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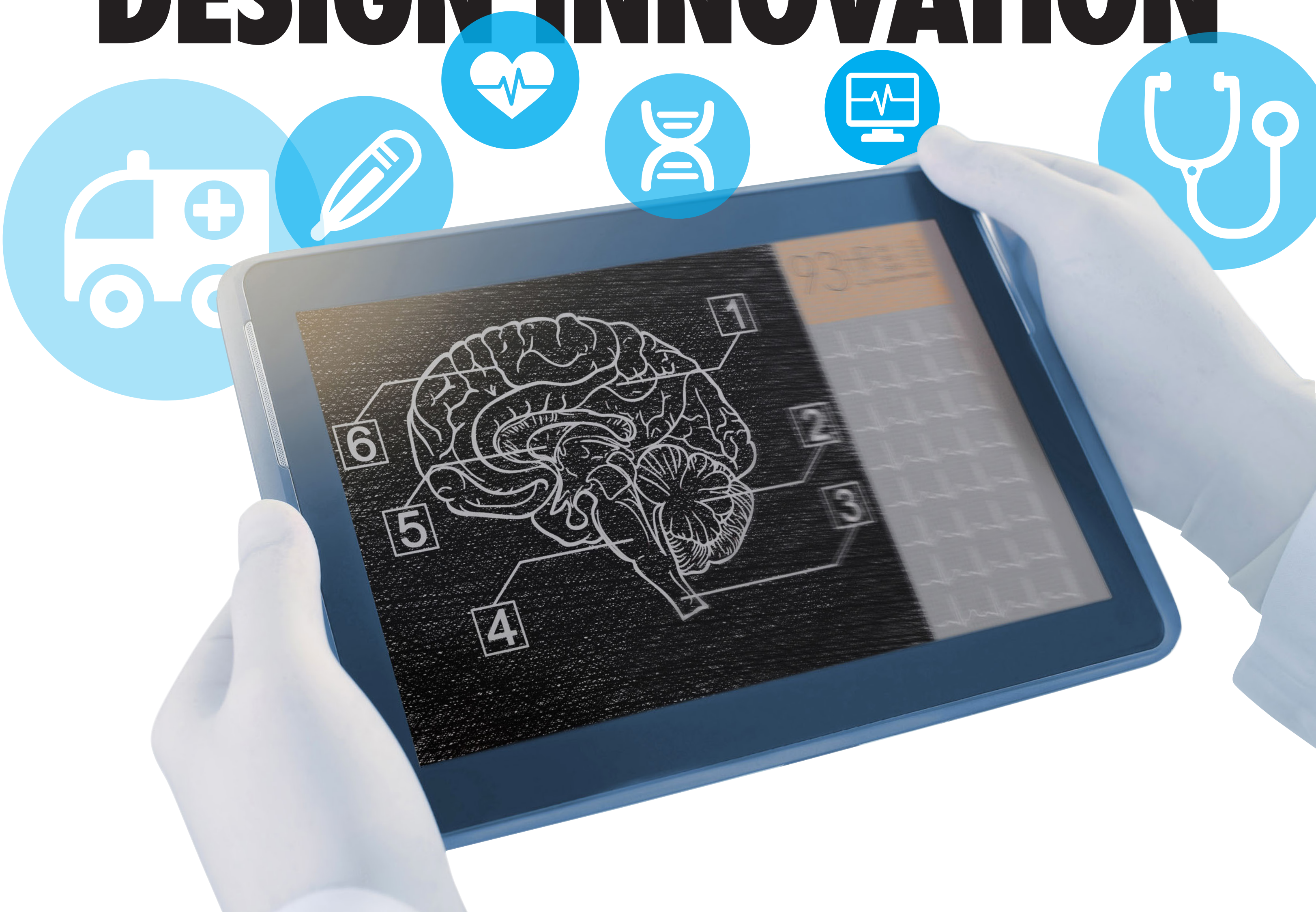
BEYOND THE PANDEMIC:
MEDICAL DEVICE DESIGN INNOVATION



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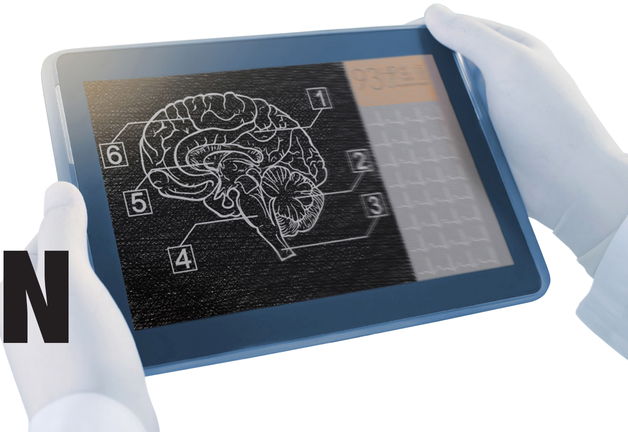

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THE MOTHER OF INVENTION

Bob Vavra, Senior Content Director for Machine Design

As we take stock of the global landscape in a world no longer in the grip of pandemic crisis, we are finding rays of light against the grim backdrop. One such area were the rapid, successful merger of advanced manufacturing and the needs of the medical device industry.

Manufacturers both in and out of the traditional medical manufacturing supply channels found themselves pressing to create product lines needed during the pandemic's early months. The output of masks, shields, hand sanitizer and ventilators sprung from need, and the rapid adaptation of manufacturing to meet those needs required a nimble workforce, quick design and prototyping, and then adjustment of the manufacturing process to deliver on those designs.

The normal design-to-operate process normally takes months, but the use of new tools such as artificial intelligence and digital design tools brought those products to market more quickly than normal. As we now take a step back and realize what we actually achieved, there should be a certain level of pride in the accomplishment.

For the medical device industry, one lesson is that speed and quality need not be at cross-purposes. Another is that technology can find answers more quickly when widely deployed, and that will lead to medical innovations getting to patients with less delay and no loss of effectiveness.

As this e-book correctly notes, so many of those pandemic lessons will continue to pay dividends for future product introductions. If we implemented these solutions in a different time frame than might have been the normal, well, we all have experienced a new normal. Necessity was the mother for these inventions, but even in retrospect, that makes them no less remarkable.

CHAPTER 1:

Dr. Robot Will NOT See You Now

BOB VAVRA, Senior Content Director, Machine Design and Hydraulic & Pneumatics

Robotics are often portrayed as the successor to human labor, but that perception's at odds with the reality.

More than 25 years ago, I was invited to view the videotape of a robotic gallbladder surgery. It was a fascinating process that demonstrated how with surgeon-controlled probes, a less invasive form of surgery was possible. Just four small incisions in the patient allowed the surgeon to guide the probes, remove the organ and cauterize the point of removal and the surgery was complete.

It was not about a robot replacing a skill, but a robot enhancing a skill. It is this distinction that can get lost in the discussion about robotics as a whole, and in medical applications in particular.

