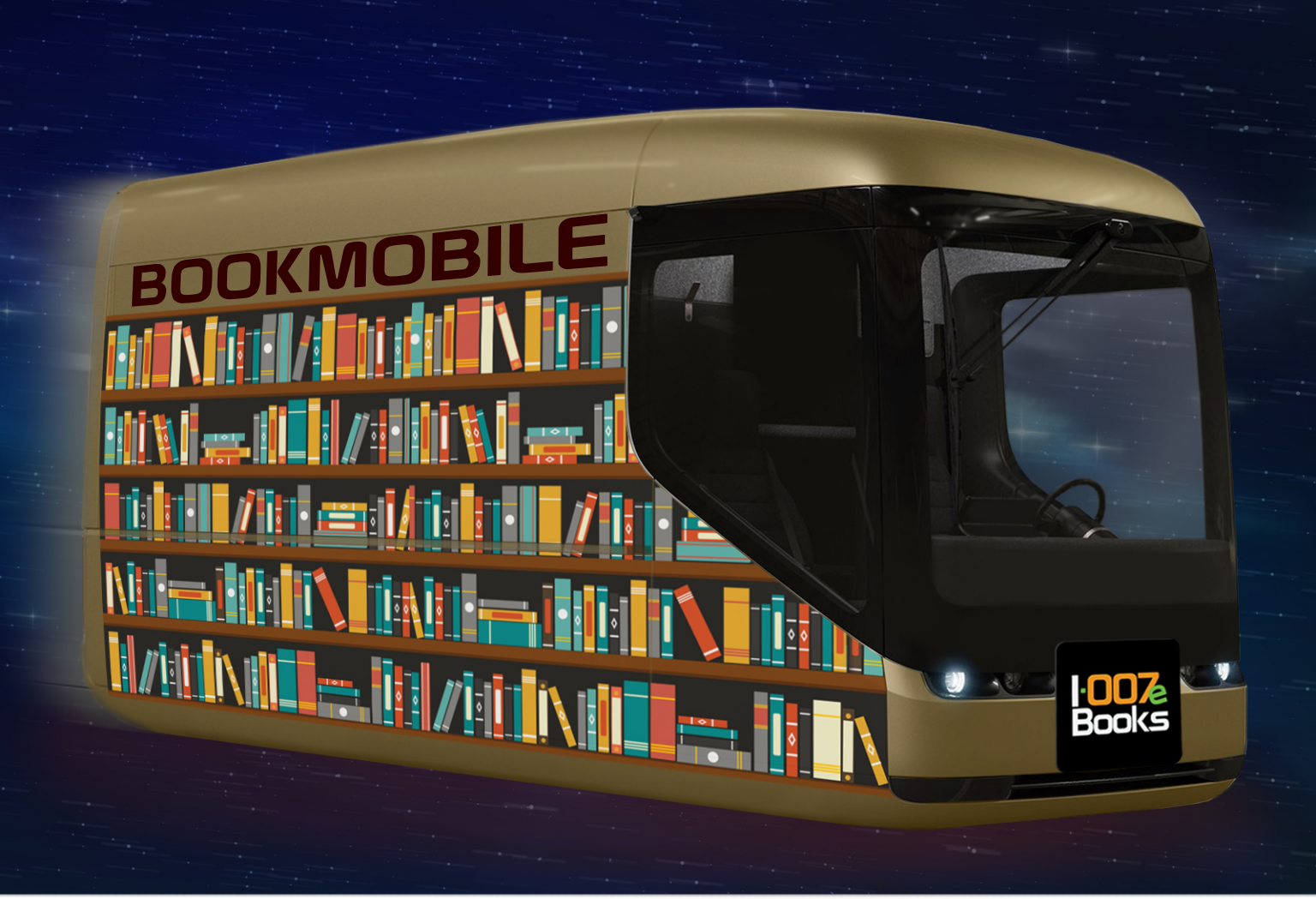
NOVEMBER 2018

I-Connect007

SMT007 MAGAZINE

Medical Electronics: Connected Healthcare



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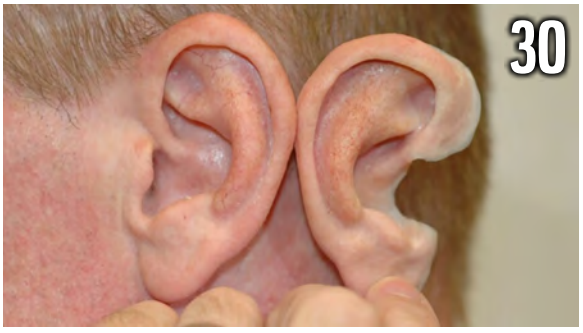
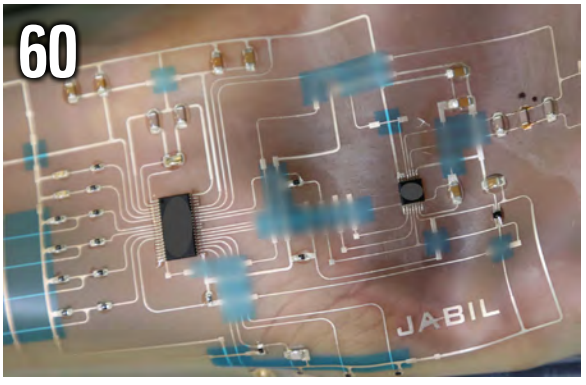
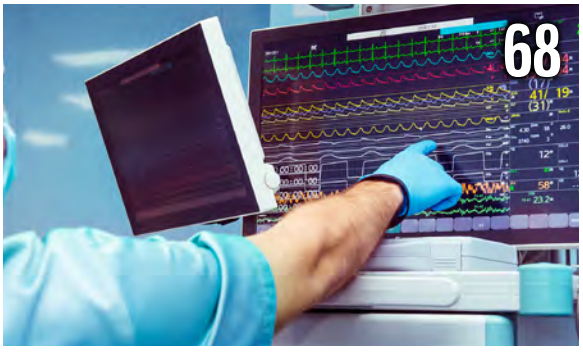


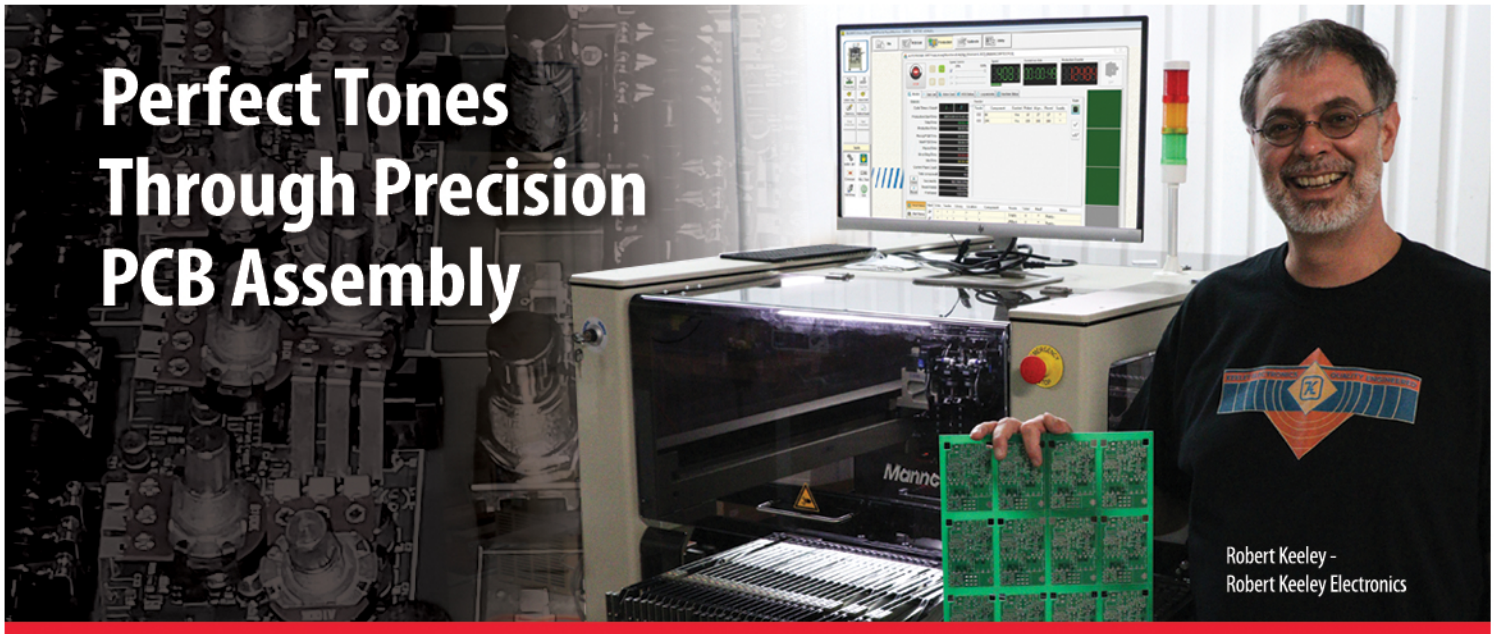




Medical Electronics

Whether or not you believe this is a golden age for medical devices, there's no denying that the amount of innovation underway in medical electronics is staggering. If you're not currently contributing to medical device development, chances are you might find yourself working with medical devices at some time in the future. In this issue, we take you deeper into the technologies, trends, and compliance constraints you're likely to encounter in your next (or first) medical device.

Perfect Tones Through Precision PCB Assembly



The tone and effect experts at **Robert Keeley Electronics** have recently started the conversion to in-house PCB assembly. From the very beginning, it's been the goal of Keeley Electronics to provide artists such as John Mayer, Nancy Wilson of Heart, Larry Lalonde of Primus, and Dweezil Zappa with the options they need to realize the compositions of their dreams. Working with an amazing array of people over the years, Keeley's unbeatable array of distortion, overdrive, boost, compression, and effects pedals have been the answer to countless artists searching for the final touch that truly defines their unique, one-of-a-kind tone.

With 27 bills of materials submitted and refined over the course of just two weeks, Manncorp provided Keeley with a list of machinery that would streamline their operation and cut down on their reliance on outside vendors. Click below to read more about Keeley and their conversion to in-house SMT work. The conversion process can streamline your production and cut down on your lead times.

Read Complete Article on Robert Keeley Electronics Conversion to In-House PCB Assembly

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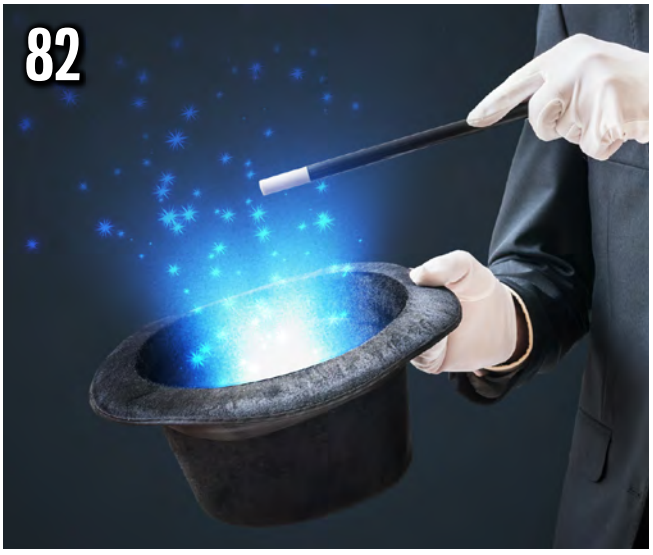

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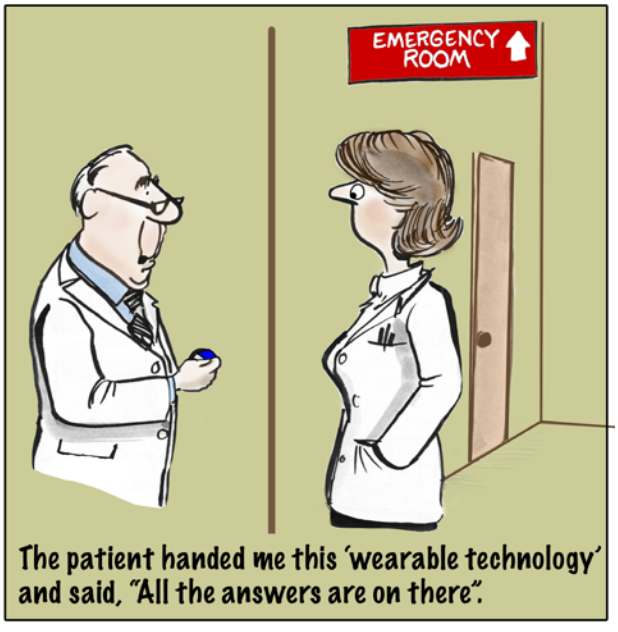
Is This a Golden Age for Medical Devices?

Nolan's Notes
by Nolan Johnson, I-CONNECT007

I grew up in the late 1960s and early 1970s. In my hometown, electronic media consisted of five television stations—one for each of the big three networks, an independent station, and a public broadcasting channel. Radios were all mono AM band. At one radio station in my hometown during this time, a twenty-something audio technician got permission to set up an "underground" FM radio station in a broom closet of the broadcast building. That little experiment grew into one of the most listened-to FM stations in my hometown today.

Further, wireless, back then, meant you had a CB radio in your car. If you tuned in to channel 18 at 9 p.m. every weeknight, you could hear my buddies and me comparing answers on our homework assignments. I think we invented the chat room!



Looking back, that period of time was the dawning of a golden age of innovation in communications technology. That era led to wireless phones, electronic data terminals and pay stations, and technology that allows us to watch our favorite shows on our own time and not the TV stations' schedule. If you had told 10-year-old Nolan that two or three decades later these things would come to pass, that version of me would have had trouble taking you seriously (my 10-year-old self was much more of a skeptic than grown-up me).

We live in a very different—but mostly better—world because of this innovative era. I say that out loud to my son every time he video calls me from his home at a Naval station in Virginia. Just as the telecommunications golden age launched 30 years ago, it seems that medical device technology is gearing up to do something similar. The Internet of Things (IoT), Internet of the Body (IoB), and printed electronics technologies are emerging, and they're converging with medical devices in a big way.

It's hard not to conclude that we're seeing the beginning of an innovative golden age in medical devices due to the confluence of these three disruptive new technologies. The way we use electronics to monitor our health and well-being will in all likelihood be unrecognizable by the middle of the 21st century—"Grandpa, tell me again why the nurses stuck the thermometer

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under your tongue when you were a kid?" This is why we decided to take a step back to survey the changes this month and have a discussion on these pages about what is happening with medical device development.

We kick things off with an experts interview on medical electronics trends featuring Dr. Despina Moschou, a lecturer at the University of Bath, and Kaspars Fricbergs, vice president of global quality, and Tom Reilly, director of marketing and sales operations, of EMS firm Vexos. We examine challenges and opportunities in medical electronics design and assembly.

Dr. Jennie Hwang's column considers solder and its role in adhering components to substrates. Could there be other options available for emerging technologies?

In "3D Printing and Medical Electronics: A Beneficial Disruptive Technology," Dan Feinberg, consulting technical editor, brings us an exposé on 3D additive processes and their innovative effect on medical and dental applications.

In "FDA Approval: A Beginner's Guide," Managing Editor Nolan Johnson explores all the basics of FDA approval and shares perspectives from two medical startups and a medical electronics contract manufacturer.

Eric Camden's testing column joins the quest for reliability in medical devices. His case studies remind us to consider not only the entire supply chain for cleanliness, but also the target work environment.

Furthering the conversation, John Mitchell, IPC president and CEO, files his column on the IPC Education Foundation and its mission to prepare the emerging workforce.

In "Printed Electronics and the Fast, Flexible Future of Connected Healthcare," Girish Wable and Ralph Hugeneck from Nypro collaborate to explore IoT and the increased use of printed electronics in medical devices.

Next, NexLogic's CEO, Zulki Kahn, sits down with I-Connect007's Stephen Las Marias to discuss what he sees as the trends and challenges in medical electronics, such as how cleanrooms will increasingly matter, and how to find a manufacturing partner.

Bob Wettermann knocks down the bone pile with his column on rework "gotchas" and guidelines to ensure successful rework.

Bringing it all home is Goepel Electronic's Jens Kokott and Matthias Müller detailing Goepel's improvements to AOI test programming.

Strap on your smartwatch, check your heart rate, and enjoy the emergence of the next golden age. **SMT007**

Nolan Johnson is managing editor of *SMT007 Magazine*. Nolan brings 30 years of career experience focused almost entirely on electronics design and manufacturing. To contact Johnson, click here.

Global Medical Device Market to Reach $410B by 2023

The future of the global medical device market looks bright with opportunities in public and private hospitals. The global medical device market is expected to reach an estimated $409.5 billion by 2023, growing at a compound annual growth rate (CAGR) of 4.5% from 2018 to 2023, according to a new report from market research firm Lucintel. Major drivers for growth include healthcare expenditure, technological development, aging population, and chronic diseases.

North America is expected to remain the largest market during the forecast period mainly due to a large target patient pool coupled with a high adoption rates for advanced treatments in this region.

Emerging trends that will have a direct impact on the dynamics of the medical device industry include the changing medical technology landscape, software as a differentiator in medical devices, and design and manufacturing of patient portable and smaller devices. Lucintel notes that the orthopedic device segment will show above average growth during the forecast period.

(Source: Lucintel)

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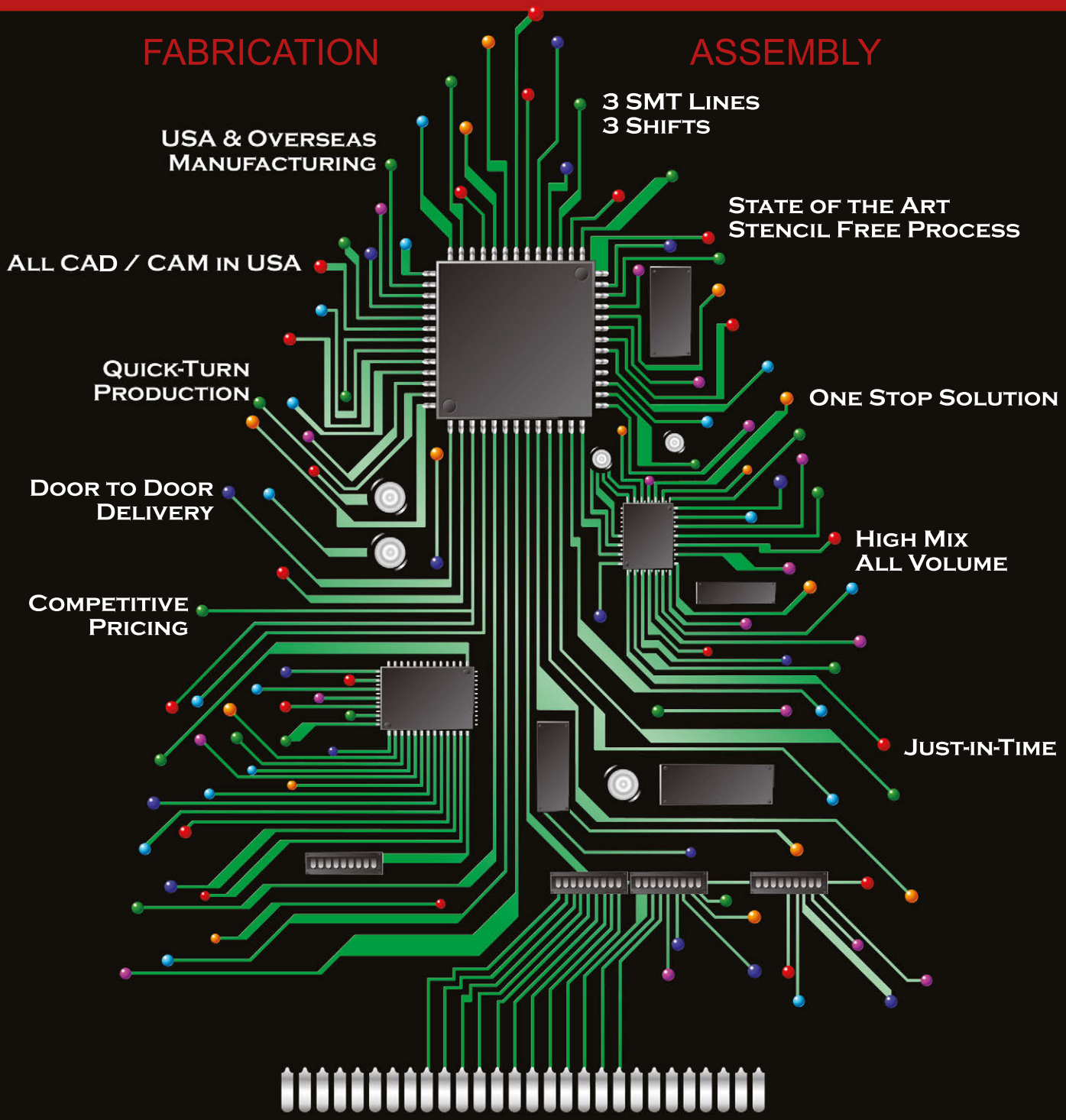

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SMT Manufacturing: Why Soldering?

SMT Prospects & Perspectives

by Dr. Jennie S. Hwang, CEO, H-TECHNOLOGIES GROUP

My last column—"Artificial Intelligence: Super-Exciting, Ultra-Competitive" (*SMT007 Magazine,* September 2018)—described compelling needs of the next generation of hardware in the artificial intelligence (AI) era. Upcoming AI hardware requires advanced semiconductors, packaging approaches, new architectures, increased speeds and capabilities of inference processing, and system design and manufacturing prowess continually developed to reach the interconnect density.

Against this backdrop, packaging and assembly levels—including surface-mount technology (SMT)—will continue to be critical technology and serve as the backbone of manufacturing electronic hardware to deliver desired products with enhanced miniaturization, functionality, and augmented intelligence promptly.

