MEDICAL DESIGN BRIEFS

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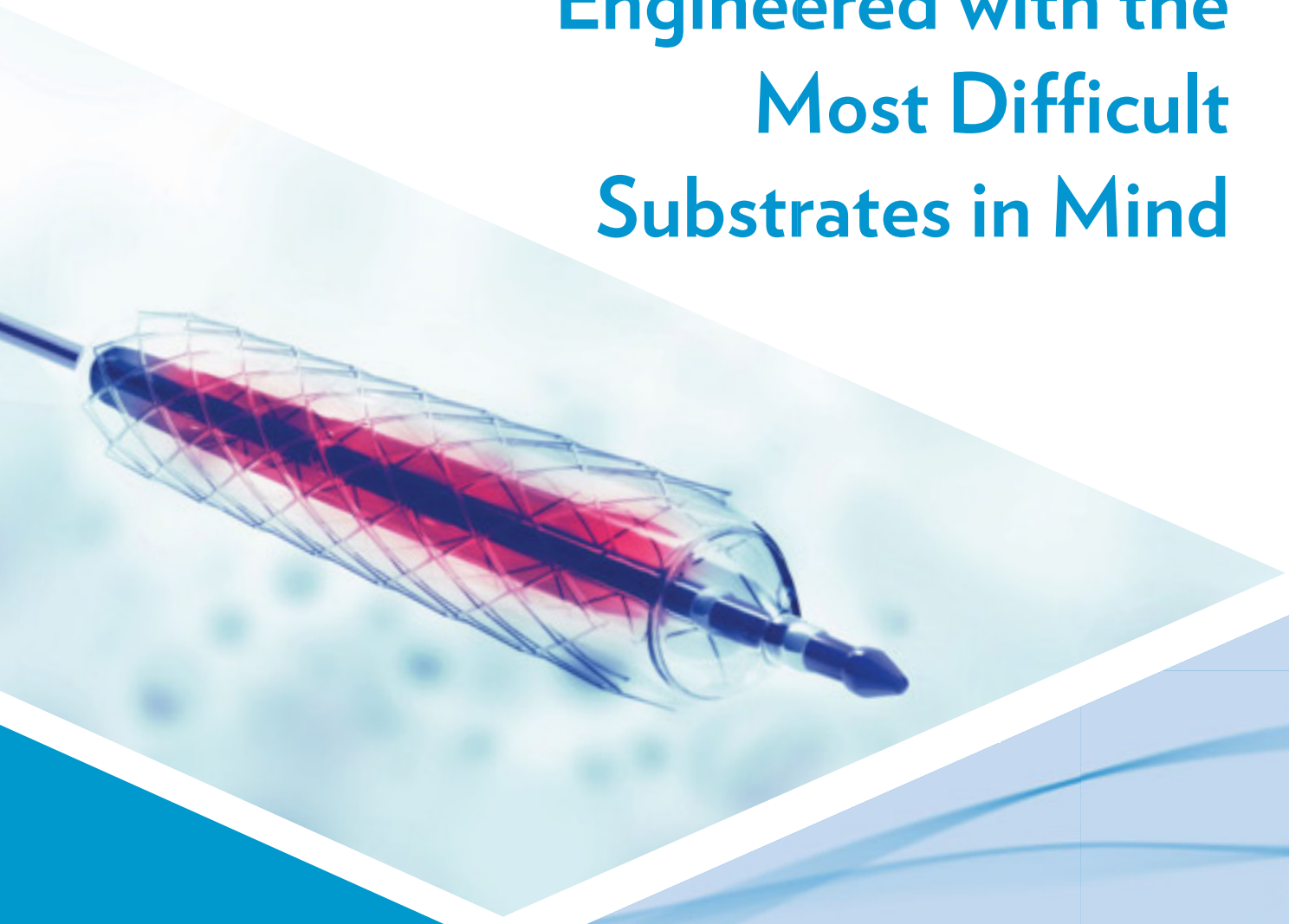

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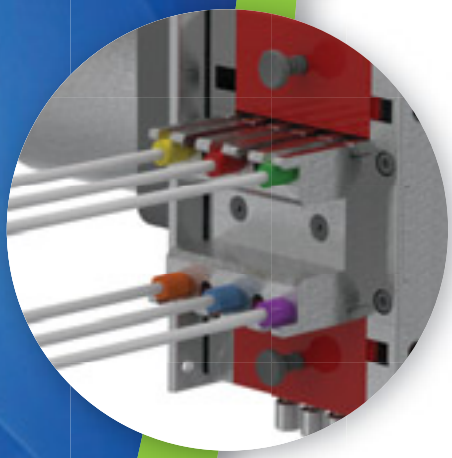

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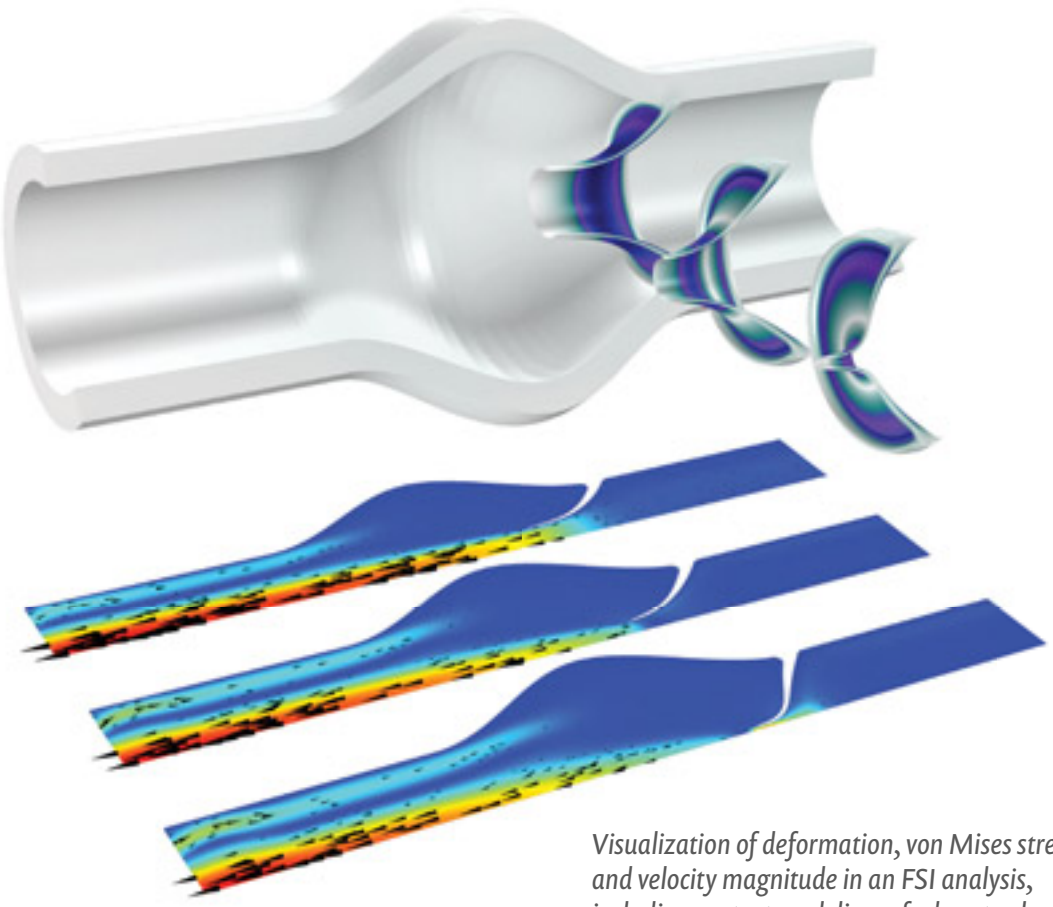
ON THE COVER

By utilizing state-of-the-art production equipment and processes, machining tolerances are held extremely close on today's multi-lumen and multi-layer medical tubing. It is important to note that any misalignment of the tools may be exaggerated in the final product output. Clean parts, especially with sealing and locating surfaces, are key to product performance and successful end products. To learn how to get the most from extrusion tooling, read the article on page 20.

(Credit: Guill Tool & Extrusion)

Visualize and predict heart valve behavior with multiphysics simulation.



Visualization of deformation, von Mises stress, and velocity magnitude in an FSI analysis, including contact modeling, of a heart valve.

Open fully, close tightly. The four valves in the human heart are expected to do this with each beat. When the valves do not function properly, cardiac health issues arise. In the quest for more effective treatments, medical researchers are studying heart valves to understand and predict their behavior. To accurately visualize a heart valve, you need to account for many coupled effects. Multiphysics simulation is up for the task.

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If Reinstated, Excise Tax Should Apply to Broader Base

New research has confirmed what device companies have been saying since the medical device excise tax was imposed on medical devices as part of the Affordable Care Act: the tax forced them to cut funding for research and development.

Daeyong Lee, an assistant professor of human development and family studies at Iowa State University, examined how certain provisions of the healthcare reform law affected families and firms. In a study published in the journal *Research Policy*, he analyzed the 2.3 percent excise tax imposed on medical devices in 2013. The research shows that the tax significantly reduced R&D investment, sales revenue, gross margins, and earnings by the following amounts:

- R&D expenditures – $34 million
- Sales revenue – $188 million
- Gross margins – $375 million
- Earnings – $68 million

The study, the first to look at the actual cost for manufacturers, found the tax also affected operating and marketing costs, Lee says. The tax was imposed on the medical device industry because the industry was supposed to benefit from expanded health coverage. The tax has applied to everything from needles and syringes to coronary stents, defibrillators, and irradiation equipment. Certain items including hearing aids, eyeglasses, and contact lenses were exempt. The medical device field is one of the top five R&D intensive industries, and Lee says a decline in investment could have long-term consequences.

Lee looked at different scenarios when calculating the tax effect, controlling for economic factors that might affect investment. To limit the tax impact, firms could have increased prices, passing the burden to consumers but Lee says that did not happen, likely because of the market power of large hospitals and clinics. The data for the study is specific to large customers, not individuals.

In response, medical device firms diversified their customer base and increased global market sales, which were exempt from the tax, Lee says. The findings also suggest that firms significantly reduced operating costs for selling and cut general and administrative expenses but not advertising and labor expenses.

Congress passed an appropriations act in 2015, which included a two-year moratorium on the medical device excise tax. In January, it was extended to 2020. Given the study findings, Lee says the moratorium could provide time to consider other tax options that do not target a single industry. He suggests that policymakers expand the tax base and include other industries, such as health insurance companies, which also have benefited from increased demand as a result of the healthcare reform act.

"If there is a broader tax base, the negative effects will be reduced," Lee says. "The government needs to raise revenue to cover the costs of the Affordable Care Act, but there are other ways to do it without harming a research and development intensive industry."

Sherrie Trigg
Editor and Director of Medical Content

To obtain a copy of the study, go to ***https://www.sciencedirect.com/science/article/pii/S0048733318300416****.*

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Orthopedic Replacement Implants Market: *Drivers and Developments*

The global market for minor orthopedic replacement implants exceeded $1.5 billion in 2017. Analysts from The Business Research Company forecast the market value to grow at a rate of over 7 percent and to reach $2.2 billion in 2021 in their report "Minor Orthopedic Replacement Implants."[1] According to the report, the primary reason for this growth is the high incidence of arthritis and fractures. Osteoarthritis and rheumatoid arthritis are the major causes for joint replacement surgery, including minor orthopedic joints. The other cause for joint replacement surgery is failed previous joint replacement surgery. This article examines the trends that are driving this market, including a look at materials, regions, procedures, and regulatory developments that are shaping the future of orthopedic implants.

Market Segments. Minor orthopedic implants include implants used in shoulder, wrist, ankle, and foot joints. Shoulder replacement holds the largest market share. Growth in all four segments — shoulder, wrist, elbow, and foot and ankle implants — has accelerated recently (see Figure 1).

The United States accounts for more than half of all minor orthopedic replacement implants. (Credit: The Business Research Company)

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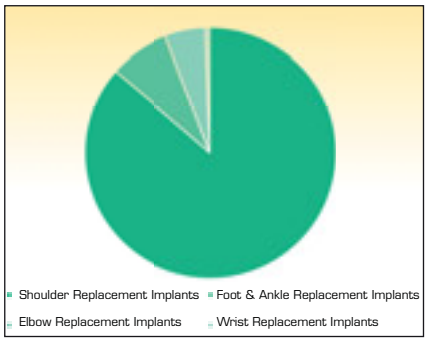


Fig. 1 – Minor orthopedic replacement implants market segmentation. (Credit: The Business Research Company)

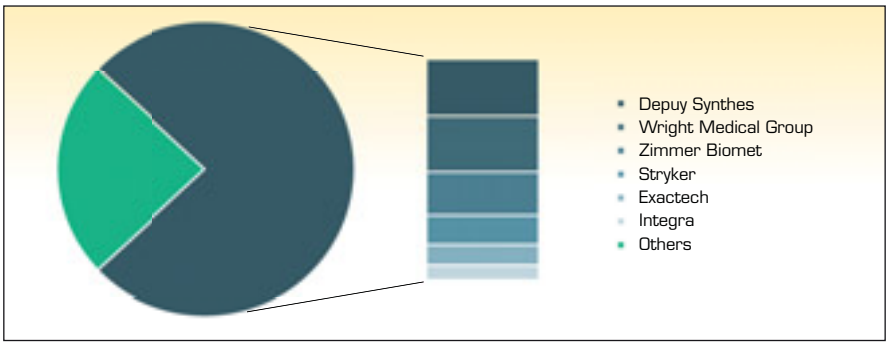


Fig. 2 – Minor orthopedic replacement implants market, 2017, estimated competitor market shares. (Credit: The Business Research Company)

Regional Analysis. With more than three-fifths of the market share, North America was the largest region in the minor orthopedic replacement implants market in 2017, with the United States, being the largest country in the market, accounting for more than half the market share. The smallest market for minor orthopedic implants was in South America with a market share of just over 1 percent.

Market Drivers

Better Materials. Minor joint replacements are highly complex and have previously suffered from a high failure rate. Recent technological advances in both the implants themselves and the surgeries involved have both contributed to the growth of the market. For example, metals such as titanium, cobalt, chromium, molybdenum, and other materials such as polyethylene, have replaced the plastics and ceramics that were earlier being used in the design and manufacture of implants. The metals have a porous surface that enhances osteointegration, thus reducing revision rates. Polyethylene, by contrast, reduces wear and improves the longevity of the minor joint replacement implants. This shift toward new high-quality materials in implants has driven the market since 2013. Longer life for implants makes them suitable for use in younger fracture patients, for whom they were previously not recommended owing to the need for replacement every 10–15 years.

Other major trends are also shaping the minor orthopedic replacement implants market, including the availability of generic implants and the growth of economies in the BRIC countries (Brazil, Russia, India, and China).

Generic Implants. Generic orthopedic implant companies have also gained traction. Following the expiry of patents for implants, some 16 generic companies have entered the orthopedic replacement implants market in the United States, including Orthosolutions, Covenant Orthopedics, Ortho Direct USA, and Emerge Medical. These generic companies are making copies of legacy implants, capitalizing on the proven designs and biomaterials.

These generic orthopedic implant companies' offer lower prices compared to branded implants and thus could pose a threat to the big orthopedic devices manufacturers such as Stryker, J&J/DePuy/Synthes, Zimmer/Biomet, Smith & Nephew, and Medtronic Spine. Because there is a wide scope of entry for many generic orthopedic device manufacturing companies, these generic companies should focus on marketing strategies in order to compete with the big orthopedic manufacturers.

Emerging Markets. The big orthopedic implant manufacturers are showing interest in emerging markets. The BRIC countries are faster growing economies than the United States, and these countries represent around 41 percent of total world population. Converging uncertainty about regulatory, economic, and reimbursement trends in the U.S. market are driving the big orthopedic device companies (Stryker, J&J/DePuy/Synthes, Zimmer/Biomet, Smith & Nephew, and Medtronic Spine) to shift their resources, training, inventories, clinical studies, and R&D efforts to these big four emerging orthopedic countries. Due to high growth for orthopedic implants in BRIC countries, other orthopedic implant manufacturers (other than the big five orthopedic companies) should also consider entering the market to profit from its growth.

Technological advances in implants themselves and in orthopedic surgical techniques have contributed to the growth of the orthopedics market. (Credit: The Business Research Company)

Positive Trends for Minor Joint Procedures

Recently, small bone plating, especially in the distal radius segment, has been a major trend. There is also an increasing trend toward new shoulder prostheses and total ankle replacements. For example, 100,000 shoulder arthroplasties were performed in 2016 in the United States, compared to only 14,000 in 2000. This rapid rate of growth is largely due to the expanding indications for minor joint procedures and their rising popularity, as well as the size of an aging population that desires to remain active.

The healthcare market has seen an increased use of reverse shoulder arthroplasty. The procedure numbers for

reverse shoulder arthroplasty are continuously increasing. According to the BRC report on minor orthopedic replacement implants, approximately half of the shoulder replacements in the United States and more than two-thirds of shoulder replacements in Europe are reverse shoulder replacement surgeries.