Sean Hägen, founder and director of research and synthesis for *BlackHägen*, amplifies this point in a recent *Machine Design* article. "These medical constructs and devices facilitate and increase the abilities of the user, but do not replace them," Hägen writes. "A surgical robotic system can be considered an extension of the surgeon's abilities and can impact the rest of the surgical workflow as well as all the other actors involved in the surgical procedure."

When robotics are discussed, it is seen as the successor to human labor as opposed to the enhancement of it. That is not how it is working out, certainly not in the medical field. Robotics can provide faster, safer and less intrusive procedures, but a doctor still is at the helm in the decision-making process, and the patient is still in charge of care. Those fundamentals shouldn't ever change.

Those same fundamentals do, of course, apply to the rest of robotics use across manufacturing sectors, but there still are pockets of confusion over the proper role of robots in our plants, and in our lives. The technology shouldn't replace the human endeavor; it should enhance it. The best robotics deployments have done just that.

Manufacturing long has been seen by those who don't know anything about manufacturing as dark, dirty and dangerous. The robotics revolution has helped fully debunk this myth, just as it should reaffirm the value of the human worker in our operations.

Manufacturing is not as dramatic as surgery. But the vital role of technology in making manufacturing safer, smarter and more efficient has created the potential for a dramatic change in our lives and in our work.

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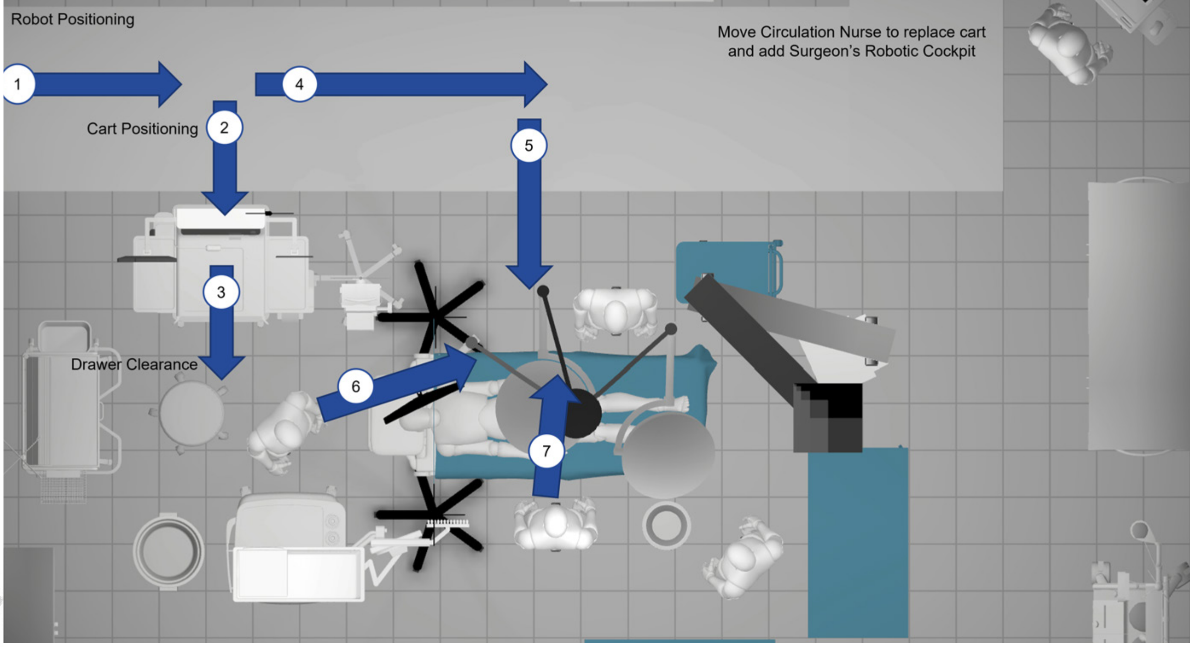


CHAPTER 2:

Adapting Medical Design in a Virtual World

SEAN HÄGEN, Founder and Director of Research and Synthesis, BlackHägen

Applied VR methodology plays a key role in product and process development.

The pandemic changed medical device research and development and drove conformance to an alternative usability engineering process to inform design. In-person protocols practically stopped, forcing usability evaluation methods to be primarily remote. These changes helped to drive the accelerated development of virtual reality (VR) technology in medical device design processes.

Greatly evolved by the high-volume gaming industry, VR technology has become an affordable and easy-to-use development tool. Applied readily to training, VR technology is now valuable upstream in early device development. Configuration modeling is seen as valuable because it is intended to inform system architecture, especially as it correlates to user interfaces (UI).

Getting the Study Methodology Right

This established design methodology incorporates study models that allow the user to assess, at a feature level, disparate UI configurations to inform systems engineering and industrial design before these disciplines are engaged. This complements additional system-level design inputs that could involve mechanical engineering, manufacturability, service, sustainability and power management.

While the study models are not iterations of a design direction under development, these models are considered a mock-up or prop. Such a methodology can provide a user with the way to determine their own set of alternative UI configurations and preferred features. Deliberately configured to demonstrate UI features in various ways, each model presents an alternative UI.

Differences between configurations may be as simple as one that is in portrait and one in landscape orientation. Additional examples of differentiation include features such as handles positioned at different attitudes and disposable sets being loaded from different orientations. Taking such an approach enables study participants to evaluate their preferred feature configurations by trying out numerous configurations in a simulated context of use environment, enabling them to express why certain features or configurations are favored prior to selecting a complete design solution.

Unfortunately, each study model has to be engineered in CAD for fabrication in order to provide the study participant with a sufficient level of interaction for the UI to be experienced in a meaningful way. Features that open and close, for instance, will require hinges and latches to be engineered.

Even though models are not put through an extensive design process for manufacturability, significant time is still required to engineer, fabricate and debug such features. Unfortunately, this engineering time and CAD data is considered “throwaway engineering”—not a predecessor CAD database to evolve into the eventual design direction.

However, a study model’s development time can be substantially reduced by providing a virtual means for the study participate to evaluate the study models. Evaluating virtual models eliminates the need to engineer all the mechanically functional details and the costs associated with fabrication. Rather, functions are assigned kinematic characteristics. This way, if a display (for example) is to tilt and swivel, the extent of those kinematics is defined without designing those mechanisms.

Contextual Environment Simulations

The initial investment to create a reusable environment of use is an important consideration. For instance, utilizing the fabricated methodology still means that the study would require a high-fidelity, simulated environment to be utilized for context. Depending on the device, this may be the patient’s home, the ER, the ICU, etc.

In this case study, the alternative configurations are for a surgical robot being evaluated in the contextual environment, which in this case is an operating room (OR). It is important to note that all the people and equipment involved are critical components to achieve a realistic system evaluation. For instance, it is important to incorporate all the details of the OR environment such as surgical lights, monitors, patient table, booms, IV poles, anesthesia cart, infusion pumps, etc.