The SMT electronics manufacturing sector with OEMs and EMSs alike has overcome many challenges in the past. I do not doubt that we will tackle new challenges head-on to produce the required hardware in the AI era. Under the established infrastructure, will soldering (reflow, wave, selective, etc.) remain a necessary technique?

Soldering—the process to make solder joints—sounds like an ancient technique and is typically deemed unglamorous. However, substantial innovations and refinements in process and equipment have been made over the last three decades. Soldering offers an array of characteristics that bear both scientific and practical merits that will continue to maintain viability in the electronics industry. Here is my list of top five characteristics:

1. Application flexibility and agility: Solder can be readily made and applied in various physical forms, including bar, ingot, wire, powder, preform, solder sphere, solder column, paste, ink, and in a molten state.

2. Compatibility: Soft solder alloys fit into the process temperature range that electronic components—such as integrated circuits (ICs), passives, and optoelectronic devices—and the internal structure of the PCB are designed for and can withstand. Any other joining techniques (e.g., brazing, welding) need a much higher process temperature that is unsuitable for electronic components and PCBs.

3. Practicality: Solder alloys have the required environmental stability during manufacturing and in service (e.g., not prone to excessive oxidation, not corrosive, not unduly toxic).

4. Performance: A solder alloy—specifically a tin-based alloy with designed compositions—delivers the required physical properties (e.g., melting temperature, thermal and electrical conductivity, wetting ability, surface tension) and mechanical properties (e.g., strength, creep resistance, thermal fatigue resistance).

5. Cost and competitiveness: Solder alloys and soldering processes in the SMT infrastructure can be readily synchronized with intel-

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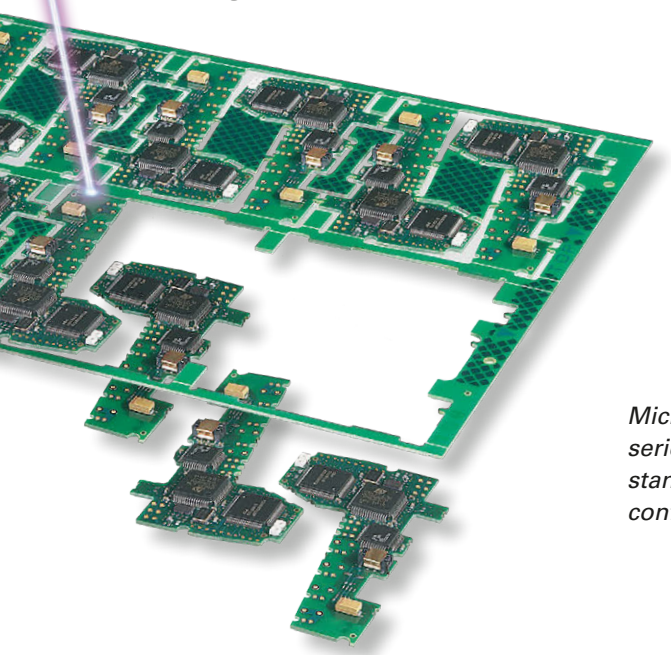

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ligence-enabled manufacturing and automation, which is key to the future of electronic hardware manufacturing and producing reliable products economically.

Conclusion

Overall, the flexibility, agility, compatibility, practicality, performance, cost, and competitiveness offered by soldering are crucial to making both today's electronic products and those anticipated in the future. This collective array of characteristics is unique. There is no better substitute in existence that delivers all of the necessary attributes previously listed.

For example, conductive adhesive and solder material have been studied in parallel when SMT was implemented for manufacturing PCB assemblies in the 1980s. Conductive adhesive worked in some selective applications but did not fill the interconnection role in a broad scope and or in mass production. This does not imply that new materials coupled with advanced techniques are not welcome. Instead, better methods, technologies, and materials should and will always be embraced by the industry.

Soldering process know-how is closely linked with production defects, yields, and costs of electronic devices.

The role of solder as the electrical, mechanical, and thermal linkage of circuitry is essential to electronic products. Soldering process know-how is closely linked with production defects, yields, and costs of electronic devices. An additional level of performance and reliability of solder joints is required mainly stemming from the confluence of three fronts: powerful chip designs, advanced IC packages, and higher density PCBs. Accordingly, SMT soldering is expected to deliver increased precision and heightened automation using solder materials that possess enhanced properties to make reliable solder interconnections for the new generation of electronic AI hardware. **SMT007**

Upcoming Appearance

Dr. Hwang will present a lecture on "Preventing Production Defects and Product Failure" at IPC APEX EXPO on January 28, 2019, in San Diego, California.

About the Author

Dr. Hwang, an international businesswoman and speaker, and business and technology advisor, is a pioneer and long-standing contributor to electronics hardware manufacturing as well as to the environment-friendly lead-free electronics implementation. Among her many awards and honors, she was inducted to the International Hall of Fame–Women in Technology, elected to the National Academy of Engineering, an R&D-Stars-to-Watch, and YWCA Achievement Award. Having held senior executive positions with Lockheed Martin Corp., Sherwin Williams Co., SCM Corp, and CEO of International Electronic Materials Corp., she is currently CEO of H-Technologies Group providing business, technology and manufacturing solutions. She is the Chairman of Assessment Board of DoD Army Research Laboratory, serving on Commerce Department's Export Council, National Materials and Manufacturing Board, Army Science and Technology Board, various national panels/committees, international leadership positions, and the board of Fortune-500 NYSE companies and civic and university boards. She is the author of 500+ publications and several books, and a speaker and author on trade, business, education, and social issues. Her formal education includes four academic degrees as well as Harvard Business School Executive Program and Columbia University Corporate Governance Program. For more information, please visit www.JennieHwang.com. To read past columns or contact Hwang, click here.

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A Look at Medical Electronics

Design and Assembly Challenges

Feature interview by I-Connect007 Editorial Team

For this month's issue of *SMT007 Magazine,* we speak with Dr. Despina Moschou, lecturer at the University of Bath, as well as Kaspars Fricbergs, VP of global quality, and Tom Reilly, director of marketing and sales operations, of EMS firm Vexos Corp., to know more about the challenges and opportunities in medical electronics design and assembly.

Dr. Moschou speaks about designing and manufacturing her lab-on-a-chip device, while Fricbergs and Reilly discuss the regulatory requirements as well as supply chain issues when it comes to medical electronics manufacturing.

Stephen Las Marias: Tell us more about yourself, Despina, and your lab-on-a-chip project.

Dr. Despina Moschou: I always start by introducing people to what lab-on-a-chip is in general. Lab-on-a-chip is not my invention—I have to be very clear on that. Professor George Whitesides from Harvard and Professor Andreas Manz first suggested it. They came up with this idea in the mid-1990s. The concept was miniaturizing a complete biomedical laboratory in a microchip. This vision is what we, the scientific community all over the world, have been trying to do for the past 20–30 years.

Before I became involved in this field, my original background was purely electronics. I'm an electronics engineer, I graduated from Athens, and I have a Ph.D. in microelectronics. During my first post-doctoral research, I ran into the field of lab-on-a-chip—in particular, microfluidic devices. Since then, I have been involved in that because the impact of this technology is enormous once it reaches everyday life.

What does this technology do? Imagine if you could have the whole biochemical laboratory on your hand. Wouldn't that be cool? And apart from being cool, let's assume we have a biomedical laboratory such as a health-care facility. What do you do when you want to identify a diagnosis? Either you or your doctor will take a sample—such as blood, urine, or any other kind of biological sample—and will take a bottle of it and ship it to a laboratory. The laboratory will do an analysis. It will take a few hours, days, or even weeks, and then you will receive the results. This is the current routine in health-care practice for all kinds of diseases, whether infectious, routine checking, or monitoring your pregnancy or cancer treatment. Wouldn't it be great if we could avoid all the delays? How different would it be if instead of taking things to the laboratory, we could bring the laboratory to the people who need it.

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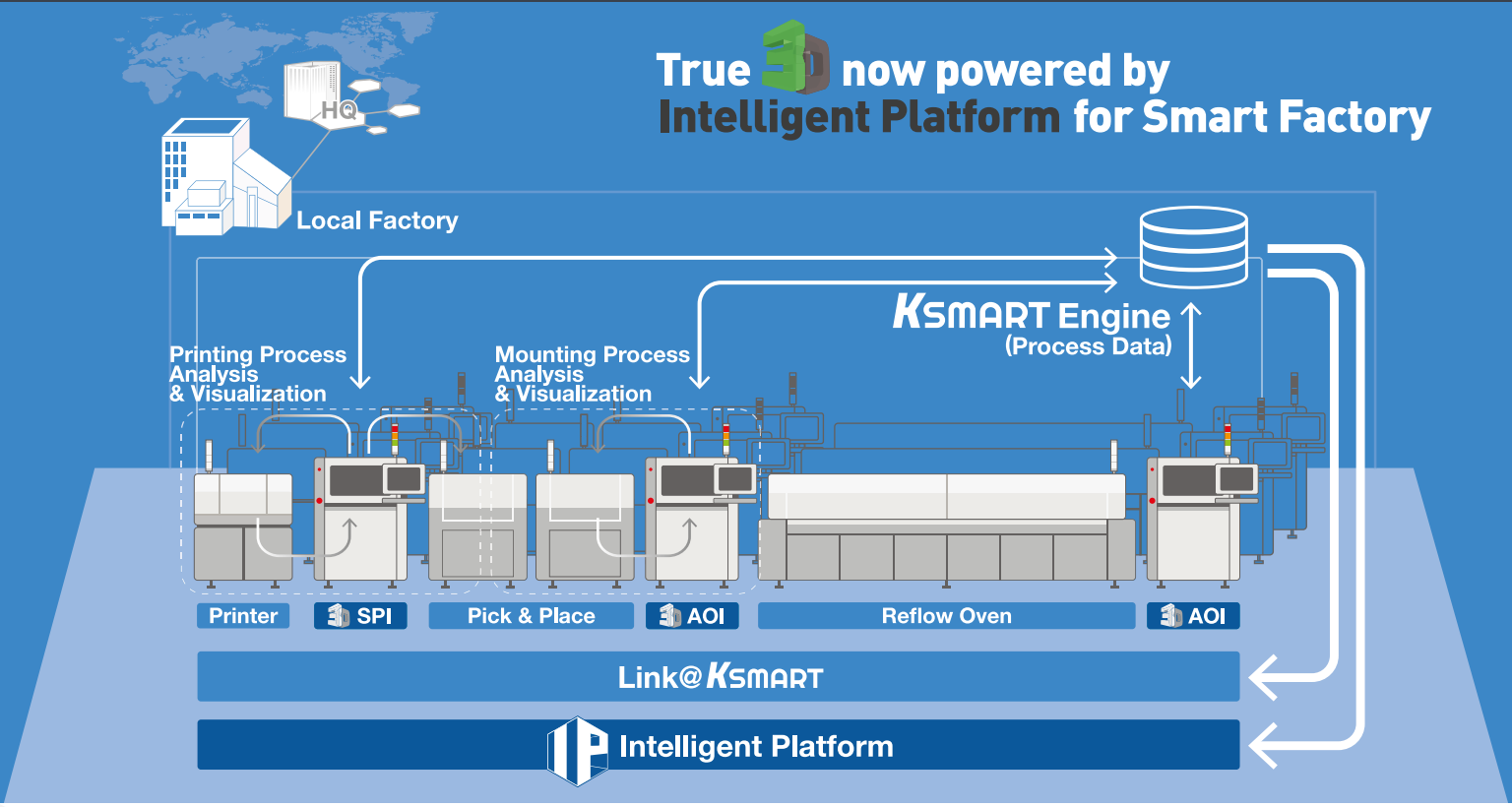

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And because you don't have to delay, treatment can start immediately. You wouldn't have to wait. Starting treatment is extremely important for overcoming any kind of disease. It will also have a huge impact in environments and countries where you don't have access to health-care facilities whatsoever, such as remote islands or low- and middle-income countries where you don't have access to health-care facilities with laboratories. In all of these cases, having a miniaturized laboratory can make a huge difference. This is roughly the vision of what we are trying to realize with our Research at the University of Bath.


Dr. Despina Moschou

Barry Matties: The technology itself is really interesting because they're using these miniature micro-pumps to move fluid around, and the idea was to actually incorporate it into the build of the circuit board. And it's really a game-changer. What's interesting about this also is it's one and done, meaning you use it, you throw it away and you buy more. So, from a consumption point of view, millions and millions of units will be sold. And you've already had success in creating the lab onboard and doing diagnostics, correct?

Moschou: Yes, we have.

Matties: This really goes with the continued desire for smaller, faster electronics, more affordable, and it's going to revolutionize the way that medical diagnostics is done.

Moschou: Exactly. What I have been driving for the past few years is trying to implement Lab-on-Chip technology on PCBs. At the moment, and ever since the invention of lab-on-a-chip, every research laboratory in the world has been using their own in-house technique to fabricate those devices. We don't have lab-on-a-chip technology with one way to manufacture things. In electronics, we have PCBs. We have the standard card that we all use to simulate and design boards, and manufacturers globally that have standardized procedures because this is an industry that's been around for many years.

In lab-on-a-chip, this is not the case. We are still at the research stage and are gradually transitioning into actual commercialization of devices the past few years. One of the problems delaying this process is that we don't have factories. We don't have a lab-on-a-chip factory where I can make something in my lab, design it, and then I can go and get millions of them. This is why I have been trying and persisting on the lab-on-PCB approach because we can actually use the factories that are out there right now fabricating electronic boards and transition into something more advanced—something smaller and more intelligent that can add further functionality to the electronic boards. This time, we can incorporate miniaturized channels to transport the liquids and the fluids that we want to analyze, which are called microfluidic tunnels. We can have analytical biomedical devices on a PCB.

This is not conceptual. I have been presenting for the past few years on the projects and prototypes we have made. We started making things in the lab with PCB technology, but lately, I've been working with several manufacturers around the world. I have shown several prototypes for many applications—mainly medical applications—involving DNA and protein detection for different cancer diagnoses. Currently, we are working in the lab on several of the prototypes for diagnosis. It's a proven concept. It can be done

Las Marias: Thank you, Despina. Meanwhile, Tom and Kaspars, please tell us more about Vexos and your roles in the company.

Tom Reilly: Sure. My name is Tom Reilly, and I'm the director of marketing and sales oper-

ations for Vexos. Vexo is a full service, high-mix, low- to mid-volume mid-tier electronics manufacturing services (EMS) provider, operating in focus market sectors such as: medical, industrial, semiconductor, automotive, safety, security and industrial internet of things (IIoT) markets. Vexos has a global manufacturing presence with two manufacturing sites in China, Shenzhen and Dongguan along with its North American sites in Markham, Ontario, and LaGrange, Ohio. All sites are ISO-9001 and ISO 13485 certified. We have more than 25 years' experience in providing a high-level of electronic manufacturing services, value engineering solutions and global supply chain management services that supports all our sites. We are deeply involved with provisioning highly complex, fine-pitch electronics assemblies, electromechanical assemblies, full turnkey solutions and custom mechanical parts.

The medical and life sciences sector is about 15–20% of our business and we currently specialize in manufacturing a number of difference products such as; visual aid, monitoring systems, diagnostics and connectivity-type products. As we grow in this market sector, we continue to meet the needs of our customers through a range of offerings in manufacturing and engineering services. Apart from our electronic services, which include printed circuit board assembly (PCBA), sub-system assemblies, and full box-build product. Our engineering services include design for supply chain (DFSC), design for fabrication (DFF), design for manufacturability (DFM), design for test (DFT), and complementary development services.

It's important to mention we work very closely with our customers and partners and some of the companies are world-renowned corporations, who rely on these high-level services. We also worked with smaller, localized companies to help develop and bring their products to market.

As I mentioned, we work very closely with customers and provide them with value engineering support in the early stages of product development, from quick-turn prototyping to new product introduction, right through to full mass production, whether that be localized within one of our North American facilities or one of our China facilities for a more low-cost, high-volume region. These facilities also give our customers the opportunity to launch products into the market as well.

Kaspars Fricbergs: I am the VP of quality for Vexos. I'm based in the Toronto facility, and I'm responsible for the coordination of the quality functions across the various Vexos locations. I've been with the organization and its predecessors for about 17 years now. I have a long background in quality in electronics and electromechanical devices, including experience in the medical realm as well. We're ISO-13485 registered at all our manufacturing facilities, as well as ISO 9001 certified. In China, we are IATF 16949 registered in one of our facilities; and both of our facilities have ISO-14001 and OSHAS 18001 registrations as well.

Las Marias: Earlier on, Despina was telling us about her problems and challenges when it comes to the lab on a PCB. From your perspec-

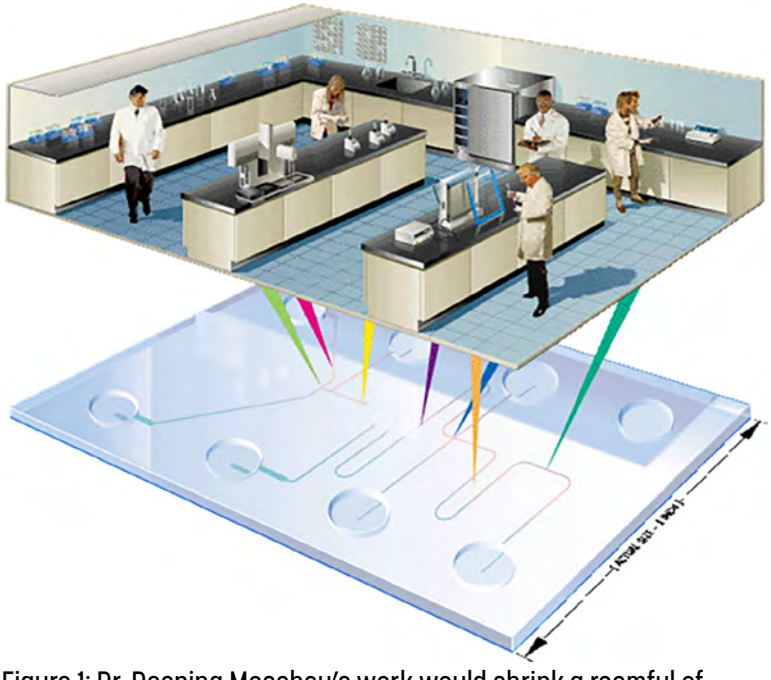

Figure 1: Dr. Despina Moschou's work would shrink a roomful of laboratory diagnostics systems into a compact module.

tive as an EMS provider covering the medical electronics industry, what are some of the top challenges you're seeing in this sector?


Kaspars Fricbergs

Fricbergs: There are a number of challenges associated with the field. I was about to say one of the top ones is the regulatory regime in medical devices. We are an EMS company, so we're not design responsible, and we don't do product submissions to the FDA; but there are a whole host of regulations surrounding the manufacture of the products that need to be met. Those are largely covered by the ISO 13485 registration, but there are also the regulatory regimes of the FDA and other local, jurisdictional regulations. In Canada, we would need to deal with Health Canada requirements as well for any products that would be marketed and sold in Canada.

The ISO 13485 certification largely covers the specific requirements that the FDA has outlined in their Quality System Regulation, 21 CFR Part 820, although there are some differences. You also have FDA regulations surrounding the use of software and the compliance of software, that's 21 CFR Part 11. You have specific requirements for documentation, validation, traceability, validation of process, validation of software, medical device files, and medical device histories. All of that has to be in place to provide the level of assurance to regulatory authorities and to our customers that we produced the product properly according to the processes that have been defined. Some of those requirements go beyond and are different than those of other industries.

Another challenge that we often run into is simply the time to market. Often, customers can come with an immature design. It may not be manufacturable, so Vexos can help in those cases. We offer design for assembly feedback services and design for test feedback services, that can help make the products manufacturable and bring the product to market faster. Sometimes with new product launches, because our customers don't have a strong view of the manufacturing process, they come with an idea, they may have a design that's been provided that may not be manufacturable. Or they may not have explored all the regulatory regimes and may not be clear on what requirements they may specifically have for quality.

We'll work with them on that, but again, a typical challenge is simply the time to market. Usually, when a design and concept have been firmed up and there's some backing for it, the desire is to quickly get it out to market, or at least get it into the approvals stage from a regulatory point of view.

Those are some of the bigger challenges we have. Of course, we have to have a very strong eye on the product's quality and make sure we're complying with all the requirements and regulations in order to avoid any situation that's going to affect our customers.

Moschou: I agree. Even with the medical devices that I am involved with, FDA approvals are extremely important and cause most of the delays in achieving commercialization. It's extremely important to have absolute control of the repeatability and reliability of the devices because we are talking about medical applications. Even tolerances that may be tolerated in non-medical applications, in our case, may not be acceptable, especially for the biomedical diagnostic devices that I work with. The highest degree of cleanliness is critical.

Fricbergs: Yes, and those are all part of the FDA and ISO 13485 regulations. When you're looking at sterlization, cleanliness, control of contamination, those are all aspects from a manufacturer's point of view that we have to have the appropriate controls over. Vexos typically does not deal with invasive or implantable medical devices. We typically operate for

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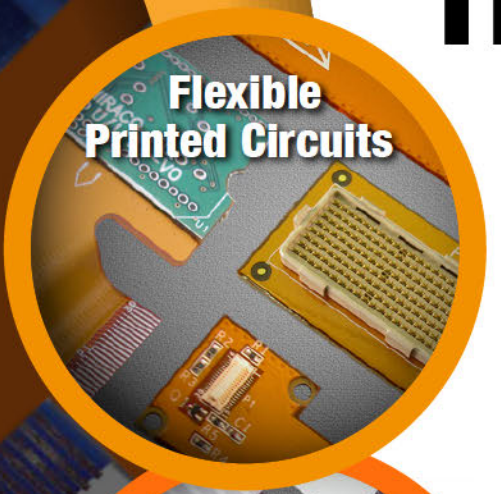

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our customer base in Class I and Class II, from the FDA perspective of medical devices.