The balance of shoulder replacements are total shoulder arthroplasty or hemiarthroplasty procedures. This upward trend of reverse shoulder arthroplasties is due to their increasing utilization to treat shoulder fracture patients and expanding applications to both elderly and more active patients. The highly successful outcomes of the procedure and surgeons becoming more comfortable with the procedure are also leading to an increase in the number of arthroplasties.

Regulation Dominates the Minor Orthopedic Market

The medical device market is highly regulated with authorities and regulatory bodies governing the development and marketing activities of medical device manufacturers in each country. Medical devices must comply with quality standards developed by International Organization for Standardization (ISO).

Due to the financial pressures on healthcare budgets in many European countries, several governments are trying to reduce the cost of healthcare devices and improve their efficiency. Increasing privatization of healthcare is also forcing manufacturers to reduce product costs. In some European countries, several healthcare segments such as orthopedics, plastic and corrective surgery, aesthetic surgery, and total pain management, are being privatized.

In the United States, medical device manufacturers must submit a premarket notification to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. The changes may be related to the design, material, and chemical composition, energy source, manufacturing process, or intended use.

In terms of the price of the implants, the U.S. government, for instance, is unwilling to intervene directly to reduce the cost of joint replacement implants. This has led to insurance companies pressuring implant manufacturers to reduce their prices. Even though the U.S. government does not cap the prices of medical devices, it is worth noting that a 2.3 percent medical device excise tax applies to sales of taxable medical devices. By contrast, the Indian government has capped the prices for orthopedic implants, which thus regulates the margin for these implant companies.

Reference

1. "Minor Orthopedic Replacement Implants," The Business Research Company, https://www.thebusinessresearchcompany.com/reports/healthcare/minor-orthopedic-implants-replacement-market-2018

This article was written by Abhilash Pyata, Research Consultant for The Business Research Company, Hyderabad, India. TBRC is a market research and intelligence company with research professionals at its offices in the U.K., India, and the United States, as well as a network of trained researchers globally. For more information, visit ***http://info.hotims.com/69509-161****.*

Microservices Drive Digital and Connected Health Efficiencies and Growth

Healthcare is poised for significant change over the coming years as a result of emerging technologies like artificial intelligence (AI), virtual assistants, sensors, and wearables. Significant investments have been made in transitioning providers to EMR systems, but the benefits of this digital transformation has not yet been fully realized. Microservices are a new software development technique that provides a number of advantages in architecting back-end solutions while offering particular benefits in developing digital and connected healthcare solutions.

There are significant market pressures in developing new healthcare solutions. Expectations are that these solutions will improve outcomes while also reducing costs as providers and payers look for added value, new operating business models, and improved patient engagement. The opportunities within this sector are also bringing in new competitors to the fold like Google, Amazon, and Apple, along with nimble start-ups, so time to market is becoming increasingly important.

Data volumes are increasing in all sectors, and healthcare is no exception with the adoption of wearables, electronic medical records, and medical-grade sensors. Data privacy and regulatory requirements in the healthcare sector drive additional demands around how this data is collected, stored, and managed, particularly around access to personal health information (PHI).

The traditional approach to developing back-end platform technologies is to develop it as a monolithic architecture. This has a significant drawback in limiting reuse of components for use in developing other solutions. For instance, if you have a successful chronic disease application targeting people with type 2 diabetes and you want to adapt that solution for managing patients with COPD, there is likely a significant portion of your original diabetes solution that you could reuse but that would be difficult to do.

With a chronic disease platform built as microservices, you could replace the component that interfaces and manages data from patients' connected glucometers with one that tracks readings from their pulse oximeters instead. The services that communicated with a companion mobile application or that captured additional insights from an Alexa virtual assistant would all be reusable in each case.

Advantages of a Microservices Architecture

So, let's get into more detail around how microservices provide these unique advantages and some of the elements to consider in mitigating some of the concerns that have been expressed around this architectural approach. It's important to note that microservices are a new approach to architecting software solutions to address complex system level problems. There are still architectural decisions that need to be made to get the most benefit out of them. Given that it is a tool to encapsulate specific functionality in a healthcare solution, the first decision to be made is around how to structure those components or services. It is important to define services that are loosely coupled and independent of each other, with a clear and simple interface/protocol. Ideally you would target components or services that are complete in and of themselves and that are tied to a specific function or user service that you are offering, or a component or service that has potential for use in other applications outside of the one you are designing it for.

The portability and interoperability benefits from a microservices architecture stems from their adoption of open standards such as JSON and HTML, which allows for integration of third-party solutions and integration with microservices that are written using different programming languages. This results in the development of building blocks that can be repurposed in new projects or solutions in the future. It also means introducing new technologies or components in a future road map enhancement can also be accomplished more easily and with less risk of impacting existing components in the process.

One advantage of particular importance in a healthcare solution that falls under regulatory oversight is the isolation achieved between components. In a medical device, this isolation on an electronic printed circuit board would be achieved through an optocoupler that completely isolates (electrically) one part of the board from another. The equivalent functionality is delivered through message queues between microservices. The practical implications of this are that components of a solution that deliver a diagnosis through a proprietary algorithm or machine learning tool can be isolated from components that manage networking functionality, device connectivity, or other nonpatient critical capabilities of the solution. The latter might need to be updated to patch vulnerabilities in a networking stack or to update support for a new communication protocol while ensuring that there is no unintended impact to other microservices within the system.

Microservices are naturally event and data oriented, lending themselves well to solutions that require compliance under HIPAA or GDPR regulations as personal health information data can be isolated from other system data, and access to that data can be more readily audited for specific access.

The Hive Architecture

Macadamian's Hive implementation of a microservices architecture, for example, goes one step further and implements user-based roles and authentication mechanisms to ensure that at the fundamental data access points, only users authorized by role to access specific patient information can, and the architecture is intrinsically secure by design.

It has a message-driven, microservices architecture designed to support a Backend-as-a-Service (BaaS) offering. The system is deployed into a container system (Docker) that is instantiated into typical cloud infrastructures (Azure being its primary choice in that realm). The entire platform is optimized to provide recomposable application logic "building blocks" running in the cloud. These building blocks, which Macadamian refers to as *cells* are derived from common patterns the company has seen in developing solutions over the years.

The goal of this approach is to be able to quickly assemble a working set of backend services and application logic out of pre-existing cells that maintained or created as part of typical application development sprints. The benefit to a customer using Hive is that it implements only the innovative elements of that customer's solution rather than reinventing the wheel for each customer.

The platform can be understood by analyzing the typical cloud/Web application that might be implemented in an MVP product. On average, a standard cloud-based Web application is composed of several layers:

- Back-end volatile and persistent storage (databases and caches).
- Intermediate "application logic" that assembles models and the relationships between them.
- Optionally, an API that provides access to the application logic across the network.
- Optionally, a streaming network endpoint for submission of transient information like device telemetry or state.
- A front end that captures user interaction and translates this back into the application logic.

The thesis of the platform is that 1–4 are nearly identical throughout the types of solutions implemented. The only thing that usually differs is the semantics of the models, their relations, and the orchestration of the activity between them. Therefore, the platform replaces those components with a composable set of generic services that are knit together with a light orchestration logic that is implemented on a per-solution basis.

Additionally, there are some common elements in the user interaction logic that can be captured in shared front-end components. In this system, this commonality is shared via reusable patterns of interaction rather than via reusable code.

Figure 1 provides additional details that visually summarizes the overall system that

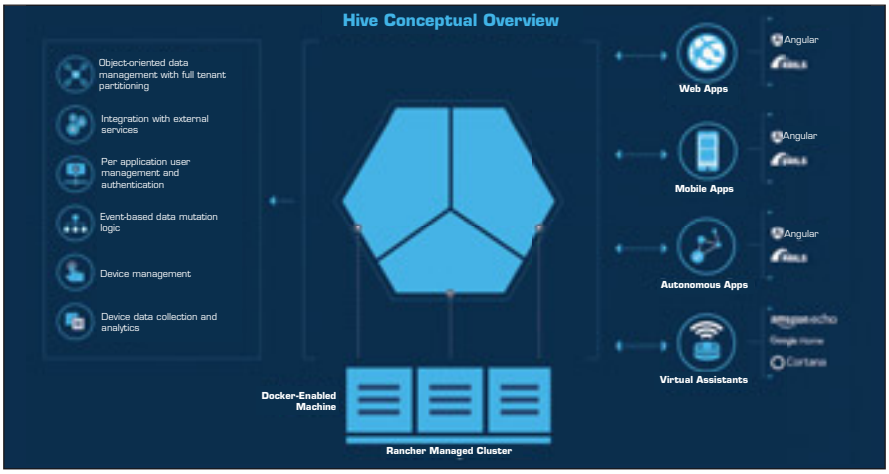


Fig. 1 – Macadamian Hive microservices implementation.

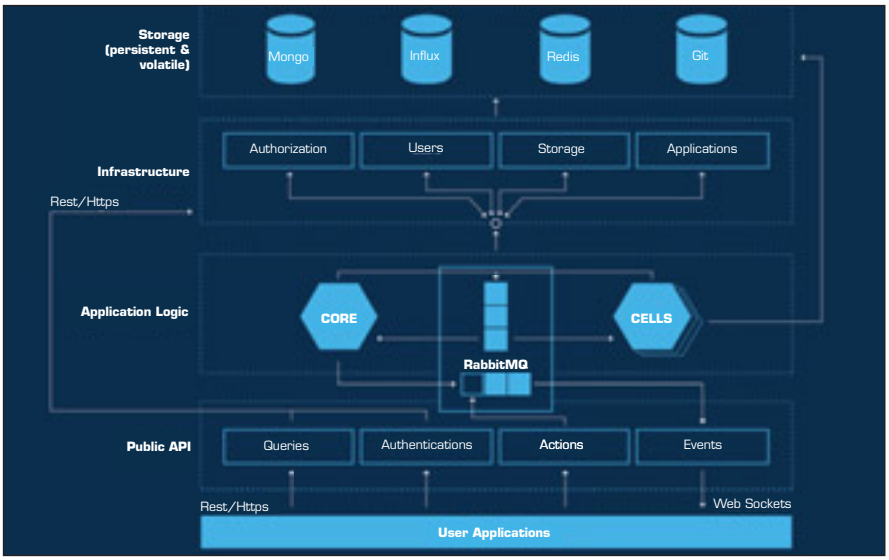


Fig. 2 – Macadamian HIVE™ platform architecture.

has been described above. It shows that the Hive assembles a running system (the Hive is symbolized as a hexagon) out of container-based services. Included with the diagram is an enumeration of the application development frameworks already integrated with the system.

The diagram in Figure 2 is much more complex. It is a bird's-eye view of the Hive platform architecture. Moving from the top down, at the base of the system is volatile and persistent storage. All data moving through the system eventually ends up here. It is integrated with MongoDB for persistent storage of principal application data. Time series data, like device telemetry, is retained in InfluxDB. Git is used to maintain versioning history of application logic. Influx or volatile data is kept in Redis.

The next layer is a set of infrastructural microservices that enforce the key features of the platform. The storage service provides object modeling capabilities (much like a traditional ORM) and enforces our very strict data partitioning scheme that provides separation of data on a per-tenant, per-application, and per-user basis. This layer also provides services for authentication (who are you?), authorization (what would you like to do?), and user management.

Following on from the Infrastructure layer is the Application Logic layer. This is the most complicated layer in the system. The microservices in this layer are arrayed in a constellation of cells surrounding a specific core cell. Between these services, there exists a network of message queues (RabbitMQ) that traffic data to and from outer cells and the core cell. This traffic contains a type of message called a behavior. Behaviors are the most basic atom in the orchestration scheme. They represent a single piece of application logic (create or update data, send an e-mail, send an sms, etc.). These behaviors are composed together into a second type of message called an *action*. Actions are essentially macros of behaviors chained together in serial or parallel. They can be triggered by a front-end application via a Public API as shown in Figure 2. A third type of message, a *reaction*, occurs when the state changes in the application logic. These messages are emitted from cells back to the core or to front-end applications via WebSockets.

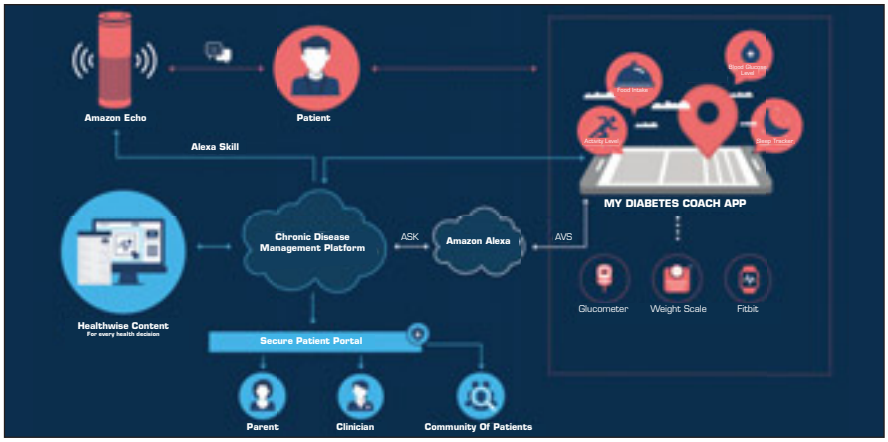


Fig. 3 – Macadamian My Diabetes Coach™.

The final layer is a Public API. User-facing application UIs will connect to this layer in order to authenticate, query data, trigger actions and receive notifications of changes in application state. This platform is optimized in two directions: scalability and composability.

The microservices architecture that dominates the layers allows the addition of processing capacity by simply deploying new instances of a taxed service. The reliance on a container system substantially decreases the pain of new service deployment. The use of an event-based model allows it to be statefully clean within those microservices. New applications can be composed simply by instantiating only the services that a particular application would require. The cell model ensures that only the logic required by the specific application is running. The Infrastructure layer ensures that critical services required by any application are reusable.

This design represents a novel and significant concept that fully exercises modern cloud-native patterns. This design also represents significant time-to-market improvements for customer applications. As explained previously, the platform implements the common parts of typical applications, leaving teams to only implement customer-specific front-facing elements.

To demonstrate the potential to leverage Hive in a real-world connected health application, Macadamian developed a solution to help youth with type 2 diabetes better manage their care (see Figure 3). Components of this solution now represent reusable building blocks that can be leveraged by customers to accelerate their time to market.

For solutions leveraging voice, this provides a back end that can synchronize data between an Alexa Skill and a mobile companion application and provide data integration from third-party sources, as well as allow solutions to be deployed across other popular virtual assistants, like Google Home.

Microservices Drive Digital

As a business grows and the number of users on a system increases, microservices are designed to scale as the system needs change and are particularly well adapted to modern cloud infrastructure where the majority of these solutions will be hosted. Not all data or processing needs to happen in the cloud though, and the containers associated with microservices can be run on servers within a healthcare facility or even in a medical device itself, lending flexibility in the manner and location in which they are deployed. These are capabilities that are nearly impossible to achieve in traditional development approaches.

Maintenance and Support

As solutions become more complex, maintenance and support considerations crop up. How do you add functionality or fix bugs in a system that has thousands of users running on it? Microservices enable continuous deployment processes to be leveraged in the operation of a solution once deployed. This allows new services to be added to the solution or code fixes to be introduced without affecting existing users. It also allows new functionality to be deployed on a specific subset of users before a wider rollout to test new capabilities or support A/B testing across different user groups as part of a product management strategy. Fault tolerance is also improved as one service can go down without affecting all of the other services.

Conclusion

With new approaches come new challenges. A microservice architecture does add some complexity to the system that must be managed by the team. Communications between the different microservices can introduce latencies that need to be considered. Deployment of these microservices requires coordination between the services that can add additional complexities. These can be managed by a modern DevOps team, though, with the right automation tools.

In summary, the benefits of microservices are well positioned to address the challenges in delivering modern digital and connected health solutions in a way that "future proofs" a solution so that it can grow and be built upon over many years without impacting its overall security or stability.

This article was written by Timon LeDain, Director, Emerging Technologies for Macadamian Technologies, Gatineau, Quebec, Canada. For more information, visit ***http://info.hotims.com/69509-163****.*

Miniaturized Wireless Medical Wearables

Antenna placement on the PCB. (Credit: Johanson Technology)

Traditionally, small chip antennas used in RF-enabled medical devices have required a designated ground "keep out" area to minimize interference from other components and ensure the ideal radiation pattern for wireless signals. In some cases, this reserved space can eat up as much as 15 × 20 mm of the printed circuit board.

However, with the drive to further miniaturize next-generation medical biosensors and wearables, new alternatives are entering the market that allow the chip antenna to be mounted directly above metal surfaces. By doing so, as much as 10–20 percent of the space traditionally reserved for the keep out area is no longer required, allowing designers to reduce the overall size of the product.

This has major implications for wireless medical devices in which even the miniaturized printed circuit boards (PCBs) along with coin-cell batteries often used are limiting factors in the minimum form factor. Products that could be positively affected by this development include an array of smart devices such as watches, clothing, eyeglasses, patches, pills, and even adhesive bandages.

