping data from Taiwanese circuit board manufacturers. Annual volume increases every year, despite slow monthly cycles.

2 Aspocomp Raises Outlook for Net Sales and Operating Result in 2018 ▶

Aspocomp Group Plc upgrades its outlook for full-year 2018 net sales and operating result. In 2018, net sales are expected to grow approximately 15% compared with 2017 and the operating result to be approximately EUR 2 million. In 2017, net sales amounted to EUR 23.9 million and the operating result to EUR 0.8 million.

3 Ventec at electronica 2018: No Compromises for High-Frequency Materials ▶

Ventec International Group will announce the launch of its extended ceramic-filled hydrocarbon thermoset material series designed for the world's most demanding high-frequency printed circuit board applications at this year's electronica show in Munich.

4 I-Connect007 Publishes Automation eBook by Happy Holden ▶


Happy Holden

I-Connect007 is excited to announce the release of the latest title in our eBook library: *Automation and Advanced Procedures in PCB Fabrication.*

5 It's Only Common Sense: What the Heck is an SEO?


Dan Beaulieu

Have you ever wondered what it takes to get to the top of a Google page? Why do some companies always seem to have all the business they need even without any outside salespeople? It seems to be some kind of black magic. How do they do it? Read on.

6 The Changing Shape of the HDI Market


Roger Massey

With more mobile device designers looking to utilize the benefits of FOWLP and other direct attach package types, a new generation of HDI PCBs is already in the market. Targeting less than 30 mm features and based on mSAP techniques, these substrate-like PCBs make use of the latest high-end manufacturing processes and materials, to enable the next evolution in advanced HDI boards.

7 IPC President Commends White House for Assessment of US Defense Industrial Base

On behalf of the electronics industry, I commend the White House for the release today of a sweeping and detailed assessment of the nation's defense industrial base. The report reflects more than a year of painstaking data collection, sector by sector analysis, and industry engagement.

8 GP Ventures' Tom Kastner on PCB Mergers and Acquisitions


Tom Kastner

Tom Kastner, president of GP Ventures, he has his finger on the pulse of the industry's mergers and acquisitions (M&A) more than anyone. In this interview, Kastner provides insights on the right time to buy, how to evaluate your company's worth, and when it is too late.

9 What's FLITE About? An Old Man's Observations

FLITE—Female Leaders in Tech, Everywhere—aims to raise the visibility of females in technology, manufacturing, and engineering by celebrating their achievements and learning from their experiences. I-Connect007 Technical Editor Pete Starkey sit in on FLITE's networking event at the recent What's New in Electronics (WNIE) Live show to find out more about this enterprise, which turned out to be an inspirational eye-opener.

10 FPCB Market to Display Significant Growth by 2027

The demand for flexible printed circuit boards by manufacturers of smartphones, other mobile devices, LCD display, connectivity antennas, and rechargeable batteries, is currently on the rise. With exploding consumer electronics sector, soaring popularity of IoT, and growing applications in the automotive sector are identified to be the key factors that are likely to hold a positive impact on the sales of FPCBs in near future.

Career Opportunities

MivaTek Global

Multiple Positions Available

Want to work for a fast-growing company? MivaTek Global may be the place for your next career move. 2018 has brought significant growth, increasing sales and revenue. And, we are just getting started! To support the current customer base and fuel further expansion, we are looking for bright and talented people who are energized by hard work in a supportive and flexible environment.

Open Positions:

- Technical Service Technicians
- Regional Sales Representatives
- Regional Leader for Asia Sales and Support

Proven experience in either PCB or Microelectronics and willingness to travel required for all positions.

More About Us

MivaTek Global is a distributor of manufacturing equipment with an emphasis of Miva Technologies' Direct Imager, Mask Writer, Flatbed Photoplotter imaging systems and Mach3 Labs X-Ray Drills. We currently have 45 installations in the Americas. Expansion into Asia during 2018 has led to machine installations in China, Singapore, Korea, and India.

To be part of our team, send your resume to n.hogan@kupertek.com for consideration of current and future opportunities.

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FREEDOM CAD SERVICES

Sr. PCB Designer - Allegro

Freedom CAD is a premier PCB design service bureau with a talented team of 30+ dedicated designers providing complex layouts for our enviable list of high-tech customers. Tired of the commute? This is a work-from-home, full-time position with an opportunity for overtime at time and a half.

Key Qualifications

- EXPERT knowledge of Allegro 16.6/17.2
- Passionate about your PCB design career
- Skilled at HDI technology
- Extensive experience with high-speed digital, RF and flex and rigid-flex designs
- Experienced with signal integrity design constraints encompassing differential pairs, impedance control, high speed, EMI, and ESD
- Experience using SKILL script automation such as dalTools
- Excellent team player that can lead projects and mentor others
- Self-motivated, with ability to work from home with minimal supervision
- Strong communication, interpersonal, analytical, and problem solving skills
- Other design tool knowledge is considered a plus (Altium, PADS, Xpedition)

Primary Responsibilities

- Design project leader
- Lead highly complex layouts while ensuring quality, efficiency and manufacturability
- Handle multiple tasks and provide work leadership to other designers through the distribution, coordination, and management of the assigned work load
- Ability to create from engineering inputs: board mechanical profiles, board fabrication stack-ups, detailed board fabrication drawings and packages, assembly drawings, assembly notes, etc.