Incorporating all contextual details optimizes the level of realism needed to be able to assess such parameters as footprint integration (relative to people and other equipment) to eliminate potential collisions with other equipment (maneuverability), and establish a line of sight relative to people and other equipment. The user interface layout, and determining access to the user interfaces, are also integral parts of the footprint. In addition, there are also such considerations as dimension priorities (height, width and depth), component configuration, and dynamic UI interferences or kinematics to incorporate.

Among the parameters that cannot be incorporated into a virtual study:

- Portability (center of gravity, weight, balance, etc.)
- Tactile experience (grip, comfort, etc.)
- Haptic feedback (draping, vibration, force feedback, etc.)
- Interaction with graphic user interfaces (touchscreen, keypad, etc.)

VR technology is evolving so rapidly that the interaction with the UI is starting to become feasible. In addition, augmented reality (AR), which typically encompasses combining VR technology with real-world props, has begun to address these parameters through the introduction of virtual surrogate objects that deliver the illusion as something else.

The surgical robot development example demonstrates how study participants (potential users and designers) can experience which feature layout in various configurations work best for their context of use. Using CAD, an evaluation of the robot's impact on the context of use is inadequate, even though it is 3D.

Unfortunately, it still presents as static and is not experiential. In figure 1, while the robot seems integrated into the sterile field appropriately, the device's kinematics are not considered, nor are the environmental context that could significantly affect usability and clinical integration. This requires adopting an interactive evaluation of configuration models.

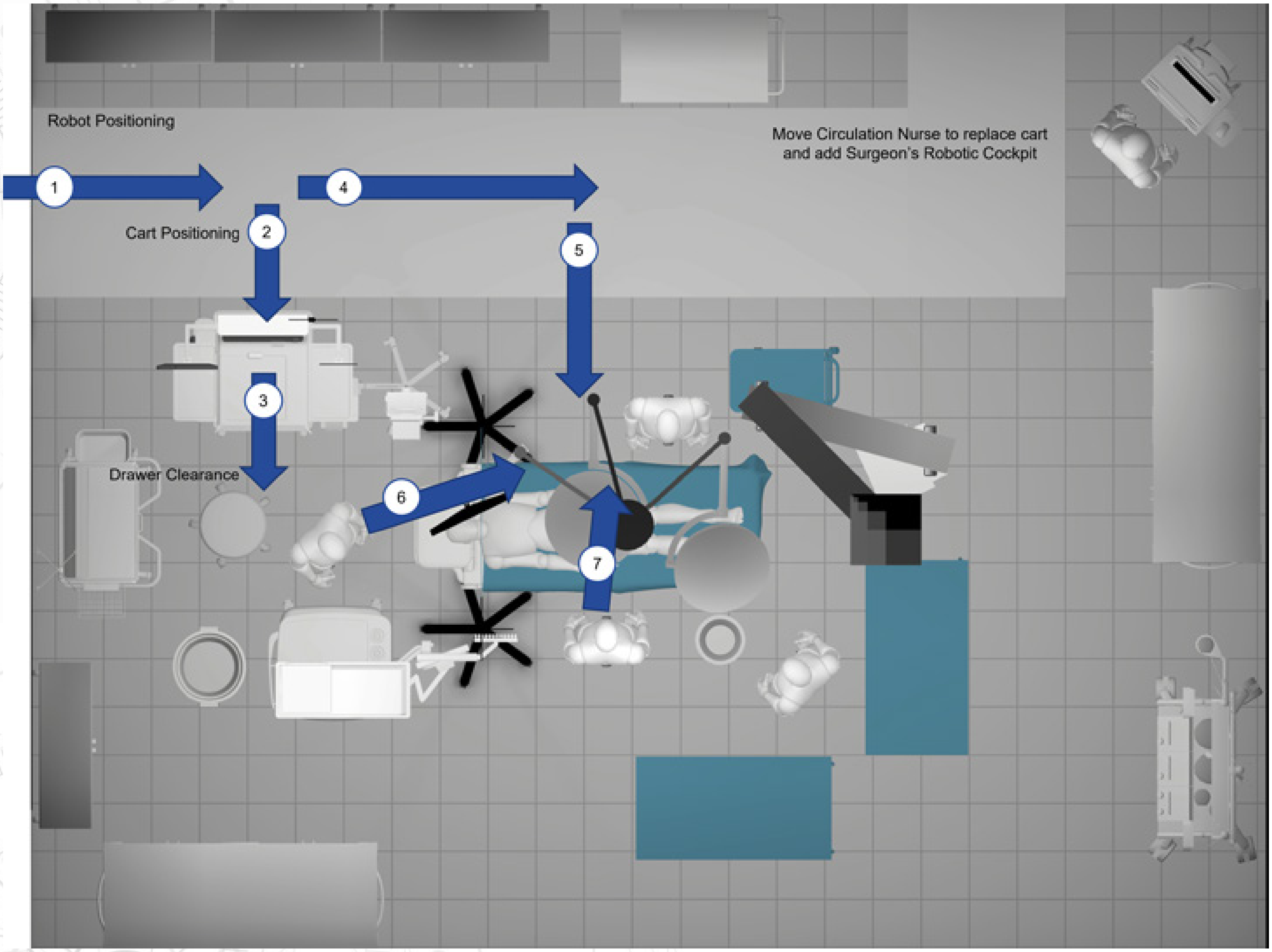
VR configuration model development begins with CAD model development for demonstrating alternative system configurations. All the user interfaces should be represented and differing between models to show options, such as handles, power button, emergency stop, break controls, power cords and data cables (**Fig. 1**).

Part of the virtual reality display of a given medical device also should show options such as handles, power button, emergency stop, break controls, power cords and data cables.

Differentiating features may not just involve user interfaces but also general architecture. They can influence use-case scenarios such as impacting the robot positioning to the OR table/patient. In addition to patient and equipment access, architecture deviations could involve the shape of the robot base or the structure of the cantilevered arm, for example. Keep in mind that models should all be rather schematic in their design in order not to bias feature preferences by the overall aesthetic.

Use-Case Scenario Planning

After modeling the digital OR environment, plan a use-case scenario, which in this case involves robotic-assisted surgery (RAS). Next, storyboard the scenario to determine what actors need interactive features, or kinematics. Since evaluating the design in context will likely reveal unintended interactions, the process will likely be iterative. Along with the storyboard (**Fig. 2**), there should be an associated script. This will allow the developer to adjust the environment and actor kinematics accordingly.



Part of the virtual reality calculations in an operating theater is to show how the humans and robots can be scripted to interact.

For example, when the robot is pushed into the room from storage, immediately note concerns due to running into the medication cart. This is solved when the cart is moved toward anesthesia away from the thoroughfare. The next action to take is to open the cart drawer to make sure there is adequate space for the anesthesiologist to conduct his procedures. After continuing to move the robot into the room, then position or dock the robot against the table, making sure it doesn't interfere with the overhead monitor and lights. Once the line of sight from the anesthesiologist to the monitors and other personnel is checked for any potential issues, then also check the line of sight between the surgeon console to the first assist and the monitors, as well as to other personnel.

