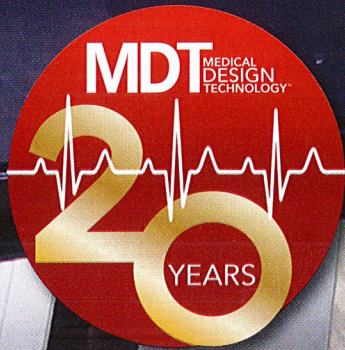


MDT MEDICAL DESIGN TECHNOLOGY™

The Medical Design Engineer's Resource for Products & Technologies



INSIDE:

How Clean is Your Cardiovascular Device?

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Exploring the Many Layers of Tubing Selection

The Impact of IEC 62304 from a Software Developer's Perspective

Automating Microplate Handling Instruments



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Q: What opportunities and/or challenges does the growing pressure to control the rising costs of healthcare present to medical device designers and manufacturers?



Andy Kelly
IC/Systems Architect, Cactus Semiconductor Inc.

Pressure brings opportunity: a trend toward evidence-based medicine. This necessitates new devices that sense, analyze, communicate, and store personalized

health indicators. These promise to eliminate subjectivity and human error, resulting in more accurate, effective, and cost-effective treatments. Evidence-based medicine coincides with a trend towards real-time and continuous diagnostics, typically only met with wearable or implantable devices. Another is the trend toward implantable device miniaturization. This enables minimally invasive surgeries performed in outpatient clinics instead of hospitals, reduces complication and infection risks, and expedites healing, leading to significantly more cost-effective solutions.

However, substantial funding is required to support the engineering efforts required to develop new therapies, systems, and devices. Due to the medical device industry's highly regulated nature, returns on these investments are not quick. Under pressure to reduce healthcare costs, it's often difficult to find the investment capital to get the required development work started. **MDT**



Luis Maseda
President, NP
Medical Inc,
a Jabil Company

It's all opportunity, said the innovators. Whether by choice, circumstance, or compliance the volume-to-value trend in healthcare economics is an eventuality. Among major worldwide markets, the US healthcare ecosystem exemplifies how the continuum care is being reinterpreted to carry total cost accountability. Whether it is an untamable entrepreneurial spirit or how publicly we pursue innovation, the compliance driven evolution in the US is playing out on center stage. Reinterpretation of healthcare delivery and stakeholder roles is blurring and re-configuring patient engagement by providers, payers, and

suppliers. As the value, or care, chain evolves there will remain three constants: the patient, their terabytes, and zero sum economics. Medical device designers will need to decide which bookend of the value spectrum they will go after. Manufacturers going after value premiums will need the vision, capabilities, and talent to develop interconnected platforms, or elements of platforms, that enable total patient management for episodic care or that better enable accountable care outcomes. Manufacturers going after straight cost advantage will need the discipline, operational excellence, and talent to provide reliable products just above the edge of clinically acceptable performance. Playing the middle of the spectrum will have value, but likely not highest growth. **MDT**



Chris Unger
Chief Systems
Engineer, GE
Healthcare

The growing pressure to control the rising costs of healthcare presents challenges and opportunities to device suppliers in the field. Hospitals are consolidating in the face of cost pressures, which has led to changing purchasing priorities. Medical device suppliers must relearn hospital needs – even better than before. This helps align the goals of customers worldwide, where ease of use and cost effectiveness have always been critical.

Companies in the healthcare field need to use “systems engineering”: a meticulous and effective methodology for identifying and addressing the totality

of a customer's need for outcomes-based solutions, evaluating all risks, and managing benefits and costs across the entire product lifecycle. For example, customers are becoming more concerned about total lifecycle costs (including installation and disposal costs, utility bills, and equipment utilization). These factors have become just as important as which new features are delivered with the product, making systems engineering more critical than ever to business success.

With a systematic approach to identifying which critical functions can be delivered at the lowest cost, the medical device industry may be able to focus and deliver products faster. However, that transformation is a culture change as well. **MDT**



Mark Lowe
VP of Sensors, Tekscan

Demands from the marketplace for smaller, lower-cost products challenge medical device designers to solidify their understanding of the product's minimum requirements. In component selection, there are often a variety of technologies available, and associated factors to weigh. Force sensors are one example. Consider the piece-price, mechanical integration, and enabling electronics costswile maintaining the minimum acceptable requirement for the application.

Load cells, while highly precise, are bulky, expensive, and require complex electronics. Strain gauges produce non-linear output, so they typically require specialized electronics, along with skilled technicians to integrate them. Piezoresistive flexible force sensors are less expensive, measure load directly and can be easily integrated. Their wide dynamic range and high resistance requires simpler enabling electronics, and less power. These characteristics offer design engineers an opportunity to design smaller, sleeker, lower-power, lower-cost products.

For custom sensors, volumes, piece-prices and design and tooling costs are key. MEMS technology typically only lends itself to very high volume applications due to the upfront NRE costs. Designers and manufacturers who do their homework in designing for manufacturing will find the right component and supplier, which ultimately saves time and money. **MDT**