Mobile Health Biosensors and Wearables

For the medical industry, the future is now when it comes to miniature battery-powered sensor devices that can be located near, attached to, or implanted in the body to monitor physiological signs such as temperature, blood pressure, and pulse rate.

These smart devices will soon monitor everything from fitness to health, environment, lifestyle, and behavior. Biological parameters that can be tracked include vital signs, sleep, emotions, stress, breathing, movement, efforts, posture, gait, body shape, lesions, mental acuity, toxins, blood glucose, ECGs, and medication adherence. The information collected is then wirelessly transmitted to nearby cell phones or remote monitoring stations or through Wi-Fi over the Internet to back-end servers for further analysis, assessment, and decision making.

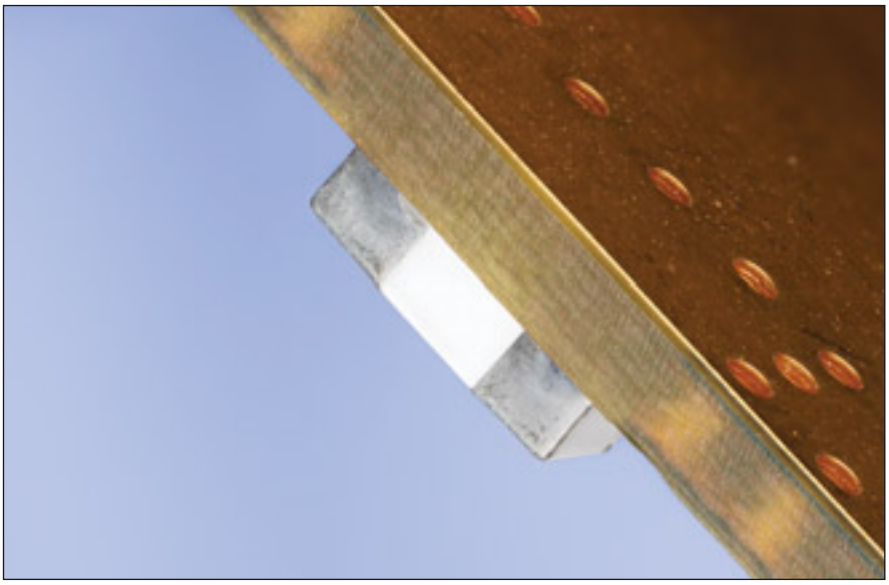
Collecting data in this manner is expected to facilitate the development of disease models and an understanding of the complex behavior of biological networks. Mobile health data can also be a valuable tool for drug discovery and clinical research. Among the products already incorporating this type of technology are adhesive bandages that contain built-in sensors that measure heart rhythm, respiratory rate, and temperature. These readings can be used, for example, to determine the precise amount of insulin that should be dispensed from wirelessly controlled insulin pumps worn by diabetics.

Embedded Chip Antennas

To transmit and receive RF wireless signals in the appropriate frequency range, smart devices must contain small RF chip antennas embedded on the PCB or behind the scenes underneath the encasement of the product. These chip antennas radiate and receive electromagnetic waves as other types of antennas, but the most notable difference is their small size. In fact, today's mobile phones incorporate a minimum of four antennas and up to 13 in some models. Smaller wearable devices may only contain one or two antennas.

To work properly, chip antennas have typically been ground plane dependent, meaning they require an appropriately sized and positioned ground plane to form a complete, resonant circuit. While the PCB can serve as the ground plane, the antenna itself must typically be placed on the edge of the board in an isolated section that is free from ground and metal components that would distort its radiation. Without the isolation distance, the performance of the antenna is significantly affected.

The keep out area is fundamental to ensure that the chip antenna can electromagnetically radiate to antenna applications, because everything affects the radiation pattern including the package size, where the antenna is mounted, and its proximity to the human body.

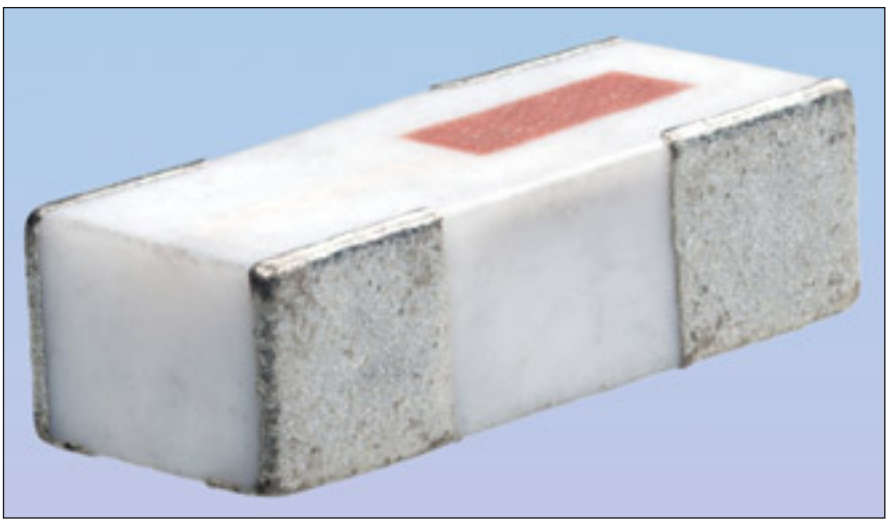


Chip antenna over ground plane. (Credit: Johanson Technology)

Johanson Technology, for example, has been able to eliminate the requirement for a designated ground keep out area through optimization of materials (ceramics and inks), manufacturing processes, and RF circuit design. Its new 2.4 GHz antenna can now be mounted directly onto the metal ground plane. The antenna measures 2 × 5 mm and is designed for small coin-cell battery operated IoT, 2.4 BLE, wearable, ISM, ZigBee, and 802.11-standard applications where metal or a battery/display covers the entire length or side of the PCB.

Miniature RF ceramic chip antennas are made using low temperature cofired ceramic (LTCC) technology, which has the ability to embed low and high dielectric constants inside the antenna. This enables them to have great detuning resilience and extreme temperature stability (~5 ppm) behavior. These types of ceramic chip antennas offer SMD manufacturability in standard or small form-factor designs and applications (i.e., miniature Bluetooth, Zigbee, ISM, and WLAN antennas) and provide great reliability and versatility while maintaining industry demanding performance. These antennas are easy to tune to unique PCB environment. They offer 2–3 times higher dielectric constant than any FR4, PCB, or standard plastic.

With PCB real estate at a prime, the size and placement of the chip antenna is critical because as everything gets smaller, it becomes increasingly difficult to place more components on the board. Therefore, design engineers are looking to component manufacturers to deliver miniaturized solutions that occupy next to no real board space.



The chip antenna measures just 2 × 5 mm. (Credit: Johanson Technology)

The design of the antenna itself is also critical to its range and performance. With medical devices, radio interference or some other glitch could result in interrupted connectivity. There can be legal ramifications as well. As with any wireless device, products that utilize RF technology, including Bluetooth, to collect or transmit information are subject to regulation by the Federal Communications Commission (FCC). Therefore, it is critical that the device perform at the designated frequency and the design and placement of the antenna is critical to proper tuning.

Despite the critical nature of the antenna, it is often overlooked until late in the design process, at which point optimal antenna performance may not be achievable within the space provided. To assist with chip antenna design and selection, Johanson Technology offers a program where design engineers can send in a miniaturized device, and the company will tune the antenna for optimum functionality.

A chip antenna that can be mounted over a ground plane opens up many applications for products that want to incorporate wireless. To date, the company has received everything from smart shirt buttons to jewelry and other wearables in various shapes and sizes.

Conclusion

Small RF chip antennas embedded on the PCB are ideal for today's smart medical devices. The medical industry is already developing devices that require miniature battery-powered sensors that can be located near the body. With tiny RF chip antennas no longer relegated to PCB keep out area, it allows product designers to further miniaturize wireless biosensors and medical wearables. These chip antennas radiate and receive electromagnetic waves as other types of antennas, but the most notable difference is their small size. And with PCB space at premium, these small antennas open new options for medical device design engineers.

This article was written by Manuel Carmona, RF Business Development & Product Manager for Johanson Technology, Camarillo, CA. For more information, visit ***http://info.hotims.com/69509-166****.*

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Securing the Future of Healthcare through the Right Cybersecurity Architecture

In 2017, the healthcare industry experienced a dramatic surge in cyberattacks. Thousands of healthcare organizations around the world suffered various attacks — from data theft to ransomware attacks. Among them was the notorious WannaCry ransomware attack, which affected over 300,000 machines across 150,000 countries, including the United States. As many as 200,000 Windows systems were impacted by WannaCry, including nearly 50 healthcare facilities in the UK, and dozens more in the United States. The infections from WannaCry impacted medical devices as well, putting hospital staff — and patient safety — at risk.

Despite suffering from the biggest ransomware attack in recent memory, organizations remain unprepared for the next round of large-scale attacks. Outdated software (and hardware) contributed to the spread of WannaCry. And any company with outdated technology can expect similar results when the next WannaCry hits.

In today's fifth-generation level of cyberattacks, an urgency to protect vulnerabilities, inherent to any organization, is paramount and should be the driving force of all healthcare organizations' cybersecurity strategy — especially now as more medical devices are connected and, thus, vulnerable to potential hacks. (In some cases, last year, many cyberattacks involved remote takeover of medical devices, disrupting medical care, potentially creating additional medical errors and increasing needs for more resources.)

In 2016, according to one report, healthcare was the fifth-most-attacked industry.[1] Last year, healthcare moved up to second-most attacked industry. And with the growing use of IoT devices, healthcare will continue to be an attractive target for attacks. See the sidebar, "Stats from Check Point's Study" for more insights into the extent of the problem.

Understanding the Environment

Before going through what medical designers should keep in mind when

Stats from Check Point's Study:

- Only 3 percent of businesses surveyed have indicated that they are equipped to defend against fifth-generation cyber-attacks (the highest level of cyberattacks, which are considered large scale and state sponsored multivector, mega attacks.
- Security professionals still do not feel prepared enough, rating their organizations as only moderately prepared for cyberattacks (3.56 on a 1–5 readiness scale). In other words, companies are only equipped to deal with a third-generation attack.
- 41 percent of organizations faced at least one cyberattack during 2017, with an average of 56 attacks per organization per year.
- The primary barriers IT and security professionals declare as standing between their organization and high-level cybersecurity effectiveness are: Staffing challenges (mentioned by 70 percent of IT and Security professionals), security conflict with business or user experience (56 percent), and outdated security infrastructure (50 percent). In staffing issues, security professionals are referring to low numbers of cybersecurity staff as well as lack of staff knowledge needed to fight 2018 cyber crime. When it comes to outdated security, security professionals are mentioning outdated security architecture as well as controls.

producing new devices, it's important to understand what makes the healthcare environment so prone to attacks:

- Regulation: HIPAA and GDPR regulations do not mandate medical device manufacturers to include cybersecurity capabilities as part of their offering.
- Lack of software updates: Due to regulations, every software update aimed at a medical device must go through FDA or other regulatory approvals to make sure no potential harm can be inflicted on the patient. This leads to insufficient updates, especially when a medical device has been compromised by an attack.
- Old/unpatched operating systems: Most medical devices carry old operating systems such as Windows XP or NT, which are subject to cyberattacks. This makes medical devices subject to older attacks, which are no longer considered as a threat for an up-to-date OS. Additionally, due to the incapability of updating medical devices without going through recertification, even newly introduced devices with a new OS will soon suffer from the same problem.
- Required uptime: Once integrated into a hospital, medical devices are fully utilized to meet patient care requirements. As a result, even if a software patch that may prevent a potential cyberattack is available, it usually taking weeks — sometimes even months — before the software patch is actually being implemented in the field.
- Flat networks: Due to the lack of cybersecurity resources, flat networks can be found more commonly in the healthcare environment in which guests, patients, doctors, building, and connected medical devices all share the same network. This situation, of course, substantially extends the attack surface and allows lateral attacks between one part of the network to the other.
- Access to resources: A healthcare environment, in general, and a hospital, in particular, is an open environment, in which patients, guests, and healthcare personnel do all have access to the various resources within the hospital. This can lead to various cases in which each of the above actors can accidently infect the hospital network by connecting an infected host to the hospital network, or any other device, such as a TV, within the hospital.
- Lack of cybersecurity resources: Despite being among the top attacked industries today, healthcare organizations, based on a recent Forrester survey, have a lower-than-average cybersecurity budget.

Prevention Is Key

As IoT systems become more widespread, cyber criminals will continue to find creative ways to gain the upper hand on their victims. Although the current situation is unsettling, there are preventive measures that designers can take when creating new devices. Below are some things to think about that can go a long way to ensuring better protection and prevention of potentially devastation cyberattacks:

- Have visibility: Medical device designers (particularly those with IoT components) should have a full view of the various parts of its system, including the various IT-related systems.
- Consider segmentation: Have the capability to segment various parts of that network, in order contain malware attacks and mitigate the potential risk of one part of the network attacking other parts.
- Integrate threat prevention solutions: Threat prevention can be executed through implementing cybersecurity best practices such as:
  - ❖ Blocking known attacks with the usage of IPS tools.
  - ❖ Blocking unknown and zero-day attacks with threat emulation tools.
  - ❖ Blocking existing infections through anti-bot tools.
  - ❖ Having granular protocol understanding such as DICOM and HL7, which are directly related to healthcare, and Modbus and KNX, which are directly related to building the management systems that are part of the general healthcare environment.

Of course, more must be done in order to secure the future of healthcare. But these first steps are key in developing more secure medical devices moving forward. Add an infrastructure with the necessary technology, and the future of healthcare will be prepared for the next major attack.

Reference

1. Check Point Study: "Achieving Fifth Generation Cyber Security: A Survey Research Report of IT and Security Professionals," March 2018, https://www.checkpoint.com/downloads/product-related/genv-survey-study.pdf.

This article was written by Yariv Fishman, Head of Product Management, Cloud Security & IoT, Check Point, San Carlos, CA. For more information, visit ***http://info.hotims.com/69509-164****.*

Getting the Most from Your Extrusion Tooling

By utilizing state-of-the-art production equipment and processes, machining tolerances are held extremely close on today's multi-lumen and multi-layer medical tubing. It is important to note that any misalignment of the tools may be exaggerated in the final product output. Clean parts, especially with sealing and locating surfaces, are key to product performance and successful end products. These surfaces receive the most care and attention during manufacturing and are the control surfaces that ensure uniformity throughout the tubing. Remember, precision-machined alignments are affected by even a speck of dirt measuring only a few thousandths of an inch. A human hair is about 0.003 in. (0.08 mm), and since there are many such surfaces in a quality tool, cleanliness is critical.

Checking tools for any deformities is also important. Burrs, scratches, and scrapes are usually a result of careless handling and/or storage of equipment. Double and triple-layer extrusion heads pose an even greater challenge for maintenance. The number of sealing and centering surfaces multiplies and can magnify the results of dirty tools.

During changeovers, the head may be disassembled in order to change compounds and/or tips and dies. Foreign matter is usually introduced at this point, and residual materials must be thoroughly removed. Physical tool damage often occurs during this phase due to mishandling and poor storage techniques. These are highly precise parts but can also be heavy and bulky to remove by hand. Use of a dedicated work cart exclusively reserved and equipped for extruder head maintenance is recommended. This cart along with a supply of spare components and hardware is easily justified, especially when examining the potential cost savings that result from well-maintained tools. The following procedures should be part of the process:

- Maintain a clean, organized work area with soft and clean renewable work surfaces.
- Use a vise with soft jaws, such as copper.
- Use special equipment, such as tip removal tools, etc. Standard tools include wrenches, soft-faced hammers, etc.
- Maintain an adequate supply of soft, clean rags.
- Use cleaning solutions in spray bottle.
- Use spare parts as suggested by the tooling supplier, properly organized and stored.

Machining tolerances are held extremely close on today's multi-lumen and multi-layer medical tubing. (Credit: Guill Tool & Extrusion)

- Keep handy the equipment's repair and maintenance manuals.
- Have a small surface plate to provide a true flat surface.
- Use a set of appropriate gauge and tip pins for initial tool location adjustment.
- Make sure you have all the proper lifting aids available, including overhead hoists, hydraulic lifts, etc.

In most situations, the head and tooling will still be at elevated temperatures; therefore, lined gloves are needed when handling. Today, tubing manufacturers compete with companies all over the world. To be a successful and profitable company, quality and efficiency are essential. This is especially true in extrusion, where material costs are usually much higher than labor costs. Like a racing car stuck in the pit, many extruders sit idle because of poor or damaged tooling, plus excess maintenance time. Overhead costs add up and losing money is the result. Some start up quickly and make scrap, whereas others start up and run a product oversized to hold minimum tolerance. They waste 10–20 percent of the material, which can run from 50–90 percent of the product cost. The tooling supplier goes to great lengths so that tips and dies are machined to a determined specification, ensuring perfect concentricity and alignment. The material is then distributed in the proper location as part of the finished product.