Following this script, the developer understands that the medication cart, robot, lights, monitors and patient table will require kinematic features for the RAS scenario. This is the point where participants can put on goggles and gloves to try out the experience. Make sure the room utilized is of similar size as the space the participant is to explore.

It is best to prepare and use a study guide in addition to discussion points so that the moderator is aware of when to prompt the participant for feedback and is prepared with what questions to ask. Some like having the participant use a think-aloud approach, which also is an appropriate and effective method. As the participant responds to prompts from the moderator and executes tasks, the insights regarding why one configuration is preferred over another becomes clear.

Examples of questions that could be asked include:

- Is there enough space for the surgical team to access the patient and exchange instruments with the robot?
- If the RAS converts to an open procedure, how would the team interact with the robot?

Applying VR technology to various configuration alternatives is highly effective for generating design inputs and for making better foundational system design decisions. Additionally, it results in much lighter CAD models, without requiring the need for extra engineering of mechanisms or the need for fabrication. A configuration model study presented in VR ultimately can reduce development time and costs by enabling quicker iterations.

Sean Hägen is founding principal and director of research & synthesis at BlackHägen.

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CHAPTER 3:

Linear Motion a Lifeline in Medicine

MARIO DeVINCENTIS, Engineering Manager, Schneeberger Inc.

Medical and clean-room applications carry specific design and operational challenges.

Life science, medical and biomedical equipment manufacturers must constantly pursue improvements in advanced technology, workflows and processes to pursue competitive pressures and market growth. But progress cannot only focus on expanding success; it must also ensure precision, reliability, functionality during operation—the prevention of in-use failures.

Neglecting improvements and safeguards in one seemingly minor component of in-process linear motion systems can generate consequences ranging from inconvenient to catastrophic. Manufacturers, as well as users, must remain vigilant.

With the proper focus, next-generation linear motion systems can be specified, designed, installed and maintained to advance and ensure the benefits of life science, medical and biomedical equipment in vital and even lifesaving applications.

Consequences

Because reliable linear motion is an operational necessity, equipment manufacturers and equipment users must monitor even relatively rare failure risks in linear motion components or systems throughout the process. This concern includes equipment ranging from DNA sequencing to bioprinting to atomic force microscopes (AFMs).

The stakes are enormous.

Failure of a single part or system can cost equipment users hundreds of thousands of dollars for even a relatively short-duration downtime event. Depending on location, severity and response time for repair or replacement, costs could mount to a great deal more.

The personnel safety risk is another paramount concern. While rare, design flaws or failure to follow operational safeguards can lead to anything from pinch points to runaway stages and cause damages from crushing injuries to electrical shock.

Specification and Design

Linear motion manufacturing facility be fully ISO-certified to ensure consistency in all its key processes. In addition, meticulous prototype builds help uncover steps that are key to maintaining the performance and the reliability of the finished motion component or system. Missing or not correctly performing any of many small, crucial steps in assembly or testing could ultimately lead to a failed system in the field.

Many manufacturers also establish targets that translate into many years of reliable service before an equipment upgrade. It is therefore important to properly calculate component service life. Because duty cycles may vary from application to application, service life is stated in kilometers traveled for many linear motion components. The linear motion maker must then translate that calculation into various decisions about the product.

For example, one widely-used cable specifies more than 10 million flex cycles if a 50-mm or greater bend radius is maintained. But, if the bend radius is not correctly sized,

From design to prototype to installation, specifying linear motion in the medical device field is as exacting as its role in helping find cures and save lives.

particulates falling from the cable or stress on the cable tracks or connectors could conceivably cause early failure in the process (especially where maintenance schedules are not strictly observed).

Consider Customization

Off-the-shelf parts play a critical role in many equipment assemblies. One concern, for example, is that a stock linear motion stage element may not have been designed and constructed to work with the precise combination of other components and structures that the supplier is assembling. Unexpected incompatibilities may arise.

The question is: Will a manufacturer catch issues during its routine design, quality control and inspection protocols? Probably. But not certainly.

Often, only customized offerings can meet the objectives of specific performance and design requirements. They allow the manufacturer to focus on the design aspects of the stage that the application requires, specifically tailoring factors from speed to acceleration to stability. They can even reduce cost by eliminating unneeded features that come standard with an off-the-shelf stage. And they ensure an integrated solution without hidden incompatibilities.

Suppliers should look for true “spec-sheet-to-prototype-build” control of their order from the linear motion manufacturer. Such intelligent customization is vital to anticipating and eliminating product shortcomings, avoiding roadblocks in integration and preventing failures throughout.

Specify products with the precise size, shape, coating or material the job demands. And insist on solutions that meet the unique targets for accuracy, speed, flatness, preloading (to increase stiffness by eliminating internal clearances), service life, maintenance levels and price.

Sometimes, more innovative materials may also help reduce risks in specific custom designs. For example, carbon fiber construction can optimize structural strength, stiffness and stability (despite its reduced weight and thickness). At the same time, ceramic bearings may be a viable solution for specific lubrication issues.

From design to prototype to installation, specifying linear motion in the medical device field is as exacting as its role in helping find cures and save lives.

Handle With Care

Once a linear motion component destined for a specific application arrives on the equipment maker’s floor, other risks can arise.

Linear motion manufacturers may be called in to solve a host of problems arising at this intermediate stage. For example, a linear motor may suffer a binding problem, where the coil traveling inside the motor track is rubbing against the track in its travel. This might be caused by a handling issue due to jarring that slightly shifts the coil or the track out of alignment. It is possible the saddle—the moving stage segment—may get bumped and suffer distortion. In building the larger tool, screws that are too long may be added, pushing through one linear motion plate into another, causing scratches and the risk of unpredictable forces during operation. It also is possible a coil may be unscrewed from its mounting to allow access to run an additional cable, then re-screwed incorrectly.

Such mishaps run risks ranging from a slight degradation of performance in the process to burnt-out motors and major downtime events. Surface preparation also merits close attention. Tolerances must match in all particulars.

In some cases, a manufacturer building tools for these processes may source a linear motion component constructed for flatness of travel, say 0.0005 in. (12.7 µm). But the toolmaker then bolts that component down to a larger assembly with a flatness of only 0.005 in. (127 µm). The consequent twisting of the stage may be almost imperceptible. For example, this may cause binding of the bearings resulting in premature wearing of the bearings, additional forces on the ball screw or higher power requirements from linear motors resulting in excessive overheating and potential failure.

Get Grounded

Ensuring that all components in the linear motion system have proper electrical grounding is another precaution that manufacturers can undertake to prevent a future problem. Such an oversight might result in electrical shock risks for operators. But it can also have an impact on system performance.

A ground loop in the system that feeds back through the ground path could induce false readings in the encoder so that a component only travels 1 mm, but the controller registers travel of 100 mm. If the oversight is missed, for example, positional accuracy may result in errors in the readings of the instruments leading to inaccurate analysis.