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Career Opportunities

Career Opportunities

MacDermid Enthone
ELECTRONICS SOLUTIONS

Director of Final Finishes
Waterbury, CT

Education: Advanced practical knowledge–formal education and experience in chemistry or related sciences. Knows all technology within the business area and has knowledge of end use processes and OEMs.

Responsibilities

- Collects and analyzes market information, understands the competitive landscape, identifies potential gaps in product portfolio and effectively communicates needs to the product development group.
- Oversees product development activities, and reviews projects as they reach PDP milestones.
- Responsible for customer presentations and participation in trade organizations and other industry activities.
- Constructs release package information for the introduction of new products and sets pricing guidance for the commercial teams.
- Responsible for customer presentations and participation in trade organizations and other industry activities. High-level customer interaction required.
- Has successfully demonstrated the ability to manage professionals and nonprofessionals in a technical and marketing environment.
- Develops and responsible for budgets and goals of the group.

MacDermid Enthone is an E-Verify Company and provides reasonable accommodation for qualified individuals with disabilities and disabled veterans in job applicant procedures. "Equal Opportunity Employer: Minority/Female/Veteran/Disabled/Gender Identity/ Sexual Orientation."

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Gardien

Careers with Gardien

The Gardien Group, a leading solutions provider in the PCB industry, is looking to fill multiple openings in their China, Japan, Taiwan and the United States service centres.

We are looking for electrical engineers, operations managers, machine operators and sales executives. Prior experience in the PCB industry is beneficial but not essential. Training will be provided along with excellent growth opportunities, benefits package and periodic bonuses.

Our global teams are from diverse cultures and work cohesively as a tight-knit unit. With performance and initiative, there are plenty opportunities for professional growth.

Interested candidates please contact us at careers@gardien.com with your resume and a cover letter. Kindly note that only shortlisted candidate will be contacted.

About Gardien Group

Gardien is the world's largest international provider of independent testing and QA solutions to the PCB industry with a global footprint across 24 service centres in 5 countries and we cater to a whole range of customers, from small, family-owned PCB shops to large international fabricators, and everything in-between. Gardien's quality solutions and process standards are trusted by leading high-tech manufacturers and important industries including aerospace, defense and medical technology.

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Career Opportunities

American Standard Circuits
Creative Innovations In Flex, Digital & Microwave Circuits

CAM Operator

American Standard Circuits is seeking a CAM Operator for its Phoenix, Ariz., office. Qualified applicants will need experience in using Valor/Genesis (GenFlex) CAD/CAM software with printed circuit board process knowledge to edit electronic data in support of customer and production needs.

Job Requirements:

- At least 5 years' experience in PCB manufacturing
- Process DRC / DFMs and distinguish valid design and manufacturing concerns.
- Modify customer supplied data files and interface with customers and engineers
- Responsible for releasing manufacturing tooling to the production floor
- Prepare NC tooling for machine drilling, routing, imaging, soldermask, silkscreen
- Netlist test, optical inspection
- Work with Production on needed changes
- Suggestions on continual improvements for engineering and processing.
- Be able to read write and communicate in English
- Must understand prints specifications
- Must be US Citizen or permanent resident (ITAR)
- High School Graduate or equivalent

Join our Team!

Founded in 1988, American Standard Circuits is a leading manufacturer of advanced circuit board solutions worldwide. Our ongoing commitment to leading-edge higher-level interconnect technology, cost-effective manufacturing and unparalleled customer service has put us at the forefront of advanced technology circuit board fabrication.

We manufacture quality rigid, metal-backed and flex printed circuit boards on various types of substrates for many applications.

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We Are Recruiting!

A fantastic opportunity has arisen within Electrolube, a progressive global electrochemicals manufacturer. This prestigious new role is for a sales development manager with a strong technical sales background (electro-chemicals industry desirable) and great commercial awareness. The key focus of this role is to increase profitable sales of the Electrolube brand within the Midwest area of the United States; this is to be achieved via a strategic program of major account development and progression of new accounts/projects. Monitoring of competitor activity and recognition of new opportunities are also integral to this challenging role. Full product training to be provided.

The successful candidate will benefit from a generous package and report directly to the U.S. general manager.

