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Medical Electronics: Connected Healthcare

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.

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-

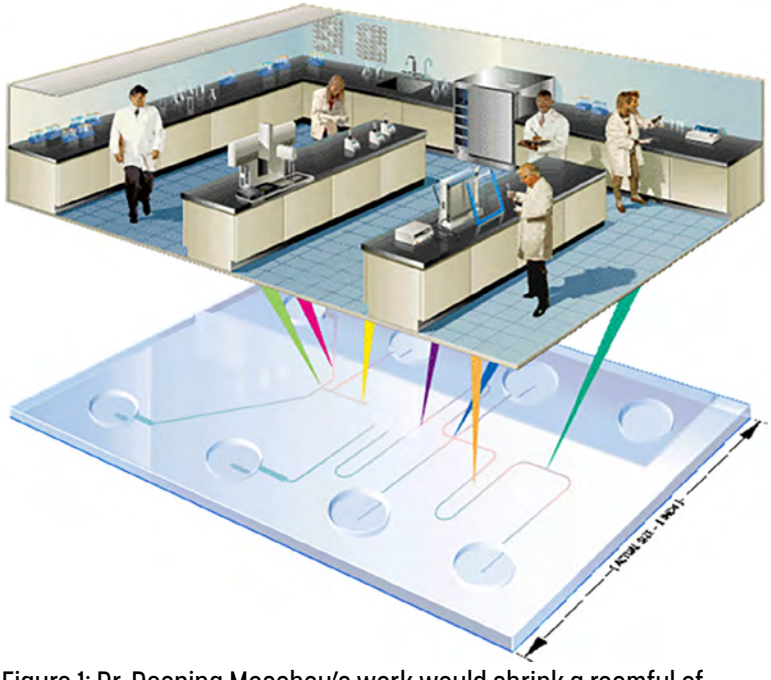

Figure 1: Dr. Despina Moschou's work would shrink a roomful of laboratory diagnostics systems into a compact module.

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

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.

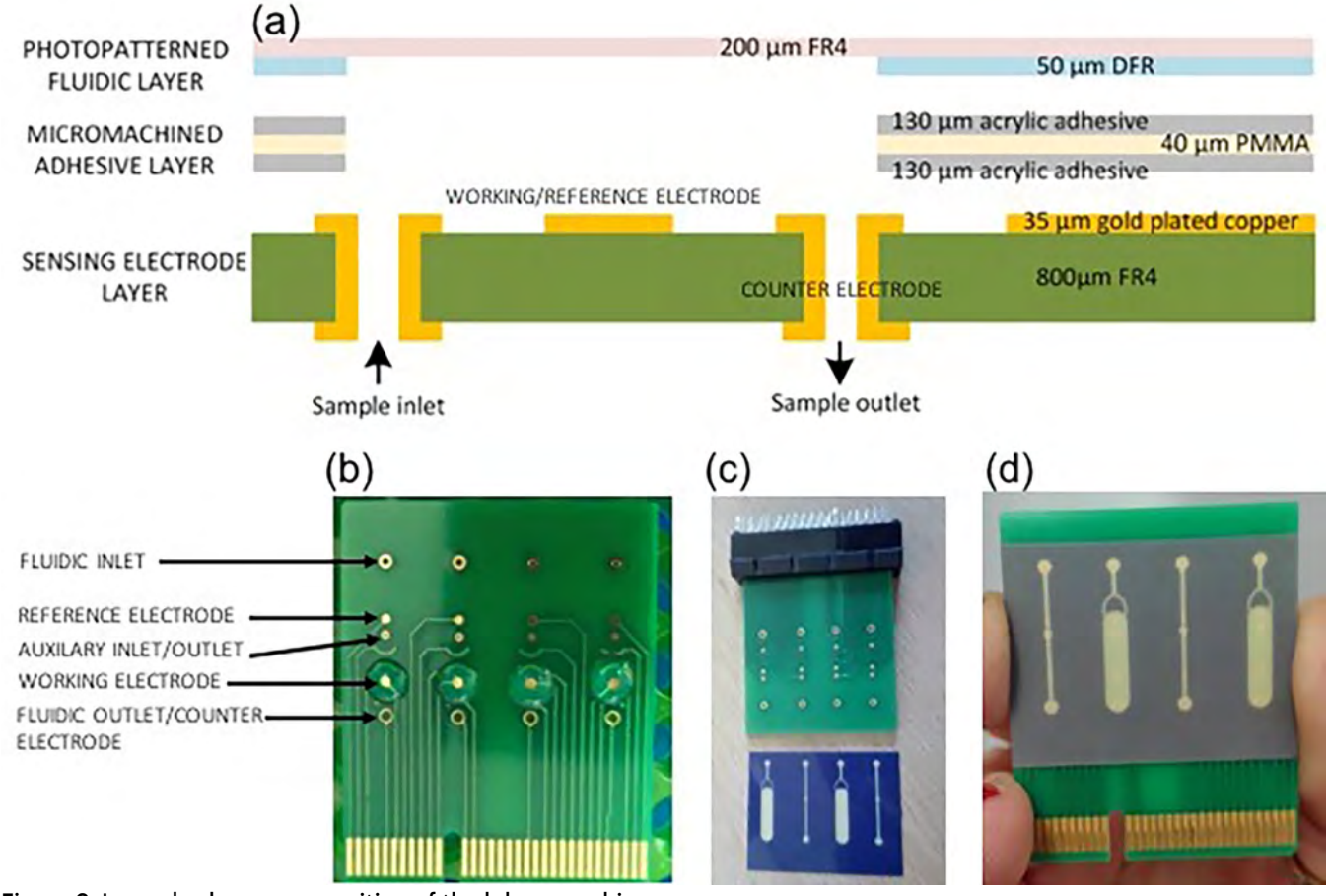

Figure 2: Layer-by-layer composition of the lab-on-a-chip.

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.

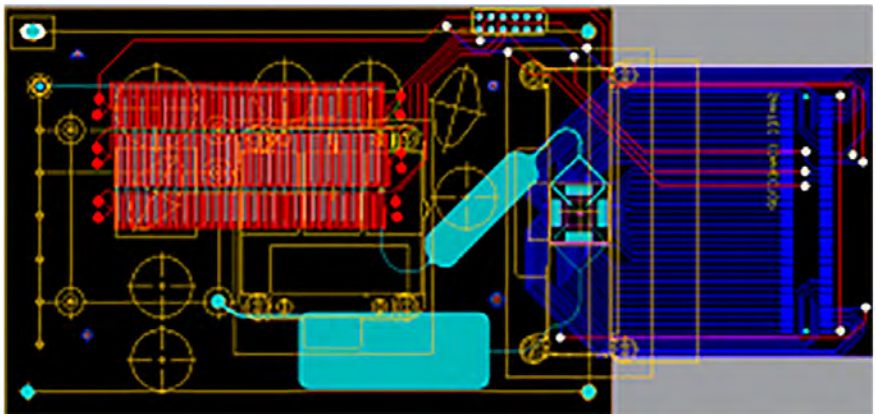

Figure 3: The complex design of the lab-on-a-chip.

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

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