Transport and Installation

The relatively low resistance of linear motion systems to impact loading was discussed earlier. The points of most significant risk naturally occur in three periods:

- During transport from linear motion supplier to equipment tool maker;
- During arrival and incorporation of the system into the equipment tool; and
- During transport of the finished equipment assembly to the process floor and installation.

A reliable, experienced linear motion supplier can significantly decrease the chance of shock damage during the first phase. Supplier experts can ascertain manufacturing space constraints early, so they do not design a stage that is too large or too heavy to be easily assembled in a cleanroom or manufacturing floor. They can also plan transport equipment usage (cranes, dollies, etc.) so that the stage can be safely transported from crate to tool, minimizing the risk of injury to onsite personnel, as well as the chance of damaging impacts.

Finally, during installation, the linear motion system or the relevant portion of the tool can be equipped with the necessary passive isolation measures (such as elastomer feet or pads) or active isolation dampers (sensor-adjusted airbag systems) to reduce the chance of excessive shock or vibration during subsequent operations.

In the Clean Room

For both the first and second phases, the linear motion supplier should follow best practices in constructing transport crates and bagging systems. For example, one leading supplier envelops the system in two bags, one applied within the nitrogen atmosphere and the second in a cleanroom, for transport. They then provide special rigging and carts for delicate transport transfers.

In the third phase, if the system will be placed on the tool assembly from above, the tool makers' crane may suffice. However, if a more challenging sideload maneuver is necessary, the supplier provides a specialized chamber crate, which can be bolted to the side of the tool until mounting is accomplished.

Lubrication

Although linear motion systems usually run cycle after cycle without trouble or extra attention, a small amount of regular maintenance is always critical. Here there are three keys to effective maintenance: lubrication, lubrication and lubrication.

Every linear motion system supplier ships their product with a specified relubrication service cycle. Yet, human nature being what it is, many problems can be traced to simple failures to follow that recommended cycle. Without necessary lubrication, friction stresses mount and eventually cause extremely undesirable events—such as shutdowns or motor burnouts.

Other lubrication issues include premature failure of the bearings resulting in reductions in performance such as straightness, flatness, pitch, roll and yaw.

Moreover, not all vacuum greases are created equal. Different systems may require different formulations, such as those marketed by Klüber, Barrierta and Krytox.

It is important to use only the correct grease on each machine. Take great care never to mix incompatible oils or greases. This includes using different greases when servicing a machine from one cycle to the next. This will change the required viscosity, often resulting in the buildup of a gummy, cement-like material that is the last thing to desire in delicate equipment. If the material also includes particulates from an over-flexed cable, a cable carrier or even elsewhere, usually rail failure will soon result.

Performance Roadmap

In response to demands from equipment manufacturers, linear motion equipment makers are continually working to push the envelope in performance. But first, they must ensure that any improvements do not inadvertently increase the risk of linear motion failures.

A good linear motion supplier will supply a “performance roadmap” highlighting elements of the system that can be designed not just for current requirements but with the performance capacity for next-generation use. This commitment is especially critical in the manufacture of advanced life science, medical and biomedical technology.

Linear motion process systems may not be the most prominent elements in most advanced technology equipment, and nor are they typically a top-of-mind concern for most users. But their failure can have severe consequences for all involved. Fortunately, proper attention to design, installation, operation and maintenance can ensure linear motion systems play a vital role in the continuing critical—and perhaps even lifesaving—successful operation of the most advanced life science, medical and biomedical equipment.

Mario DeVincentis is engineering manager at Schneeberger Inc. He is well-known in the area of linear technology, with 30 years of experience in system development, system manufacturing and applications engineering works to identify opportunities and optimize processes.

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CHAPTER 4:

Innovative Coatings Increase Design Possibilities for Medical Devices

JAY TOURIGNY, Senior Vice President, MicroCare Medical

Reduced friction and device performance are key considerations.

Friction and wear can impact a medical device's performance in the operating or treatment room…especially if the device does not function precisely, predictably and efficiently to complete a procedure. Also, during manufacturing and assembly, tight-fitting parts can make device production difficult and slow. So, it is important to think about lubricating coatings in the early stages of design to mitigate these factors. Determining the best parts lubricant for the device can help improve both production throughput as well as the completed device's performance.

Medical Grade Coatings

There are many medical-grade lubricants on the market today to help address device friction and wear, including silicone oils and greases. Dry lubricants are also a popular

Surgeon hands at work: Friction and wear can impact a medical device's performance in the operating or treatment room.

choice. These dry coatings reduce the combination of friction and sticking, or "stiction," on parts that slide, shear, twist, rock or pivot. Moving mechanisms like these are most often found in disposable medical devices such as catheters, cutting tools, staplers, hypo tubes and other surface to surface assemblies.

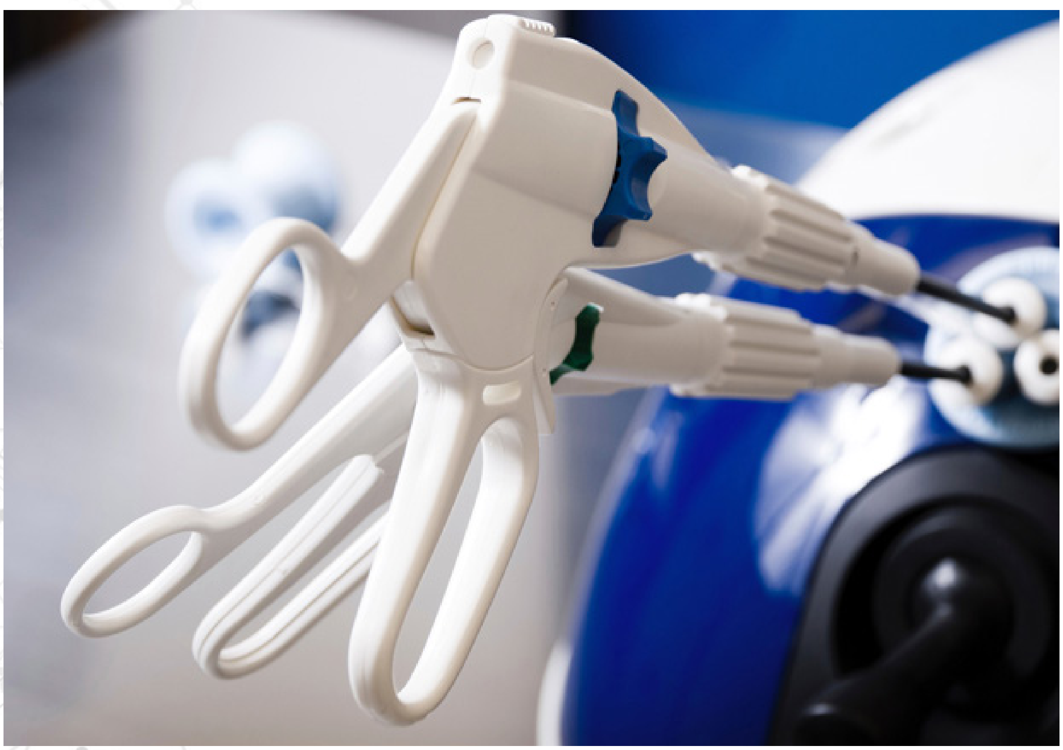
Dry lubricating parts typically reduces actuation forces by 25-30%. This allows the parts to move more freely and improves their performance. Without the use of a dry lubricating coating, many of today's complex medical devices would not be a viable option.