Las Marias: Kaspars, earlier on you were mentioning that when customers come to you with designs that are not manufacturable, you help them with modifying those in such a way that they will be easier to manufacture and assemble, right?

Fricbergs: Yes. We offer both assembly and test. We offer DFA services, for example in a PCBA, that can help to make it manufacturable. We're able to review pad sizes and pad geometries to make sure they're appropriate for the components that will be placed in those locations. We'll look at panelization of PCBs to make sure we can build them efficiently. We'll look at the mechanical design, if we're looking at a box build type up of product, which Vexos produces as well.

We provide PCBAs for the medical device industry as well as producing complete functional assemblies for our customers. We'll look at the integration of any displays or boxes, plastics, metals, hardware, things like that. We'll look at the integration of those to ensure that we can manufacture them and meet the requirements that the customers require. If there are any special tolerances, we have to make sure we can actually meet those.

One of the items that I brought up before was in terms of the time to market. One of the important things in medical devices or any device manufacturing is the ability to prove out a device through prototype and phased in production. In other words, a structured new product introduction, or NPI, process, which Vexos has in place. One of the challenges is that sometimes, a customer's time to market is so critical that they're really trying to compress that portion of it. But we feel, and I feel, that this aspect of it is critical; to be able to prove that a device is manufacturable, so we can provide consistent results to our customers once we've reached the production phase.

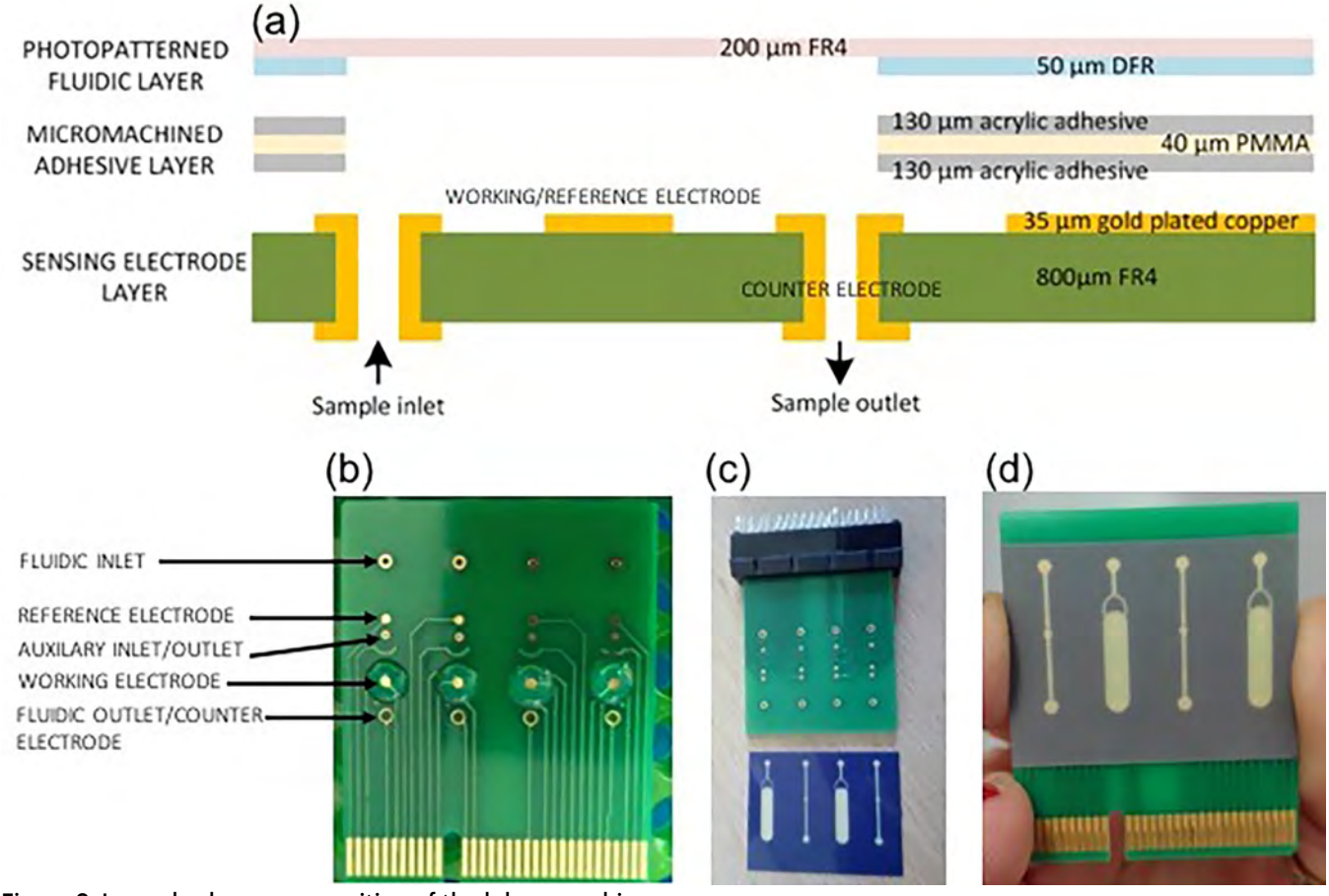

Figure 2: Layer-by-layer composition of the lab-on-a-chip.

Las Marias: In our previous conversations with the industry, they were saying it is very important for the designers to work with the assemblers to make sure what they are doing is manufacturable.

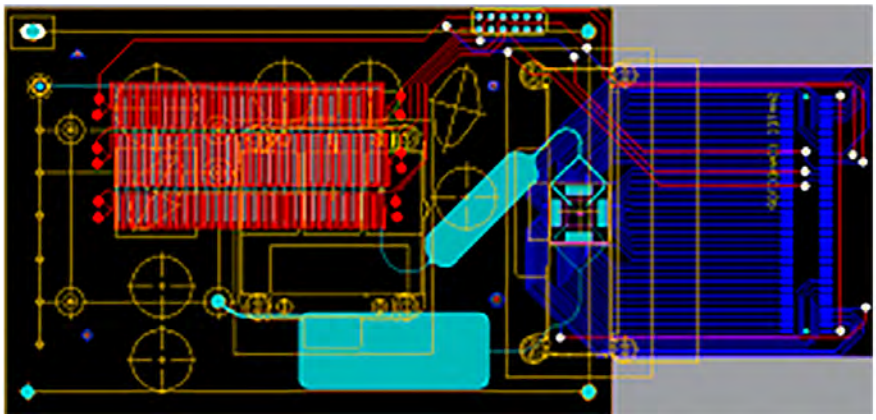

Figure 3: The complex design of the lab-on-a-chip.

Fricbergs: Yes. We've had successes in our organization when we partner with our customers at the very early design stage, even at the conceptual stage, and we can help guide the customers from a manufacturability point of view so that we have fewer hiccups down the road. It's a fundamental tenet of our quality system that proper quality planning leaves fewer mistakes and challenges downstream. Therefore, we encourage our customers to allow us to partner with them at the very earliest stages of design, so that we can provide our input to give us the best opportunity for success when we reach the production stage.

Dan Feinberg: Despina, your device sounds absolutely amazing. I can just see huge advantages not only for the industry but also for humanity. I do have a question, though. I could envision, thinking out of the technical realm, some significant pushback from the existing laboratories who obviously could become obsolete. Just wondering if you've thought of this, and what your plans might be to deal with this. Are you considering the existing laboratories or the laboratory conglomerate companies, particularly in the United States, but probably in other places in the world, too, to be competition or a partner? Or have you not gotten to that point yet?

Moschou: We have. This has come up many times. When I started working on this technology, it never crossed my mind that we would be competing with anyone. However, over the years as technology progressed and became a real thing, people kept asking this more and more. We have had several smaller research projects where we tried to find out the actual impact on the health-care systems if our devices were adopted. What we found out was that technicians working in hospitals in countries like the U.K. would feel threatened by our devices. As people developing the technology, this had never crossed our minds because we always thought this technology would complement current laboratories—not put other labs or the doctors and personnel using them out of business.

The best example of that would be to imagine the pregnancy test. Before having the lateral flow test—the home-use test—people had to go to the doctor to verify that someone was pregnant. When the home pregnancy test was invented and adopted, it didn't mean that the people wouldn't go to the doctor. You still go and have the laboratory test to confirm; it enabled people to do something they were not able to do before.

In our opinion, our technology enables things that were not possible before. The technology complements central laboratories and removes some of the burden off them and central health-care systems.

Feinberg: I can understand that. My first thought that came up as I listened to you was the economic and monetization portion of it. Have you considered partnering with the real, controlling influence in medicine today, which are the insurance companies?

Moschou: Not yet. This is a good idea because it depends on the country that you work with. For example, while working here in the U.K., every-

one told us that we should be engaging with the local National Health Service (NHS) and other local regulatory authorities to get something adopted. When we collaborate with low- and middle-income countries, the whole idea is to talk with either the local communities or non-governmental organizations that deliver health care in those rural communities.


Tom Reilly

In the U.S. healthcare system, which I'm not as familiar with, you make a strong point. We should talk with insurance companies, but we haven't engaged in that yet.

Feinberg: I would think you might want to do that, especially with the larger ones, but in any case, I wish you very good luck. I certainly would like you to continue to follow this. I'm very interested in your progress on this as time goes on.

Moschou: Thank you very much.

Andy Shaughnessy: This is Andy Shaughnessy with the *Design007 Magazine*. I was wondering as far as the design goes, do the designers need more training in this for lab-on-PCB? It sounds like something they're not just going to be able to figure it out. What kind of learning curve is it, and is anybody teaching this right now?

Moschou: At this stage, the best person to teach about it is me. Most of the people that have graduated and are graduating from my group are trained on how to do this. It's not straightforward because only my group and a few others in the world are working on this technology. Since it's not mainstream yet, we are using conventional design software that you use for PCBs. However, we use it in a nonconventional way. There is no library of microfluidic components—we make our own. There are no design rules in the design rule check for microfluidic components. Again, we have to improvise and do it manually with advice from me and more experienced researchers.

If people are interested and want to learn more, they can contact me. It is within my intentions to write a textbook to inform people on how to do this and start forming an educational package at some point. It's close to PCB design, but additional knowledge needs to be included. We are also planning a one-week summer school in the summer of 2019 in our recently founded Research Centre for Biosensors, Bioelectronics, and Biodevices (C3Bio) at the University of Bath, U.K.

Shaughnessy: It's very cool stuff. I've been reading some of the things you've written, and it's really good.

Patty Goldman: For you guys at Vexos, how does this fit in with your business? I'm just curious about your thoughts on it.

Fricbergs: It's certainly an interesting technology. We've actually had a previous customer who attempted to develop something similar. I don't think the product was ultimately successful for one reason or another, but we produced the surrounding device. Basically, the electronics, the PCBA, and we did the integration of the plastics and various tubes and valves that were used to support the specimen samples. The actual heart of the system was still rather proprietary with the customer. As electronics get smaller, it certainly poses some manufacturing challenges. We're seeing the shrinking on a yearly basis, the shrinking and compacting of designs that ultimately can be addressed through the improvement of our own technology, and moving up with our technology roadmap, to ensure we can build products with a smaller component footprint.

From a housing point of view and from a base point of view, it's not something that, if properly designed, poses a tremendous

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manufacturing challenge for us. It's sort of the surrounding processes, whether it's cleanliness or sterilization or things like that, that would be the biggest concern. Obviously, for any custom chip or device, we'd have to look at placement and soldering technology, so that's really where I think our focus would be.

Reilly: We're also seeing a shift in technology, especially in the silicon market. This new shift will play a big part in how technology is being delivered through new products. We're working closely with companies who are developing these next generation of silicon chips, to be used in printed circuit boards which will help delivery this innovated technology. These are exciting times for the electronics industry and Vexos is proud to be associated with this cutting-edge technology.

These are exciting times for the electronics industry and Vexos is proud to be associated with this cutting-edge technology.

As Kaspars said, our customers find that the more they engage with Vexos from a development and design standpoint, it's crucial to the time to market, and it's crucial to the milestones and roadmap that they have in mind for their product. So again, we are seeing a lot of this new technology. I'm more engaged with our customers in the early stage, and they're seeing the benefits of it from that standpoint.

Goldman: We hear that a lot, that if you can just work together with your customer all the way back to design, how much better that is, shall we say.

Reilly: Yes, because we may have customers, but we are very much a part of their organization. We are their manufacturing partner within their organization, and they leverage the expertise and knowledge we have from an engineering, quality and manufacturing standpoint. Also, they rely on the feedback we provide them from our DFx services in the form of DFM, DFF, DFT, and DFSC. These services allow them to focus on the next-generation product knowing they have a manufacturing partner who's helping them deliver their current product to market.

Fricbergs: That's a good point that Tom raises, that the early engagement allows for potential product design for manufacturing from the outset. That frees up engineering resources from sustaining activities to actually do new product development. As an EMS provider, we see some of both, products that are well designed and ready to manufacture, and we've had products that have been brought to us basically with errors in the design. What you end up with in these cases are challenges in first pass yield and throughput. Then, you end up going through the design and regulatory hurdles of trying to address what was a fundamental design flaw in the first place. So, we want to help our customers avoid that.

It's also the same from a testability point of view. I've talked about that as well, but we offer as part of our EMS services, design-for-test feedback services. A product that is laid out properly for both an in-circuit test, or a functional test, which we also have the development capability for, will yield better results. If you provide the proper access on the PCB, you can actually go that much further in reducing any manufacturing or component defects before you do the system integration. Then, once you've done the system integration, you can also perform a comprehensive functional test. The better planned you are for that, the more successful you are, and you can reduce your failure rate internally and externally. And the best way for reducing external failure is by eliminating the potential for defects in the first place.

Reilly: Another point I'd like to bring up is what we are seeing in the industry, with regards to

Figure 4: The Vexos production facility.

shortage of key components from a lead-time and life-cycle standpoint. So, questions of longer lead time and sourcing components for their products, and it's understanding those lead times. We're also seeing a lot of obsolete components, which, when a customer designs their new product, their design engineers like to use certain components within the BOM and in some cases are unaware of the availability and life-cycle of these components. We provide a BOM health analysis service which works alongside their engineer team in helping to identify key components within their BOM. We'll take a proactive approach to their design and use our risk management analysis tools and component engineer's expertise to provide an immediate risk assessment on specific BOM's as needed. What really cool about this, our system tool forecasts component obsolescence and conduct's a risk analysis on the entire BOM using advanced algorithms designed specifically to manage component lifecycles. This tool also allows for finding immediate potential cross references that match form, fit and function to their components if and or when required.

Goldman: Of the difficult components to get, which ones are most difficult? Actives or passives, would you say? I've heard that the passive components are the most difficult to get right now. They're the ones that have the longest lead times.

Reilly: Yes, we're seeing a lot from manufacturers from a lead-time standpoint on passives. Also, we work very closely with our component suppliers to really understand the market, the trend, where it's going, so we're able to give our customers that inside intelligence when they are a designer or have a product with us that is an existing product. We're able to guide them on alternative components, especially on passives, and give them that forecast or that heads-up knowledge that a component is becoming obsolete or there's a long lead time, which affects their go-to-market. Having that partnership with the component suppliers and our customers really benefits our customers from a product development standpoint.

Las Marias: Apart from component obsolescence and lead times, I think another issue,

especially when it comes to dealing with critical industries such as medical electronics, is counterfeit components. Do you see that as a problem?

Fricbergs: We deal with the authorized sources, where absolutely possible, of components. That's an internal requirement across our organization. If we need to go outside of those sources, we deal with well-established independent distributors that have strong counterfeit mitigation protocols in place. For example, the AS6081 counterfeit protocols. So, we do have structured protocols, both external and internal, in place for dealing with that. The availability of components can sometimes pose challenges, but we certainly don't take chances with counterfeit components because the risks for our customers are simply too high.

We deal with the authorized sources, where absolutely possible, of components.

Las Marias: Is there anything that we haven't talked about that you think we should be talking about regarding medical electronics assembly or manufacturing?

Fricbergs: I talked about some of the challenges with the regulatory regime or framework, which can include requirements like traceability; whether the product's manufacturing history needs to be tracked. I should just point out Vexos has some advanced systems across our company to manage those types of requirements, including an advanced MES system that can track and control our manufacturing processes. The best thing that a medical device manufacturer can do is have these types of systems and processes in place that meet regulatory requirements so that regardless of the nature and design of the product, we will meet all of the requirements.

Goldman: Despina, any final thoughts?

Moschou: I've enjoyed listening to the opinions of the guys from Vexos who are running a company involved in medical electronics because what we are trying to do is a bit unconventional—even for medical electronics. It's also interesting to hear that other medical electronic applications have similar challenges because this traceability is also going to be a huge issue for our devices, especially in a hospital setting. Everyone is asking for details on where this test was used, who used it, and where it came from. The technology is particularly important because it combines well with applications like the Internet of Things (IoT). The vision of devices like the ones that I make is that they're all interconnected, so in a hospital environment, you can also have traceability concerning which ward is affected.

For example, where do you have an outbreak of an infection? You'll know that immediately without having to report or fill in any paperwork—you only need the device. The same can be applied in epidemic control in a country where you have an outbreak. If you use smart devices like the ones that we are proposing—laboratory devices without anyone having to fill out paperwork or call people to report cases—these devices can be interconnected so you can automatically have a distribution of where your epidemic is. All the state-of-the-art issues that are problems in the industry at the moment are very critical and relevant to the application that I'm developing.

Las Marias: Right. Again, thank you very much, Despina, for your time, and also to you, Tom and Kaspars.

Reilly: Thank you.

Fricbergs: You're welcome.

Moschou: Thank you very much, all of you. SMT007

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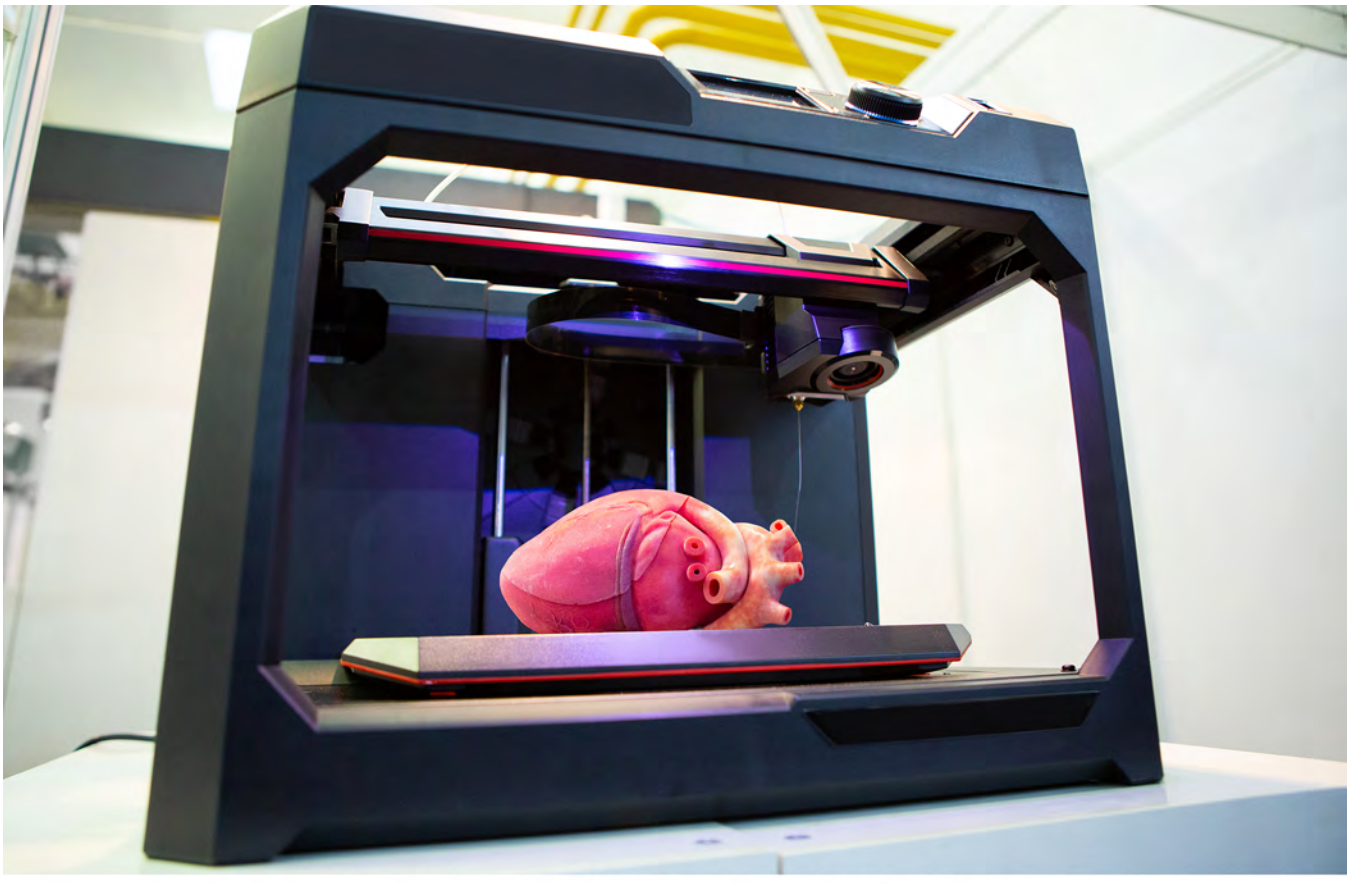


3D Printing and Medical Electronics: A Disruptive Beneficial Technology

Feature by Dan Feinberg
I-CONNECT007

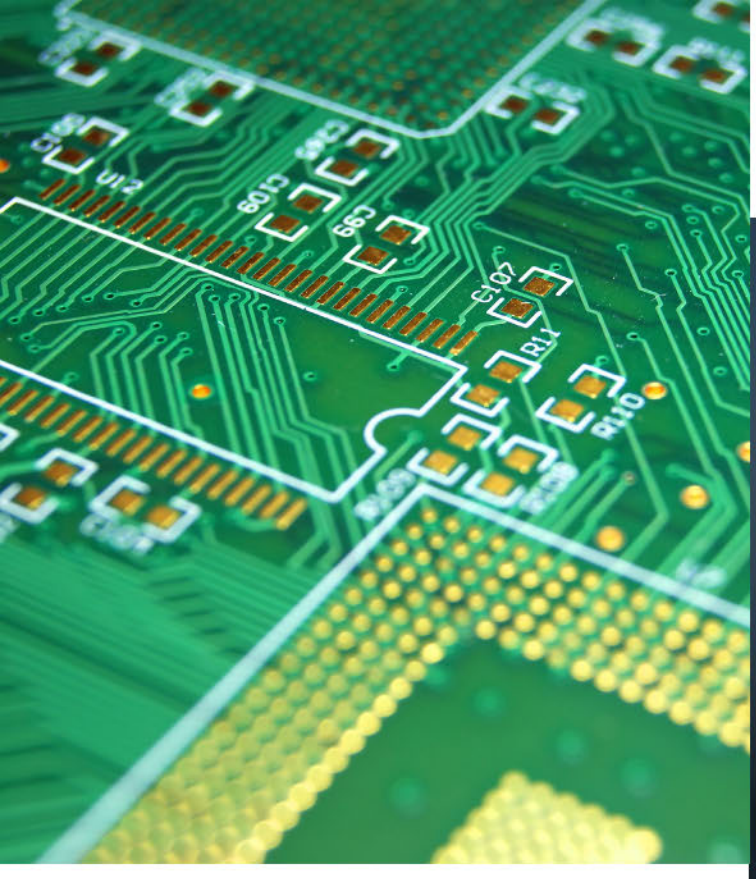
It seems that every few months, we hear about new advances in disruptive technologies. As these technologies become accepted to a greater degree, there are additional areas to research. One of the areas we have been following is additive/semi-additive 3D manufacturing with PCB fabrication as the main focus.