Understanding Maintenance Procedures

It is important to get organized before you even start. Here are some examples:

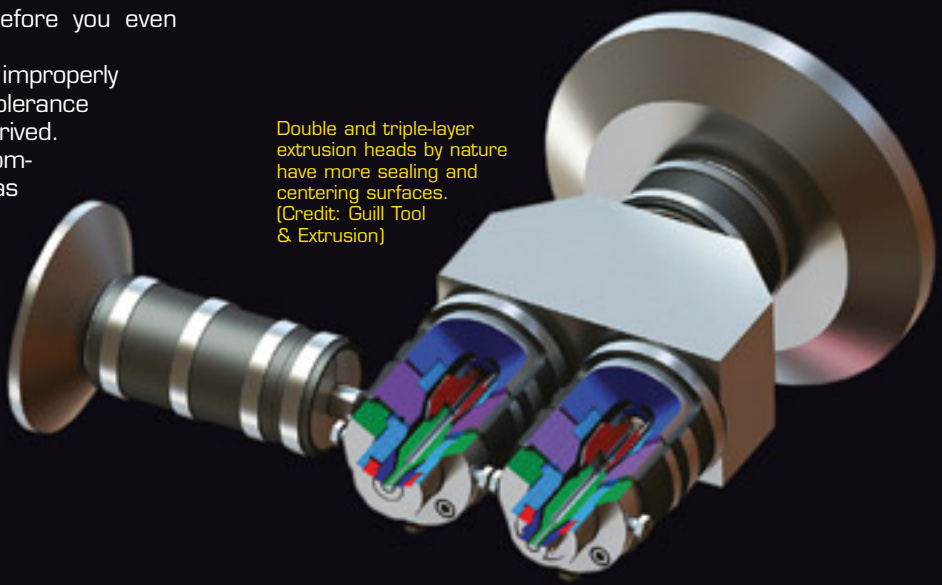
Example 1. In this example, with an improperly centered tool, a calculated out-of-tolerance area of 0.059 in^2 (38 mm^2) was derived. When the two surface areas were compared, the calculated material waste was 11.8 percent of the finished product.

Example 2. Alternatively, if the percentage wall can be increased from 80 to 95 percent, a savings of about 12 percent of total cost can result. Savings will vary depending on the designs, of course.

Get help for heavy parts and awkward situations. Surfaces and edges are hard and therefore somewhat brittle, so dropping a part or striking parts together can result in damage. Store tools properly in a dry, clean area — a dedicated spot for each tool is best. These areas should have soft surfaces, and each instrument should be covered after cleaning. Also, tools should be segregated so that they do not come into contact with each other. And tools and all instruments should be cleaned thoroughly before storage.

For disassembly of tools, it is imperative to use purpose-built tooling to facilitate disassembly. These should be available from the supplier. If they are not, consult with a reputable tooling house for replacements. The cost of these tools is easily offset by potential damages, frequently caused by improper equipment such as hammers and drifts. Follow the guidelines outlined in the operator's manual. Individual tools may have specific recommendations, so contact the supplier if anything is unclear. The supplier understands that optimum performance relies on proper care and maintenance. Here are some useful tips:

- Clean equipment while it is still hot as the residue is easier to remove. It helps to remove and clean one piece of tooling at a time in order to maintain elevated temperatures.
- When cleaning a dual compound crosshead (plastic and rub-



Double and triple-layer extrusion heads by nature have more sealing and centering surfaces. (Credit: Guill Tool & Extrusion)

tooling at a time in order to maintain elevated temperatures.

- When cleaning a dual compound crosshead (plastic and rubber), clean the plastic tooling first; the rubber second.
- Never use steel tools such as scrapers or screwdrivers because these can scratch and mar the tooling.
- Do not use open flames because this generates excessive heat, especially in thin sections, which can affect hardness, concentricity, and tolerances of components.

Recommended cleaning tools and materials include:

- Brass pliers to grip material and aid in pulling.
- Brass scrapers available in different widths for cleaning flat exposed surfaces.
- Brass bristle tube brushes that are available in diameters from 1/16 to 1 in. in 1/16 in. increments (ideal for cleaning holes and recesses).
- Brass rods — different diameter rods are good for pushing material out of flow holes.
- Copper gauze for cleaning and polishing exposed round or conical surfaces.
- Copper knives for removing residue from recesses and other hard-to-reach areas. Also, polishing compound restores polished surfaces.
- Compressed air, which is more effective for releasing plastic, but also aids in rubber removal. Be careful not to force debris into recesses with compressed air.
- Cleaning solutions may be useful, so remember to use fresh, clean rags (used rags often have metal chips embedded in them, which may scratch polished surfaces).
- Cleaning oven — for plastic only. Follow manufacturer's recommendations. If no temperatures are specified, do not exceed 850 °F (454 °C). Don't quench tooling to cool, as this could affect tooling hardness, concentricity, and tolerances.
- Purging compounds — several are offered to purge the extruder screw/barrel of residual polymer and rubber compounds.

Optimum Machining Efficiency

Remove excess material for optimum machining efficiency. Clean parts are critical to extrusion tooling performance and quality manufacturing. This is especially true for the sealing and locating surfaces that control uniformity of the production process. For general maintenance of the tools, before storage or tooling changeover, a thorough cleaning and removal of the excess material ensures the precision machining alignments required to produce end products to the precise tolerances.

Equipment should be cleaned while it is still hot because residual polymer and rubber will be easier to remove. Be sure to follow all Material Safety Data Sheet (MSDS) recommendations when heating the tooling. Thermal gloves are used to protect the hands from the heated tooling surfaces. A brass scraper, as well as a brass or copper wool cleaning cloth, are recommended because they are soft enough not to scratch the surface.

Make Tool Cleaning Easier

The quickest way to remove the die is to employ the pressure of the extruder to push it out. Clean the body by using an air compressor and brass pliers so that the material cools down, which increases the melt strength, making it into one lump versus an elastic, gummy-like substance that is harder to remove. Clean the body feed port using compressed air and brass pliers to simultaneously cool and remove the excess residue from the feed ports. This procedure is followed by brushing with a round brass brush that polishes the surface. The flow area of the 2 in. (51 mm) flange adapter should be cleaned by carefully using a brass brush.

Examine all surfaces for any irregularities such as burrs and scratches since these must be repaired before the head is reassembled. Most manufacturers recommend using a hand polishing stone to remove the offending burr. Follow stoning with a light application of 600-grit emery cloth if necessary, but avoid rounding edges that are intended to be sharp. Flat sealing surfaces can also be cleaned using a stone, followed by a 600-grit emery cloth. Place the cloth on a clean, flat surface preferably a surface plate, then apply friction in a circular hand motion until the area is clean and even. The parts in question should all be hardened steel alloys and will not be adversely affected using these methods. Inconel, Monel, and Hastelloy® are typically not heat-treated, requiring special care and handling to avoid any damage.

Don't Overlook Repairs

Tooling maintenance helps ensure a quality extruded product — one that meets dimensional specifications, maintains the specified minimum tolerance, and is economically produced. Dirty, neglected, and improperly adjusted tools contribute to excessive compound applications, which in turn complicate maintenance of minimum thickness tolerance. Excess material results in unnecessary costs, and these directly affect the profitability of the company and the relationships with customers.

The Important Final Step — Reassembly

Working from a dedicated tool cart, follow the manufacturer's instructions for reassembly. Give each component a final wipe down with a clean rag before installing. Even the smallest amount of grit, dirt, and residual material must always be removed. Use mechanical or manual assistance for heavy and awkward components to avoid unnecessary mishaps. Reapply anti-seize compound to all fasteners if required. Tighten fasteners to manufacturer's recommended specifications as well as in the recommended sequence. This fastening sequence should be specified in the manual and is generally in a star pattern.

Tighten gradually until the proper torque is achieved to prevent distortion of the tooling. One of a die manufacturer's main goals is to form a concentric cone as quickly and accurately as possible in the primary section of the die — when the extrudate first emerges from the die's distribution capillaries. A properly designed and manufactured die has even distribution close to the extrudate entrance point, but this effort is negated once the die is adjusted, shifting the extrudate off to one side. An eccentric cone is formed in the primary area, and a concentric cone exists at only one point in the process, rather than a smooth, continuous flow path with decreasing volume. A properly manufactured and aligned extruded head, along with well-maintained tooling should require little or no adjustment.

Another adverse effect of unnecessary die adjustment is the stress introduced to the extrudate caused by unbalanced flow. The net effect is the final product retains memory of this imbalance and unpredictable die swell occurs.

This article was written by Glen Guillemette, President, Guill Tool & Extrusion Co., Inc., West Warwick, RI. For more information, visit ***http://info.hotims.com/69509-160****.*

R&D ROUNDUP

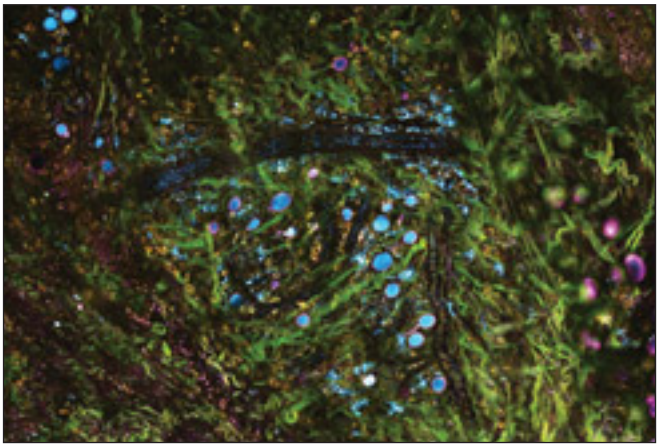
Tissue Imaging Enables Real-Time Diagnostics

A new microscope system can image living tissue in real time and in molecular detail, without any chemicals or dyes. The system uses precisely tailored pulses of light to simultaneously image with multiple wavelengths. This enables the researchers to study concurrent processes within cells and tissue and could give cancer researchers a new tool for tracking tumor progression and physicians new technology for tissue pathology and diagnostics.

The technique, called simultaneous label-free autofluorescence multi-harmonic microscopy, differs from standard tissue pathology in several ways. First, it is used on living tissue, even inside a living being, giving it the potential to be used for clinical diagnosis or to guide surgery in the operating room. Second, it uses no dyes or chemicals, only light. Standard procedure involves removing a tissue sample and adding chemical stains — which can be a lengthy process — and the chemicals can disrupt the cells.

The researchers saw that the cells near the tumor had differences in metabolism and morphology, indicating that the cells had been recruited by the cancer.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0818/diagnostics****.*



The microscope images living tissue in real time and molecular detail. (Credit: Stephen Boppart)

Dual Therapy Improves Stroke Recovery

Paralysis of an arm and/or leg is one of the most common effects of a stroke. But thanks to new research, stroke victims may soon be able to recover greater use of their paralyzed limbs. The scientists' pioneering approach brings together two known types of therapies — a brain-computer interface (BCI) and functional electrical stimulation (FES).

The key is to stimulate the nerves of the paralyzed arm precisely when the stroke-affected part of the brain activates to move the limb, even if the patient can't actually carry out the movement. That helps reestablish the link between the two nerve pathways where the signal comes in and goes out. The scientists noted a significant improvement in arm mobility among patients in the first group after just 10 one-hour sessions.

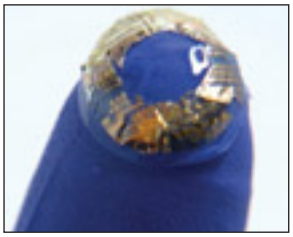
Combining a BCI with FES can help stroke victims recover. (Credit: EPFL)

Electroencephalographies (EEGs) of the patients clearly showed an increase in the number of connections among the motor cortex regions of their damaged brain hemisphere, which corresponded with the increased ease in carrying out the associated movements. Enhanced motor function did not seem to diminish with time.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0818/stroke****.*

Soft Contacts Monitor Glucose, Deliver Medication

Researchers have developed soft contact lenses that not only correct vision but also can monitor glucose and medical conditions and be used for ocular pain relief or drug delivery. The team created a novel method for attaching sensors and other small devices to soft contact lenses.



A commercial soft contact lens combined with an ultrathin conformal sensor circuit. (Credit: Purdue University)

The sensors embedded on the soft contact lens detect the levels of glucose, lactate, and pH value in a continuous manner, providing information associated with diabetes, hypoxia, and underlying ocular tissue health. With the ability to combine soft, silicon-based contact lenses with a variety of different semiconductor devices, numerous advanced eye care applications are now possible.

The unique technology enables the integration of thin film sensors with a commercially available soft contact lens. Researchers say the technology is highly novel and will significantly expand the functionality of existing soft contact lenses.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0818/contacts.***

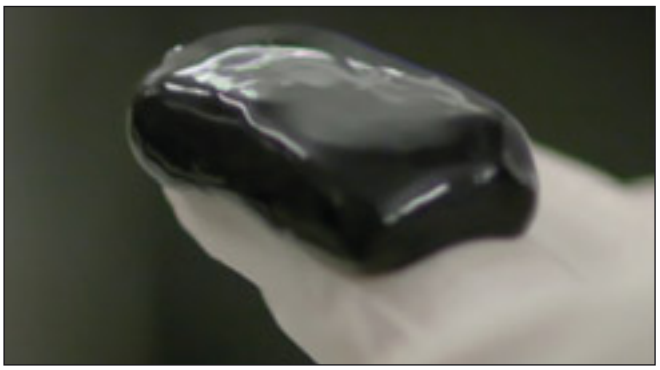
Electronic Skin Stretched to New Limits

An electrically conductive hydrogel that takes stretchability, self-healing, and strain sensitivity to new limits outperforms previously reported hydrogels and introduces new functionalities. Smart materials that flex, sense, and stretch like skin have many applications in which they interact with the human body. Possibilities range from biodegradable patches that help wounds heal to wearable electronics and touch-sensitive robotic devices.

The material is a composite of the water-containing hydrogel and a metal-carbide compound known as MXene. As well as being able to stretch by more than 3400 percent, the material can quickly return to its original form and will adhere to many surfaces, including skin. When cut into pieces, it can quickly mend itself upon reattachment.

This new dimension may be crucial in applications that sense changes in the skin and convert them into electronic signals. A thin slab of the material attached to a user's forehead, for example, can distinguish between different facial expressions, such as a smile or a frown. This ability could allow patients with extreme paralysis to control electronic equipment and communicate.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0818/skin****.*



This electrically conductive hydrogel can stretch and reshape. It has the skin-like quality of sensitivity to touch. (Credit: Kaust)

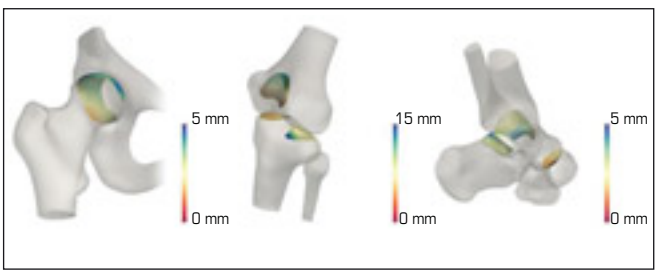
3D Imaging Technique Improves Arthritis Treatment

An algorithm to monitor the joints of patients with arthritis, which could change the way that the severity of the condition is assessed, has been developed by a team of engineers, physicians, and radiologists.

The technique, which detects tiny changes in arthritic joints, could enable greater understanding of how osteoarthritis develops and allow the effectiveness of new treatments to be assessed more accurately, without the need for invasive tissue sampling. The results are published in the journal *Scientific Reports*.

The semi-automated technique, called *joint space mapping* (JSM), analyzes the CT images to identify changes in the space between the bones of the joint in question, a recognized surrogate marker for osteoarthritis. After developing the algorithm with tests on human hip joints from bodies that had been donated for medical research, the researchers found that it exceeded the current gold standard of joint imaging with x-rays in terms of sensitivity, showing that it was at least twice as good at detecting small structural changes. Color-coded images produced using the JSM algorithm illustrate the parts of the joint where the space between bones is wider or narrower.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0818/arthritis****.*



An algorithm to monitor the joints of patients with arthritis. (Credit: University of Cambridge)

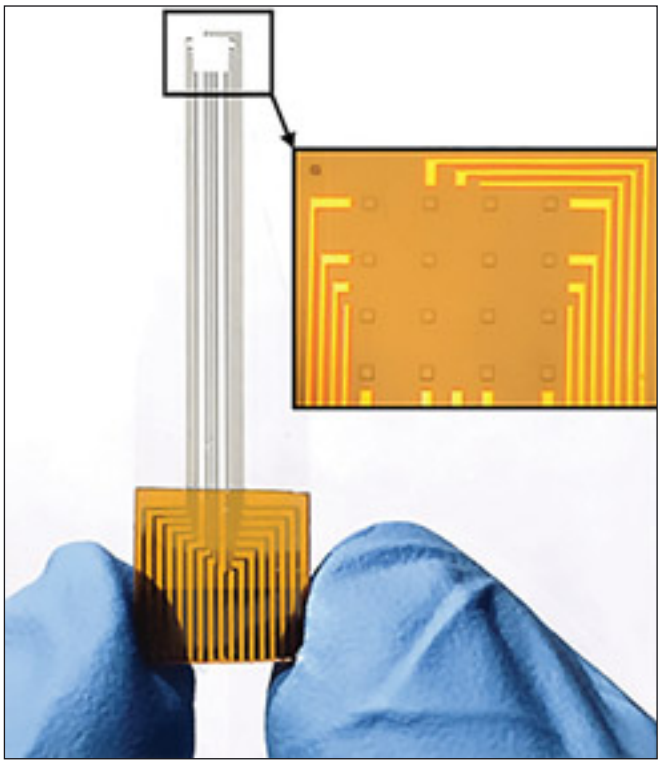
Making Brain Probes More Sensitive

Graphene electrodes could enable higher quality imaging of brain cell activity thanks to new research by a team of engineers and neuroscientists. The researchers developed a technique, using platinum nanoparticles, to lower the impedance of graphene electrodes by 100 times while keeping them transparent.