As well as using lubricating medical device parts, dry lubricants can also be used on the manufacturing and assembly equipment itself. To run more smoothly, a clean, long-lasting dry lubricant is applied to production paraphernalia such as chains and pulleys, chutes and slides, door tracks and conveyors, and other metal extrusions. Dry lubricant can also serve as a release agent for molded parts.

What is a PTFE-Based Lubricant?

Many dry lubricants use polytetrafluoroethylene (PTFE) that is suspended in a high-purity nonflammable carrier fluid for dilution and dispersion. Dry PTFE lubricant works particularly well on high-speed, high-volume mechanical assembly production fixtures to speed the assembly of plastic and metal components. It also helps the parts tolerate exposure to water, oils, chemicals, abrasion and high temperatures.

A thin layer of this non-stick solution is applied to the parts. The lubricant's carrier fluid then quickly evaporates, leaving a smooth, even dry coating on the treated part. The carrier fluid that delivers the lubricant should have low viscosity to wet and conform to the treated part's surface geometry. This helps provide a highly consistent surface coating



Coatings and lubricants in-use: Dry lubricants reduce the stiction on parts that slide, shear, twist, rock or pivot.

without leaving unwanted residue, staining, drips or runs that could disguise any Unique Device Identification (UDI) markings on the device.

Applying Dry Lubricants

The typical application techniques for applying dry lubricants inside a carrier fluid dispersion include dipping, spraying or wiping.

Dipping. This is commonly used in high-volume production since it adds a consistent coating to nearly any surface shape or size, including small, complex parts such as wire coils. Conveniently, entire finished devices can also be dipped into the carrier fluid dispersion. Normally a single immersion is enough, but the coating level can be adapted by adjusting the concentration of PTFE particles in the fluid, the rate of withdrawal and number of applications.

Wiping. Wiping or brushing is mostly used in medium- to small-batch production. Because this method covers longer, ongoing surfaces, it is ideal for components like rods, tubing or sheeting. However, it can also be used if only a small, select area of a larger part requires coating. Once brushed on, the carrier fluid dries rapidly, leaving a consistent, even and thin coat of dry lubricant behind.

Spraying. Spray application is done using a hand-held spray gun or automatic spray heads. Spraying is typically used to apply a number of thin coats, allowing the surface to dry between applications. Applying several coats over time is a better technique than one single thick coating, as the thicker coating takes longer to dry and can cause uneven coverage and poor adhesion.

Following application, the durability of the PTFE-based dry lubricant coating can be improved through heat curing or melt coating. This fuses the lubricant to the part, giving it a harder, more-permanent surface. Heating or melt coating also turns the dry lubricant completely clear, leaving an invisible coating. It's always a good idea to consult your coatings provider to get a recommendation on which process is best for the particular application.

Choosing a Dry Lubricant

When choosing a dry lubricant, there are some important features to look for.

ISO 10993 certified. Dry lubricants can typically be applied in-house within the production and assembly process, saving both time and money. In addition, using a dry lubricant that is ISO 10993 certified as a medical-grade lubricant makes it easier to add to production validation processes.

Non-migrating. Many lubricants like grease and oil can be expensive, messy and difficult to apply. The also often migrate to other surfaces or to product packaging. This makes facility cleanliness more challenging and process validations more complex. On the other hand, dry lubricants are clean, easy to apply and don't migrate after application. This makes for a cleaner production or cleanroom facility and eases validation.

Nonpyrogenic. A non-aqueous carrier fluid helps prevent bacterial growth and other biologic contamination to the parts or devices.

Compatible. PTFE-based dry lubricants have excellent materials compatibility. They are safe to use on metal, glass, plastic and ceramic parts, so they are ideal for medical devices made with mixed material components. Dry lubricants are also typically compatible with commercially used EtO (Ethylene Oxide) and radiation sterilization processes.

Hand holding syringe: Dry lubricating parts typically reduces actuation forces by 25-30%.

Don't Forget Your Coat

Medical device engineers and manufacturers must consider the lubricant coating process carefully when designing and producing medical devices. A dry lubricant contributes not only to the efficient production of the parts but also to the functionality, quality and consistency of the finished product.

Moving away from traditional silicone oils and greases and switching to a PTFE-based dry lubricant can be beneficial. It not only works well to increase the overall performance by reducing stiction, but also addresses the long list of requirements when manufacturing medical devices. From validation conditions and bioburden risk to safety concerns, materials compatibility, and reliability and consistency.

Some medical devices would never reach their potential without the properties offered by dry lubricant coating technologies. So, selecting a lubricant coating early in the planning stage of a medical device design is critical to its success.

JAY TOURIGNY is senior vice president at MicroCare Medical, which offers medical device cleaning and lubricating solutions. He has been in the industry more than 30 years and has a BS from The Massachusetts College of Liberal Arts. Tourigny holds numerous U.S. patents for cleaning-related products that are used in medical and precision cleaning applications.

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CHAPTER 5:

Breathing Life into Obsolete Medical-Device Designs

KEN GREENWOOD, Technical Sales Manager EMEA, Rochester Electronics

Authorized distribution and licensed semiconductor manufacturing can extend the life of medical devices after component end-of-life by providing long-term product support to mitigate the risks of obsolescence.

Biomedical devices are categorized in terms of risk to the patient: Class I devices with low/moderate risk to health; Class II intermediate risk equipment such as Ultra/CT scanners; and Class III/IV devices critical to sustaining life such as dialysis equipment and pacemakers.

As the risk rises for patients, so do the certification costs. Original designs need to be maintained "as-is" for as long as possible. Semiconductor obsolescence presents a serious challenge to the support of biomedical products with long in-service lives and committed maintenance periods.

It's not uncommon for large medical systems to have a concept-to-end-of-life lifecycle of 20 years, including in-service support. By contrast, semiconductor lifecycles continue to shorten, especially those of the key processor/FPGA/memory components. It's inevitable that a supply gap of some kind will need to be bridged.

Mitigating the Long-Term Risk

Component obsolescence might be undesirable, but it's generally manageable—at a cost. Typically, end users commit to a last-time-buy of finished components and the safe long-term storage of the semiconductors, often through a third party because the storage and handling of ICs require special conditions. While this solution ties up cash in long-term component and storage costs, at least precious design and qualification resources are spared. Where future demand exactly matches last-time-buy supply, this is a perfectly adequate solution.

However, as the COVID-19 pandemic took hold, there was a sudden and unpredicted demand for ventilators. Component stocks at the main-line distributors were quickly consumed, and when the semiconductor suppliers themselves were unable to increase capacity, a critical supply gap soon developed.