However, another innovative area is 3D-printed manufactured devices, replacement body parts, and medications in the medical industry. We are seeing significant advances and increased uses for 3D manufacturing in medicine—many more than 3D-printed and conductive circuits on device structural components (e.g., conductors printed on a device wall or structural angle, etc.). There is enough movement in this area that 3D additive fabrication in medicine—including but not limited to 3D-printed circuits—has become its own topic, and one that we will be watching and continuing to cover.

Overview

First, let's take a look at the present status of this segment to set a foundation for future coverage, especially as we are about to enter the high-tech trade show season where new advances will be introduced. Since we are discussing 3D-printed devices that are used on or in the human body, let's review the Food and Drug Administration (FDA) definition.

"3D printing is a type of additive manufacturing. There are several types of additive manufacturing, but the terms '3D printing' and 'additive manufacturing' are often used interchangeably. Here, we will refer to both as 3D



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printing for simplicity. 3D printing is a process that creates a three-dimensional object by building successive layers of raw material. Each new layer is attached to the previous one until the object is complete. Objects are produced from a digital 3D file, such as a computer-aided design (CAD) drawing or a magnetic resonance image (MRI). The flexibility of 3D printing allows designers to make changes easily without the need to set up additional equipment or tools. It also enables manufacturers to create devices matched to a patient's anatomy (patient-specific devices) or devices with very complex internal structures. These capabilities have sparked huge interest in the 3D printing of medical devices and other products, including food, household items, and automotive parts."

As those of you who have followed our coverage of disruptive technologies know, 3D additive technology has transformed many industry segments already, which includes significant changes to the medical and dental industries. 3D printing has been used to manufacture dentures and other oral implants for years but is also proving to be useful in other areas (Figure 1). For example, I recently chose to have a tooth replaced with an implant. In the past, it was necessary for the oral surgeon to take numerous X-rays from differing angles, combine them, and use them to measure and create the specifications for the implant fabricator. This time, I only had to do a single 360° 3D image that allowed the surgeon to design the perfect implant at the exact size and shape needed with CAD. The entire process took 15 minutes. It is no wonder that fast, high-quality 3D scanning has replaced X-rays as the preferred method of gathering the necessary data for so many areas of medicine.

Beyond dental devices, 3D printing is also being used to manufacture an entirely new generation of advanced medical implants that can be customized for individual patients' bodies.

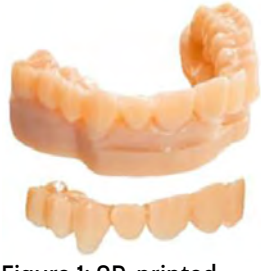

Figure 1: 3D-printed dentures.

Figure 2: 3D prosthetic.

It is also starting to become commonly used in numerous areas, such as surgery planning and patient consultations. In addition, as we have seen at the last few consumer electronics shows (CESs), 3D-printed manufacturing technology is revolutionizing the prosthetic and assistive devices segments. 3D-printed manufacturing is now providing access to reasonably priced, highly customized and optimized prosthetics for individual needs on a case-by-case basis (Figure 2).

According to a new market report from London-based industrial research firm Future Market Insights, the unexpected growth of the 3D-printed medical devices market is likely to be a fixture for some time to come. The report notes that medical communities worldwide are adopting 3D printing technology, and the use of 3D-printed devices at a consistent and rapid pace. It adds that the technology is leading to significantly improved quality of care for patients and is capable of reducing the average procedure time for most surgical applications.

This new industry benefits patients, and it also provides great improvements for doctors and hospitals by lowering the strain placed on already overworked staff. Overall, 3D printing leads to lower costs, which benefits those who would never have been able to afford traditionally manufactured devices. Now, people can afford and use greatly improved devices—such as my dental implant—rather than having to have a false tooth like my parents' generation had to endure.

Figure 3: Dental printer. (Source: MiiCraft)

Most 3D printers can do it all, but printers that specialize in specific industries seem to do a far better job in the areas for which they were designed. It is the old story of being able to do everything OK, but not being able to do many things well. For example, MiiCraft printers for dental functions and Nano Dimension printers for printed circuits and electronics are both industry leaders in their market segments. They have specifically designed and successfully optimized their equipment to meet their specific targeted applications (Figures 3 and 4).

Applications

3D printing progress is accelerating, and much more will be possible in the upcoming years, but what can be done right now? Per the 3D printing industry and the FDA, here are some examples and descriptions of what is available now.

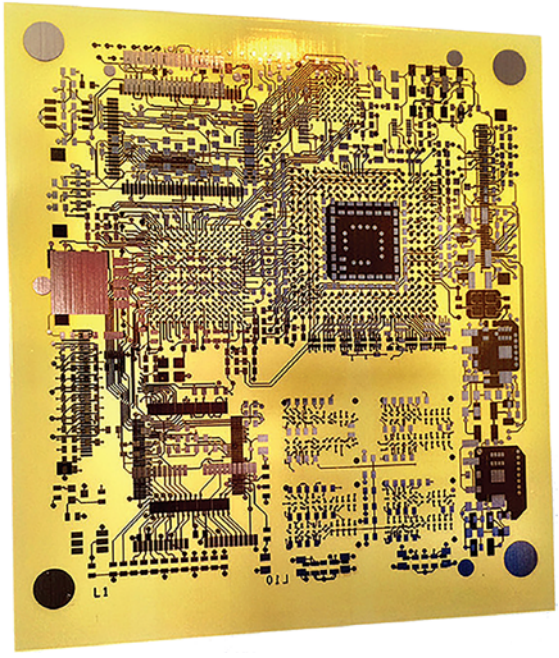

Figure 4: 3D-printed multilayer board. (Source: Nano Dimension)

Tissues with Blood Vessels

Researchers at Harvard University are making great progress in bioprinting blood vessels, a crucial step towards printing tissues with a blood supply. The lab of Dr. Jennifer Lewis designed a custom-built 3D printer and a dissolving ink to create a swatch of tissue containing skin cells interwoven with structural material that can potentially function as blood vessels.

Low-cost Prosthetic Parts

Creating traditional prosthetics is very time-consuming and destructive because any modifications to the prosthetics would destroy the original molds. Moreover, the cost of traditional prosthetics is a barrier to those without significant resources. Researchers at the University of Toronto, in collaboration with Autodesk Research and CBM Canada, used 3D printing to quickly produce cheap and easily customizable prosthetic sockets and limbs for a wide variety of patients' needs (Figure 5).

Drugs

I found a TED Talk video by Lee Cronin, a chemist at the University of Glasgow, describing a printer that would be able to 3D print custom medications (Figure 6). In this video, he describes a prototype 3D printer capable of assembling chemical compounds at the molecular level. He states that the prototype printer will make the medicine molecules in the printer using the software he describes. Patients would go to an online drugstore with their digital prescription, buy the blueprint and the chemical ink needed, and then print the drug at home as they need it. In the future, Cronin suggests that we might sell not drugs, but rather blueprints or applications. Of course, there are control issues, and this is in no way ready for prime time, but as I often say, we live in an age where if you can imagine it, we can eventually do it. Progress is already being made in this direction. Louisiana Technical University researchers have printed biocompatible, biodegradable devices for delivering bone cancer medicines.

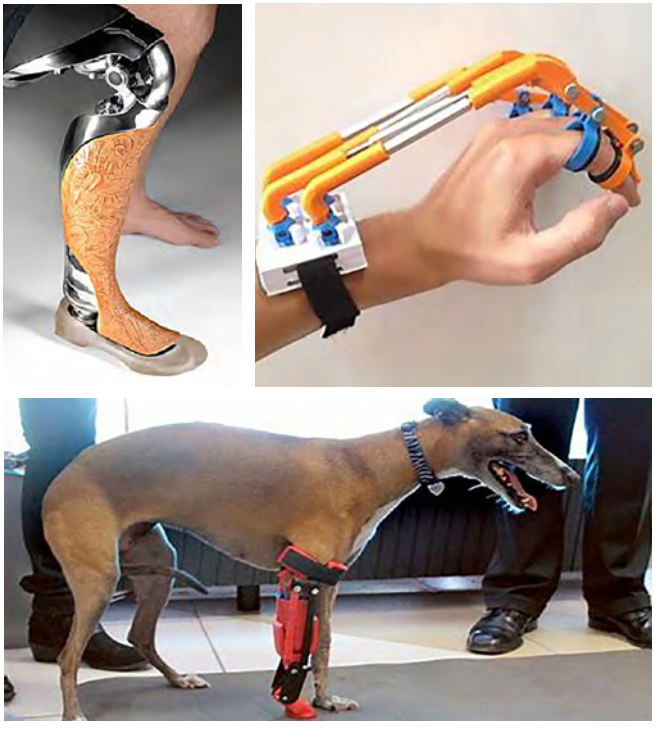

Figure 5: 3D prosthetic and medical device.

Figure 6: 3D-printed pills. (Source: Aprecia Pharma)

Medical Equipment

3D printing to make medical devices is a key focal point. It is now possible to 3D print devices made of silica glass. Making devices that are very hard to shape, such as some optical lenses, can now be made more accurately and at lower costs. The simpler devices, such as finger splints, are readily available now because they can be 3D printed locally. If you have the printer and can gain access to download the file, the complex curves and shapes needed can be accomplished and are almost limitless.

Plaster Casts Personalized for the Patient

Most of us have had a cast at some time in our lives, so you can imagine the advantages of having one that is custom designed to fit you instead of one being molded on to you.

Bones and Cranium Replacements

Professor Susmita Bose of Washington State University modified a 3D printer to bind

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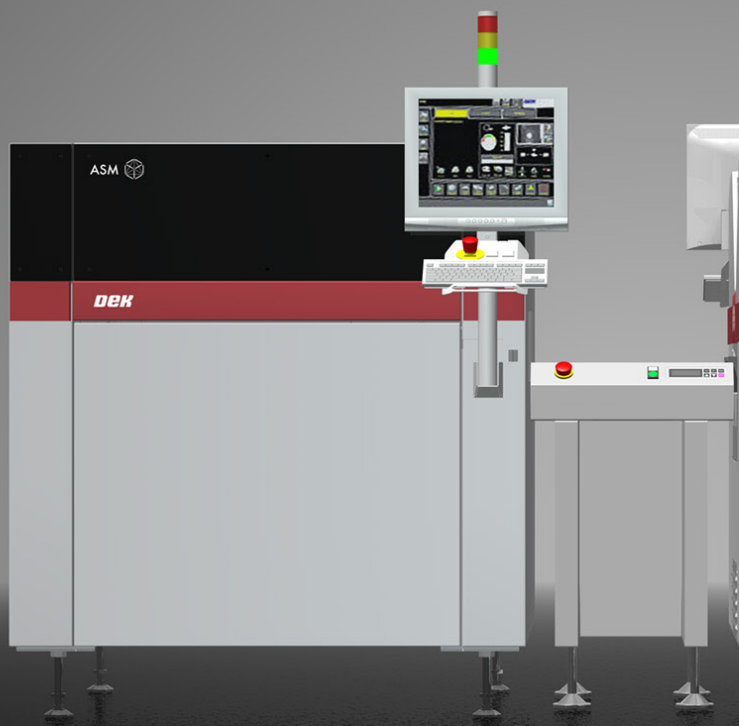

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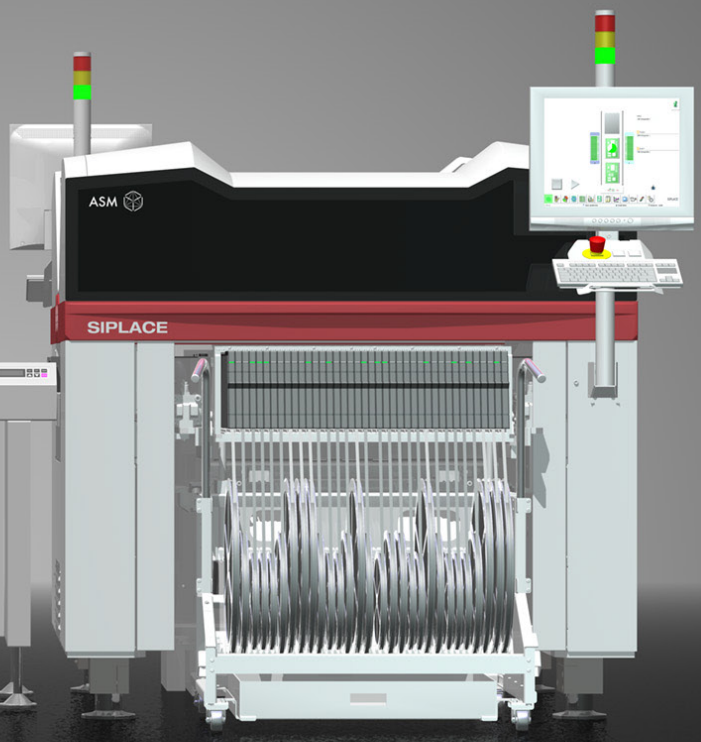

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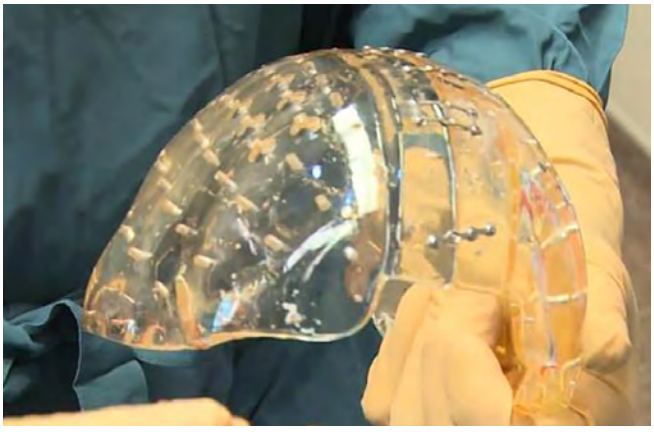

Figure 7: Skull transplant.

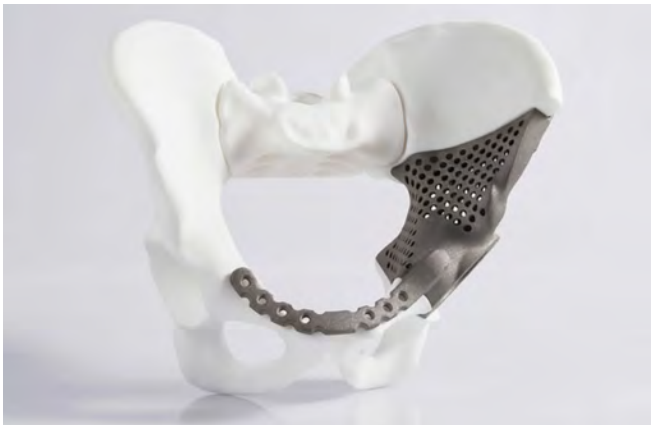

Figure 8: 3D-printed hip.

chemicals to a ceramic powder creating intricate ceramic scaffolds. It took slightly less than a day for surgeons in the Netherlands to perform the world's first complete skull transplant using a 3D-printed replacement skull (Figure 7).

This technology helps hip and knee replacements last longer through developing a body-friendly calcium phosphate-based coating for the implant materials. Once integrated, the coated implants are expected to last longer—potentially doubling the life of cemented implants. In many cases, surgeons perform partial skull removals as the brain swells, later re-grafting or replacing the skull part after the patient had recovered. Doctors used to create an implant by hand right in the operating theater using a molding compound, but those implants did not always fit well. Now, they can use 3D printing to ensure that these components are an exact fit. This has major benefits cosmetically, and patients often have better brain function compared to the old method (Figures 8).

Further, consider the combination of 3D printing an internal human organ or bone or ear replacement and combining it with 3D-printed circuits, electronic sensors, hearing aids, etc. This would make the replacement even more capable than the original (Figure 9).

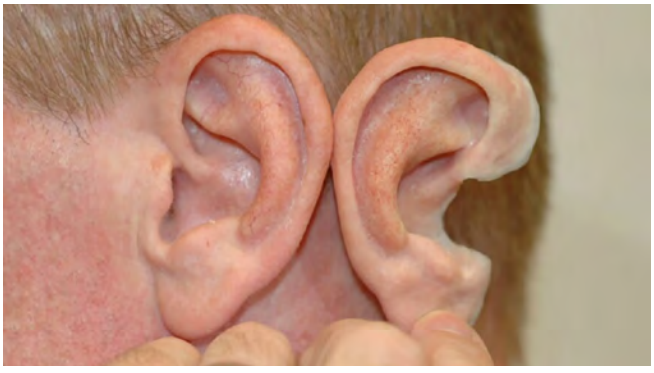

Figure 9: 3D-printed ear.

Conclusion

Of all the disruptive areas we are seeing, 3D printing used in medicine may have some of the most far-reaching benefits for mankind. Tailor-made sensors, heart valves, ear replacements, synthetic skins, and even some internal organs are all being used now or are in testing. 3D printing is one of the most disruptive technologies that will change medicine and healthcare by doing things that were not previously possible, doing it faster, and making care more affordable, accessible, and personalized. 3D printing can bring in a new era as printers become more sophisticated, materials become proven and available, and printing biomaterials become safely regulated. **SMT007**

Dan Feinberg is founder and president of Fein-Line associates and a technical editor for I-Connect007.

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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.

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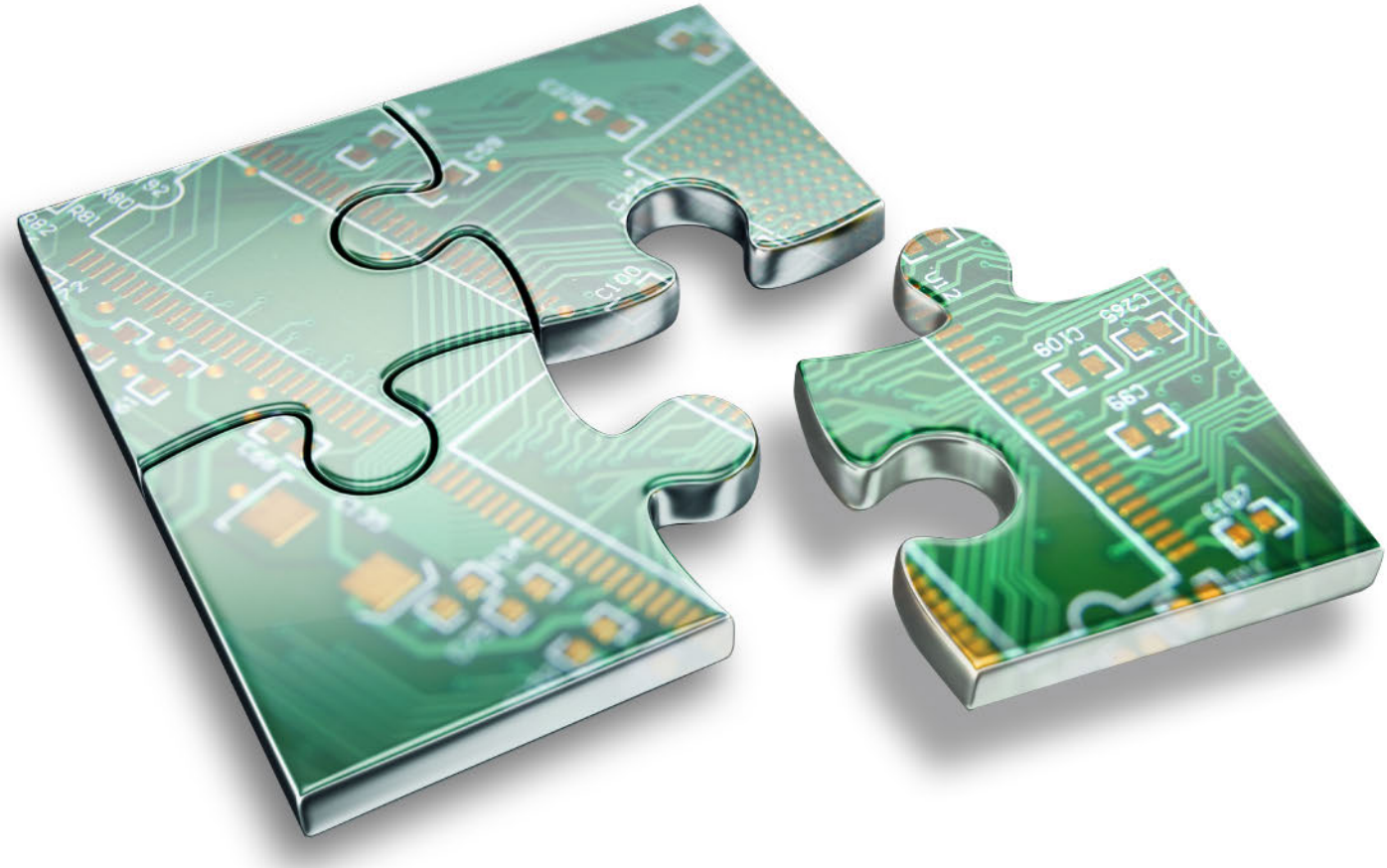

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FDA Approvals: Clearing the Hurdles

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 oftenmentioned FDA clearance is Section 510(k) of the Food, Drug, and Cosmetic Act. According to the FDA code of federal regulation, Section

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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.