In tests on transgenic mice, the low-impedance graphene electrodes were able to record and image neuronal activity, such as calcium ion spikes, at both the macroscale and single cell levels. The advance brings graphene electrodes a step closer to being adapted into next-generation brain imaging technologies and various basic neuroscience and medical applications.

Another important aspect of this work is that it is the first to uncover the root of graphene's high impedance — a fundamental property called quantum capacitance. Researchers also determined an amount of platinum nanoparticles that was just enough to lower impedance while keeping transparency high. With their method, the electrodes retained about 70 percent of their original transparency. Next steps include making the electrodes smaller and incorporating them into high density electrode arrays.

For more information, visit ***www.medicaldesignbriefs.com/roundup/0818/probes****.*



Low-impedance, transparent graphene microelectrode array. (Credit: UC San Diego)

Scientists Create Continuously Emitting Microlasers With Nanoparticle-Coated Beads

The right mix of nanocrystals and light activate unique laser properties in 5-µm spheres.

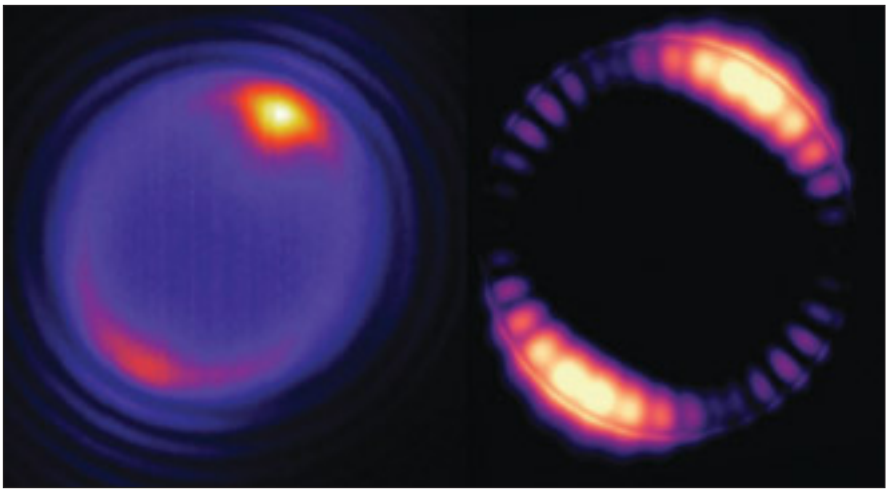
Berkeley Lab
Berkeley, CA

Researchers have found a way to convert nanoparticle-coated microscopic beads into lasers smaller than red blood cells. These microlasers, which convert infrared light into light at higher frequencies, are among the smallest continuously emitting lasers of their kind ever reported and can constantly and stably emit light for hours at a time, even when submerged in biological fluids such as blood serum.

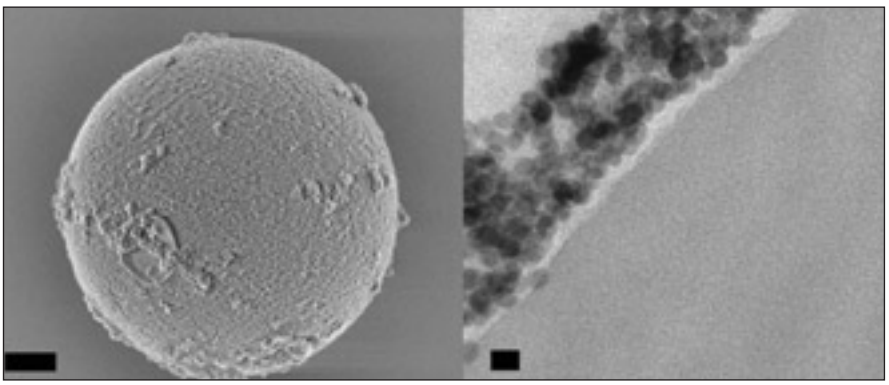
The innovation, discovered by an international team of scientists at the U.S. Department of Energy's Lawrence Berkeley Laboratory (Berkeley Lab), opens up the possibility for imaging or controlling biological activity with infrared light, and for the fabrication of light-based computer chips. Their findings are detailed in a report published online in *Nature Nanotechnology*.

The unique properties of these lasers, which measure 5 µm (millionths of a meter) across, were discovered by accident as researchers were studying the potential for the polymer (plastic) beads, composed of a translucent substance known as a colloid, to be used in brain imaging.

Angel Fernandez-Bravo, a postdoctoral researcher at Berkeley Lab's Molecular Foundry, who was the lead author of study, mixed the beads with sodium yttrium fluoride nanoparticles "doped," or embedded, with thulium, an element belonging to a group of metals known as lanthanides. The Molecular Foundry is a nanoscience research center open to researchers from around the world.



At left, a tiny bead struck by a laser (at the yellowish spot shown at the top of the image) produces optical modes that circulate around the interior of the bead (pinkish ring). At right, a simulation of how the optical field inside a 5-µm (5 millionths of a meter) bead is distributed. (Credit: Angel Fernandez-Bravo/Berkeley Lab, Kaiyuan Yao)



A scanning electron micrograph image (left) of a 5-µm-diameter polystyrene bead that is coated with nanoparticles, and a transmission electron micrograph image (right) that shows a cross-section of a bead, with nanoparticles along its outer surface. The scale bar at left is 1 µm, and the scale bar at right is 20 nm. (Credit: Angel Fernandez-Bravo/Berkeley Lab)

Emory Chan, a staff scientist at the Molecular Foundry, had in 2016 used computational models to predict that thulium-doped nanoparticles exposed to infrared laser light at a specific frequency could emit light at a higher frequency than this infrared light in a counterintuitive process known as *upconversion*.

Also at that time, Elizabeth Levy, then a participant in the lab's Summer Undergraduate Laboratory Internship (SULI) program, noticed that beads coated with these "upconverting nanoparticles" emitted unexpectedly bright light at very specific wavelengths, or colors.

"These spikes were clearly periodic and clearly reproducible," says Emory Chan, who co-led the study along with foundry staff scientists Jim Schuck (now at Columbia University) and Bruce Cohen.

The periodic spikes that Chan and Levy had observed are a light-based analog to so-called "whispering gallery" acoustics that can cause sound waves to bounce along the walls of a circular room so that even a whisper can be heard on the opposite side of the room. This whispering-gallery effect was observed in the dome of St. Paul's Cathedral in London in the late 1800s, for example.

In the latest study, Fernandez-Bravo and Schuck found that when an infrared laser excites the thulium-doped nanoparticles along the outer surface of the beads, the light emitted by the nanoparticles can bounce around the inner surface of the bead just like whispers bouncing along the walls of the cathedral.

Light can make thousands of trips around the circumference of the microsphere in a fraction of a second, causing some frequencies of light to interact (or interfere) with themselves to produce brighter light while other frequencies cancel themselves out. This process explains the unusual spikes that Chan and Levy observe.

When the intensity of light traveling around these beads reaches a certain threshold, the light can stimulate the

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emission of more light with the exact same color, and that light, in turn, can stimulate even more light. This amplification of light, the basis for all lasers, produces intense light at a very narrow range of wavelengths in the beads.

Schuck had considered lanthanide-doped nanoparticles as potential candidates for microlasers, and he became convinced of this when Chan shared with him the periodic whispering-gallery data.

Fernandez-Bravo found that when he exposed the beads to an infrared laser with enough power the beads turned into upconverting lasers, with higher frequencies than the original laser. He also found that beads could produce laser light at the lowest powers ever recorded for upconverting nanoparticle-based lasers.

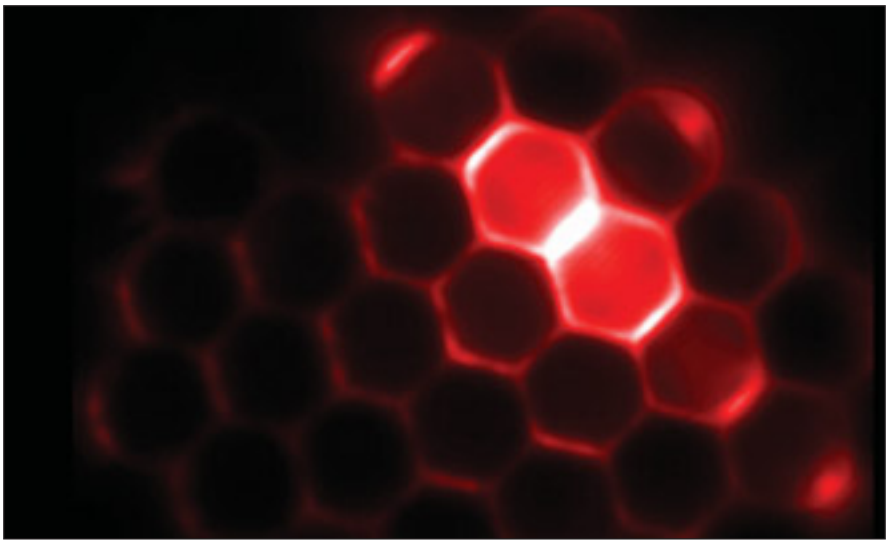
"The low thresholds allow these lasers to operate continuously for hours at much lower powers than previous lasers," says Fernandez-Bravo.

Other upconverting nanoparticle lasers operate only intermittently; they are only exposed to short, powerful pulses of light because longer exposure would damage them.

"Most nanoparticle-based lasers heat up very quickly and die within minutes," Schuck says. "Our lasers are always on, which allows us to adjust their signals for different applications."

In this case, researchers found that their microlasers performed stably after five hours of continuous use. "We can take the beads off the shelf months or years later, and they still lase," Fernandez-Bravo says.

Researchers are also exploring how to carefully tune the output light from the continuously emitting microlasers by simply changing the size and composition of the beads. And they have used a robotic system at the Molecular Foundry known as WANDA (Workstation for Automated Nanomaterial Discovery and Analysis) to combine different dopant elements and tune the nanoparticles' performance.



A wide-field image showing the light emitted by microlasers in a self-assembled 2D array. (Credit: Angel Fernandez-Bravo)

The researchers also noted that there are many potential applications for the microlasers, such as in controlling the activity of neurons or optical microchips, sensing chemicals, and detecting environmental and temperature changes.

"At first these microlasers only worked in air, which was frustrating because we wanted to introduce them into living systems," Cohen says. "But we found a simple trick of dipping them in blood serum, which coats the beads with proteins that allow them to lase in water. We've now seen that these beads can be trapped along with cells in laser beams and steered with the same lasers we use to excite them."

The latest study, and the new paths of study it has opened up, shows how fortuitous an unexpected result can be, he says. "We just happened to have the right nanoparticles and coating process to produce these lasers," Schuck says.

Researchers from UC Berkeley, the National Laboratory of Astana in Kazakhstan, the Polytechnic University of Milan, and Columbia University in New York also participated in this study. This work was supported by the DOE Office of Science, and by the Ministry of Education and Science of the Republic of Kazakhstan.

The Molecular Foundry is a DOE Office of Science User Facility.

For more information, ***visit www.lbl.gov****.*

Low-Cost Plastic Sensors Could Monitor a Range of Health Conditions

Sensor measures the amount of critical metabolites.

University of Cambridge
Cambridge, UK

An international team of researchers have developed a low-cost sensor made from semiconducting plastic that can be used to diagnose or monitor a wide range of health conditions, such as surgical complications or neurodegenerative diseases.

The sensor can measure the amount of critical metabolites, such as lactate or glucose, that are present in sweat, tears, saliva or blood, and, when incorporated into a diagnostic device, could allow health conditions to be monitored quickly, cheaply and accurately. The new device has a far simpler design than existing sensors, and opens up a wide range of new possibilities for health monitoring down to the cellular level. The results are reported in the journal *Science Advances*.[1]

The device was developed by a team led by the University of Cambridge and King Abdullah University of Science and Technology (KAUST) in Saudi Arabia. Semiconducting plastics such as those used in the current work are being developed for use in solar cells and flexible electronics, but have not yet seen widespread use in biological applications.

"In our work, we've overcome many of the limitations of conventional electrochemical biosensors that incorporate

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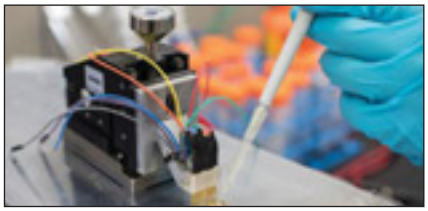
enzymes as the sensing material," says lead author Dr. Anna-Maria Pappa, a postdoctoral researcher in Cambridge's department of chemical engineering and biotechnology. "In conventional biosensors, the communication between the sensor's electrode and the sensing material is not very efficient, so it's been necessary to add molecular wires to facilitate and boost the signal."

To build their sensor, Pappa and her colleagues used a newly synthesized polymer developed at Imperial College that acts as a molecular wire, directly accepting the electrons produced during electrochemical reactions. When the material comes into contact with a liquid such as sweat, tears, or blood, it absorbs ions and swells, becoming merged with the liquid. This leads to significantly higher sensitivity compared to traditional sensors made of metal electrodes.

Additionally, when the sensors are incorporated into more complex circuits, such as transistors, the signal can be amplified and respond to tiny fluctuations in metabolite concentration, despite the tiny size of the devices.

Initial tests of the sensors were used to measure levels of lactate, which is useful in fitness applications or to monitor patients following surgery. However, according to the researchers, the sensor can be easily modified to detect other



The sensor can measure the amount of critical metabolites, such as lactate or glucose, that are present in sweat, tears, saliva, or blood, and, when incorporated into a diagnostic device, could allow health conditions to be monitored quickly, cheaply, and accurately. (Credit: University of Cambridge)

metabolites, such as glucose or cholesterol by incorporating the appropriate enzyme, and the concentration range that the sensor can detect can be adjusted by changing the device's geometry.

"This is the first time that it's been possible to use an electron accepting polymer that can be tailored to improve communication with the enzymes, which allows for the direct detection of a metabolite: this hasn't been straightforward until now," says Pappa. "It opens up new directions in biosensing, where materials can be designed to interact with a specific metabolite, resulting in far more sensitive and selective sensors."

Since the sensor does not consist of metals such as gold or platinum, it can be manufactured at a lower cost and can be easily incorporated in flexible and stretchable substrates, enabling their implementation in wearable or implantable sensing applications.

"An implantable device could allow us to monitor the metabolic activity of the brain in real time under stress conditions, such as during or immediately before a seizure and could be used to predict seizures or to assess treatment," says Pappa.

The researchers now plan to develop the sensor to monitor metabolic activity of human cells in real time outside the body. The Bioelectronic Systems and Technologies group where Pappa is based is focused on developing models that can closely mimic our organs, along with technologies that can accurately assess them in real-time. The developed sensor technology can be used with these models to test the potency or toxicity of drugs.

The research was funded by the Marie Curie Foundation, the KAUST Office of Sponsored Research, and the Engineering and Physical Sciences Research Council.

Reference

1. "A.M. Pappa et al. 'Direct metabolite detection with an n-type accumulation mode organic electrochemical transistor.' *Science Advances* (2018). DOI: 10.1126/sciadv.aat0911.

For more information, visit ***http://www.cam.ac.uk/research/news.***

Promising Research Could Lead to New Strategies in NMR and MRI Using Diamonds and Lasers

New technique harnesses tiny crystallites of diamond to obtain signal gains by light.

University of California at Berkeley
Berkeley, CA

Defects in the lattice of diamonds produce more than just beautiful coloration. A new approach developed by researchers at UC Berkeley's College of Chemistry shows great promise for enhancing the signal from magnetic resonance imaging (MRI) and nuclear magnetic resonance (NMR) using lasers without expensive magnets.

In newly published research in the journal of *Science Advances*, lead researcher Ashok Ajoy, a postdoctoral scholar at UC Berkeley and an international research team, have announced the development of a new technology that has the potential to decrease the cost of multimillion-dollar medical imaging and spectroscopy devices. The research was carried out in the lab of Professor Alexander Pines, Glenn T. Seaborg Chancellor's Professor Emeritus, and in close collaboration with Professor Jeffery Reimer, The Warren and Katharine Schlinger Distinguished Professor in Chemical Engineering.

Alex Pines says of the research, "What Ashok with his team and collaborators Carlos Meriles and Jeff Reimer have accomplished is amazing. In a powder of diamond nanocrystals, they achieved a hyperpolarization almost three orders of magnitude higher than thermal, by means of optical pumping together with a novel method of microwave DNP by multiple sweeps."