During this time, approving alternative IC sources, or a full product redesign, wasn't possible given the re-qualification timescales. This is especially true where component obsolescence also impacted software performance.

To bridge the supply-chain gap, ventilator manufacturers looked to breathe life into discontinued systems to fulfill this critical need. By using previously approved ICs, such as older die iterations, or by resurrecting older system designs, production was able to continue.

Authorized distributors, such as Rochester Electronics, have become trusted sources for discontinued semiconductors after end-of-life. Stock remains fully authorized, stored under AS6496 conditions, providing a risk-free source of supply.

Furthermore, partnering with a licensed semiconductor manufacturer can mitigate the risks of component end-of-life. A licensed manufacturer can produce devices no longer supplied by the original component manufacturer (OCM).

When a component is discontinued, the remaining tested wafer and die, the assembly processes, and the original test IP, are transferred to the licensed manufacturer by the OCM. This means that previously discontinued components are still available newly manufactured, and 100% in compliance with the original specifications. No additional qualification is required or software changes.

Supply issues over the last 12 months have undermined the normal delivery certainties. COVID-19-related manufacturing, shipping disruptions, and even unexpected natural disasters have led to supply-chain uncertainty and lengthening lead times. Component discontinuation notices have risen by 15% over the same period as third-party fab priorities have changed and the industry refocuses its fab investments to address a lower-powered battery-dominated landscape.

It's essential for companies in the medical sector to:

- Insist on the maximum number of cross-references from the design phase onward.
- Plan component purchases further in advance.
- Consider carrying more inventory of critical semiconductors.
- Monitor lead times and component lifecycles regularly.
- Understand supply risks and prepare dual/multi-sourcing strategies to cover all eventualities.
- Partner with an authorized distributor and/or licensed manufacturer to help manage and maintain consistent longevity of supply.

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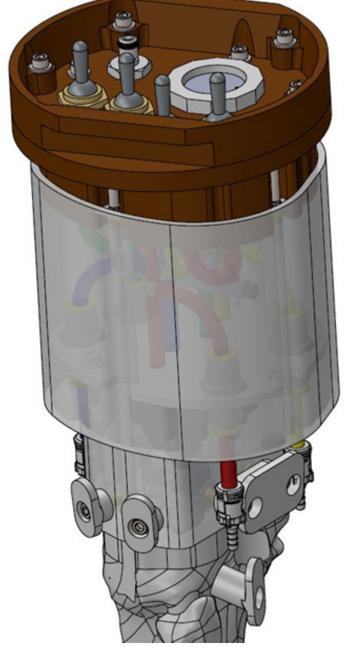


CHAPTER 6:

Manufacturing Manikins for Medical Simulation and Training

REHANA BEGG, Senior Editor, Machine Design

Human patient simulators and life-imitating technologies enable medical and frontline workers to respond with confidence in emergency situations.

Angela Alban had aspirations of becoming a physician before fashioning a career in developing manikins. Her aspirations were short-lived once she discovered that she fainted at the sight of blood.

Instead, Alban pursued a master's degree in computer engineering at the University of Central Florida, which placed her near the heart of Central Florida Research Park, a modeling, simulation and training hub that links defense, government, industry and academia.

Finding a niche in medical simulation and training, it turns out, was an excellent fit for Alban, as it created the impetus to start her own company. "I started SIMETRI in 2009 seeking to do direct work with the government in research and development of new training technologies to address training gaps," said Alban.

Angela Alban, President and CEO, SIMETRI.

Today, SIMETRI, based in Winter Park, Fla., manufactures state-of-the-art lifecycle designs of anatomical models that help prepare medical professionals for critical care situations and for training critical procedures without the safety concerns of practicing on live patients. The goal is to mimic real-life emergencies as accurately as possible so that complex medical scenarios can be performed safely, without risk to patients and to reinforce learning.

Human patient simulators may mimic the human body with varying degrees of realism—or fidelity—and can be used in almost every aspect of healthcare education. The most effective medical training devices are those that have the ability to create accurate modeling of the underlying structures of the human body and replicating them digitally and physically, noted Alban. It is why SIMETRI's anatomical models and medical training aides integrate electronic, mechanical and computational components and turns to materials science for innovations in soft and skeletal tissue.

SIMETRI's anatomical modules may be designed for the purpose of diagnosis, treating injuries or studying anatomy in support of military medics, first responders and trauma center personnel, explained Alban. Still others—e.g., partially amputated limbs—may be integrated with partner technologies such as those employed by the Laerdal SimMan.

Modular manikins have an advantage that allows one to add or change features, by adding or taking away fidelity to control costs, and to provide only what is needed for the training experiences. "We're already starting to see modules sold with different kinds of arms and legs for different purposes," Alban said.

In fact, it is this opportunity that is defining SIMETRI 's role in the market, said Alban, as her company has veered toward catering to the peripheral market, or where the manufacturer augments what customers already have or what they're buying. "We're pushing the envelope that way," she said. "I'm starting to see that some of the manufacturers are starting to come out with those optional limbs and capabilities that we're already developing."

Product Development

For a recent design—supported by the Small Business Innovation Research (SBIR) program—Alban and her team were challenged to not only develop an anatomical prototype for a procedure called humeral head intraosseous insertion (HHIO), but to also prove whether the innovation could be commercialized.

In basic terms, the HHIO procedure allows the medic to quickly introduce fluids and medications into a patient's arm. "Imagine a scenario where you're in the military and doing the procedure in the dark," explained Alban. "This is very quickly done on the head of the humerus; you can push fluids through within 30 sec. and a with much higher volume than through any other means. It was a particular procedure that they were not able to train with accurate anatomical models; they were using other means to train."

SIMETRI's solution was a static arm that sat in a recommended position so one could feel the bone, insert or drill into it, then aspirate bone marrow and inject fluids. In effect, SIMETRI developed the mechanisms to help simulate the elbow and the

Angela Alban works with a team of experts to develop realistic models of human anatomy by using synthetic tissue and materials that mimic human tissue in look and feel.

shoulder, as well as the underlying bone and soft tissue.

The prototype or Phase I of the project demonstrated the concept and was done manually, said Alban. For the next phase, Alban's team brought in SolidWorks models and created CAD designs. Alban said her team purchased a "less expensive" 3D printer for prototyping the part's form, fit and function when fitted under the anatomical soft tissue simulating the arm and shoulder. They created a model that could articulate and rotate the arm so it could accurately rotate the humerus head. ("Once we're able to feel humerus head, we can inject," she said.)

Her team produced various designs and 3D printed versions of the model in-house. "Once we perfected it to provide the kind of friction and pushback comparable to the experience of drilling into a human bone, we had it mass-manufactured by a vendor," Alban said. "All of that saved us a ton of time and a ton of money, and also helped us accelerate the speed at which we could get to a point where we could get a usable model into the war-fighters' hands."