Jim Taylor

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."

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-

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

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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."


Mary Elizabeth McCulloch

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. **SMT007**

Researchers Develop Bioresorbable Electronic Medicine

Researchers at Northwestern University and Washington University School of Medicine in St. Louis, Missouri, have developed the first example of a bioresorbable electronic medicine: an implantable, biodegradable wireless device that speeds nerve regeneration and improves the healing of a damaged nerve.

The collaborators—materials scientists and engineers at Northwestern and neurosurgeons at Washington University—developed a device that delivers regular pulses of electricity to damaged peripheral nerves in rats after a surgical repair process, accelerating the regrowth of nerves in their legs and enhancing the ultimate recovery of muscle strength and control. The size of a dime and the thickness of a sheet of paper, the wireless device operates for about two weeks before naturally absorbing into the body.

The scientists envision that such transient engineered technologies one day could complement or replace pharmaceutical treatments for a variety of medical conditions in humans. This type of technology, which the researchers refer to as a "bioresorbable electronic medicine," provides therapy and treatment over a clinically relevant period of time and directly at the site where it's needed, thereby reducing side effects or risks associated with conventional, permanent implants.

"These engineered systems provide active, therapeutic function in a programmable, dosed format and then naturally disappear into the body, without a trace," said Northwestern's John A. Rogers, a pioneer in bio-integrated technologies and a co-senior author of the study. "This approach to therapy allows one to think about options that go beyond drugs and chemistry."

The research was published in the journal *Nature Medicine*.

While the device has not been tested in humans, the findings offer promise as a future therapeutic option for nerve injury patients.

(Source: Northwestern University)

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Does Medical Device Reliability Worry You Sick?

Quest for Reliability

Feature Column by Eric Camden, FORESITE

I like to have a little fun with this column while also trying to convey some lessons learned, but this month's topic is more serious than most. If your television stops working, it's no big deal, right? You probably have at least seven other ways to watch "The Bachelor" (Did I say, "The Bachelor?" I meant to say, "Nova…"). However, when you look at critical segments of the electronics industry—such as medical, aerospace, defense, automotive safety systems, and other on-demand hardware—the eye used for most electronics must be even more critical.

Overall cleanliness is essential for all classes of electronics, but none more so than Class III high-performance electronic products where continued or on-demand performance is vital. Cleanliness is a cumulative measurement of each material and process choice that contributes to the sum. Beyond the fluxing process, the raw components can also contribute to ionic contamination and need to be analyzed separately from the final assemblies. This is especially important in cases of products built with no-clean flux, as there is not a final wash process that can help overcome contaminated bare panels and components.

Generally, medical devices are classified as either IPC class II or class III based on what the expectation is for service and the effect if it fails. For example, a glucose meter is an important piece of medical equipment, but if that doesn't work for some reason, it is relatively easy to obtain another one from a local drug store. In contrast, with devices like implantable cardioverter-defibrillators, failure could be a matter of life or death.

Active implantable medical devices would be in the Class III realm and have characteristics that are among the most difficult to maintain—extremely low levels of ionic cleanliness in conjunction with miniaturization. This means

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extensive testing of the assembly and cleaning processes are necessary to ensure that all flux and processing residues are removed from the assembly. Implantable devices demand the highest level of cleanliness on the surface of the product but also call for 100% protection from any outside influences as well. This is achieved using a hermetic seal that can be as rudimentary as a compressed gasket, but bioimplants are more likely to use a full penetration fusion weld.

Medical devices that aren't placed in the human (or an animal's) body could waiver between Class II or III based on the end-use expectation. For instance, for monitoring equipment that is not hermetically sealed but has an uninterrupted on-demand operation, cleanliness is just as important. Consider one supplier that met all the cleanliness requirement as directed by the customer but saw a rash of field failures. They had tested new production using ion chromatography and global and localized extractions and had very low levels of ionics, but the failures showed high levels of chloride contamination. With the known baseline cleanliness levels, the focus became outside contributors.

The field return housings were visually inspected but nothing was found, so the next step was to look at the housing ionically. An ingress path of cleaning solution was found using localized extractions in several areas around the housing on the inner and outer surfaces. The hospital cleaning staff was using a bleach and water solution on the monitor housings, and because they were not a hermetically sealed product, the bleach mixture had flowed into the housing. Bleach is very high in chloride, so it only takes a small amount to create an electrical leakage path and corrosion. The fix was to include a small bead of industrial assembly adhesives (RTV) around the housings to help eliminate the ingress path, along with alerting the cleaning staff not to use excessive amounts of solution when cleaning that type of equipment. The point of this example is that it isn't always the fault of the assembler when it came to the high-reliability product failure.

The next example of a medical equipment failure concerns one of the previously mentioned devices—glucose testers. The problem was thousands of units were showing up at the customer location with dead batteries. The product was built with a no-clean flux, so there wasn't an opportunity to remove excess manufacturing residues from contaminated components. This is another case of the contract manufacturer not being the root cause of the failure; instead, it was a component manufacturer. A capacitor on the battery line had enough plating residues to facilitate a leakage path that drained the battery in shipment. In this example, the component manufacturing process did a poor job at neutralizing the end termination plating chemistries. This issue was never realized until after the product was fully built because the supplier did not perform any cleanliness testing.

Another scenario I am familiar with concerned a contaminated ferrite capacitor but on a much more important piece of equipment—an external defibrillator. In the case of the glucose tester, the parts were scrapped and replaced because they were considered a low-dollar part that was less expensive to replace than repair. The external defibrillator was the opposite, so the company decided to perform a secondary cleaning process to remove the contamination from the ferrite filter (Figure 1).

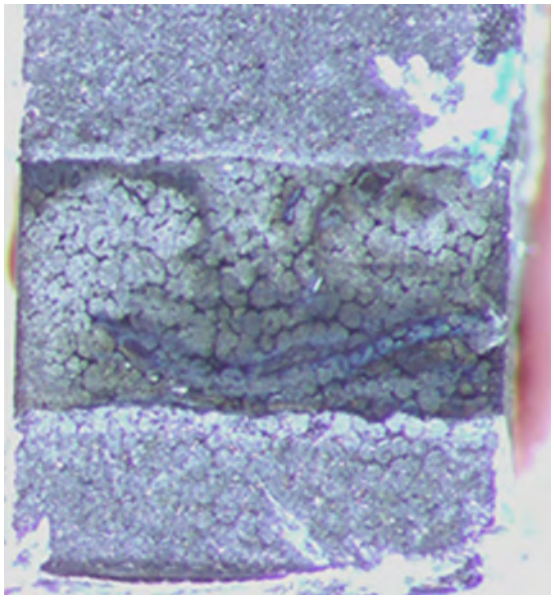

Figure 1: Contaminated ferrite filter.

ID	Sample Description	CHLORIDE	WOA	SODIUM	AMMONIUM
1	Filter 1	5.05	41.54	6.11	4.74
2	Filter 2	5.44	57.98	5.98	4.40

all values in ug/in²

Table 1: Ion chromatography results of ferrite filter.

Another main difference between these two parts was the introduction of the contamination. With the glucose meter, it was an issue at the component manufacturer, but in the case of the external defibrillator, it was an issue with residual water-soluble flux remaining under the filter after an ineffective deionized water (DI) water-only wash process. The condition that made recovery of this even more difficult is there were already battery packs soldered onto the boards. This means the cleaning process had to be localized so moisture did not get on the rest of the board in areas that would be detrimental to the parts on the battery line.

You can see in Table 1 that the level of chloride and weak organic acid (WOA) was so high that cleaning was needed. The cleaning process required a specialized steam nozzle to be used at the filter location that was fortuitously located on the edge of the PCBA, so the likelihood of the steam condensate being deposited on moisture intolerant areas was very low. After the concentrated steam cleaning process, the PCBAs were placed in an elevated heat and humidity chamber for 500 hours to ensure that the removal of the residues was fully effective and the product was no longer at risk of field failure.

Conclusion

The point of this month's column was that when you are manufacturing high-reliability assemblies related to medical industry, it is critical to take a very close look at the assembly process and all other processes that can influence the end-use reliability—even seemingly unrelated processes, such as post-installation cleaning. It really could be a matter of life or death.

Now, back to "The Bachelor…" I mean "Nova." **SMT007**

Eric Camden is a lead investigator at Foresite Inc. To read past columns or contact Camden, click here.

New Devices Test Retinal Cells

Researchers Elizabeth Vargis, a Utah State University (USU) assistant professor of biological engineering and Farhad Farjood, a Ph.D. student in Vargis' Lab, wanted to better understand the triggers of age-related macular degeneration (AMD), a degenerative eye disease and the leading cause of adult blindness in developed countries.

USU Engineering Ph.D. student Farhad Farjood.

Physical changes within the retina are an important factor in the development of AMD. However, the effect of physical changes during the disease is not clearly understood.

Currently, there are no devices to realistically model varying levels of physical disruption available on the market. Therefore, the researchers created two new devices: one that mimics slow and continuous stress levels and one for mimicking high levels of stress. Using these devices to replicate stress on retinal cells, the researchers found that mechanical stress results in the expression of vascular endothelial growth factor, a protein that can cause disease initiation and progression.

"There are many clinical studies taking place to discover the causes of disease," said Farjood. "Our work is an example of how engineering techniques can help us better understand the disease mechanisms."

The study was published in *Lab on a Chip*.

(Source: Utah State University)

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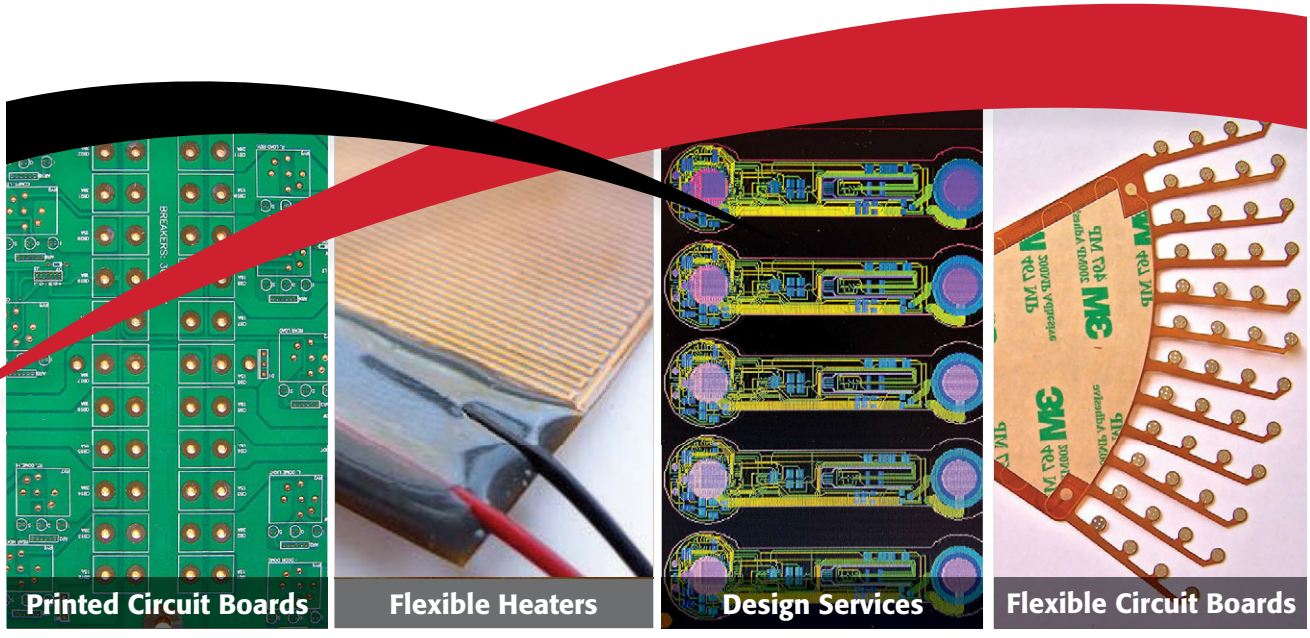

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Supplier Highlights

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.

Electronic Components Market Update ▶

Unfortunately, there is still no end in sight to the electronic component shortage, and some lead-times are being quoted with 2019 and even 2020 delivery dates! So if you are working with an EMS provider, it remains vital that you communicate and share forecast information with them. You may also want to start looking at the option of fitting, or designing in, smaller components to your PCB assemblies.

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.

Tips to Improve Soldering Tip Life and Reduce Cost ▶

Whether in production, or repair and rework, the cost of soldering iron tips can be easily overlooked, but with today's requirement for higher temperatures in lead-free solder applications, the consumption of tips has dramatically increased. This fact, combined with changes in tip design to meet the higher thermal load requirements, has also resulted in escalating tip costs, making tip care a high priority.

Indium on Voiding and Auto Electronics Test Standard ▶

In this interview with I-Connect007, Indium Corporation Technical Manager Jonas Sjoberg discusses voiding and other key challenges in soldering, as well as an automotive electronics testing standard based out of South Korea that is seeing increased utilization all over Asia. He also talks about the increasing trend in manufacturers moving to Type 5 and Type 6 solder powders, and how this is causing its own set of challenges in printing.

IoT: Driving Change in Manufacturing ▶

In the manufacturing world, the Internet of Things (IoT) can be seen as an element of Industry 4.0. The idea behind it is that factories would evolve to become smarter, to become a lot more flexible—to be able to make the products that customers want, basically at any time that they need.

XR Update: Emerging Realities ▶

The rate of advance in the use of XR—the term now being used to cover AR (augmented reality), VR (virtual reality), and MR (mixed reality)—in many areas, along with advances in the hardware and network capability supporting the use of XR, is accelerating. And because things are moving so quickly, here's a quick review and an update on recent developments in this field.

ESI's New Allegro LC Extends High-Volume Test Capability to Larger MLCCs ▶

Electro Scientific Industries, Inc. has announced the availability of its new Allegro LC test system, designed to address the high-level testing of larger multilayer ceramic capacitors (MLCCs) used increasingly in rapidly growing applications, including handheld, IoT and automotive products.

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IPC Education Foundation: Bridging the Skills Gap

One World, One Industry

by John Mitchell, IPC—ASSOCIATION CONNECTING ELECTRONICS INDUSTRIES

IPC is proud to announce the IPC Education Foundation. Our mission is to attract the best talent to our industry and prepare the emerging workforce with the knowledge to bridge the skills gap.

The Foundation is a separate organization from IPC and is set up as a non-profit 501c3. We've begun our fundraising efforts and are actively seeking IPC members to take a lead role. At least 50% of the funds raised will be earmarked for scholarships for students interested in careers offered by the electronics manufacturing industry. Our goal is to award thousands of dollars in scholarships by 2019.

The Foundation will also sponsor STEM programs closely related to our industry. We plan to develop curricula with accompanying badge and certification programs to engage high school and post-secondary students. Our goal is to introduce students to the innovative careers in our industry and prepare the talent pipeline with the skills to make them more marketable in the job market.

During IPC APEX EXPO 2019, we are building on the success of last year's STEM Outreach Program. We are excited to engage the emerging workforce. Be on the lookout for more information as we get closer to the conference.

One of our major initiatives is to start a network of IPC Student Chapters at universities and community colleges. The Foundation is speaking with several universities to gain faculty support for the student chapters. As we move forward, we want to target univer-

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sities and community colleges that are regionally adjacent to IPC member sites.

These IPC Student Chapters will create opportunities for IPC members to connect with prospective job candidates and get them interested in our industry. IPC members can hold lectures on the latest processes and how they were developed. Member sites can hold plant tours, offer internships, and give students an inside look at the industry. IPC Student Chapter members will have the opportunity to connect their coursework with real-world applications, expand their professional network, and apply for internships and scholarships.

IPC is excited to start the IPC Education Foundation. It will allow us to engage the emerging workforce, improve the perception of our industry, prepare the talent pipeline, and offer scholarships to deserving students. This is just the beginning. Opportunities and achievements are limitless in partnership with the IPC membership.

For more information about participating, please contact Colette Buscemi, IPC senior director of education programs. **SMT007**

John Mitchell is president and CEO of IPC—Association Connecting Electronics Industries. To read past columns or contact Mitchell, click here.

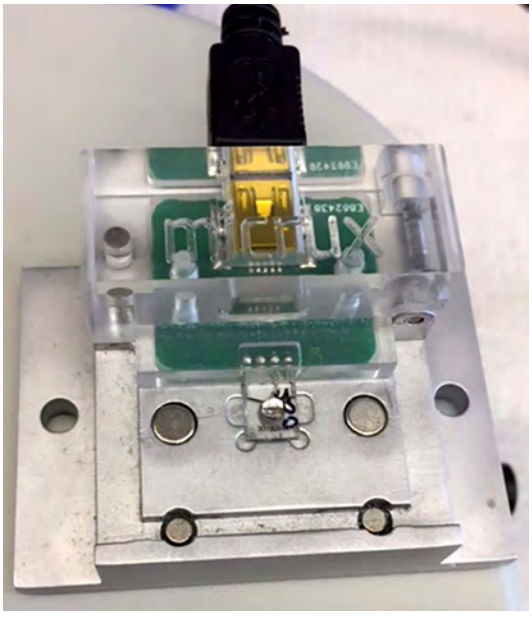
Researchers to Develop Sensors Able to Detect Manganese from Single Drop of Blood

A three-year, $1.8 million grant from the National Institutes of Health will enable researchers at the University of Illinois at Chicago to develop portable, easy-to-use sensors that can detect toxic metals in a single drop of blood. The sensors would allow for faster and cheaper research, as well as rapid detection of metals including manganese and lead–powerful neurotoxins that can affect cognitive development and neuromotor function.

Small point-of-care sensors exist to detect lead in blood and water, but no such sensor exists to detect manganese. For researchers studying manganese in populations, they may only collect a few samples a day and wait until they have enough material to send to the lab for processing.

According to Ian Papautsky, the Richard and Loan Hill Professor of Bioengineering in the UIC College of Engineering and a principal investigator on the grant, this means the research is often slow, with results coming in months after samples are collected. "Our sensors could help speed research so that scientists can get answers faster," he said.

Papautsky and his colleagues will work to develop and integrate several parts needed for the sensors: the chip on which a drop of blood or water is placed, the equipment that sends current through the chip to separate out the metal, the software to process the results, and the user interface that displays the results.



"We want the sensor to be easy for anyone to use, and the results easy to interpret," Papautsky said. Ultimately, he thinks his sensors will cost around $10 each, not including the hardware and software, which need to be purchased just once.

Photo: A closeup of the experimental sensor.

(Source: University of Illinois)

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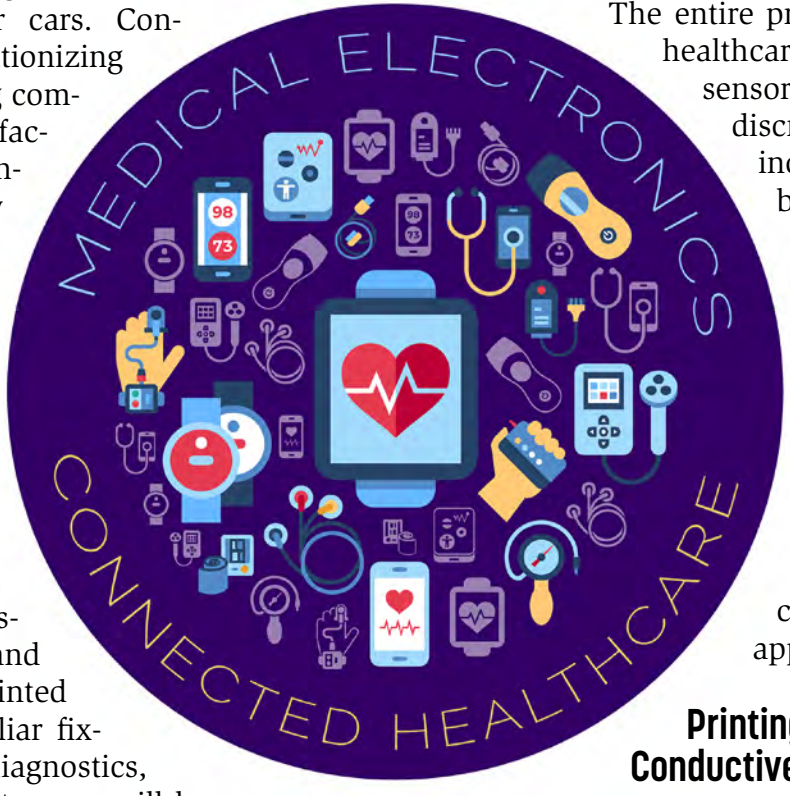
I-Connect007
GOOD FOR THE INDUSTRY

Printed Electronics and the Fast, Flexible Future of Connected Healthcare

Feature by Girish Wable and Ralph Hugeneck
NYPRO

The Internet of Things (IoT) is slowly but steadily infusing devices all around us with connected intelligence from appliances at home, to the lighting at work and safety systems in our cars. Connectivity is revolutionizing industries including communications, manufacturing, and entertainment. While slightly trailing the pack in mass market adoption, connected healthcare is advancing in targeted applications at an accelerating pace with the aim of improving patient outcomes, increasing efficiencies, and reducing costs. Printed electronics—a familiar fixture in medical diagnostics, therapy, and patient care—will be an increasingly pervasive and instrumental enabler for the component technologies underlying connected healthcare.