The new technique harnesses tiny crystallites of diamond to obtain signal gains in MRI and NMR by light instead of magnets. In particular, the diamond consists of microscopic defects within the crystal structure with the remarkable property that possess electron spins that can be optically aligned by a modest application of laser light. This alignment — termed as *polarization* — is what a magnet traditionally does in MRI; instead, here the role is played by the laser. This optically induced spin alignment can be transferred to surrounding nuclei, for instance 13C nuclei in the diamond to "hyperpolarize" them, i.e., providing NMR signals that are orders of magnitude larger

than possible even with room-sized superconducting magnets.

Chandrasekhar Ramanathan, a physics and astronomy faculty member at Dartmouth, says of the research, "The versatility of NMR spectroscopy and imaging demonstrate its remarkable ability to probe local physical and chemical environments at the atomic scale. However, it's low sensitivity remains a drawback. While multiple efforts have been made to overcome this limitation, the ability to hyperpolarize nuclear spins at room temperature across a broad range of materials remains a holy grail in NMR. This work demonstrates a new way to achieve large hyperpolarization of carbon-13 spins in diamond powders for the first time."

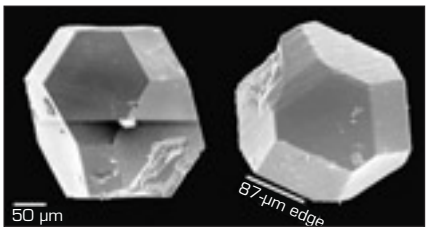
Today's MRI peers into the body "slice by slice" for medical imaging as well as its spectroscopic equivalent NMR in the pharmaceutical industry. The spectrum, acting as a unique chemical fingerprint, uniquely identifies molecules apart from similar ones suffering from low sensitivity. The signal remains proportional to the amount of nuclear spin that is situated in the same direction with each other. For instance, nuclei of hydrogen in water is targeted in clinical imaging. Even modest increases in signals can introduce daunting technological challenges — often requiring the use of large room-sized superconducting magnets that are expensive to set up and hard to maintain. This research shows that there could be alternative paths to resolving this problem that do not require magnets.

A key to this undertaking is the ability to work with diamond in powdered form. A chalk-like diamond dust, comprising of micro- or nanocrystalline particles, are hyperpolarized by the introduction of laser light. The smaller the size of polarized diamond particles, the more it increases the surface area that can be bought into contact with a liquid, which can in turn might be hyperpolarize.

"Optical hyperpolarized nanodiamonds has been an outstanding open problem in our field," says Ajoy. "The technical challenges stemming from the orientations of the different crystallites in a random powder were perceived to be extremely difficult to surmount."

"The solution proved remarkably simple," Ajoy continues, "and involved the use of a modest field, about the strength of a refrigerator magnet and low-power laser excitation to set up the hyperpolarization." The experimental breakthrough proved that hyperpolarized diamond powder was not only very easily achievable, but also astonishingly efficient. The team thus found a "completely new" polarizing mechanism partly because they probed a regime of ultralow magnetic fields that previously had been considered uninteresting.

One key to the discovery was the close collaboration of the Pines group with the College of Chemistry machine shop. Emanuel Druga, an electrician in the shop, played a crucial role in the design of several experimental tools that helped in debugging and benchmarking the polarization mechanism. "Druga led the development of a field cycling device that proved the most important step necessary to observe the first hyperpolarization in diamond powders," says Ajoy.



Two SEM micrographs of diamond microparticles employed in the investigation. The particles have uniform size distributions and are characterized by their unusual truncated octahedral shape set by particle growth size. (Credit: University of Berkeley)

The Berkeley team also involved participation from College of Chemistry undergraduate students. Two students in particular, Kristina Liu and Raffi Nazaryan (recipient of the 2017 College of Chemistry Saegebarth Award), played an important role in the study and are listed as contributing authors in the published article.

"This was a multi-person effort," notes Nazaryan. "It involved a big team working in multiple disciplines. Once we pushed beyond the initial boundaries and had tackled all the technical challenges, we were welcomed to quite a surprise. We are at the cusp of an exciting venture. Our discovery has lead us closer to polarizing liquids and will help to drive the next research challenge."

Colleagues from City College of New York, Peking University in China, and Technische Universität, Dortmund, were also contributors of the research.

This article was originally published on the UC Berkeley College of Chemistry Web site. For more information, visit ***https://vcresearch.berkeley.edu/news****.*

Bringing a Human Touch to Modern Prosthetics

Electronic skin allows user to experience a sense of touch and pain.

Johns Hopkins University
Baltimore, MD

Amputees often experience the sensation of a "phantom limb"—a feeling that a missing body part is still there. That sensory illusion is closer to becoming a reality thanks to a team of engineers at Johns Hopkins University that have created an electronic skin. When layered on top of prosthetic hands, this e-dermis brings back a real sense of touch through the fingertips.

"After many years, I felt my hand, as if a hollow shell got filled with life again," says the amputee who served as the team's principal volunteer. (The research protocol used in the study does not allow identification of the amputee volunteers.)

Made of fabric and rubber laced with sensors to mimic nerve endings, e-dermis recreates a sense of touch as well as pain by sensing stimuli and relaying the impulses back to the peripheral nerves.

"We've made a sensor that goes over the fingertips of a prosthetic hand and acts like your own skin would," says Luke Osborn, a graduate student in biomedical engineering. "It's inspired by what is happening in human biology, with receptors for both touch and pain.

"This is interesting and new," Osborn adds, "because now we can have a prosthetic hand that is already on the market and fit it with an e-dermis that can tell the wearer whether he or she is picking up something that is round or whether it has sharp points."

The work, published online in the journal *Science Robotics*, shows it's possible to restore a range of natural, touch-

The e-dermis recreates a sense of touch as well as pain by sensing stimuli and relaying the impulses back to the peripheral nerves. (Credit: Larry Canner/Homewood Photography)

Luke Osborn interacts with a prosthetic hand sporting the e-dermis. (Credit: Larry Canner/Homewood Photography)

based feelings to amputees who use prosthetic limbs. The ability to detect pain could be useful, for instance, not only in prosthetic hands but also in lower limb prostheses, alerting the user to potential damage to the device.

Human skin is made up of a complex network of receptors that relay a variety of sensations to the brain. This network provided a biological template for the research team, which includes members from the Johns Hopkins departments of biomedical engineering, electrical and computer engineering, and neurology, and from the Singapore Institute of Neurotechnology.

Bringing a more human touch to modern prosthetic designs is critical, especially when it comes to incorporating the ability to feel pain, Osborn says.

"Pain is, of course, unpleasant, but it's also an essential, protective sense of touch that is lacking in the prostheses that are currently available to amputees," he says. "Advances in prosthesis designs and control mechanisms can aid an amputee's ability to regain lost function, but they often lack meaningful, tactile feedback or perception."

That's where the e-dermis comes in, conveying information to the amputee by stimulating peripheral nerves in the arm, making the so-called phantom limb come to life. Inspired by human biology, the e-dermis enables its user to sense a continuous spectrum of tactile perceptions, from light touch to noxious or painful stimulus.

The e-dermis does this by electrically stimulating the amputee's nerves in a noninvasive way, through the skin, says the paper's senior author, Nitish Thakor, a professor of biomedical engineering and director of the Biomedical Instrumentation and Neuroengineering Laboratory at Johns Hopkins.

"For the first time, a prosthesis can provide a range of perceptions from fine touch to noxious to an amputee, making it more like a human hand," says Thakor, co-founder of Infinite Biomedical Technologies, the Baltimore-based company that provided the prosthetic hardware used in the study.

The team created a "neuromorphic model" mimicking the touch and pain receptors of the human nervous system, allowing the e-dermis to electronically encode sensations just as the receptors in the skin would. Tracking brain activity via electroencephalography, or EEG, the team determined that the test subject was able to perceive these sensations in his phantom hand.

The researchers then connected the e-dermis output to the volunteer by using a noninvasive method known as transcutaneous electrical nerve stimulation, or TENS. In a pain-detection task, the team determined that the test subject and the prosthesis were able to experience a natural, reflexive reaction to both pain while touching a pointed object and non-pain when touching a round object.

The e-dermis is not sensitive to temperature — for this study, the team focused on detecting object curvature (for touch and shape perception) and sharpness (for pain perception). The e-dermis technology could be used to make robotic systems more human, and it could also be used to expand or extend to astronaut gloves and space suits, Osborn says.

The researchers plan to further develop the technology and work to better understand how to provide meaningful sensory information to amputees in the hopes of making the system ready for widespread patient use.

Johns Hopkins is a pioneer in the field of upper limb dexterous prosthesis. More than a decade ago, the university's Applied Physics Laboratory led the development of the advanced Modular Prosthetic Limb, which an amputee patient controls with the muscles and nerves that once controlled his or her real arm or hand.

For more information, visit ***https://hub.jhu.edu****.*

Low-Voltage Cap Could Improve DBS Devices

Device could be customized to keep a person in his or her ideal brain state.

University of Oregon
Eugene, OR

Treatment to control involuntary body movements characteristic of Parkinson's disease could someday be guided by brain signals recorded by electrodes inside a fashionable hat. That is a piece of a larger goal in the research of Nicole Swann of the UO's department of human physiology. She's the lead author of a newly published study in the *Journal of Neural Engineering* that, she says, offers encouragement to pursue that notion.

In the study, done while Swann was a postdoctoral researcher at the University of California, San Francisco, researchers adjusted levels of deep-brain stimulation in real time based on brain signaling captured by electrode probes attached to a device surgically implanted just under the skulls of two patients. The approach also delivered energy savings for the battery-powered device.

"We found in this proof-of-principal demonstration that we could implement this adaptive stimulation using a brain signal to adjust therapeutic delivery," says Swann, who joined the UO last fall. "We found we could do it without any negative effects in the patients. They had the same clinical benefits with pretty significant energy savings."

In her UO lab, Swann is seeking to use electroencephalography, commonly known as EEG, to capture and understand brain signaling related to body movement in healthy people and in those with brain diseases such as Parkinson's, in which dyskinesia, or involuntary body movements, is one visible and disturbing side effect.

Deep-brain stimulation was approved for treating essential tremor, another movement disorder, in 1997 and for Parkinson's disease in 2002.

"Deep-brain stimulation has been a standard FDA-approved therapy for movement disorders since the 1990s. It works well, but with limitations," Swann says. "Today's devices are much like cardiac pacemakers were a long time ago. When pacemakers first came out, they just delivered stimulation, but now they are tuned to sense abnormal heart rhythms and only deliver stimulation when it is needed. This adaptation of the stimulation is the advance we are trying to make with brain stimulation."

Kelsey Schultz, a doctoral student in the Swann lab, wears an electrode-filled cap being used to capture brain signals. (Credit: Dusty Whitaker)

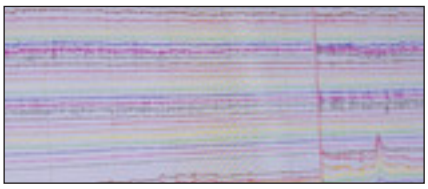
Current devices deliver electrical stimulation at a set level determined by trial-and-error tests to find a setting that best controls patient's symptoms. Settings are adjusted using a remote-control device over a battery pack, which is implanted in the upper chest of patients and connected to the probes under the skull by wires running under the skin of the neck. Replacing batteries requires surgery to access the battery pack.

Swann's team used a device made by Medtronic that was capable of recording brain signals that could be used in real time to automatically raise or lower stimulation levels. Neither patient, both males in their 60s diagnosed with Parkinson's seven and eight years earlier, reported feeling changes in stimulation. Energy savings of 39 percent and 45 percent were seen in the devices when using the adaptive algorithms.

"Side effects of deep-brain stimulation can include increased dyskinesia as a result of too much voltage," Swann says. "The idea was to lower the voltage to reduce or stop these side effects and then increase voltage to give optimal therapy when the situation changed. We sought to hold the treatment in a sweet spot."

The findings, Swann says, lay the groundwork for more complex algorithms to achieve that balance in improved versions of the device.

"Ultimately, this could be customized for each person to keep them in their ideal brain state," Swann says. "We absolutely need to do more research, including longer-term studies with larger groups of subjects. What we found in this study, combined with our earlier work, indicates that this is worth pursuing further."



Swann's team used a device capable of recording brain signals that could be used in real time to automatically raise or lower stimulation levels. (Credit: University of Oregon)

Members of the UCSF team, including Swann, have recently published related papers in the *Journal of Neurosurgery* and *Journal of Neuroscience*.

Initially, noninvasive EEG experiments in Swann's UO lab will focus on healthy people to study the brain regions associated with movements. Next, she will recruit Parkinson's patients to look for altered body-movement signaling, including signals related to dyskinesia. She also is working with surgeons at Oregon Health & Science University in Portland, OR, to obtain motor-related data from patients with a variety of neuro-related diseases using invasive human recordings.

"One way to move forward is to use the information we gather to improve algorithms in devices like those we used in our study," Swann says. "We also imagine that, for some patients, having implanted electrodes may not be the best option. In the future, we might be able to use an EEG electrode placed in a fashionable cap to record data that could be used to inform changes in the settings."

Such a cap, she says, also might also allow wireless transmission of information from patients, especially those living in remote locations, to neurologists who could adjust medications also being used in treatments.

The UCSF project was primarily funded by the National Institutes of Health. Engineers at Medtronic reviewed the team's paper for technical accuracy, but the company did not provide funding. UCSF has filed a preliminary patent on the adaptive device used in the research. Swann and study co-authors Coralie de Hemptinne, Dr. Philip A. Starr, and Dr. Jill L. Ostrem, all of UCSF, and are listed as co-inventors.

For more information, visit ***https://around.uoregon.edu***.

Using Optical 3D Scanning to Measure the Human Body

The latest advances in 3D technologies are revolutionizing the ability to measure the human body, and this is having a tremendous impact on the healthcare industry and in the development of healthcare products. For example, Japanese research company Unitika Garments Technology is using optical 3D scanning to measure the human body to research use of dimensional inspection for quality control of textile products. Optical 3D measurement produces data that cannot be gathered using traditional methods.

The company's goals include verifying the hygiene level of the tested products, performing chemical and bacteriological analysis, and assessing the product's impact on the human body, including the differences between the amount of swelling when using various materials. In particular, the company wanted to verify the effectiveness of its client's compression socks and assess their specific effect on the body and the degree to which they could reduce leg swelling. However, during the project, the company was unable to sufficiently determine the daily level of a patient's leg swelling and whether the socks were able to reduce their swelling. The researchers found that traditional measurement methods did not provide the needed dimensions to compare the amount of swelling before and after wearing the socks. Measurements obtained by calculating water displacement turned out to be too imprecise due to the barely discernible level of the swelling in the legs.

To address the issue, Unitika used an optical metrology system from SmartTech3D, Warsaw, Poland. The scan3Dmed system, which is factory calibrated, is a metrologically certified device that enables researchers to obtain precise data in color by projecting strips of light onto the measured object. The cloud of points that represent the scanned surface has an accuracy of up to 0.01 mm. Because the system's measurement method is based on white LED structured light, there is no laser or physical contact involved so the entire process is safe for use on a patient's skin. In addition, the large volume of the device allows researchers to precisely measure the entire body — legs, arms, chest, and face. Scanning time is less than 0.7 seconds, which reduces the effect that a patient's respiratory system has on the results.

Fig. 1 – 3D scanning using a rotary stage.

By retaining the saved source data, the company was also able to conduct future additional analysis without the participation of volunteers, which reduced not only costs, but also time.

Case Study: Introduction

Unitika Garments Technology conducts research in the field of dimensional inspection and quality control of textile and plastic products in accordance with ISO/IEC 17025 standards. The company's research produces reports that are designed to not only improve the comfort of textiles, but also to optimize production costs. It uses the latest methods to analyze and assess the changes that take place in the body when the body is in contact with various materials. The company's research focuses on the following areas:

- Textile product quality performance, measurement assessment.
- Measurement assessment of safety and hygiene functions.
- Chemical analysis, optical/electron micrography.
- Assessment of comfort and functionality.
- Human physiology measurement.

The Problem

When assessing human physiology, it is sometimes necessary to make calculations related to the body, such as measuring of the human face before and after some sort of treatment or measuring a person's waist before and after wearing a belt. For this case study, the calculation needed was a measurement of a person's leg swelling in order to verify the influence of a compression sock on the swelling.

