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WHITE PAPER

Leveraging Engineering Simulation to Fast-Track Personalized Healthcare

When it comes to healthcare, one size does not fit all. Today, computational modeling and simulation are allowing a more customized approach. The current "one size fits all" approach to healthcare fails to recognize the significant differences between the bodies and behaviors of different patients. This creates inefficiencies and cost overruns — but it also affects the quality of care provided. By personalizing the specific treatment to each patient, healthcare will become more affordable for patients and more profitable for providers due to increased efficiency. Implanted medical devices and wearables are becoming more commonplace, saving millions of lives each year. Yet personalized healthcare still requires a significant paradigm shift, as well as a new technology toolkit for collecting data via devices and wearables that is used to customize treatment. Engineering simulation provides a cost-effective, rapid and straightforward solution for modeling patients' bodies and designing devices that interact optimally with the body. This allows healthcare providers to devise truly personalized treatment plans, as well as to predict health problems before they occur, enabling early intervention. While this "medical digital twin" concept might seem like science fiction, advanced technology is poised to improve quality of life for people around the world.

/ Custom-Tailored Healthcare: Short- and Long-Term Benefits

Whether you call it precision medicine, individualized medicine or customized medicine, all these terms refer to the same idea: Someday, all of us will be under permanent intensive care. All our vital and non-vital signs — body temperature, blood pressure, glucose level, cardiac rhythm, breathing pace, number of platelets or cells, etc. — will be continuously monitored. Warnings or alarms will be recorded and sent to us, and possibly to medical staff or close family members, whenever a key reading deviates too much from its standard.[1]

In the future, this level of participatory medicine will be the norm, and most of us will be sharing medical data and contributing to a pool of big data necessary for statistical analysis. The combination of available data and advanced methods to predict the outcome of a given treatment for a given patient will naturally lead to predictive medicine — and the opportunity to pay for treatment based on the expected outcome, rather than on an a priori imposed price. Our society will have all the components needed to ensure effective preventive medicine, where pathologies are cured before they break out or evolve. P4 medicine — personalized, participatory, predictive and preventive — a concept imagined a few years ago, will progressively become a reality.

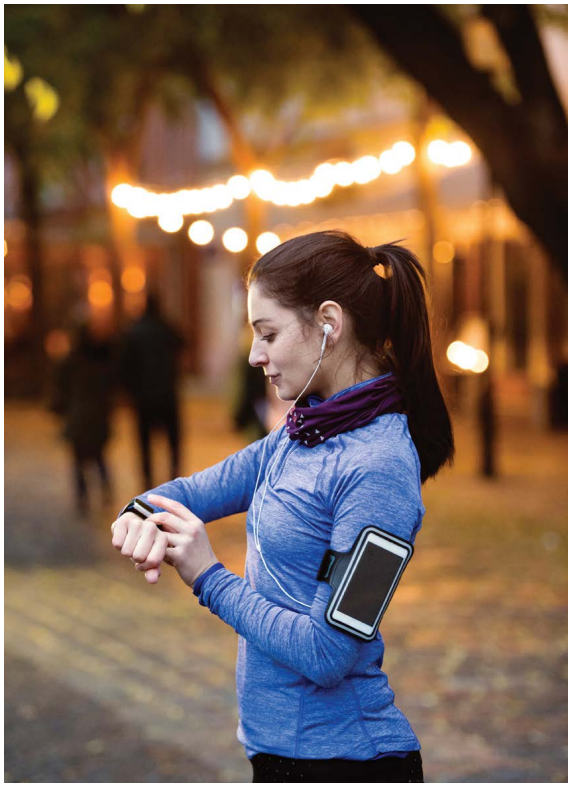
While this might be a long-term vision, the trend toward personalized healthcare has already begun, and the short-term benefits are obvious. Numerous applications for smart phones and smart watches are already available, enabling the measurement of personal physiological parameters. These applications are too often considered gadgets, but in fact their role in monitoring and caring for weak patients — including senior citizens and young children — could be significant.

If we can collectively reduce the cost of medical wearables to a price that's affordable for the majority of the population, simplify their user interface, synthesize their collected data together with relevant medical information and strongly communicate their value, we can create an enormous, positive impact on individual patients and the global population.

Participatory medicine leading to big data

/ Facing — and Solving — the Challenges of Personalized Care

Our society is already taking advantage of the first "baby steps" of personalized healthcare, but there are still many challenges to overcome before we benefit fully from this new paradigm. To fulfill this vision, the healthcare industry will need to address several bioelectronics technology gaps[2]. Among these are six key areas where innovation is needed.



Measuring Target Parameters Reliably Across Patients

The challenge: While wearables are measuring specific healthcare parameters across patients today, they are not yet reliable. The variation between two measurements can be so large that no meaningful insights or subsequent diagnosis can be obtained.