Analysts, such as Research and Markets, expect printed electronics to register a compound annual growth rate of nearly 25% over the next five years. If the market for connected healthcare expands as rapidly as experts predict, then this expected growth in printed electronics is inevitable and may even be understated. The market potential for compact, wireless, and non-invasive sensors alone spells opportunity for printed electronics according to IDTechEx who predicts the market for fully printed sensors will reach $7.6 billion by 2027.

The entire premise of connected healthcare is based on such sensors being placed near discrete points of data, including patients, pill bottles, wearables, medical devices, and hospital beds. Printed electronics are tailor-made for such applications and can also replace or enhance existing products in medical, pharmaceutical, and related applications.

Printing Techniques and Conductive Inks

Today, many electronic components are produced by printing. In addition to sensors, batteries, and antennas, other examples include memory, logic, and light sources. While similar to the printing techniques used in industries like graphics or electronics, the manufacturing processes used to print electronics need to accommodate specialized inks for complex designs. For example, inkjet print-

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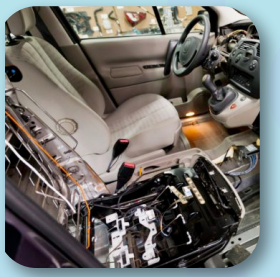

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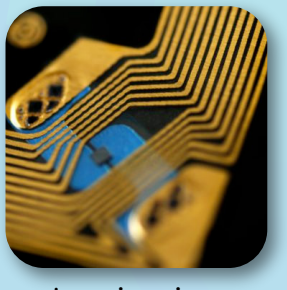

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ing equipment needs a different head for the metal-loaded conductive inks applied, and inks used for graphic screen printing operations must hold tolerances designed for increasingly complex circuits. Further complicating things is the wide variety of inkjet and screen printer types. Techniques include continuous inkjet and drop-on-demand (DOD), which can be further divided into thermal DOD and piezoelectric DOD, polyester, metal-mesh, or stainless-steel screens.

Screen printing is one of the most commonly used techniques for printed electronics. This process produces a circuit by aligning the substrate beneath the screen and applying conductive ink like a graphic ink or solder paste. Curing is usually achieved by applying heat. However, some inks are cured with an application of ultraviolet (UV) or infrared (IR) light, or photonic curing. In addition to screen printing, other widely used methods include flexo, gravure, inkjet, and offset printing. There isn't a single printing technique for every healthcare application. Thus, when selecting the optimal combination of ink and process equipment, it's important to consider factors such as manufacturing throughput, feature size, resolution, layer thickness, design considerations (e.g., stretchability), as well as subsequent integration steps (e.g., molding or laminating).

Surface-mount technology (SMT) can improve the functionality of printed structures where necessary and practical by using conductive adhesives or even low-temperature solders (Figure 1). In some cases, the addition of copper plating can enhance printed ink traces by improving their conductivity or promoting soldering. Printing and attachment processes are usually followed by high-level integration with processes like lamination, encapsulation, coating, or molding. Higher-level integration immediately after printing can simplify the assembly processes and enable thinner, flexible, and more compliant products.

While single or dual layers are common, multilayer printing is attracting growing interest. As on PCBs, printed circuits and components are stacked; however, the stacks for print-

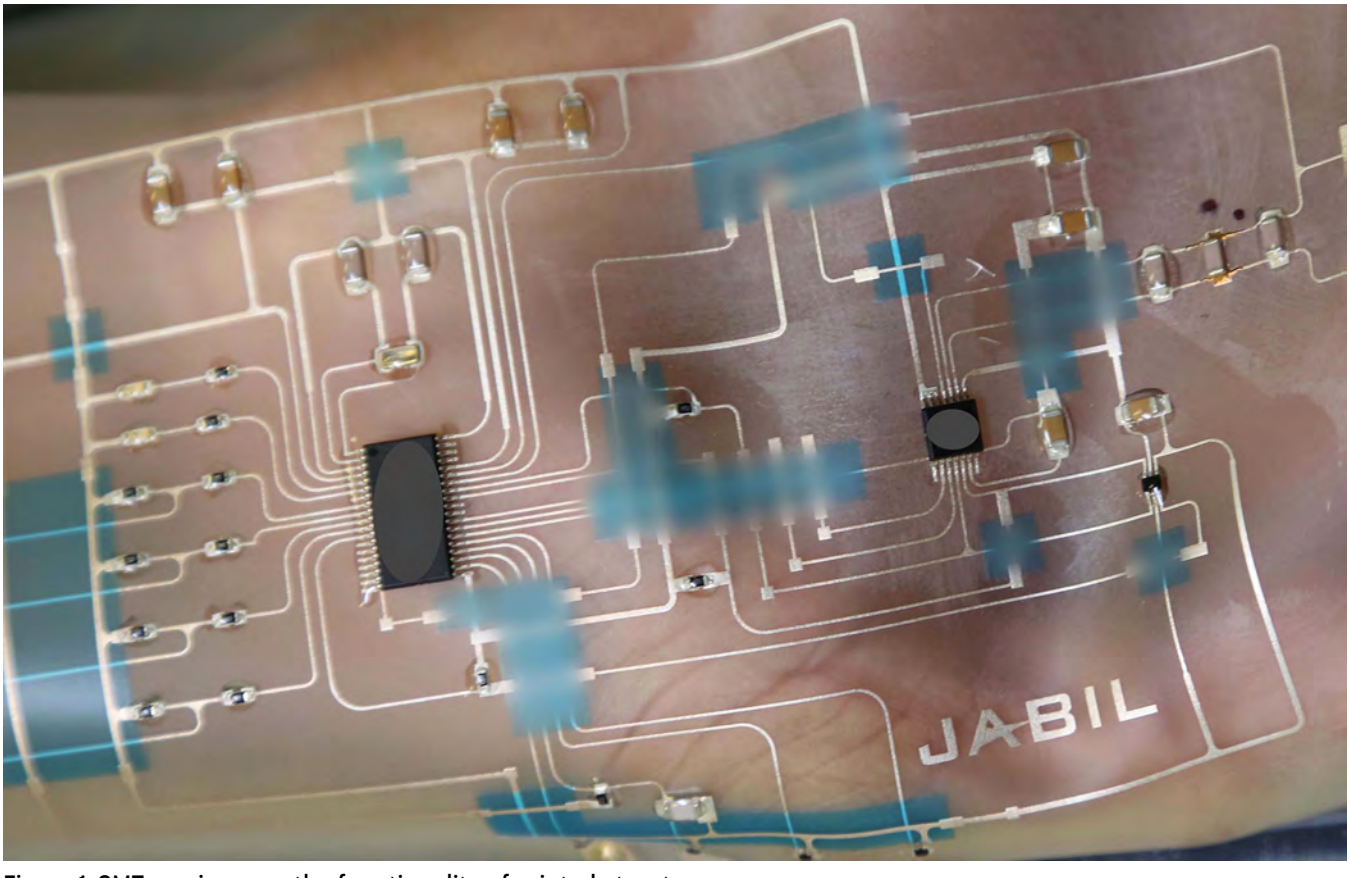

Figure 1: SMT can improve the functionality of printed structures.

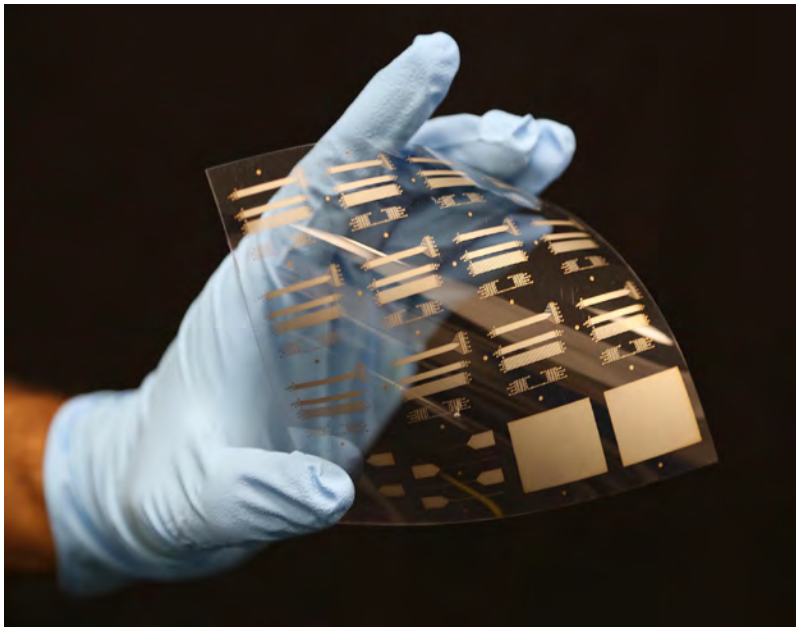

Figure 2: Printed electronics can create functional structures on flexible plastic, glass, and paper.

ed electronics are much more planar. The inks applied contain fillers with conductive or semiconductive properties. Organic light-emitting diodes (OLEDs) are the exception since the polymer itself is conductive. OLEDs are used most often in displays, but also find applications in wearable devices with advanced sensing techniques, such as acoustics, gesture recognition, and fingerprint recognition.

Printed electronics are also used in photonic devices and lab-on-a-chip (LOC) applications. Examples of photonic devices include large-area photodetectors and image sensors[1]. Plastic and glass can also be converted into smart surfaces for medical imaging (Figure 2). Proponents of organic photodetector technology claim it will replace amorphous silicon technology and improve the performance of image sensors by providing reduced sensitivity to temperature. With LOC applications, a printed OLED light source on one side and a printed sensor on the other can miniaturize the entire structure[2].

Advantages of Printed Electronics

Whether the application requires interconnection, sensing, illumination, or battery power, printed electronics offer compact, flexible solutions. They are ideal for connected healthcare applications that need to fit tight spaces, allow proximity to patients, stretch and conform to the human body, or spread over other large areas where data is collected (Figure 3).

Examples include minimally invasive devices, such as endoscopes and catheters, that integrate a large number of small sensors, or wearable air quality monitors that alert asthmatics of poor conditions. As with any emerging technology, comparing the cost to value is critical. This is particularly true for cost-sensitive commodity applications, such as intravenous (IV) tubing or bags where printed electronics can monitor for air bubbles, maintain a certain temperature, or alert staff when a fluid bag needs replacement. The unique value of printed electronics is their ability to solve difficult design challenges, simplify integration, and offer greater design freedom.

The emergence of this connected healthcare ecosystem depends entirely upon the deployment of a vast number of sensors at the network's edge. Printed electronics can support this demand for distributed data and provide a powerful solution to both design and deployment challenges. For example, compact, printed sensors can conceivably incorporate flexible batteries and/or wireless communication components capable of sending data to and from the point-of-care. In anticipation of the

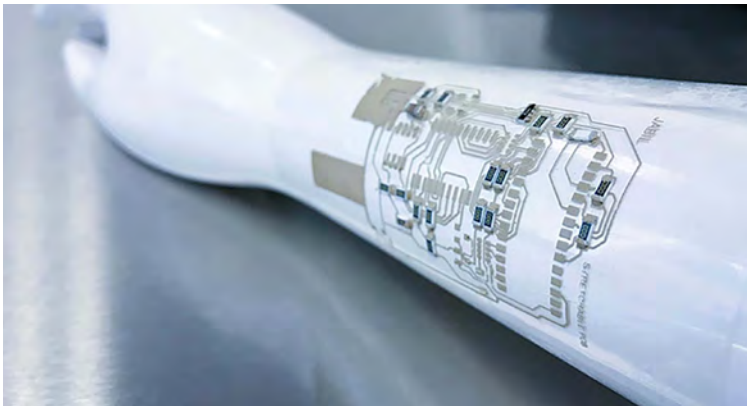

Figure 3: Printed electronics offer potential value in connected healthcare applications.

millions of wireless sensors and devices likely to be transmitting soon, new network protocols are being prepared to facilitate the IoT.

The Evolution of Printed Electronics

Several decades ago, printed electronics began to become selectively competitive with semiconductor components. Designers compared technologies and considered potential applications. While there were some early successes, purely ink-based solutions couldn't match the cost or performance of silicon-based electronics in all cases. Moore's Law also mandated that devices based solely on printed inks couldn't match the exponential advance of faster, cheaper transistors.

Today, designers mix conventional semiconductors with printed electronics to achieve the best of both worlds. Semiconductors are powerful and can make products lightweight, flexible, and compact when integrated with printed electronics. In some cases, they also allow devices to be tether free. Instead of connecting a PCB and radio to a device's architecture, system architects can achieve integration within the device form factor itself. In addition to supporting data collection then, printed electronics provide design flexibility.

For example, Nypro recently developed a fully-functional proof-of-concept wireless inhaler that replicates how a smart inhaler for asthma and COPD patients is expected to work (Figure 4). The future evolution of the device needs to minimize size, support the lowest landed cost, and overcome power and space issues that could limit performance. Challenges include finding a way to position a sensor as close to the inhaler's air channel as possible and figuring out how to minimize the profile of the system. Engineers could explore the role of printed sensors, batteries, and antennas in helping meet these evolution challenges, and technology providers could help meet them.

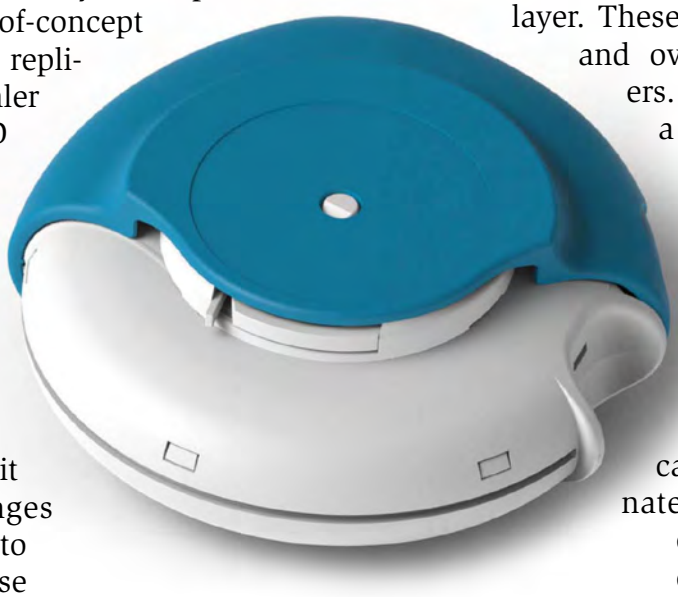

Figure 4: Nypro engineers are exploring how printed sensors, batteries, and antennas can enable and enhance medical device concepts, such as smart inhalers for asthma and COPD patients.

In another connected healthcare initiative, Nypro collaborated with 3M to develop a low-power, disposable electrocardiography (ECG) patch that can be worn for seven days. The device measures real-time single-lead ECG and fall episodes using a tri-axis accelerometer. This low-power disposable Bluetooth-enabled patch was integrated on a single flexible hybrid PCB with an average current consumption of 3.6 mA from a 3.0 V stack of four flexible batteries. Silver-silver chloride (Ag-AgCl) ink sensors were directly printed on the PCB, eliminating the need to attach external sensors and making the device smaller, thinner, and more compliant than earlier designs. These devices play an important role in the connected ecosystem, and the data collected from them can allow for customization and personalization of healthcare and deliver immense value.

Printed electronics also offer benefits from a manufacturing perspective where high-volume processing and a lower total cost of ownership are especially important. Traditional electronics manufacturing is a subtractive process requiring several steps to create one layer. These steps are repeated over and over to get multiple layers. Printed electronics use a two-step additive process where a substrate is exposed to deposition and then dried and cured. This two-step process can be repeated to develop multilayer designs.

Printed electronics can also reduce or eliminate assembly steps where electronics are integrated into final products. With machines and equipment, structural electronics (SE) can replace traditional com-

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Expanding Applications and Adding Value

By adding features that can offer both performance and manufacturing benefits, printed electronics are expected to support connected healthcare developments in machine interfaces, antennas, and lighting and heating sources. Disposables, such as small flexible patches, will also need smart solutions. However, before adding features, device designers expect actionable outcomes. With printed electronics, these can include patient safety and compliance, such as tamper-proof drug compartments and counterfeit protection.

Connected healthcare applications for printed electronics are also expected to include smart packaging that can automate drug identification, track expiration dates, and evaluate a medication's diminishing potency or capacity. Temperature-sensing smart labels will measure the integrity of packaged pharmaceuticals during transport and in storage. In some cases, these labels will incorporate printed memory or displays to communicate contextual information like temperature or humidity. Paper or plastic packaging can include radio frequency identification antennas or incorporate near-field communications for accessing text and graphics.

In hospitals or homes, printed electronics can also support human-machine interfaces, such as curved three-dimensional panels on larger devices and equipment like hospital beds. These technologies could also display patient information and embed TV controls. Applications for printed electronics in connected healthcare may also include humidity control for hospital beds, thermal sources that maintain fluids at body temperature, and medical wearables, such as smartwatches, fitness bands, and virtual and augmented reality headsets. Sensors incorporated in pillows or mattress could help monitor sleep, breathing, or heart rate.

Conclusion

If the demand for connected healthcare is as large as many experts predict, the expected growth in printed electronics is inevitable. As is the case with all emerging technologies, the rate of adoption will vary with cost and value. Shifting this cost-value ratio in favor of value will be especially important for commodity applications compared to personalized medicine. However, the value that printed electronics provide will also drive growth for newer, more sophisticated, and highly functional medical devices.

For companies that are designing devices with printed electronics, the opportunities in connected healthcare are clear. There are also continuing advances in printing techniques, conductive inks, and substrate capabilities. Industry groups and government organizations are supporting advances, too. The connected healthcare ecosystem will grow with the proliferation of small, compact, and wireless sensors that are powered and processing at the network's edge. Printed electronics can produce these structures and deliver increasing value.

The authors would like to acknowledge the efforts of several colleagues in global labs and technology solutions partners in advancing this strategic capability. **SMT007**

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Girish Wable is a senior manager for strategic capabilities at Jabil.

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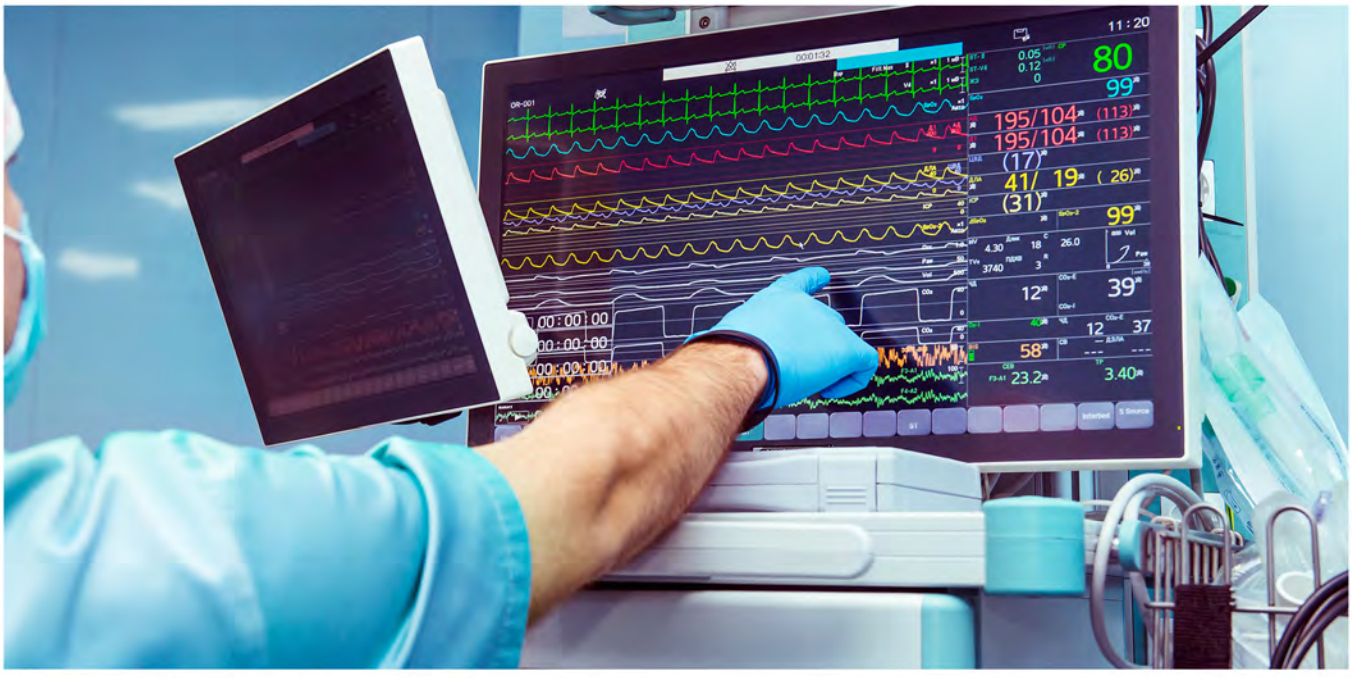


Vital Points in Medical Electronics Manufacturing

Feature interview by Stephen Las Marias
I-CONNECT007

Zulki Khan, founder and CEO of NexLogic Technologies, discusses challenges, technology trends, and developments in the medical electronics industry from PCB design to fabrication and assembly. He also highlights key considerations when finding a manufacturing partner for your medical electronics products.