Initially using traditional measurement methods, Unitika asked volunteers to avoid wearing socks all day so that it could then measure the natural level of swelling. The test

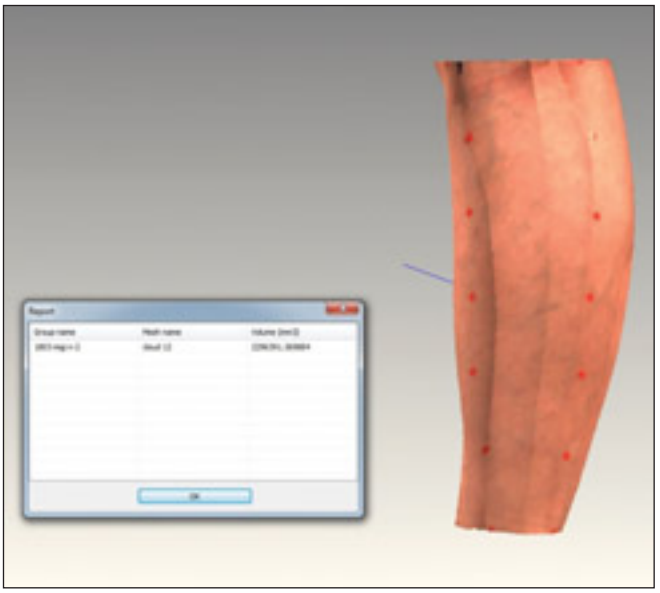


Fig. 2 – Volume measurement by S3DM.

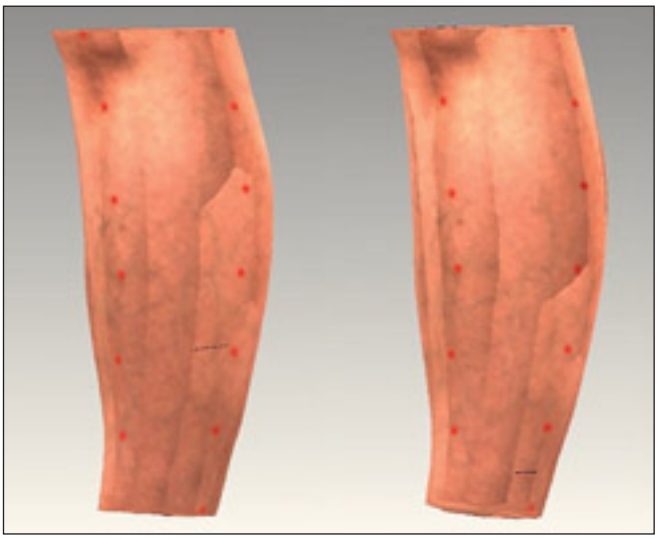


Fig. 3 – Calf measurement of morning with no swelling (left) and evening with swelling (right).

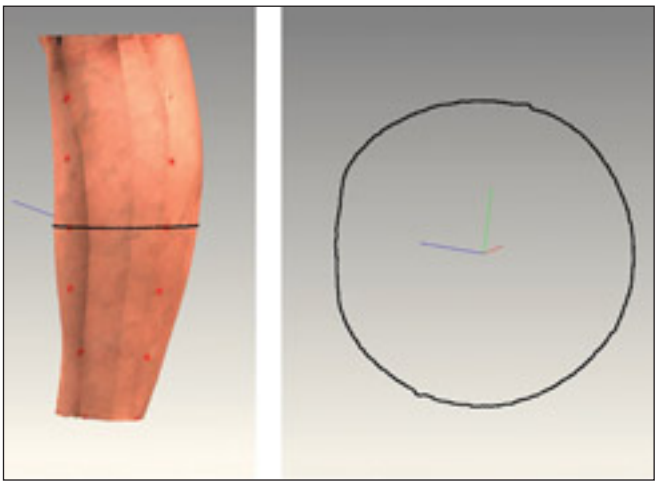


Fig. 4 – Leg radius data.

was then repeated with volunteers wearing a compression sock. Measurements were taken in the morning and in the evening. The researchers measured the volume of the legs using a container with water to calculate the volume based on the filling.

It was quickly apparent that it was extremely difficult to calculate swelling in this way, because the amount of leg swelling is too small to obtain an accurate measurement. Modifications made to the assess functionality of a textile product also made obtaining measurements difficult. In many cases, such modifications were imperceptible when using traditional methods. For these reasons, the study required a more accurate and precise metrology system. In addition to providing accurate measurements, the system needed to be capable of determining the influence of individual textile products on the leg swelling at a particular measuring point.

3D Measurement and Assessment

For measurement, the researchers used an optical 3D scanner operating in structural light technology. The device obtains precise data in color by projecting stripes of light on the measured object. In addition, the device instantly detects markers, thus meeting the requirements regarding the determination of the measuring point.

Sample	Volume (cm^3)			Rate of change (%)
	Morning (10 am)	Evening (4 pm)	Change amount	
Socks Type A	2445	2391	–54	–2.2
Socks Type B	2364	2358	–6	–0.3
No socks	2442	2490	– 48	2.0

Table 1. Volume measurement results. Target: Four people.

In addition, because the scan3Dmed system measures a large volume (800 × 60 × 350 mm), it allowed researchers to measure not only the legs, but also the arms and chest. Because of the system's rapid measurement time, the team was able to minimize the impact of the patient's respiratory system on the measurement. In addition, the system's SMARTTECH3Dmeasure software and a dedicated rotary stage enabled the measurements to be automated (see Figure 1).

Data Processing

The 3D scanner and software were sufficient to carry out all of the research needed for the study and generate a report that could be presented to the customer. The system provided all of the results necessary to conclude the tests (see Figures 2 and 3) and obtain required data. As shown in Table 1, the volunteer's natural daily leg swelling increases its volume by 2 percent from 10 am to 4 pm when wearing no socks. When looking at the effect of the compression socks on the swelling, the Type B sock was determined to maintain the volume of leg swelling throughout the day, whereas compression sock Type A reduced the swelling by 2 percent compared with the subject's original condition. In addition, as shown in Figure 4, software added to the optical 3D scanner allowed the researchers to measure the diameter of the perimeter of the leg at rest for further investigation later.

Conclusion

Advances in optical 3D technologies are greatly improving measurement of the human body to aid in research and in the development of products for treatment. For Unitika, the 3D scanning technology enabled it to assess the product's impact on the human body, including the differences between the amount of swelling when using various materials for the compression socks.

The analysis not only made it possible to evaluate the effectiveness of the client's textile products, but the system also collected a lot of additional data. And because the system could store the 3D models, the researchers were able to conduct further analysis without re-engaging volunteers, thus reducing costs and time.

This article was written by Andrew Ostrowski, Marketing Manager for SmartTech3D, Warsaw, Poland. For more information, visit ***http://info.hotims.com/69509-190****.*

In-Wheel Suspension on SoftWheels Provides Smooth Ride for Wheelchair Users

Daniel Barel's initial objective was straightforward. He wanted to make life more comfortable for people who are confined to wheelchairs. Curbs, different surfaces, and the energy required to propel a wheelchair took a tremendous toll on one of Barel's friends, who had tried his own hand at an improvised solution for the discomfort.

After an unsuccessful start, Barel refocused his energy on reinventing the wheel. The result is SoftWheel, a business based in Tel Aviv, Israel, that incorporates in-wheel suspension technology to help wheelchair users absorb shock and vibration. The company has seen double-digit growth in sales since the product became available in the United States in 2016. And the company is not stopping there. Barel and his team are working to adapt the technology to bicycles, airplanes, and automobiles.

"Even today, when we try to be have more places that are wheelchair accessible, it is still a challenge," Barel says. "SoftWheel provides much more freedom to a user to go wherever they want."

With a load limit of 300 lb, the 4-lb wheels come with aluminum and magnesium rims in 24- or 25-in. sizes.

Putting the Focus on the Wheel

When Barel started his company, the initial work focused on improving the suspension of the chair. "Suspension at its core is very limited. It hasn't evolved a whole lot in the past 90 years," he says. "No matter what we tried to do in putting suspension inside the wheelchair simply didn't work."

The team funding Barel's early work threatened to pull its support. Barel and his team of engineers and designers went back and looked again at their mission. It became clear where they had to focus their attention. "It's just wheels and a chair," Barel says. "We knew we couldn't put the suspension in the chair. There was nowhere else. We said let's put it in the wheel."

The challenge engineers faced in designing the product came in controlling the movement of the wheels efficiently and effectively to limit the impact on riders. Engineers worked for nearly two years to develop the suspension technology to control the movement of the wheel and reduce the vibration on the chair. "We met many challenges in the development of the suspension technology," says Yoav Satz, product manager for SoftWheel, "such as connecting the suspension system to the rim and designing a new hub with unique characteristics."

SoftWheel's key technology lies in a triangular hub. It connects to the wheel with three suspension arms and will absorb shock from any direction. "All the magic happens inside the hub," Barel says. The In-wheel™ suspension allows the hub to move freely within the diameter of the wheel. The wheel stays rigid, but the hub within it moves.

Four Trademark Technologies

With its In-wheel Suspension™, SoftWheels include three other trademark technologies. Its patented Adaptive Rigidity™ keeps the suspension arms rigid and strong like spokes, but automatically compress to absorb shock when they encounter obstacles. After impact, the suspension arms reset quickly and absorb almost all of the shock. With its Rapid Shock-Reset™, the suspension arms are ready to roll after just one-third of a turn of the wheel.

"It's a breakthrough in how you look at suspension," Barel says. "It is selective. When you don't need it, it does not work. Only when needed will it spring into action and make those movements."

SoftWheel's technology is demonstrated in a video of a drop test compared to a common wheel. In a drop of 15 cm with 110 lb of weight, the common wheel returns to a stable position in 10 seconds. The SoftWheel takes just two seconds to become stable.

The final piece to the SoftWheel puzzle are single-piece Rigid Rims™, which are built extremely rigid and strong. They offer as much stability and as fast a ride as the highest-quality regular rims on the market.

Some wheelchair manufacturers have tried to make smoother rides for users, but SoftWheel's three-arm suspension technology takes the focus away from the chair and onto the wheel. "The in-wheel suspension activates only when needed," Satz says. "The technology enables the wheel to act as a rigid wheel over flat surfaces, thereby conserving a rider's energy and maintaining forward momentum (and reducing bounce on flat surfaces). It activates and acts as shock absorbers when the wheelchair encounters an obstacle or rough terrain, thereby reducing shocks and vibrations."

Satz says springs or suspension that are used in some wheelchair frames do not achieve the same riding stability for users as the SoftWheels. "Our technology works no matter the angle of impact from the obstacle," he says. "And the suspension shocks reset immediately so the wheel returns to rigid, leading to a smoother, more stable ride.

By providing on-demand suspension, SoftWheels reduce the amount of vibrations that are transmitted to the body of a rider. The design also enables riders to maintain their forward momentum, which can help reduce fatigue after a long day of riding in a wheelchair.

Statistics provided by SoftWheel report that the product absorbs 50 percent more of initial impact compared to standard premium wheels. SoftWheels are also up to 25 percent more energy efficient than standard wheels, can absorb 2.5

The technology acts as shock absorbers when the wheelchair encounters an obstacle or rough terrain.

SoftWheels enable wheelchairs to roll off curbs with ease.

times the force per millimeter of travel, and react and recover twice as fast as any conventional suspension.

Motion Plastics Control the Hub

One of the key components to SoftWheel hubs that help them achieve superior shock absorption are plastic bushings manufactured by igus, based in Germany with a presence in Providence, R.I. SoftWheels include igus' L280 bushings, which provide superior wear resistance in harsh environments or when used with rough shafts. The bushing, called "The Marathon Runner," is frequently used when low coefficients of dynamic friction and wear resistance are essential. The bushing also has a high service life.

The bushing's compressive strength of 8,847 psi and tensile strength of 18,130 at 68 °F help the SoftWheels provide their signature stability. igus bushings also require no lubrication and require low maintenance. All of igus' products are extensively tested, and data reliably predicts the service life of the bushings.

"Using slide bearings based on a nonmetal material has many advantages," Satz says. "Engineers tried several types of bushings and decided to proceed with igus since it provided the best solution."

The wheels come with aluminum and magnesium rims in 24- or 25-in. sizes. They have a load limit of 300 lb, weigh about 4 lb, and costs start at nearly $2,000 for a pair.

A Life-Changing Development

Allaina Humphreys has been confined to a wheelchair since 1994 when a gymnastics accident left her paralyzed. The Chicago mother of three had been searching several years for a solution to alleviate the pain nearly every time she went places in her wheelchair. "It was horrendous," Humphreys says. "I was taking four Advil every four hours and it wasn't touching the pain. Nobody could find anything wrong, and it was just agony. I would spend days in bed, barely moving around the house."

She had to tell her children the pain was so severe she couldn't hug them. "It was so hard," she says. "They understood, but they didn't understand. I was desperate. I needed some way to do more with them."

Humphreys started a GoFundMe account to purchase the SoftWheels in advance of an upcoming vacation with her family. Within 24 hours, donors gave her enough money to purchase the SoftWheels. Humphreys says she "chased down" Barel on Twitter, and he helped arrange to have the SoftWheels before she left for vacation.

The previous year, she felt distraught because she could not participate in events with her family at City Museum in St. Louis and stayed stationary while her family enjoyed the exhibits. That changed when she visited the museum with the SoftWheels. She was a participant in her family's activities, and not just an observer.

"As soon as we got the SoftWheels, I started going over different types of flooring and threshold bumps," Humphreys says. "They had been causing me a lot of pain. But I was able to roll over them and didn't notice anything. Outside the front door, there was a drop that was an inch and a half. I could roll right over it. I could go down the sidewalk without worrying about cracks. It was an immediate difference."

The company hopes to expand its design and is working to develop similar technology that can be used with bicycles. A new wheel for the automotive industry is in the research and development stage, and the company is also considering developing a wheel for airplane landing gears. The technology developed by SoftWheel will continue to transform lives, much like it has for Humphreys and her young family.

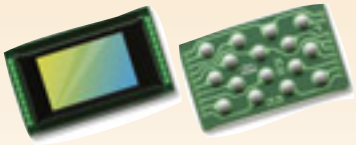
"My life is different," Humphreys says. "I have the freedom to go out and about and try new things. Before I was afraid, because I didn't know if I was going to feel pain. It just allows me to be able to be who I want to be."

This article was written by Thomas Renner, who is based in Connecticut, and writes frequently for U.S. trade publications on a variety of topics. For more information, visit ***http://info.hotims.com/69509-191****. A video of the technology is available at* ***http://softwheel.technology/videos.***

NEW PRODUCTS AND SERVICES

PRODUCT OF THE MONTH

MEDICAL DESIGN BRIEFS 2018 Product of the Year Finalist



High-Definition Sensor

OmniVision Technologies, Santa Clara, CA, has released the latest member of its high definition (HD) medical image sensor family. The OH01A employs the PureCel®-S stacked-die architecture to provide the compact size, high resolution, and cost-effectiveness required for the next generation of disposable and reusable endoscopes and catheters. The sensor is the world's first medical image sensor to provide 1280 × 800 resolution at a rate of 60 frames per second (FPS) in a tiny 2.5 × 1.5 mm package. These features make it an ideal imaging solution for many diagnostic endoscope procedures, including airway-management (esophagoscopes, laryngoscopes, thorascopes, pleuroscopes, bronchoscopes, mediastinoscopes) and urology (utero-renoscope) applications. Being stereo-ready, two sensors can be synchronized to create 3D images for surgical procedures. Power consumption is 25 percent lower than that of previous-generation medical image sensors, which keeps the distal tip of the endoscope cooler for greater patient comfort. A high chief ray angle of 32° enables a wider field of view in a slimmer module, resulting in a shorter rigid endoscope distal tip that allows for a tight bend radius.

For Free Info Visit http://info.hotims.com/69509-168

Product Focus: Connectors/Wires/Cables

Metal-Clad Wire and Ribbon

Precious metal-clad wire and ribbon from Anomet, Shrewsbury, MA, are a cost-effective alternative to solid wire while offering greater ductility and formability than filled or plated wire. The company's clad-wire features a complete metallurgical bond between layers, making it the wire of choice for medical device manufacturers for high reliability and high quality. Precious metal-clad wire is manufactured using various heat, pressure, and reduction techniques. To meet specific requirements, the clad-metal wire can include platinum for oxidation-corrosion resistance and biocompatibility, gold for contact resistance, and palladium or silver. Each alloy can be clad to core materials such as copper, niobium, molbdenum, stainless steel, tantalum, and titanium.

For Free Info Visit http://info.hotims.com/69509-169

Medical Connectivity

Fischer Connectors, Atlanta, GA, has launched a new microsite along with a video and brochure focused on the use of its connectors to ensure the safety and performance of medical devices in applications. Sections of the microsite highlight the company's products for diagnostic and imaging, interventional and surgical, and monitoring and therapeutic applications. The company offers a range of connectors and cable assemblies, including miniature, sterilizable, hybrid, disposable, silicone-coated, and custom-made options. A white paper, "Considerations for Connector Design in Mobile and Patient-Worn Medical Devices," is available for download.

For Free Info Visit http://info.hotims.com/69509-171

Small Form Connector

Binder USA, LP, Camarillo, CA, has added the M8 12-pin to its Series 718 and 768 lines of M8 Connectors. The 12 gold-plated contacts allow for more data connections in a small form connector, making it easy to combine multiple connections into one connector to save panel space. The IP67-rated connectors are typically used with automation-related products. The M8 12-pin is suitable for smaller devices that require both smaller connectors and protection from liquids and small particles. It is available in male or female molded cable and panel-mount connectors with cable lengths 2 and 5 m and standard single-wire length of 200 mm. Gold-plated contacts provide low contact resistance, and each receptacle is prewired with 16-gauge wires using UL PUR cable or single wires. The M8-12 is rated up to 30 V DC, 1 A.