Embedding Sensors

In another example, the Defense Health Agency, issued a call for a training device that supported training on how to reduce a dislocated shoulder joint. "It's very hard to teach this procedure unless you actually are in the emergency room or in the clinic when someone comes in," said Alban. "You rarely will be able to actually physically train it."

SIMETRI responded by developing a medical device that incorporates sensors within the shoulder's soft tissue and behind the scapula, "where one should be massaging," said Alban. Part of the procedure is to give patients a sedative to help them relax. "It's very painful, so they're very tense," said Alban. "What's happening is that the muscles are constantly trying to bring that shoulder back—so they're fighting and having spasms."

Sedatives help calm the patient, but the medic still has to fatigue the muscles by massaging them in the correct locations and based on the inputs from the sensors. The sensors capture position data as well as pressure data to ensure that medics are doing it in the correct manner. "The simulator reduces the joint back into location, but it does not reduce back into location until you do it the right way," Alban said.

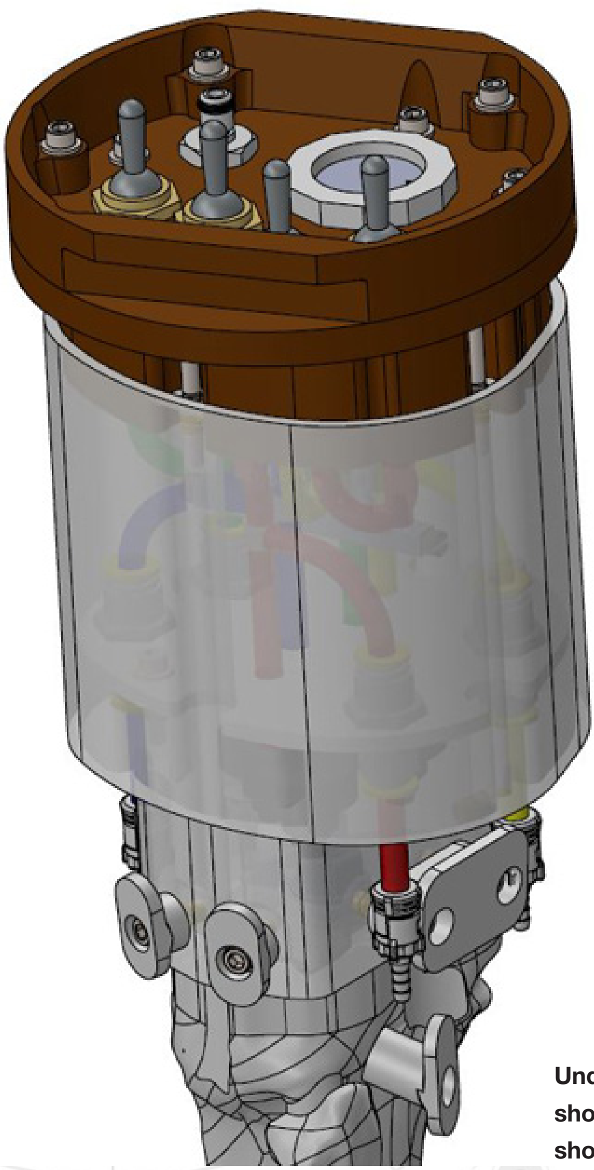
(The device was undergoing training effectiveness evaluation at the time of this writing.)

Going Digital

The roadmap to digitization for SIMETRI, said Alban, started first on the mechanical side, when mechanical models started to go from sketches to using SolidWorks and 3D models, and then embedding sensors to capture data before writing the related software and then advancing the software development capability.

For instance, SIMETRI has developed a standalone training device (which can also attach to a manikin) that has the ability to understand if and when tissue has been cut or incised correctly or, depending on the procedure, if it has been incised in way that sufficient pressure is released. Alban explained that most instructors within the military are interested in the standalone model, but there are some who are doing more advanced training and want to digitally connect the device to a mannequin.

In another development, software can monitor when the fascia (connective tissue encasing the muscle) of a specific muscle compartment has been cut, and when and if the correct fascia has been cut enough to release pressure that is increasing in the compartment. That data is transmitted digitally to the manikin, and the physiology model of that manikin is updated as a result of that new data and, therefore, displays new vital signs. "If you have not done it the right way, you will have no pulse at the foot, but if you do this procedure correctly, you will gain back pulse at the foot because you relieved the pressure and are allowing circulation to flow through," explained Alban.



Innovation is in Demand

As a small business, said Alban, SIMETRI can be agile by using additive manufacturing to speed up the process and by using the collaborative business environment to accelerate innovations that are eventually going to be adopted.

"Once a manufacturer sets up a production line for an OEM product such as a manikin that requires tooling and a lot of investment, there will [necessarily] be some changes in how we operate in the future in order to allow for that modularity and to allow for more rapid changes and revisions of baseline manikin designs," she said.

Still, while there's a market for high-fidelity manikins, Alban said it isn't a big one. "That requires significant investment; I'm hoping and I know the government is interested in modular manikins," she said.

The manikin-based simulation market in the U.S. was estimated at $367.5 million in 2020, according to ResearchAndMarkets.com. Globally, amid the COVID-19 crisis, it was estimated to rise to $1.2 billion in 2020, with projections to $5 billion by 2027.

The demand in the marketplace for making components smaller and less expensive is having an effect, too. "The miniaturization of electronic components has definitely affected the manikin market, but at the same time, during the pandemic, electronic components were hit because of the inability in the U.S. to source materials," said Alban.

This scenario will likely regain its balance once the pandemic settles down and the manikin market will continue to evolve. "Just

Under a U.S. Army contract, SIMETRI designed and developed a human shoulder joint, including bones and connective tissues, to simulate a shoulder dislocation and reduction part.

like with any other electrical mechanical device, we're going to start seeing advancement for manikins as well," she said.

A Future for Manikin-Based Training

At a recent aviation conference Alban learned that beyond what's currently available on a manikin for medical use, or available in the physical simulator of a jet in aviation, virtual simulations are viewed as an opportunity to frequently immerse trainees and to make learning more accessible. The prevailing sense, she said, was that the use of virtual and augmented reality simulation and training is being used tactically to provide additional capability, in-depth knowledge and more opportunities for repetition and experience.

"Trainees don't have to travel to where the simulators are and they don't have to go inside a classroom," said Alban. "Ideally, they're going to have a headset that will allow them to do simulations anywhere—because it's just software. In the case of medical training, I think it's going to augment what's currently available. I don't know that it can necessarily be a replacement," she said.

When it comes to manikins, however, Alban asserts that the greatest value in medical simulation is patient safety and team training. "Within the military there's a significant opportunity for point-of-injury care and even prolonged care, which is a scenario where you're not necessarily a physician, but you are taking care of a patient as a paramedic or a special operations medic for a prolonged period of time," she said.

"This is where the skills are needed to be able to sustain that patient," points out Alban. "Patient safety is an area that has grown tremendously and will continue to drive the market in a way where we are proactively making sure that we are improving outcomes in the hospital or in the clinical setting."

WISE WOMEN IN SCIENCE & ENGINEERING

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