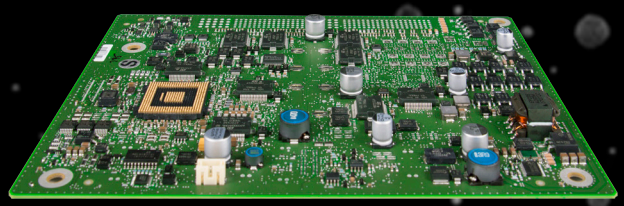
Stephen Las Marias: Zulki, tell us more about NexLogic and your role in the company.

Zulki Khan: I started NexLogic in 1995, so this has been a 23-year journey for us. We offer full turn-key solutions from PCB design to layout, fabrication, assembly, and box-build testing—the whole nine yards. For the last three years, we have also been doing product design where if somebody has an idea, we can devise the scope of work that they want the product to be doing, and then design the hardware, which is one more step vertically other than PCB. We design the hardware, firmware, and software—we can basically create the whole device.

When it comes to layout, we have three different tools. We have Cadence Allegro, PADS, which is now a Siemens product, and Altium. We have multiple designers with CAD qualification and EEs who do the layout. For fabrication, we have a team of different fabricators either within the U.S. or overseas. That's not something we do in-house, but we have a network of many companies that will do the fabrication for us.

In terms of assembly, we do that in-house. We either buy the components for full turn-key assemblies, or the customers consign the components to us, and we do the labor portion of the assembly with the components and boards provided by the customers. In some cases, we do hybrid assemblies where we buy some components, and the customers will provide others.

We've been manufacturing medical devices for a very long time—close to 20 years. We have ISO-13485 certification, which is what



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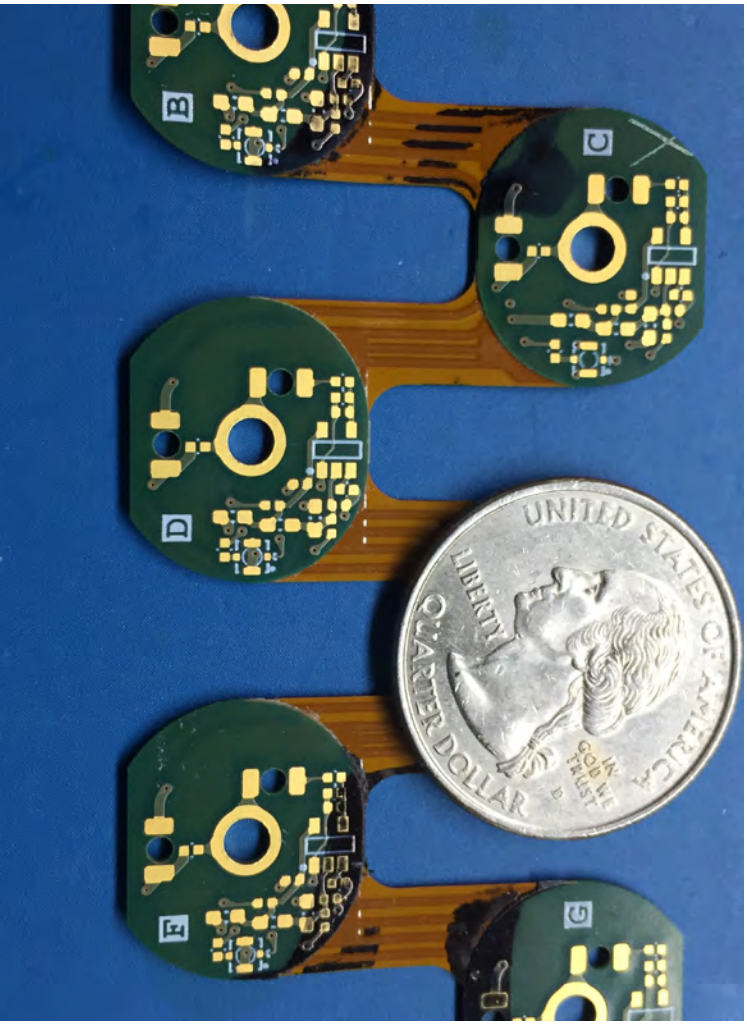

Figure 1: A rigid-flex circuit.

you need for making the medical devices, in addition to ISO 9001:2015, which is the latest ISO standard for general manufacturing. We either do the full turn-key or the consignments or layouts for medical devices. Some of the medical device customers we've worked include Boston Scientific, Medtronic, Abbott Point of Care, Abbott Labs, Covidien—which is now part of Medtronic—and a bunch of other companies. We have a variety of experience. We don't claim to know everything, but we learn along the way.

Las Marias: From your perspective, what are the challenges when dealing with medical electronics?

Khan: There are three classes of manufacturing: Class 1, 2, and 3. Class 1 is for toys and items that don't require much reliability. Class 2 is mainly consumer electronics, industrial, and commercial industrial products. Class 3 typically manufactures for two segments: first, military and aerospace, and second, medical and biomedical. What's special about Class 3 is the highly specific requirements for manufacturing in terms of the tolerances of components and specifications for the assemblies. Class 3 requires extra careful manufacturing where you have to make sure you have reliability and repeatability. There are many checks and balances that you need to embed throughout the manufacturing process, so that you don't have surprises towards the end of the process.

When you talk about challenges in layout, medical products are not designed any differently. The limitations or challenges come from the packages and materials that you use for making the product, and the technology that you run. Some of the portable devices, such as hearing aids, do enter a different arena—making products out of flex or rigid-flex circuits. In some cases, you have to bend the circuit for it to be able to adhere to the physical shape of the device it is going to take. Regarding hearing aids, it has to be very precisely bent and controlled.

As I've mentioned, the only limitation with layout is the kind of component and technology you use. Technology is moving further and faster. You have to keep records of traceability and reliability for possible recalls in the field in three, five, or even seven years, in some cases, so that if the product was recalled, you had the source of where the material was purchased, etc. You also have to perform a multitude of tests (e.g., flying probe, in-circuit, and functional tests, etc.). This is still the case, but recently, everything has been shrinking in size. Everything is becoming smaller, more portable, Bluetooth enabled, and wearable and medical devices are not immune to that. Microelectronics are a challenge in themselves because we must have all the dimensions for medical device manufacturing, which are really small and tolerances are extremely tight.

There's nothing wrong with these trends except for the fact that when you deal with

smaller devices with less footprint and real estate, challenges start to come. Regarding physical packages, a couple of years ago, a physical passive package was 0201 for capacitors and resistors, which is very challenging, but most people were able to handle that. But then a smaller package entered the picture: 01005, which is half the size of a 0201 passive device package. Now, the 01005 package physically speaking, is essentially a speck of salt or pepper, which you can barely see, let alone manufacture, inspect, and ensure that you installed it properly and it's functioning correctly.

When it comes to active devices like BGAs—which used to have 0.5-mm pitch a few years ago, but have now dropped to 0.4, 0.3, 0.25, 0.2 mm (and will soon be 0.15 mm pitch) —it becomes challenging because you also do not have the luxury of real estate on the board itself. You used to running two traces between the pads of the BGA when doing the layout for a medical device in the days of 0.5-mm pitches, but now you're talking about 0.2 mm, so you're barely able to running one trace out of the two between the two pads during layout, and that will probably be two or three mils at most. These are very fine traces, which would possibly limit the fabricators because not everybody can successfully manufacture with a 2 mils trace going from one place to another. This is the new challenge, which needs to be properly addressed as well.

Zulki Khan

What's happening now is you are creeping into the microelectronics world when it comes to medical devices. Now, you remove the packaging—glass, plastic, or ceramic based—from the component—such as a resistor, IC, or whatever the case may be—and placing these components directly onto the substrate or PCB. What happens is the traditional surface-mount manufacturing cannot handle that, and manufacturing companies and contract manufacturers must have special capabilities to handle those.

Why? Because when you're placing these components directly on the substrate or PCB, you need to have specific devices, and a specific environment and manpower to do that kind of manufacturing. When you're wire bonding, wedge bonding, or ball bonding in microelectronics to produce medical devices, you have to have a clean room—Class 10,000 or 1,000—because you're dealing with very fine components without packaging, so you need to control the dust, debris, and contamination within the room where you're manufacturing the medical product.

In traditional SMT, you don't need a cleanroom as long as you are controlling the humidity and the temperature, but not in the case of microelectronics. Not only do you need the clean room, but you also need specific machines—such as a wire bonder, wedge bonder, and shear strength testing device—and you also need specific micro dispensing capabilities because of the major difference between traditional SMT manufacturing and microelectronics—size. In traditional SMT manufacturing, we do the design and discuss items in mils, which is a hundredth of an inch, but in microelectronics, you talk in microns.

You have to place the devices with the tolerance in microns to measure and inspect them, and in some cases, even calculate the loop of the wire bondage you are putting together to a specific wire bonder that you have in place. Then you need devices with the shear or pull strength measurements to make sure the device can withstand the force of the product (physical exertions, mechanical vibrations, rugged environments, etc.). Microelectronics are not new, but they are a relatively new beast where everything is moving, and the medical industry is not immune to that.

The companies that come to mind for wearable, medical devices are all the big ones already doing it—Fitbit, Nike's wearable division, etc. There are some known companies as well as some startups, which are making some medical devices. Amongst the numerous startups, and most of them are making devices for monitoring, diagnosis, and analysis. The applications that everybody knows and works with right now include physical exertions, number of steps taken, calories burned, flights of stairs climbed, heart rate, and more.

These products are way beyond us now. The product that we're dealing with today is a medical device that you wear on your wrist, and it has sensors that will monitor the chemical composition of your body fluids. It has proprietary algorithms where if there's a specific change in the composition of chemicals in your body fluids occurs, it will alert you and or your doctor in real time. For example, if your blood sugar goes too low, the device will warn you that you should start driving to a hospital because it's probable that you will have a medical incident in the next 30 minutes (e.g., stroke, heart attack, etc.). These devices are becoming more predictive of medical conditions that may occur in humans. Soon, we will have devices that alert you to call 911 and say, "I'm going to have a medical issue within the hour, please send an ambulance."

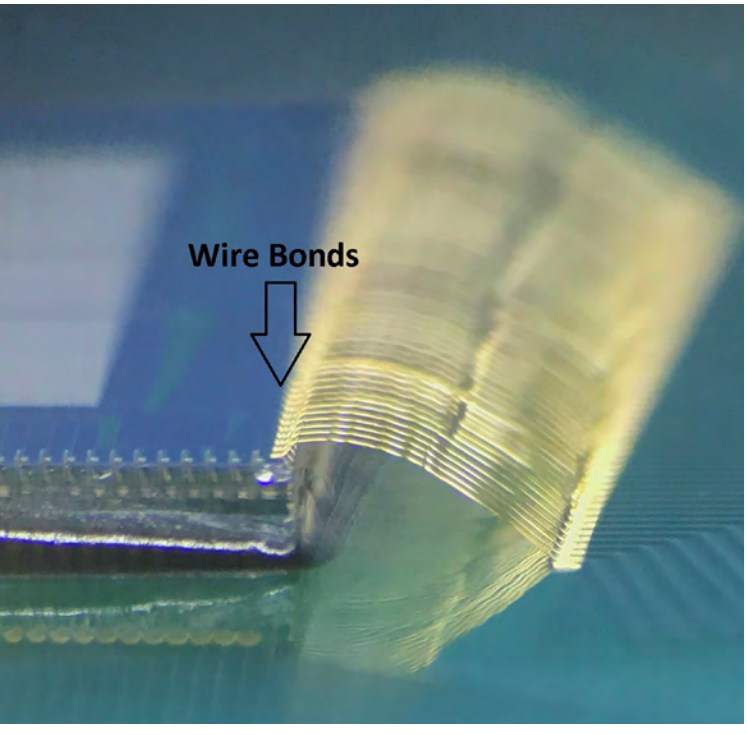

Figure 2: Wire bonding.

Due to miniaturization, another challenge we see in medical devices is the need for a new set of tools to be able to do bonding—wedge, ball, or ribbon bonding—and inspect and provide qualitative evidence because these devices are so small you can barely see and make anything out of the images through regular human eyes. You need a sophisticated inspection tool that will provide measurements of the curve of a wire bond in microns (e.g., ±5 to ±10 microns) to be able to see if that will run through the amount of current that the device requires.

Thus, specialized tools are required for bonding and inspection methodologies that can look at loops, curves, bends, and height. You also need to provide evidence that it will withstand the test of time. Sometimes, you find that it's a bottom-terminated device—like your fine BGA—but you need to do underfill to make the device sturdier. Sometimes with underfilling materials, such as a membrane-like material, you have to control the thickness underneath the device so that it will adhere to your mechanical dimension requirements. These are some of the challenges in assembly.

You have covered a lot of flex circuitry in the past couple of issues of your magazine, so when it comes fabricating portable, handheld, and wearable devices, you marry rigid with flex for PCBs. This brings additional challenges when trying to bond between the two. To be able to place certain components on the rigid side versus flex, and make sure the current flows through properly—and in some cases where the board needs to be bent—you have to calculate the bend radius. There are specific challenges that are now coming into the picture because of the change in technology.

Las Marias: The increase in the manufacturing of medical devices is driving growth in the use of flex printed circuits. You also mentioned challenges when dealing with medical elec-

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KEYNOTE SPEAKER

Heterogeneous Integration Roadmap and SiP

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KEYNOTE SPEAKER

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KEYNOTE SPEAKER

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Figure 3: Wirebond clean room at NexLogic Technologies.

tronics and marrying rigid PCBs with flex. Can you talk more about that?

Khan: Yes. Usually, the difference is in the change in the thermal coefficient between the rigid and flex boards, so it contracts and expands at a different rate. There is a difference in bonding it together that needs specialized lamination. Where to place the components—either on the rigid side or the flex side—is another challenge. Sometimes, the board is entirely flex with 16- to 20-layer flex circuits.

Further, wire bonding of the devices is different because of the materials. It could be a gold wire bond, aluminum, or copper, depending on the application of medical devices. The thickness also becomes an issue. It could be one-mil aluminum wire or two-mil gold wire, but it could also go on a finer sub mil, like 20 microns. Concerning manufacturing, you have to be precise, control finer wires for bonding, and assemble them properly (wedge bond).

What we see now is kind of a mixture of assemblies—a portion of it is SMT, and the other portion with microelectronics. The technology is merging between traditional and microelectronics assembly, which is fine, but again, OEMs for medical devices need to go to somebody who can do all of these processes in-house because that's the way to manufacture it. You need to do SMT manufacturing first and cover all the areas where you'll be doing the microelectronics first. Once you finish with SMT, then you go to the clean room and finish up the microelectronics assembly. There's a process to making a product, whether it's a medical device or any other kind. You could have a hybrid of both, but then you need to make sure that you are going to the right EMS Company who has the process dialed in.

Some startups are developing sensors in a specialized material that can measure the temperature of your skin and bodily fluids. Through the specialized material that they're developing, they can get an accurate reading of your body chemistry. Companies are trying to make machines that used to be huge, such as scanning oncology products for detecting cancer, into small portable devices the size of

desktop PCs with a handheld device that is a size of a remote control. Through that device, they want to scan the body for tumors or abnormalities.

This would provide tremendous savings for the cost of a product because a similar machine costs millions of dollars now. If companies can make these products successfully, you could have it for 20–30% of the cost. The cost is coming down, but again, the manufacturing process is becoming tight and difficult. You have to make sure that all of these different steps are adequately taken care of, and that there are checks and balances along the way. Moreover, you should have a final QA before the product is shipped out of the contract manufacturing company.

Las Marias: Many experts in the industry are saying that communication between the designers and assemblers is important. What do you think?

Khan: Communication is crucial because with these are newer devices coming in the marketplace, you need to make sure you're in contact with the designer and the manufacturer. What used to happen for traditional medical devices is you made a device and ensured that the components you placed on the design were available at a reasonable price. This isn't an issue with the manufacturing itself. With newer technology, some of the datasheets don't call out the specifics of how you need to do the layout. If you don't communicate properly, you might end up making a product that may not work optimally.

What do I mean by that? If you're making a medical device—such as one that is limited in size because it's a portable or a wearable device—that means in manufacturing, you have to run through all the signals properly, and you are short or limited in real estate. In PCB for fabrication, for example, you will have limited space to place the components on the top and bottom of the board. Also, the components that you select should have their form factor in terms of the Z-axis—the height of the component—which will be low because the size, thickness, and weight of portable devices are issues.

Next, are they available? If yes, there might be a differential in cost or something, it is hard to say. Again, when it comes to fabrication, the same board might require blind or buried vias, which means the costs will increase. At the same time, you are trying to cram the same functionality in a small footprint of a circuit board, so you have to use techniques like blind or buried vias that are required to run all the signals properly to make sure all the input and output signals travel correctly.

These types of issues need to be discussed between the people who are going to design and make the product so they can foresee the issues that might come up in manufacturing. One thing that gets overlooked by many designers regarding component placement is that since the devices are small, they want to stack these all the way to the edge, which makes it difficult to manufacture because if these panelized boards need to be sheared or de-panelized, there is a risk of damaging these components which are at the very edge of the board.

These are typical issues that can be overcome if you have a strong team that communicates from design through manufacturing. Work together and collaborate to minimize these issues.

Las Marias: Do you have any final thoughts about what our readers should know regarding PCB design and assembly when it comes to medical electronics?

Khan: Go to somebody who knows what they are doing. The company should be ISO 13485 certified, and they should look at the history of what kind of products the company has made for the medical device industry, as well as the types of challenges that they faced and overcome. That would be my word of caution.

Las Marias: Great. Thank you very much, Zulki.

Khan: Thank you. SMT007

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.

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.

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.

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.

Fighting Forgetfulness with Nanotechnology ▶

About 29 million people around the world are affected by the disease "Alzheimer." In an international collaboration, scientists of the Max Planck Institute for Polymer Research (MPI-P) in Mainz together with teams from Italy, Great Britain, Belgium and the USA are now working together on an approach for a therapy.

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Proper Thermal Shielding Yields Highest Rework Results

Knocking Down the Bone Pile

by Bob Wettermann, BEST INC.

There are numerous "gotchas" if the rework technician does not care for components and materials neighboring the component rework area. If this care is not taken, the rework component might have been properly reworked, but the PWB itself may not be functional due to thermal damage. While PCB rework processes using best-in-class methods, materials, and equipment may have a high yield, an even higher yield can be achieved by protecting surrounding components.

During component rework, taking extreme care of nearby components—whether they are adjacent to the device being reworked or on the opposite side of the board—is required to avoid collateral heat damage, inadvertent reflow, and altered characteristics, such as discoloration or part skewing. Damage can be done to the part physically when the heat from the rework source is beyond the range of what the component is rated. This is common with connectors, relays, and batteries.

In addition to component damage, de-wetting, pad damage, starved solder fillets, and component surface finish oxidation can result. In some cases, the damage is unseen in the form of increased intermetallic growth in the solder joint, which may impact the reliability of the assembly. In end-use environments where reliability is critical, this increased reliability risk must be investigated for its impact. Also, a process capability study might have to be completed to verify the rework process.

Further, there can be other materials damaged on the assembly that are part of the proper operation and design for its end-use operat-

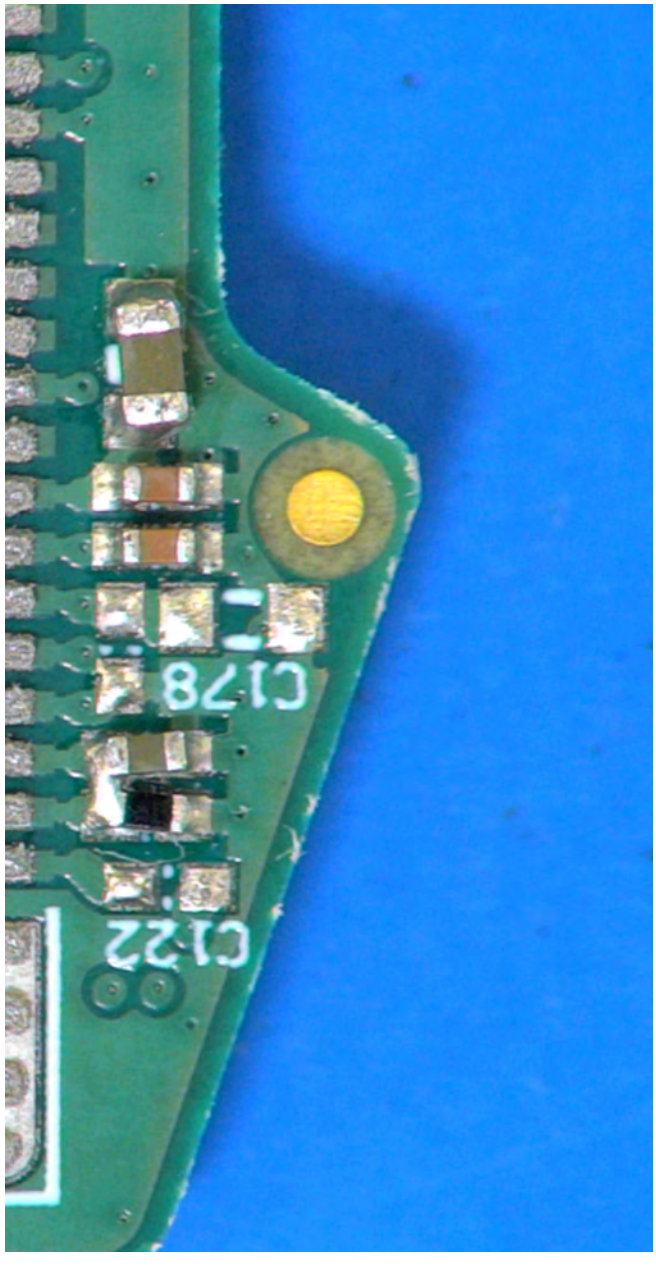

Figure 1: Skewed component due to proximity to the one being reworked and improper shielding.

ing environment. These materials can include, but are not be limited to, the following items:

- Underfill materials underneath the components
- Staking materials on the PCB
- Insulative coating materials
- Conformal coatings
- Thermal grease

These materials can dry up, become nonfunctional, soften, or migrate to other areas of the assembly, which all have a detrimental effect. For example, underfill materials have a softening temperature below that of the reflow temperature of the solder. When an underfilled device reaches this temperature, it pushes out solder that reaches reflow temperature and causes shorts underneath the neighboring device. Thus, it is important to know the materials on the board and be aware of technical information on the datasheet from the material supplier or have experience about the materials' properties.