For Free Info Visit http://info.hotims.com/69509-170

Flexible Elastomeric Cable

Minnesota Wire, St. Paul, MN, has expanded its medical market with a new patent for its elastomeric and flexible cable. The company's fifth patent supports its iSTRETCH technology, an electrical conductor that stretches. The patent strengthened its medical wearable patient monitoring. The cable's conductive materials allow it to stretch 40 percent of its initial length without change to its electrical integrity. The company's iSTRETCH can be woven into textiles and survives extreme elements, including machine washing and weather. According to the company, the cable, which can withstand drastic vibration, is stronger and more comfortable for the end user than standard wire and cable.

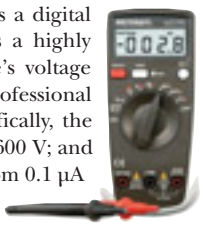
For Free Info Visit http://info.hotims.com/69509-172

IP 66 Enclosures

ABS electronic enclosures from ROLEC, Bridgeville, PA, are now available in 10 sizes, many of which are compatible with other standard products. TechnoBOX enclosures are suitable for a wide range of industrial electronic and electrical applications. Separate screw channels outside the enclosure's interior maximize the space available for components. The ergonomic and aesthetically pleasing beveled lid is recessed to accommodate a membrane keypad or front plate. The lid screws are made of corrosion-resistant stainless steel and are captured to avoid accidental loss.

For Free Info Visit http://info.hotims.com/69509-173

Digital Multimeter



Conrad Electronic, Hirschau, Germany, offers a digital multimeter. The Voltcraft VC175 multimeter is a highly robust unit with automatic scaling. The device's voltage measurement range of up to 600 V enables professional tasks to be performed reliably and safely. Specifically, the AC and DC voltage ranges are from 1 mV up to 600 V; and the AC and DC current measurement range is from 0.1 µA up to 10 A. The unit's current measuring ranges are also protected by high-performance fuses against overload.

For Free Info Visit http://info.hotims.com/69509-176

Touch Panel Computer

Technologic Systems, Fountain Hills, AZ, unveiled the newest addition to its touch panel computer (TPC) suite. Built on the NXP i.MX6 Cortex-A9 ARM CPU and available in a solo or quad core configuration, the TS-TPC-7990 comes in either a resistive or capacitive screen, making it ideal for applications that require a touch-based human machine interface (HMI) such as medical terminals. An onboard socket, capable of supporting NimbeLink cellular modems, provides a simple path to cellular connectivity for applications such as remote equipment monitoring and control.

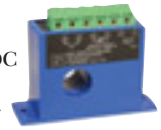
For Free Info Visit http://info.hotims.com/69509-174

External Power Supply

Gresham Power Electronics, Salisbury, UK, has launched a series of desktop power supplies for medical applications. The universal AC input of the Polytron MUI310-A product range offers a wide selection of output voltages from 12 to 44 Vdc and up to 310 W output power. Typical applications include ultrasound equipment and monitoring systems. The power supply is provided in a compact 197.61 × 101.85 × 51.05 mm (7.78 × 4.01 × 2.01 in.) desktop package and meets a range of safety approvals and compliances, including CEC level V1, UL/CUL 60601-1, EN 60601-1, IEC 60601-1 3rd Edition, FCC, CE, CB, Active PFC Function DoE VI, and RoHS.

For Free Info Visit http://info.hotims.com/69509-177

Ground Fault Relay



NK Technologies, San Jose, CA, has introduced a new DC ground fault detector. The DG series was designed to keep operators and machinery safe from accidental shocks by detecting fault currents quickly and easily. According to the company, it can be installed at a fraction of the cost of products currently available. The one-piece, solid-core design allows for installation over wires feeding loads to about 50 A. The output relay will change state at factory setpoint between 5 and 50 mA of DC current to earth. Features include electromechanical relay outputs, externally powered with choice of fail-safe or standard auto reset or latching contact, and a solid core case.

For Free Info Visit http://info.hotims.com/69509-180

Battery Holder

Memory Protection Devices, Farmingdale, NY, has released a new lithium battery holder. Part number BU1632-JJ-1-G holds a single CR1632 Lithium battery. According to the company, it is designed to meet the stresses of handheld portable applications. A heavy-duty plastic body and robust battery contacts meet requirements for typical medical products. Contacts were specifically designed for the rigors of portable applications and have gold-flash-over-nickel plating onto a phosphor bronze base metal. The contacts feature low electrical resistance and offer intermittent free connections.

For Free Info Visit http://info.hotims.com/69509-182

Power Supply

A series of rugged AC-DC chassis-mount power supply units from XP Power, Sunnyvale, CA, delivers up to 350 W of power. Incorporating built-in fan cooling, screw terminal connections for simple installation, and low EMI emissions, the SMP350 series offers easy integration into end equipment, reducing design and manufacturing costs and time to market. Packaged in a 3.6 × 7 × 1.7-in. enclosure, the series delivers power densities up to 13 W/in.^{3}, enabling a compact, highly efficient and low-noise solution. Versions suitable for use in medical equipment offer reduced earth leakage current of less than 300 A.

For Free Info Visit http://info.hotims.com/69509-185

Power Supply

Power Partners, Hudson, MA, has released a 65 W, 2 × 4 in. AC/DC open frame power supply available in single-output models. The PEA65 series delivers maximum 65 W as a Class I power supply with a universal input voltage range of 90–264 VAC and six output voltage selections (12, 15, 19, 24, 36, and 48 V), with measurements in a 2 x 4 × 1.31 in. package and weighs under a half pound (0.44 lb). The series is approved and certified to UL/cUL/TUV 60950-1 and is compliant to Energy Star V2.0 and ErP STEP 2. Additional highlighted features of the series include short circuit, overvoltage, and overload protection, 5000 m altitude operation rating, operating temperature of 0° to +70 °C (derating), 100 percent burn-in/hi-pot testing, and MTBF of >100K hours per MIL-STD-217F.

For Free Info Visit http://info.hotims.com/69509-179

Self-Clinching Captive Panel Screws

Self-clinching captive panel screws from Penn-Engineering, Danboro, PA, install permanently into stainless steel enclosures to enable easy access whenever necessary and eliminate risks associated with loose screws. The PEM® PFC4™ captivated screw remains reliably in place where designed in a door or panel and will not loosen, fall out, or damage internal components. The spring-loaded fastener assemblies comply with UL 60950 equipment access standards. They install successfully in stainless sheets as thin as 0.060 in./1.53 mm with hardness up to HRB 88. They are available in assorted screw lengths and in thread sizes #4-40 through #10-32 and M3 through M5.

For Free Info Visit http://info.hotims.com/69509-187

Tabletop Enclosures

Designer tabletop electronic enclosures are now available in a new smaller 100 size from OKW, Bridgeville PA. The new size increases the range to four plan sizes. According to the company, the ergonomic EVOTEC is elegant and comfortable to use, but tough enough for challenging working environments. It can also be wall mounted for access control, and it is available in two versions: one with a large flat top for switches, push buttons, and touch displays and the other with a 12° inclined top for desktop applications. The sloping top version can be specified either with or without a recess for a membrane keypad or product label. The new 100 size and the recently launched 150 size are available only with the flat top.

For Free Info Visit http://info.hotims.com/69509-178

General-Purpose Digitizers

Spectrum Instrumentation, Grosshansdorf, Germany, has added five new models to its general-purpose M2p.59xx series of PCIe 16-bit digitizer cards. The new versions extend the performance range by increasing the maximum sampling rate from 80 MS/s up to 125 MS/s. The increased sampling rate, together with higher overall bandwidth, enables the new cards to capture a wider range of electronic signals. It makes them ideal for use in applications where signals in the DC to 50 MHz frequency range need to be acquired and analyzed with speed and accuracy. Based on the latest 16-bit analog to digital (ADC) technology, the M2p-596x series includes models that provide 1, 2, 4 or 8 input channels. Multichannel models each have their own ADC and signal conditioning circuitry to allow fully synchronous acquisitions on all the inputs.

For Free Info Visit http://info.hotims.com/69509-183

Controlled Room Temperature Indicator

A controlled room temperature (CRT) indicator from Timestrip, Cambridge, UK, provides evidence of temperature breaches in the storage or transport of medical products outside the 15°–25 °C (59°–77 °F) range. Designed for the medical and pharmaceutical sectors, the indicators travel with the products from the manufacturer through to the end user and give a clear visible indication if transport or storage conditions have moved outside the acceptable temperature thresholds. Controlled room temperature (or ambient) shipping and storage is an increasing concern for the healthcare sector as adoption of international Good Distribution Practice (GDP) increases.

For Free Info Visit http://info.hotims.com/69509-181

XY-Theta Alignment Stage

An alignment stage from Optimal Engineering Systems, Van Nuys, CA, is a high-resolution, high-repeatability XY-theta stage for such applications as angular glass cutting and grinding and laser cutting and drilling. The linear resolution of the X and Y axis is 5µ (non-micro-step) or 0.125µ (20 micro-steps per step motor driver in use). The repeatability is 1.5µ, and positional accuracy is 5µ. The 1-mm per-turn lead screws and preloaded V-groove and crossed roller bearings add to the high precision and stiffness of the XYR-03-01 alignment stage. The linear travel of the X and Y axes is 50 × 50 mm.

For Free Info Visit http://info.hotims.com/69509-186

Automated Dispensing System

Nordson ASYMTEK, Carlsbad, CA, has released a new automated dispensing system for medium and bulk volume deposits of single- (1K) and two-component (2K) materials in electronics manufacturing and printed circuit board assembly. The Helios™ SD-960 Series is ideal to deposit volumes greater than 1 cc, and line widths and dots that exceed 1 mm, but it can deposit volumes down to 0.3 cc and line widths as narrow as 0.3 mm. The system supports highly abrasive thermal interface materials, silicones, epoxies, and grease for applications such as potting, sealing, gasketing, and structural adhesives. The system was made specifically to accommodate large parts and substrates. The frame is 200 mm taller and the robotics 150 mm higher for more overhead clearance than a standard dispensing platform.

For Free Info Visit http://info.hotims.com/69509-184

Custom ESD Foam Packaging

BEST Inc., Rolling Meadows, IL, has released a custom ESD insert cutting program. The inserts are designed to protect high-valued PCBs or electronic components from shipping damage during the design phase prior to the board and packaging design being finalized. The company can take in material and design the package cutout from mechanical drawings or samples. Custom cutouts can be shipped within two working days after acceptance of the drawing.

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‘Smart Stent’ Detects Narrowing of Arteries

University of British Columbia
Vancouver, BC, Canada
https://news.ubc.ca

For every three individuals who have had a stent implanted to keep clogged arteries open and prevent a heart attack, at least one will experience restenosis — the renewed narrowing of the artery due to plaque buildup or scarring — which can lead to additional complications.

Now, a team led by UBC electrical and computer engineering professor Kenichi Takahata has developed a type of “smart stent” that monitors even subtle changes in the flow of blood through the artery, detecting the narrowing in its earliest stages and making early diagnosis and treatment possible.

“We modified a stent to function as a miniature antenna and added a special microsensor that we developed to continuously track blood flow. The data can then be sent wirelessly to an external reader, providing constantly updated information on the artery’s condition,” says Takahata.

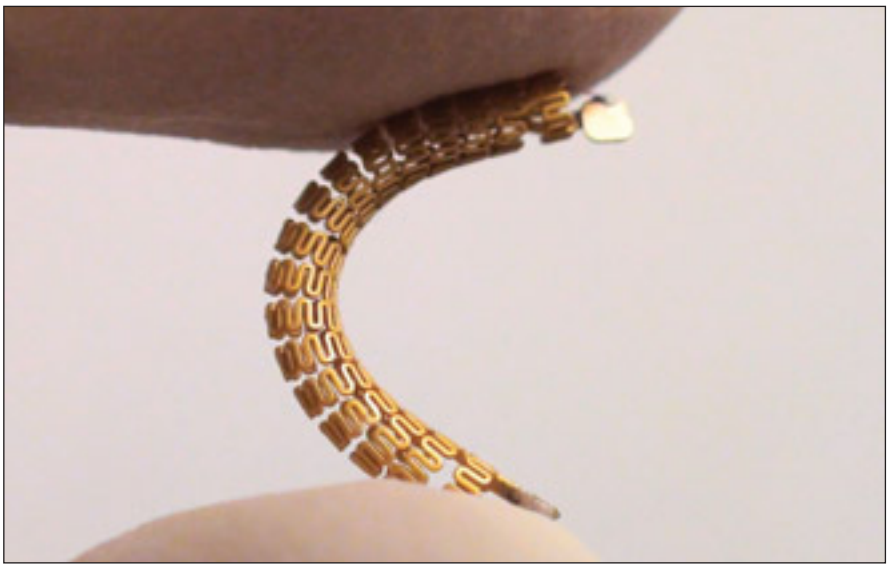
The device uses medical-grade stainless steel and looks similar to most commercial stents. Researchers say it’s the first angioplasty-ready smart stent — it can be implanted using current medical procedures without modifications.

Research collaborator Dr. York Hsiang, a UBC professor of surgery and a vascular surgeon at Vancouver General Hospital, notes that monitoring for restenosis is critical in managing heart disease.

“X-rays such as CT or diagnostic angiograms, which are the standard tools for diagnosis, can be impractical or inconvenient for the patient,” says Hsiang. “Putting a smart stent in place of a standard one can enable physicians to monitor their patient’s health more easily and offer treatment, if needed, in a timely manner.”

The device prototype was successfully tested in the lab and in a swine model. Takahata, who holds patents for the technology, says his team is planning to establish industry partnerships to further refine the device, put it through clinical trials and eventually commercialize it.

The research is described in the May issue of *Advanced Science*. According to the article, “Enabling Angioplasty-Ready “Smart” Stents to Detect In-Stent Restenosis and Occlusion,” the smart stent, which is equipped with microscale sensors and a wireless interface, enables continuous monitoring of restenosis through the implanted stent. This electrically active stent functions as a radio-frequency wireless pressure transducer to track local hemodynamic changes upon a renarrowing condition. The authors note that the stent is devised and constructed to fulfill both engineering and clinical requirements while proving its compatibility with the standard angioplasty procedure.



The device uses medical-grade stainless steel and looks similar to most commercial stents. (Credit: University of British Columbia)

The article explains that “prototypes pass testing through assembly on balloon catheters withstanding crimping forces of >100 N and balloon expansion pressure up to 16 atm and show wireless sensing with a resolution of 12.4 mmHg. In a swine model, this device demonstrates wireless detection of blood clot formation, as well as real-time tracking of local blood pressure change over a range of 108 mmHg that well covers the range involved in human. The demonstrated results are expected to greatly advance smart stent technology toward its clinical practice.”

How It Works

A pressure-microsensor-integrated wireless stent that is crimped on the balloon catheter is positioned at the targeted stenosis site in the artery. The smart stent is then deployed by balloon inflation to start self-diagnosing while scaffolding the narrowed artery after removal of the catheter; the stent’s resonant frequency is at its nominal level. In-stent restenosis changes local blood pressure and shifts the stent’s frequency as a sign of the problem; the implant is continuously monitored through a handheld wireless reader that sends out a warning of restenosis upon occurrence.

Engineering researcher Xing Chen, now a research associate at the Johns Hopkins School of Medicine, and Babak Assadsangabi, a postdoctoral fellow at UBC’s faculty of applied science, also contributed to the study.

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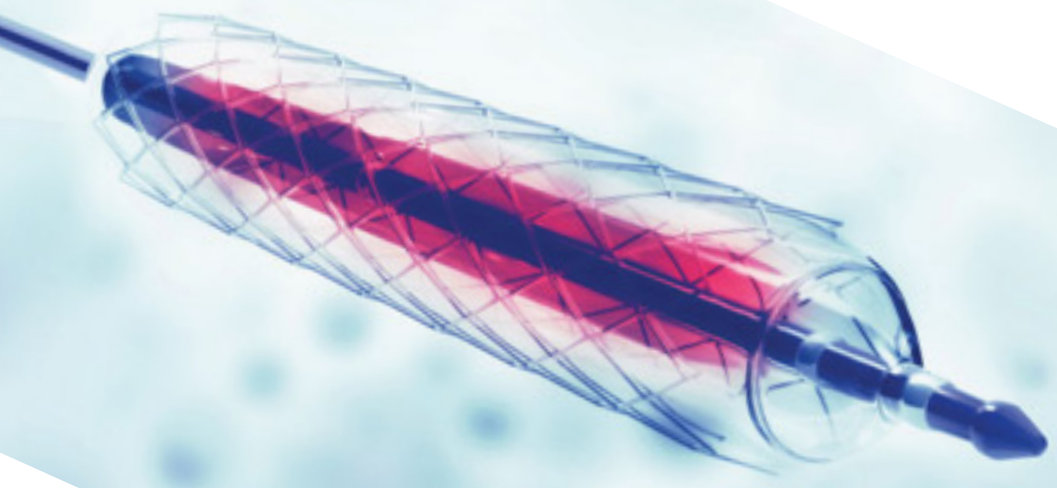

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