The solution: To improve reliability and produce meaningful data, healthcare professionals first need to determine which parameters are both relevant and easy to measure with a small sample from the patient. A close collaboration between engineers and clinicians can produce the best approach for achieving reliable, consistent results. By varying the geometry of the material or operating conditions of wearables via computer models, healthcare professionals can assess the likely, reasonable variation of these parameters. Once a standard protocol is defined with clinicians, simulation can be used to quickly adjust existing wearables and test the stability of measured parameters over a large variety of patients and a wide range of operating conditions.

Optimizing the Size, Weight, Power and Cooling (Swap-C) of Medical Devices

The challenge: Smaller, lighter, more energy-efficient and cooler wearables or implanted devices are necessary for patient comfort and device reliability. In addition, today's wearables and implants are increasingly incorporating automated "in vivo diagnostic" and Internet of Things (IoT) technologies — including pervasive connectivity and a higher density of electronic components. This means making strategic trade-offs to balance many aspects of performance for overall device optimization. As one example, Casey Murray, senior radio frequency design engineer at Starkey Hearing Technologies, recently noted, "Manufacturers are adding wireless technology and other features, while hearing aids are becoming smaller than ever."[3]

The solution: Significant device improvements can result from leveraging engineering simulation to analyze trade-offs and optimize the overall design from the earliest stages of product development. For instance, in the case of fluid samples including blood, microfluidic modeling — possibly involving piezoelectric or electricity-driven separation processes — enables engineers to investigate various solutions for reducing the test sample to an acceptable size. In the case of electronic devices such as hearing aids, product developers use computer models to simulate a wide range of design alternatives that take into account the actual geometry of the antenna, components within the hearing aid and the user's body. Murray of Starkey Hearing Technologies added, "Simulation saves months of testing time and tens of thousands of dollars in resources for each design project."[4]

Optimizing the Electromagnetic Interactions of Devices with Their Environment

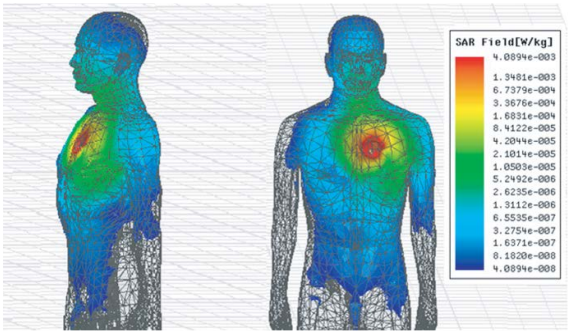
The challenge: In today's connected world, medical devices do not operate in isolation. Instead, they are surrounded by other electronics and thus electromagnetic activity. Electromagnetic interference (EMI), electromagnetic compatibility (EMC), signal integrity and cyber security (CS) are all major challenges that can slow down or even stop the deployment of personalized healthcare. Interference or compatibility problems could endanger the life of numerous patients. Vulnerable electronic interfaces could lead to the possibility of devastating cyberattacks.

The solution: By modeling the electromagnetic interaction between varying devices that are worn, implanted or surrounding the patient, engineers can assess the weaknesses, vulnerabilities and risk level as the device interacts with the body. Because of the time, costs and human safety risks involved, it is simply not possible to build and test every combination of prototypes. Instead, rapid device innovation requires a digital prototyping strategy via engineering simulation.[5]

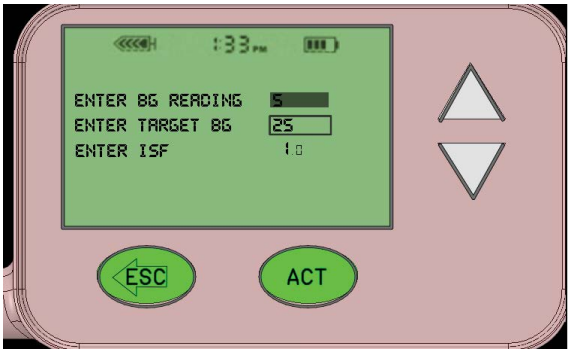
Ensuring Patient Safety and Regulatory Compliance

The challenge: Considering that future patients may have a greater number of body-worn or implanted medical devices as these technologies evolve, there is a serious risk that emitted energy, if not properly controlled, might exceed the specific absorption rate (SAR) and impact the patient's health. Engineers need the ability to measure the electromagnetic absorption of the patient's body to minimize harm. In addition, many medical products operate in safety-critical environments and need to meet relevant reliability and safety standards. Before devices are near or implanted within the patient, regulatory authorities require proof that they will not harm the patient in any possible way.