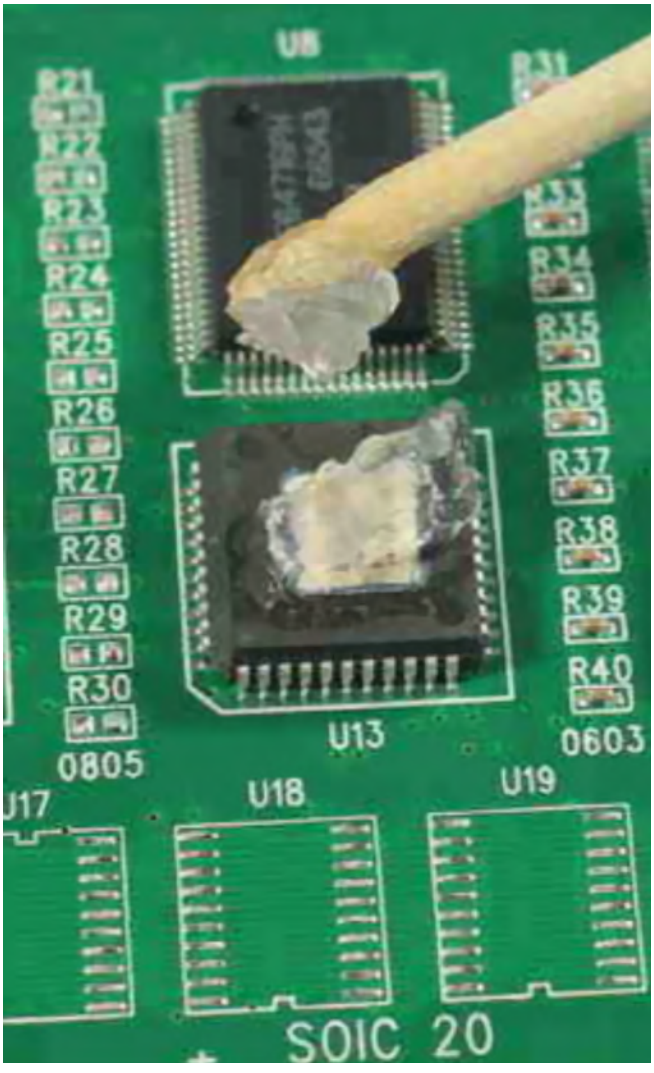

Figure 2: Use shielding materials, like gel, to mitigate the effects of heat in the rework area.

There are numerous steps the rework technician can take to avoid these neighboring reflow "gotchas." One of the first steps to prevent having to scrap a board or perform rework a second time (if allowed by the customer) is to investigate the materials and components on the board before starting the rework operation. It is better to take a moment to question the material composition of nearby components and pull a few component or material datasheets then to start again.

After the risk areas are identified, protect at-risk parts by either removing or shielding them. The use of ceramic non-woven tape, a metal shield, or shield gel has been shown to be the most effective thermal shields [1]. Finally, placement of thermocouples around the component being reworked when performing rework profiling will help identify issues. If a hot-air or an infra-red (IR) reflow source is used, this will help to pinpoint potential problem areas instead of guessing.

The reflow of surrounding devices in the rework area is a yield detractor in PCB rework. If you are not careful with the reflow source being used, nearby materials may be destroyed or cause the PWB not to meet the initial specifications or design of the assembly. However, careful planning, shielding, and sometimes removing neighboring device or material will ensure the highest possible rework yield. **SMT007**

References

1. Shielding Effectiveness of Polyimide Tape During Rework by Gaynor Adam and Robert Wettermann, Circuits Assembly, October 2014.

Bob Wettermann is the principal of BEST Inc., a contract rework and repair facility in Chicago. To read past columns or contact Wettermann, click here.

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AOI Programs with a Magic Click

Article by Jens Kokott and Matthias Müller
GOEPEL ELECTRONIC GMBH

For many manufacturing service providers, this is a daily challenge: Once again, the new job is a series of 50 pieces. Important staff are on vacation, and component delivery times make your hair stand on end. The customer is determined to have AOI, but the layout of the assembly is highly customized, making it virtually impossible to use complete library entries. The customer is also demanding delivery at short notice.

Figure 1: Production runs of 10–1,000 assemblies are everyday life for an EMS provider.

In situations like these, an AOI program that is available quickly can make a crucial difference in significantly reducing the time from the start of production to delivery.

SK-Tronic: Flexible Manufacturing for a High Level of Diversity

SK-Tronic is an example of a medium-sized traditional EMS provider; its portfolio covers everything from PCB assembly of prototypes to producing complex equipment systems. The company handles conventional small batches as well as larger production runs. SK-Tronic provides its customers with advice and support with developing the layout and procuring materials. Surface-mount assembly is carried out using a total of three Mycronic systems to guarantee highly flexible production without any downtime. Quality assurance is performed on the assemblies produced using Goepel electronic's 3D AOI system—Vario Line 3D—which is fed by all three pick-and-place systems.

As is typical for EMS providers, SK-Tronic is also confronted with a wide range of products. There is always a high degree of time pressure, and customers demand an AOI inspection of all components as the standard. In situ-

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Figure 2: Surface-mount assembly at SK-Tronic.

ations like these, creating AOI programs can result in a bottleneck situation that can slow the production rate—unless you have a tool that takes care of the difficult task of creating a test program itself as if by magic.

The Old Way

The traditional way of creating a test program starts with importing data. The next step of assigning item numbers to existing library entries is the most laborious because each item code number has to be assigned manually. The final adjustment of the test parameters is also carried out manually. The complexity of the programming depends on the characteristics of the assembly.

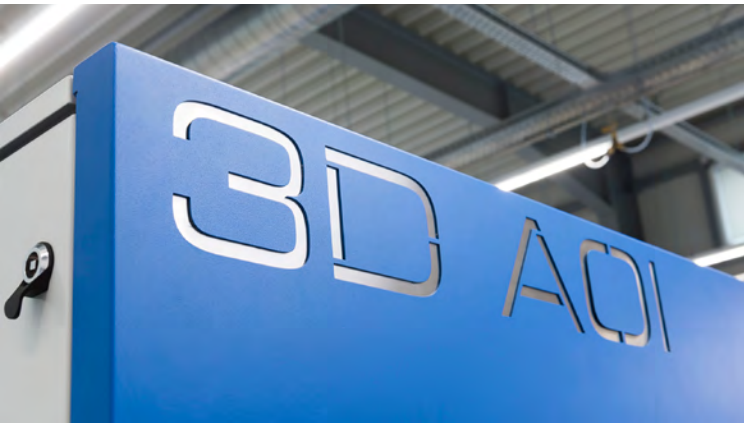

Figure 3: Quality assurance on all assemblies using 3D AOI.

"In the past, some test programs would take a day to create, and then there was a manual inspection on top of that," explains Oliver Barth, production manager at SK-Tronic. That's why AOI was only scheduled for batch sizes of 100–200 pieces, as a manual visual inspection under the dynascope was more time-efficient than creating an AOI test program.

As if by Magic

To make it even more economical to use AOI systems, Goepel electronic has developed the MagicClick tool for the PILOT AOI system software. This enables test programs using 3D AOI to be created and optimized automatically. And the really special thing? A production-grade test program can be created in just a few minutes—complete with a component library—without any library entries whatsoever. The parameters are also adjusted completely automatically and even consider process variations. At most, only small manual adjustments are necessary afterwards. MagicClick aims to enable efficient use of AOI, right from the second assembly.

This is possible when used in combination with the AOI system Vario Line·3D. What sets

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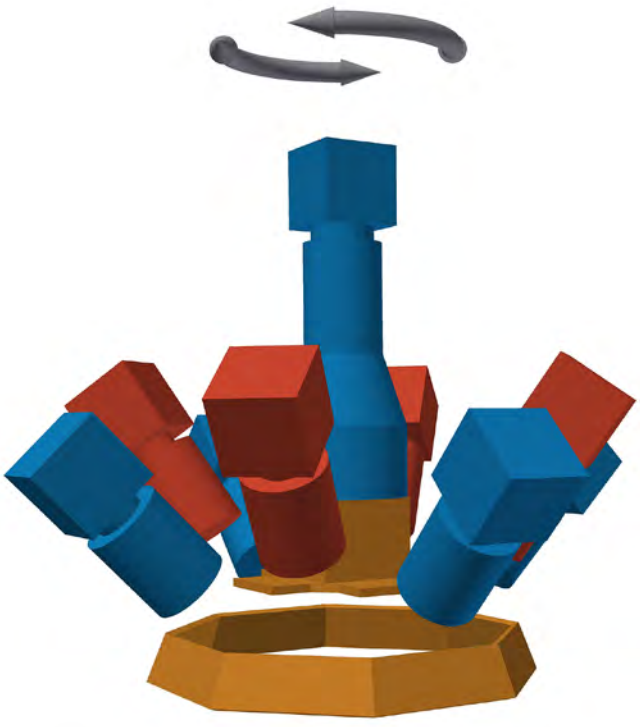

Figure 4: Structure of the rotating camera module 3D·ViewZ (blue: cameras; red: projectors for structured light; yellow: lighting units).

it apart is the 3D · ViewZ camera module, which combines various measurement and inspection technologies for maximum fault detection. In addition to the 3D measurement based on structured light, the module also includes cameras for angled-view inspection.

Both 3D projections and 2D inspections are possible in 360° steps, which guarantees maximum fault detection even in critical component situations. 3D · ViewZ is available both in the in-line system—Vario Line · 3D—and in the stand-alone system—Basic Line · 3D.

Intelligent Algorithms in the Background

Automatic generation of programs using MagicClick begins in the first step with the import of insertion and Gerber data. If available, the ODB++ format is also a suitable option. Therefore, this step includes both component parameters—name, position, item number, etc.—and information on the layout and pad. However, detailed information is not available about the housing and the solder joint.

This is where a 3D AOI system shines. Unlike the 2D technology, where each pixel merely represents a brightness value, a height value can be assigned to each pixel with 3D technology. Thus, it is possible to automatically create an exact replica of the respective housing, including the solder joint. In the next step, this information is accurately used to determine the particular housing shape based on intelligent algorithms and assign all the test functions necessary. At the same time, the test program is created, and a component library is automatically generated based on item numbers.

Figure 5: In-line and stand-alone AOI systems with the camera module 3D · ViewZ.

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Figure 6: Fault statistics and test program generation on the system.

In the final step, the test parameters are adapted to the actual process variations as the test program is executed. To avoid slippage, tolerance limits are set close to either side of the measured values and are corrected according to the actual variations—considering plausibility criteria. This is based on an intelligent algorithm, which can be compared to artificial intelligence (AI)—a comparison that should be avoided at this point due to overuse and the ambiguous definition of the term. Because the automatic creation of test programs only requires insertion and Gerber data and data, even users without any knowledge of the components can carry out the programming.

Two months after MagicClick was introduced at SK-Tronic, more than 1,300 package shapes had already been added to the component library. "We get more 'green ticks' every week, which means we have more known components and there are fewer for us to add," explains Barth. MagicClick also learns over time that the more often a recurring project is run, the better optimized the adjustment of the parameters. Since the introduction of MagicClick, SK-Tronic has identified significant changes.

"3D AOI and the automatic creation of test programs have enabled us to more than halve pseudo faults," says Barth. 3D AOI significantly simplifies manual classification of the inspection in the event of a fault. It is barely worth even glancing at the actual component because evaluation is made significantly easier thanks to the variety of 3D display options, such as the coloured TopoColor error images.

Increased Efficiency Guaranteed

For EMS providers with a wide variety of products, AOI inspection is a time-consuming part of everyday business. However, by using automated test program creation with MagicClick, time savings of up to 80% can be achieved on creation and optimization. The result is efficient AOI use, even with the smallest batch sizes. What's more, you get a return on investment for an AOI system in a short span of time. It's clear the investment has paid off for SK-Tronic, according to Barth. "We have been able to cut the time needed to create a test program to a third. We were able to reduce pseudo faults verifiably, and test times were greatly reduced," he adds.

Now, AOI is used at SK-Tronic for production volumes of 30 assemblies or more—a substantial improvement compared with the past. The total throughput of manufactured and tested assemblies even increased by 300% over a 10-year period. Ultimately, the customer benefits as efficient use of AOI is also reflected in the final price and delivery quality. **SMT007**

Matthias Müller is a public relations manager at Goepel electronic GmbH.

Jens Kokott is the AOI product manager at Goepel electronic GmbH.

JOIN IPC'S JOB TASK ANALYSIS COMMITTEE

Make sure your voice is heard on the critical issue of skills gap in the electronics manufacturing industry. Help IPC define the workforce skill requirements needed for today and the future.

Join **IPC's Job Task Analysis Committee (JTA)** to help address the skills gap and provide training and career opportunities for your employees.

Why Join JTA?

- To address the skills gaps in your own company.
- To ensure that your staff will be well trained moving forward.
- To decide which jobs need focus and which skills are most important for your industry.

Help us help you shape IPC education and certification offerings that keep your company moving forward and improve recruiting and retention.

For further information, please contact **Dave Hernandez**, senior director of learning and professional development, at **davidhernandez@ipc.org**.

1 How to Measure Manufacturing Employee Engagement ▶

Disgruntled employees have the ability to sap the lifeblood from your organization. And in some cases, one or two negative views can spread quickly throughout a business like an uncontrollable virus. While it is important to deal with issues the moment they arise, it is also vital to have a system in place to measure views and opinions on a regular basis and with a long-term view.

2 Electronic Components Market Update ▶

Unfortunately, there is still no end in sight to the electronic component shortage, and some lead-times are being quoted with 2019 and even 2020 delivery dates! So if you are working with an EMS provider, it remains vital that you communicate and share forecast information with them. You may also want to start looking at the option of fitting, or designing in, smaller components to your PCB assemblies.

3 Indium on Voiding and Auto Electronics Test Standard ▶


Jonas Sjoberg

In this interview with I-Connect007, Indium Corporation Technical Manager Jonas Sjoberg discusses voiding and other key challenges in soldering, as well as an automotive electronics testing standard based out of South Korea that is seeing increased utilization all over Asia. He also talks about the increasing trend in manufacturers moving to Type 5 and Type 6 solder powders, and how this is causing its own set of challenges in printing.

4 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.

5 Session 2 of IPC-SMTA Conference: Conformal Coating Dense Electronics ▶

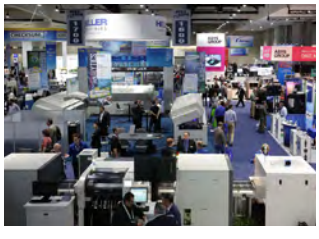
The conference is focused on the cleanliness of highly dense electronic assemblies to achieve quality and reliability within the stated in-field environment.

6 India's Smart Cities Mission Spurs Domestic Manufacturing ▶


Narendra Modi

In 2015, India's Prime Minister Narendra Modi created the Smart Cities Mission Program, which is an urban improvement initiative. One hundred Indian cities were selected to participate in the project after a competitive process that compared funding with each city's individual ability to comply with the program and reach its goals.

7 IPC APEX EXPO 2019 Offers Future-focused Courses, Sessions and Research ▶



Changing technologies that are driving the electronics industry will take center stage throughout the IPC APEX EXPO 2019 technical conference and professional development sessions, which will take place January 26-31 at the San Diego Convention Center in San Diego, California.

8 Kimball Electronics Completes Acquisition of GES ▶

Kimball Electronics Inc. has completed the purchase of substantially all of the assets and assumed certain liabilities of GES Holdings Inc., Global Equipment Services and Manufacturing Inc., and its subsidiaries (GES).

9 IMI Opens 21st Manufacturing Site in Serbia ▶

Integrated Micro-Electronics, Inc. (IMI), the 5th largest automotive EMS in the world and a subsidiary of AC Industrial Technology Holdings, Inc. (AC Industrials) recently inaugurated IMI Serbia, its latest manufacturing facility, on September 29, at the City of Niš, Republic of Serbia.

10 Varitron's Patrice Lavoie Joins intelliFLEX Board of Directors ▶


Patrice Lavoie

Patrice Lavoie, vice-president of sales and business development at EMS provider Varitron, has joined intelliFLEX Innovation Alliance's board of directors. An industry veteran with more than 22 years of experience, Lavoie has industrial engineering background combined with IPC Class 3 training and has previously worked as a business unit manager, director of operations, and supply chain manager, among other roles.

For the latest news and information, visit SMT007.com. Subscribe to our newsletters or premium content at my I-Connect007.

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Place your notice in our Help Wanted section.

For just $500, your 200 word, full-column—or, for $250, your 100 word, half-column—ad will appear in the Help Wanted section of all three of our monthly magazines, reaching circuit board designers, fabricators, assemblers, OEMs and suppliers.

Potential candidates can click on your ad and submit a résumé directly to the email address you've provided. If you wish to continue beyond the first month, the price is the same per month. No contract required. We even include your logo in the ad, which is great branding!

To get your ad into the next issue, contact:
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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

MacDermid Enthone
ELECTRONICS SOLUTIONS

Product Group Field Manager
Waterbury, CT

The Product Group Field Manager is responsible for creating and driving the regional product line strategic plan in coordination with the global product line managers, strategic account manager and regional business managers. The successful candidate must balance commercial obligations to assist the sales teams in closing new business, perpetuating technical expertise throughout the field and develop best practices for the region.

Education: Bachelor's degree; 5 years of related experience; or equivalent combination of both.

Responsibilities

- Thorough understanding of the PCB business; specifics in wet processing areas.
- Facilitate developing commercial and technical strategy for customers.
- Create and deliver customer facing presentations.
- Training.
- Create and execute a product rationalization program aligning with global product managers.
- Develop roll-out packages for new product introductions, including operating guides.
- Excellent written and oral communication skills.
- Expert in chemistry and chemical interaction within PCB manufacturing.
- Willingness to travel globally.

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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MacDermid Enthone
ELECTRONICS SOLUTIONS

Global Application Specialist
Waterbury, CT

Qualifications: Bachelor's in Chemistry, and seven years progressive experience in related field. Expertise preferably in ENIG and ENEPIG. Global travel required: up to 40%.

Responsibilities

- Chemical analysis and experiments of final finish chemistries; characterize new processes from research prior to beta site installations, establishing operating parameters, problem solving tools and analytical guidelines.
- Recommend product, process, and analytical method improvements; including changing composition of compounds.
- Develop final finish product line. Install products at beta sites; collect data.
- Lead technical teams during beta site installations of new products and problem-solving groups at customer locations.
- Train personnel.
- Set up tests of final finish chemistries and products for laboratory personnel to identify customer problems, analyze result to resolve customer issues, and communicate results to customers.
- Oversee laboratory analysis and processing of customer samples through our global technical centers; summarize data, make recommendations and write reports.
- Document technical bulletins.

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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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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GO 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 electro-chemicals 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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GO 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

ZENTECH

Zentech Manufacturing:
Hiring Multiple Positions

Are you looking to excel in your career and grow professionally in a thriving business? Zentech, established in Baltimore, Maryland, in 1998, has proven to be one of the premier electronics contract manufacturers in the U.S.

Zentech is rapidly growing and seeking to add Manufacturing Engineers, Program Managers, and Sr. Test Technicians. Offering an excellent benefit package including health/dental insurance and an employer-matched 401k program, Zentech holds the ultimate set of certifications relating to the manufacture of mission-critical printed circuit card assemblies, including: ISO:9001, AS9100, DD2345, and ISO 13485.

Zentech is an IPC Trusted Source QML and ITAR registered. U.S. citizens only need apply.

Please email resume below.

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Manncorp™

Sales Associate - Mexico

Manncorp, a leader in the electronics assembly industry for over 50 years, is looking for an additional sales associate to cover all of Mexico and to be part of a collaborative, tight-knit team. We offer on-the-job training and years of industry experience in order to set up our sales associate for success. This individual will be a key part of the sales cycle and be heavily involved with the customers and the sales manager.

Job responsibilities:
- Acquire new customers by reaching out to leads
- Ascertain customer's purchase needs
- Assist in resolving customer complaints and queries
- Meet deadlines and financial goal minimums
- Make recommendations to the customer
- Maintain documentation of customer communication, contact and account updates

Job requirements:
- Located in Mexico
- Knowledge of pick-and-place and electronics assembly in general
- 3+ years of sales experience
- Customer service skills
- Positive attitude
- Self-starter with ability to work with little supervision
- Phone, email, and chat communication skills
- Persuasion, negotiation, and closing skills

We offer:
- Competitive salary
- Generous commission structure

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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
Anaheim, California, USA

EIPC 2019 Winter Conference ▶
February 14–15, 2019
Milan, Italy

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

Additional Event Calendars

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What to expect—from new technologies and products, to demos and conferences—at the biggest event in the PCB and electronics manufacturing and assembly industries.

JANUARY: **MANAGING THE SUPPLY CHAIN CRISIS**
The parts supply chain is full of long lead times, price volatility, shortages, obsolescence, tariffs, and counterfeits. We help you cope.

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