Applicants should apply with their CV to
melanie.latham@hkw.co.uk
(agencies welcome)

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Career Opportunities

Ucamco
Former Barco ETS

International Field Service Engineer located in ITALY

The successful candidate will:

- Install and service our plotters and direct imaging machines at customer sites Europe-wide
- Carry out maintenance in the field
- Frequent travel: 4 to 5 days a week, 3 to 4 weeks a month
- Assist product manager

We are looking for a team player who is:

- Strongly customer-oriented and experienced in on-site support
- Accustomed to travel, and willing to travel frequently
- Motivated, independent and enterprising
- Technically-minded with training/background in electromechanics/electronics
- Experienced with software (setup, configuration, and usage of Windows-based CAM front-end software and Linux-based RIP software)
- Fluent in Italian and English (German and/or French is a plus)
- An analytical thinker
- Capable of problem solving

The right candidate will be a valued member of a friendly, team-oriented, growing international company that is a leader in its field, dedicated to excellence in all it does. Dynamic and fun, the company offers a great working atmosphere, and this new position is forward-looking and open, with plenty of opportunities for enterprising individuals whose results could be rewarded with prospects for progression in technical development.

Apply to Anja Ingels after clicking below.

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Gardien

Role: Vice President Gardien Taiwan
TAOYUAN COUNTY, TAIWAN

Gardien Taiwan is a service provider of circuit board (PCB) quality solutions, including electrical testing, AOI optical inspection, engineering (CAM), fixture making, repair and rework. Gardien Taiwan operates service centers in Taoyuan and employs about 100 employees and is currently seeking a vice president to manage and oversee the entity.

Candidate Profile:

- Proficiency in Chinese and English (written and spoken)
- Excellent communication and organization skills
- Experience in change management
- PCB background appreciated, but not mandatory
- Management experience in internationally operating companies
- Savvy in standard office software (Word, Excel and Power Point)

If this sounds like you, please click here to send us an email with your attached CV.

About Gardien Group - Gardien is the world's largest international provider of independent testing and QA solutions to the PCB industry with a global footprint across 24 service centres in five countries and we cater to a whole range of customers, from small family owned PCB shops to large international fabricators. Gardien's quality solutions and process standards are trusted by leading high-tech manufacturers and important industries including aerospace, defense, and medical technology.

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Career Opportunities

Career Opportunities

Mentor®
A Siemens Business

PCB Manufacturing, Marketing Engineer

Use your knowledge of PCB assembly and process engineering to promote Mentor's Valor digital manufacturing solutions via industry articles, industry events, blogs, and relevant social networking sites. The Valor division is seeking a seasoned professional who has operated within the PCB manufacturing industry to be a leading voice in advocating our solutions through a variety of marketing platforms including digital, media, trade show, conferences, and forums.

The successful candidate is expected to have solid experience within the PCB assembly industry and the ability to represent the Valor solutions with authority and credibility. A solid background in PCB Process Engineering or Quality management to leverage in day-to-day activities is preferred. The candidate should be a good "storyteller" who can develop relatable content in an interesting and compelling manner, and who is comfortable in presenting in public as well as engaging in on-line forums; should have solid experience with professional social platforms such as LinkedIn.

Success will be measured quantitatively in terms of number of interactions, increase in digital engagements, measurement of sentiment, article placements, presentations delivered. Qualitatively, success will be measured by feedback from colleagues and relevant industry players.

This is an excellent opportunity for an industry professional who has a passion for marketing and public presentation.

Location flexible: Israel, UK or US

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BLACKFOX®
Premier Training & Certification

IPC Master Instructor

This position is responsible for IPC and skill-based instruction and certification at the training center as well as training events as assigned by company's sales/operations VP. This position may be part-time, full-time, and/or an independent contractor, depending upon the demand and the individual's situation. Must have the ability to work with little or no supervision and make appropriate and professional decisions. Candidate must have the ability to collaborate with the client managers to continually enhance the training program. Position is responsible for validating the program value and its overall success. Candidate will be trained/certified and recognized by IPC as a Master Instructor. Position requires the input and management of the training records. Will require some travel to client's facilities and other training centers.

For more information, click below.

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Events Calendar

IPC/SMTA High-Reliability Cleaning and Conformal Coating Conference ▶
November 13–15, 2018
Schaumburg, Illinois, USA

electronica 2018 ▶
November 13–16, 2018
Munich, Germany

International Printed Circuit & APEX South China Fair ▶
December 5–7, 2018
Shenzhen, China

IEEE Rising Stars Conference ▶
January 4–6, 2019
Las Vegas, Nevada, USA

48th NEPCON JAPAN ▶
January 16–18, 2019
Tokyo Big Sight, Japan

IPC APEX EXPO 2019 ▶
January 26–31, 2019
San Diego, California, USA

DesignCon ▶
January 29–31, 2019
Santa Clara, California, USA

MD&M West 2019 ▶
February 5–7, 2019
Milan, Italy

IPC High Reliability Forum ▶
May 14–16, 2019
Hanover (Baltimore), Maryland, USA

Additional Event Calendars

IPC | SMTA Surface Mount Technology Association | iNEMI | pcb007

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Coming Soon to *PCB007 Magazine:*

December: IPC APEX EXPO 2019
Preshow Issue.

January 2019: SUPPLY CHAIN
We look into the affects of the supply chain crisis on fabrication.

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