The solution: Engineering simulation provides a demonstration of product performance in a low-cost, risk-free virtual environment. "Often it is simply impossible for us to perform experimental tests — as is the case with medical devices," said Chris VanHoof, director at Imec, a nanoelectronics research company, explaining the need for engineering simulation. "Ansys also handles variability well, which is important to our medical device investigations, as there is a lot of variability in the human body."[6]



SAR in the adult chest during connected pacemaker emissions



A wearable insulin pump interface is tested with patients before the first prototype is manufactured.

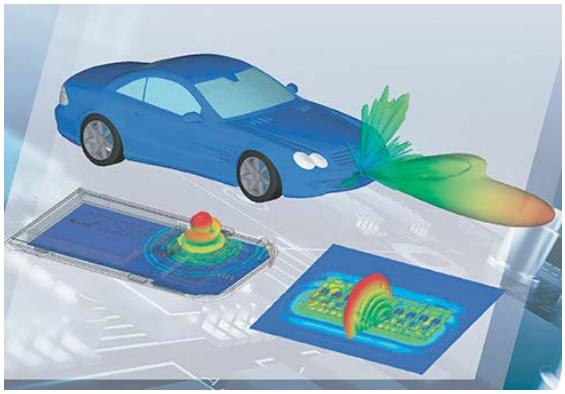
Delivering Flawless Embedded Software and a Patient-Friendly Interface

The challenge: Although healthcare is clearly lagging behind aeronautic and automotive applications in this area, there is no doubt that future connected medical devices will include software containing millions of lines of code required to properly interpret the large amounts of continuously acquired data and respond appropriately. Because many healthcare products and systems are safety-critical — defibrillators, for example — the control software must operate flawlessly. Devices must also be properly controlled by a user-friendly interface that's easy for patients to interact with.

The solution: Using modeling, it is possible to design a virtual interface and test it with numerous patients. A comprehensive virtual model, including both the interface and the embedded software, makes it possible to test the behavior of the embedded tools during interactions with patients. This real-life situation modeling is critical, as some commands could be erratic or inappropriate if the user is in a panic mode. It is crucial to ensure that the device will never harm the patient, so the control software might be programmed to take autonomous actions if irrational behavior is detected. A model-based embedded software development and simulation environment with a built-in automatic code generator — like the Ansys SCADE Suite — significantly accelerates the pace of embedded software development projects, while ensuring error-free operation of healthcare devices.

/ Engineering Innovation: Lessons from Other Industries

This list of challenges is intimidating, but the healthcare industry can make faster progress by studying other industries that are much more advanced in their use of engineering simulation technologies. As leaders in these industries have progressed in the level and sophistication of their engineering simulation approaches, they have much to teach product developers in the healthcare segment. The following list of engineering innovations in other industries may help inspire healthcare companies.



Achieving product autonomy. The global automotive industry is certainly leading in product autonomy today, with its goal of engineering a self-driving car — which is not that far away. For more than a decade, onboard computers have been providing a wealth of information such as the level of gas in the tank, water temperature, tire pressure and interior and exterior air temperatures. Drivers receive warnings to service the car if the oil level is low or if they have exceeded the recommended mileage since the car's last service. Increasingly, vehicles are equipped with numerous sensors to detect obstacles while parking, as well as to detect a passing vehicle or a car slowing down ahead. Ironically, we are investing much more to protect our car or prevent any deterioration in its functionalities than we are investing to protect the human body. Applying this same degree of rigor to healthcare would eliminate many health problems. Of course, measuring the level of cell-free DNA in the blood is more complex than measuring tire pressure. However, many vital parameters such as body temperature, blood glucose level, cardiac rhythm and physical activity are routinely measured today. If we can gather and synthesize the right biometric information —then feed it back the patient, the physician and the medical device — we could create more autonomous healthcare products.

Increasing energy efficiency and capitalizing on renewable energy. Each year, billions of dollars are invested to use energy more intelligently, reduce unexpected energy leakage and identify sustainable and renewable ways to produce energy. If achieving greater energy efficiency is so important, why not take advantage of the most advanced energy technologies for our own bodies? Today, the global energy industry is developing different processes to store mobile energy in very efficient batteries that can be recharged remotely. As we multiply the number of wearable and implantable medical devices, it is important to maximize their energy efficiency, minimize energy loss and address issues such as thermal buildup caused by a density of electronic components. As all batteries will inevitably run out of power sooner or later, the energy industry has developed several approaches to remotely recharge devices— including overnight recharging of consumer electronics and fast remote recharging. As devices proliferate, the worldwide healthcare industry must take advantage of these technologies, while also ensuring patient safety with regard to the specific absorption rate (SAR) of electromagnetic energy.

The future may hold exciting developments like self-sustaining devices, or devices that are able to extract energy from the human body itself. Inspired by renewable energy research, electro-physiology approaches to extract energy from the blood are already under investigation. Similarly, electronic prostheses could extract their energy from a patient's movements.

Making healthcare products smarter. Today the high tech industry is leading in its efforts to increase the digital nature of products, making them smarter and adding new functionality. Most of the necessary components for future personalized healthcare innovations have already been developed by the high tech industry — and are in use in other products today. While the healthcare industry may need to customize digital technology to its specific medical needs, the first step is simply to learn more about what is currently available, and the limitations of these technologies. It is not a surprise to see so many high tech companies investing heavily in the healthcare business today. **Learn more about product digitalization.**

Just as the healthcare industry is learning from others, it can help inspire innovations in other industries. In the future, it is likely that we will see more products customized for each specific user, starting with consumer products[7] — including packaging applications, food and beverage products and sports equipment, where athlete-specific solutions are already common. The global automotive and construction industries are also increasingly introducing some user-specific geometries, physiologies and activities in their models to customize their solutions to their actual end users. There's no doubt that these industries will be influenced and inspired by the healthcare industry's growing focus on a patient-specific approach, as well as its libraries of data on virtual patient populations. **Learn more about personalized healthcare.**

/ Join the Personalized Healthcare Revolution: A Step-by-Step Approach

For companies just beginning to explore the world of personalized healthcare, it can be difficult to know where to start. A simple five-step approach should help them realize the potential to make their own products more personalized and capitalize on existing technology innovations.

1. **Keep an open mind and observe developments in other industries.**

   The healthcare industry should not repeat what other sectors have already done, but may be able to leverage similar technologies in the future. Looking at recent innovations in the automotive, aeronautic, energy and high tech industries will trigger a lot of valuable insights — and may spark new innovations. Making medicine more personalized is often just a question of adapting solutions from other industries to specific healthcare challenges.

2. Develop meaningful digital prototypes.

In the early stages of product development, a computational model is extremely helpful, and it can be very simple. The goal is not to develop a nice-looking or impressive digital prototype, but to exploit engineering simulation to address specific questions that can't be cost-effectively answered via a traditional physical prototyping approach. Best engineering practices in other industries have demonstrated the value of digital prototyping, so healthcare companies are bound to rely heavily on simulation in the future. The earlier your company starts leveraging simulation, the greater the benefit — provided you are continuously driven by the return on investment in your modeling activities.

3. Simplify — but don't oversimply.

For those engineering teams just beginning to exploit simulation, the most difficult question to address is, "What should I include in my model and what can I overlook in order to get meaningful results quickly and cost-effectively?" There are many simulation experts in healthcare with years of experience in generating models with the right level of detail. They can be a valuable resource. A solution provider such as Ansys can typically connect you with experienced experts who can help by providing you with guidance on best simulation practices.

4. Invest in patient-specific modeling:

As every patient is different, a solution optimized for a specific person will work differently on another individual; this is the essence of personalized healthcare. At the beginning of your modeling efforts, you need to consider a multipatient approach and investigate which patient-specific component (geometry), parameter (material properties) or operating conditions (activities) should vary in your personalized models. A typical approach involves developing a general model that can be relatively easily and quickly adjusted later to accommodate patient-specific variations. Once you have reached this personalization stage, it is crucial to exploit patient-specific simulation data and synthesize the results, so you can see meaningful trends and variations among different individuals.

5. Engage with regulatory authorities.

Regulatory authorities and policymakers around the world are encouraging the adoption of in silico medicine, which relies on computer modeling and simulation. It is important that you communicate early and often with your regulatory contacts about the potential use of your simulation results for regulatory approvals, especially with regard to personalized medicine. Your regulatory contact might not be familiar with simulation technology, but solution providers such as Ansys can help bridge this gap and make the most of your simulation results during the regulatory approval process.[8]

/ Simulation and Healthcare: A Healthy Outlook

There can be no doubt that personalization represents the future of healthcare. By customizing the performance of devices, wearables and treatment plans to individual patients, the quality of care can be significantly improved — while also cutting overall healthcare costs. With other industries leading in product autonomy, digitalization and electrification, it's time for the healthcare industry to capitalize on these technology advances and move into a new generation of individualized, targeted care.

While personalization is quickly becoming a competitive imperative for healthcare companies, the cost of building product prototypes and testing them on patients is prohibitively high. Simulation is the answer, and it has already been proven as a best practice in many other industries. By constructing prototypes in a low-risk, cost-effective virtual design space, healthcare product development teams can quickly create product models and verify their performance. Computer modeling accelerates the overall design process and supports the development of smarter devices that gather individual patient data and facilitate an appropriate response — laying the foundation for a new era of custom-tailored healthcare.

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